EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, Maryland 21152 USA.
Manufacturer SRN:	US-MF-000018910
Authorised Representative:	Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26 Ireland
Authorised Representative SRN:	IE-AR-000007610
Product:	**Catalog No.** 491103 — **Product Trade Name** BD PrepMate™ Automated Accessory
Basic UDI-DI:	**Catalog No.** 491103 — **Product Trade Name** BD PrepMate™ Automated Accessory — **Basic UDI-DI** 038290XFQQTAMRM4
Risk Class and Rule:	Class A, Rule 5 (b)
Intended Purpose:	**Catalog No.** 491103 — **Product Trade Name** BD PrepMate™ Automated Accessory — **Intended Purpose** The BD PrepMate ™ Automated Accessory is an accessory to the BD SurePath Liquid-based Pap Test, the BD PrepStain Slide Processor, and the BD Totalys SlidePrep. The BD PrepMate Automated Accessory automates the initial

1.6

			enrichment process of mixing and dispensing the specimen over BD Density Reagent. The BD PrepMate Automated Accessory mixes and removes the specimen from a BD SurePath Collection Vial or BD CytoRich Clear Vial. It then layers the specimen onto the density reagent in a centrifuge tube. The automated process handles from one to twelve specimens per cycle.
Notified Body:	Not applicable, device(s) self-certified		

We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Directives/ Regulation(s):

- Regulation (EU) 2017/746 on *In vitro* Diagnostic Medical Devices.
- Directive 2011/65/EU as amended (EU) 2015/863 on Restriction of the use of certain hazardous substances in electrical and electronic equipment as amended by Commission Delegated Directive 2015/863 (RoHS)

Conformity Assessment Route:

☐ ANNEX IX Technical File Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX IX Full Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX X Type Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX XI Production Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☒ ANNEX I & II+III	N/A

Common Specifications (CS):

Number:	Title:	Full or Partial Application:

Common Specifications have not been issued for this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
491103	BD PrepMate™ Automated Accessory	Class A

Authorised Signatory:	
Name & Title:	Anne Zavertnik, Vice President, Regulatory Affairs
On behalf of:	Becton, Dickinson and Company
Place of Issue:	Sparks, MD, USA
Date of Issue:	10-Nov-2022
Signature:	DocuSigned by: Anne Zavertnik Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 | 11:30:15 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release.
02	Updated to remove WEEE Directive as it is not a CE-marking regulation. Minor formatting changes.
03	Revision 04 Template change, ‘Assigned BUDI’ changed to ‘Basic UDI-DI’, Intended Purpose updated in Table Format, Removed ‘Not Available’ in Common Specification table, Legal manufacturer name updated in Authorised signatory section

BD Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	490100 - BD PrepStain Slide Processor 490407 - BD PrepStain Slide Processor Refurbished

1.6

We hereby declare that the above mentioned product(s) manufactured after 2015/02/16 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2015/02/16
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	

Technical File Number: BALTER490100

BD SurePath™ Manual Method

500017024(03)
2021-10
English

REF 491266 BD SurePath™ Manual Method Kit Σ 480

1.1
1.2

INTENDED USE

The BD SurePath™ Manual Method is a method for producing liquid-based cell preparations (LBPs). The BD SurePath™ Manual Method is intended as a replacement for the conventional Pap smear preparation method for use in cervical cancer screening.

BD SurePath™ Preservative Fluid is an appropriate collection and transportation medium for gynecologic specimens tested with BD ProbeTec™ Chlamydia trachomatis (CT) Qx and Neisseria gonorrhoeae (GC) Qx Amplified DNA Assay.

SUMMARY AND EXPLANATION

Cervical cytology screening by the Papanicolaou (Pap) method involves the microscopic examination of cell samples that have been taken primarily from the ecto- and endocervix, smeared on glass slides and stained using the Pap procedure.[1-3] Cervical cytology screening with the Pap smear has decreased the mortality rates of invasive cervical carcinoma by 50 to 70 percent.[4] Because cervical cytology is a screening test, abnormal findings must be confirmed histologically.

Specimen collection and preparation are extremely important to accuracy in Pap smears. Randomization or uniform sub-sampling is essential for complete accuracy. The conventional Pap smear technique does not provide for mixing of the sample prior to slide preparation. Due to the entanglement of cells in mucus on the sampling device, the cells actually transferred to the slide may not be representative of the total population collected. The cells are transferred to the slide in relation to where they happen to be on the sampling device. Many cells are left on the device.[5]

The non-homogeneity of a typical cervical sample can make conventional smears difficult to prepare, screen and interpret. Large areas of the conventional slide are often covered with debris, inflammatory cells and sheets of epithelial cells that can obscure valuable diagnostic material. In addition, if the smear is not fixed immediately after preparation, cellular morphology can be distorted as the smear dries (air-drying artifact).

The BD SurePath™ Manual Method is a method for converting a liquid suspension of a cervical sample into a consistently stained, homogeneous BD SurePath™ Liquid-based Pap Test slide while maintaining diagnostic cell clusters.[6-9] The process includes cell preservation, randomization, enrichment of diagnostic material, pipetting, and sedimentation to create a cellular preparation. The result of the preparation process is a BD SurePath™ Liquid-based Pap Test slide for use in routine cytology screening and categorization as defined by the Bethesda System.[10]

PRINCIPLES OF THE PROCEDURE

The BD SurePath™ Manual Method is a procedure for the preparation of LBPs of cervical cells. Gynecologic specimens are collected by qualified medical personnel using broom-type sampling devices (e.g., Rovers® Cervex-Brush®, Rovers Medical Devices B.V., Oss - The Netherlands) or combination plastic spatula and endocervical brush devices (e.g., Cytobrush Plus® GT and Pap Perfect® Plastic Spatula, CooperSurgical, Inc.) with detachable heads. The head of the brush is removed from the handle and placed into a vial of BD SurePath™ Preservative Fluid. The vial is capped, labeled and sent with appropriate paperwork to the laboratory for processing.

In the laboratory, the preserved sample is mixed by vortexing, and transferred into a tube containing BD Density Reagent. An enrichment step, consisting of centrifugal sedimentation through BD Density Reagent, partially removes non-diagnostic debris and excess inflammatory cells from the sample. After centrifugation, the tube containing the enriched cellular component is reconstituted with buffered deionized water and the cellular material is re-suspended with a pipettor using an aspirate/dispense sequence. The sample material is then transferred to a BD Settling Chamber mounted on a BD SurePath™ PreCoat Slide. Gravity sedimentation occurs during a short incubation. Excess material is decanted. The BD SurePath™ Liquid-based Pap Test slide is stained cleared and coverslipped with the cells presented in a circle, 13 mm in diameter. The BD SurePath™ Liquid-based Pap Test slide is examined by trained cytotechnologists and pathologists in conjunction with other relevant patient information.

LIMITATIONS OF THE PROCEDURE

- Gynecologic specimens for preparation using the BD SurePath™ Manual Method should be collected using a broom-type sampling device or combination plastic spatula and endocervical brush device with detachable head(s) according to the standard collection procedure provided by the manufacturer. Wooden spatulas should not be used. Endocervical brush/plastic spatula combinations that are not detachable should not be used.

- The production and evaluation of BD SurePath™ Liquid-based Pap Test preparations should be performed only by personnel who have been trained by BD or others authorized by BD to provide such training.
- Proper performance of the device requires the use of only those supplies supported by BD, or recommended by BD. Used supplies and product should be disposed of properly in accordance with institutional and governmental regulations.
- All supplies are intended for single use only and cannot be reused.
- A volume of 8.0 ± 0.5 mL of the sample collected in the BD SurePath™ Collection Vial is required for the BD SurePath™ LBC Test process.

WARNINGS AND PRECAUTIONS

Cytologic specimens may contain infectious agents. Wear suitable protective clothing, gloves, and eye/face protection. Follow appropriate biohazard precautions when handling samples.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. For Use by Trained Laboratory Personnel.
3. Good laboratory practices should be followed and all procedures for use of the BD SurePath™ Manual Method should be strictly observed.
4. Reagents should be stored at room temperature (15–30 °C) and used prior to their expiration dates to assure proper performance.
5. Microbial contamination of reagents may give incorrect results.
6. Substitution of other than BD SurePath™ PreCoat Slides may result in less than optimal results.
7. Avoid splashing or generating aerosols. Use appropriate hand, eye and clothing protection.
8. BD SurePath™ Preservative Fluid was tested for antimicrobial effectiveness against: *Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, Mycobacterium tuberculosis,* and A*spergillus niger* and found to be effective. BD SurePath™ Preservative samples inoculated with 10^6 CFU/mL of each species yielded no growth after 14 days (28 days for *Mycobacterium tuberculosis*) of incubation under standard conditions. However, universal precautions for safe handling of biological fluids should be practiced at all times.
9. Dispose of all used reagents and any other contaminated disposable materials following procedures for infectious or potentially infectious waste. It is the responsibility of each laboratory to handle solid and liquid waste according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulation

OPTIONAL ALIQUOT REMOVAL

- Sufficient volume is available in the BD SurePath™ Collection Vial to allow removal of up to 0.5 mL of homogeneous mixture of cells and fluid for ancillary testing, prior to the BD SurePath™ Liquid-based Pap Test while still allowing sufficient volume for Pap testing.
- While there is no evidence that removal of an aliquot from the BD SurePath™ Collection Vial affects the quality of the specimen for cytology testing, rare instances of misallocation of pertinent diagnostic material may occur during this process. Healthcare providers may need to acquire a new specimen if the results do not correlate with the clinical history of the patient. Furthermore, cytology addresses different clinical questions than sexually transmitted disease (STD) testing; therefore, aliquot removal may not be suitable for all clinical situations. If necessary, a separate specimen may be collected for STD testing rather than taking an aliquot from the BD SurePath™ Collection Vial.
- Aliquot removal from low-cellularity specimens may leave insufficient material in the BD SurePath™ Collection Vial for preparation of a satisfactory BD SurePath™ Pap Liquid-based Test.
- Aliquot must be removed prior to processing the BD SurePath™ Liquid-based Pap Test. Only one aliquot may be removed from the BD SurePath™ Collection Vial prior to performing the BD SurePath™ Liquid-based Pap Test, regardless of the volume of the aliquot.

Procedure

1. In order to ensure a homogenous mixture, the BD SurePath™ Collection Vial must be vortexed for 10–20 seconds at 3,000 rpm and the 0.5 mL aliquot must be removed within one minute of vortexing.
2. A polypropylene aerosol barrier pipette tip that is sized appropriately for the volume being withdrawn must be used for aliquot removal. Note: Serological pipettes should not be used. Good laboratory practices must be followed to avoid introducing contaminants into the BD SurePath™ Preservative Fluid Collection Vial or the aliquot. Aliquot removal should be performed in an appropriate location outside an area where amplification is performed.
3. Visually check the aliquot material in the pipette for evidence of large gross particulates or semi-solids. Evidence of such material encountered while withdrawing the aliquot material should prompt return of all the material to the specimen vial and disqualify the specimen for ancillary testing prior to performing the Pap test.
4. For instructions on processing the aliquot using the BD ProbeTec™ CT Q^x and GC Q^x Amplified DNA Assays, refer to the assay Package Inserts provided by the manufacturer.

MATERIALS REQUIRED

Materials Provided

2 x 240 – BD Settling Chambers

5 x 96 – BD SurePath™ PreCoat Slides

Materials Required But Not Provided

BD SurePath™ Collection Vials

BD Density Reagent

BD Centrifuge Tubes

BD Syringing Pipettes

BD Aspirator Tips

BD PrepMate™ Automated Accessory

Centrifuge

Slide Racks

Easy Aspirator (optional)

Broom type sampling device or endocervical brush/plastic spatula with detachable head(s)

Vortex Mixer

Precision Pipettes with Disposable Tips

Deionized Water (pH 7.5–8.5)

Isopropanol and Reagent Grade Alcohol

Staining Reagents

Clearing Agent, Mounted Media, Coverslips

STORAGE

- BD SurePath™ Preservative Fluid without cytologic samples may be stored at room temperature (15–30 °C) for up to 36 months from date of manufacture.
- The storage limit for BD SurePath™ Preservative Fluid with cytologic samples is 6 months at refrigerated temperatures (2–10 °C) or 4 weeks at room temperature (15–30 °C).
- BD SurePath™ Preservative Fluid containing cytologic sample intended for use with the BD ProbeTec™ CT Q^{x} and GC Q^{x} Amplified DNA Assays can be stored and transported for up to 30 days at 2–30 °C prior to transfer to the Liquid-based Cytology Specimen (LBC) Dilution Tubes for the BD ProbeTec™ Q^{x} Amplified DNA Assays.

PROCEDURES

1. After the sample is collected using a Rovers Cervex-Brush or equivalent sampling device, the brush head is rinsed directly into the fluid, removed from the handle and dropped into a BD SurePath™ Collection Vial. The vial is then tightly capped, labeled, and sent to the laboratory.
2. When sample vials have been accessioned into the lab, place each vial into a tray with a labeled centrifuge tube pre-filled with 4 mL of BD Density Reagent and a labeled BD SurePath™ PreCoat Slide. BD Density Reagent must be added to the centrifuge tube before the sample is added or performance will be reduced.
3. Vigorously vortex each sample vial for 10–20 seconds at 3,000 rpm. (Sufficient volume is available in the BD SurePath™ Collection Vial to allow removal of up to 0.5 mL of homogenous mixture of cells and fluid for ancillary testing, while still allowing sufficient volume for Pap testing. The aliquoting may be performed after this vortexing step in the BD SurePath™ LBC Test process.)
4. Use the BD PrepMate™ Automated Accessory and BD Syringing Pipettes to transfer 8 mL of the sample into the appropriately labeled centrifuge tube containing BD Density Reagent. See the BD PrepMate™ Operator's Manual for instructions.
5. Place the tubes into a centrifuge rack. Arrange tubes according to the placement sequence diagram in the BD PrepMate™ Operator's Manual.
6. Placement sequence is critical and must be balanced. Balance the centrifuge tubes by adding BD SurePath™ Preservative Fluid if necessary.
7. Centrifuge specimens for 2 ± 0.25 minutes at 200 ± 25 rcf.
8. Remove centrifuge tube racks from the centrifuge.
9. Aspirate supertanant using one of the following methods.
   - Use the Easy Aspirator to aspirate supertanant.
     - — Turn on the tube vac for the Easy Aspirator system and adjust the pressure to 8–10 in. Hg for a Schuco vacuum pump or 5.5 in. Hg for a KNF vacuum pump. Allow the pump to come to equilibrium vacuum pressure before beginning aspiration.
     - — Place the Easy Aspirator block on a rack of disposable BD Aspirator Tips (clear) so that the tip adaptors on the block fit down into 12 tips. Apply moderate pressure to attach the tips onto the Easy Aspirator block. All 12 tips are needed on the apirator block even if the centrifuge tube rack is not full.
     - — Hold the Easy Aspirator block with tips over the centrifuge tubes to be aspirated. Slowly lower the aspirator tips into the supernatant, staying just below the dropping fluid level, until the aspirator head rests evenly across the tops of the centrifuge tubes. At this point you should hear the tips drawing air into the vacuum tubing.

- — Carefully withdraw the aspirator head with the tips from the centrifuge tube rack. BD Aspirator Tips are single use only and should be discarded after one sample transfer.
- — To prevent clogs, run water through the aspirator before shutting off the vacuum pump. Perform this rinse after the last c-tube rack is aspirated and with tips still seated on the aspirator block.
- — When aspiration is complete, load the Easy Aspirator block onto the tip ejector. Hold the aspirator head in front of and at the same plane as the white Delrin wedge in the top of the tip ejector. Slide the aspirator head along the top of the wedge so that the posts align into the slots of the tip ejector.
- — Sliding the aspirator head into the tip ejector should eject all of the tips into the disposal tray. Withdraw the aspirator head by pulling it up and out of the tip ejector.
- — Turn off the vacuum using the on/off switch on the vacuum. This will stop the vacuum and release the tips from the Easy Aspirator block into the waste bucket below the tip ejector.

Or

- Use disposable transfer pipettes to aspirate supertanant.

10. Centrifuge the tubes for 10 ± 1 minutes at 800 ± 50 rcf to concentrate the diagnostic component into a cell pellet at the bottom of the tube.
11. Remove the tube rack from the centrifuge. In a single, rapid motion, decant the supernatant by inverting each tube rack 180 degrees so as not to disturb the cell pellet. While inverted, blot the tubes carefully on absorbent paper, making sure that the cell pellet stays in the tube. Turn the rack upright after 3 to 5 seconds.
12. Place the slides into a Slide Rack and lock a BD Settling Chamber onto each slide. The position of each numbered BD SurePath™ PreCoat Slide on the Slide Rack must match to the position of the corresponding centrifuge tube.
13. Add 4 mL of buffered deionized water (pH 7.5–8.0) to each specimen tube.
14. Working with one sample tube at a time, use a clean disposable transfer pipette tip to mix the sample eight (8) times. Immediately transfer 800 µL of cell suspension into the correspondingly numbered BD Settling Chamber/ BD SurePath™ PreCoat Slide. Repeat for each sample.
15. Allow 10 minutes for full sedimentation to occur. After the sedimentation, gently invert the Slide Racks to decant the remaining fluid and blot the excess liquid on absorbent paper.
16. Rinse each BD Settling Chamber with 500 µL of denatured ethanol and decant. Repeat alcohol rinse and decant the remaining fluid and blot the excess liquid on absorbent paper, allowing the BD Settling Chamber to remain inverted for at least 1 minute.
17. Remove the BD Settling Chamber from each slide being careful to not disturb the sample deposition area.
18. Stain and coverslip the BD SurePath™ Liquid-based Pap Test slides.

RESULTS AND INTERPRETATION

- All diagnostic criteria currently utilized in cytology laboratories for conventional Pap smears are applicable to BD SurePath™ Liquid-based Pap Test preparations.
- Any abnormal or questionable screening observations should be referred to a pathologist for review and diagnosis. Any cellular morphologic changes are significant and should be noted.

AVAILABILITY

Catalog Number	Description
491266	BD SurePath™ Manual Method Kit

REFERENCES

1. Papanicolaou GN: A New Procedure for Staining Vaginal Smears. Science 1942; *95*:438-439.
2. King A, Clay K, Felmar EG, Heustis DG, Karns RM, Krahl P, Tench WD: The Papanicolaou Smear. West J Med 1992; *156*:202-204.
3. Mandelblatt J, Gopaul I, Wistreich M: Gynecological Care of Elderly Women: Another Look at Papanicolaou Smear Testing. J Am Med Assoc 1986; *256*:367-371.
4. Koss LG: The Papanicolaou Test for Cervical Cancer Detection: A Triumph and a Tragedy. J Am Med Assoc 1989; *261*:737-743.
5. Hutchinson ML, Isenstein LM, Goodman A, Hurley AA, Douglass KL, Mui KK, Patten FW, Zahniser DJ: Homogeneous Sampling Accounts for the Increased Diagnostic Accuracy Using the ThinPrepÒ Processor. Am J Clin Pathol 1994; *101*:215-219.
6. McGoogan E, Reith A: Would Monolayers Provide More Representative Samples and Improved Preparations for Cervical Screening? Overview and Evaluation of Systems Available. Acta Cytol 1996; *40*:107-119.
7. Bishop JW: Comparison of the CytoRich System with Conventional Cervical Cytology: Preliminary Data on 2,032 Cases from a Clinical Trial Site. Acta Cytol 1997, *41*:15-23.
8. Geyer JW, Hancock F, Carrico C, Kirkpatrick M: Preliminary Evaluation of CytoRich: An Improved Automated Cytology Preparation. Diagn Cytopathol 1993; *9*:417-422.
9. Grohs HK, Zahniser DJ, Geyer JW: Standardization of Specimen Preparation Through Mono/Thin-Layer Technology in Automated Cervical Cancer Screening. Edited by HK Grohs, OAN Husain. New York, Igaku-shoin, 1994, pp 176-185.
10. Solomon D, Nayar R (editors): The Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses. New York, Springer Verlag, 2004.

Technical Service and Support: In the United States contact BD at 1.800.638.8663 or bd.com.

For regions outside of the United States, contact your local BD representative or bd.com.

EU Only: Users shall report any serious incident related to the device to the Manufacturer and National Competent Authority.

Outside EU: Contact your local BD representative for any incident or inquiry related to this device.

Change History

Revision	Date	Change Summary
(03)	2021-10	Updated Intended Use Added Intended User Updated Warnings and Precaution Updated Technical Information Added Serious Incident statement, Safe Disposal statement Added Availability section Updated Symbols Glossary Added CH REP symbol with address

SYMBOLS GLOSSARY [L006715(06) 2021-08]

Some symbols listed below may not apply to this product.

US Customers only: For symbol glossary, refer to **bd.com/symbols-glossary**

Symbol	Meaning
	Manufacturer
	Authorized representative in the European Community
	Authorised representative in Switzerland
	Date of manufacture
	Use-by date
	Batch code
	Catalogue number
	Serial number
	Sterile
	Sterilized using aseptic processing techniques
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Sterilized using steam or dry heat
	Do not resterilize
	Non-sterile
	Do not use if package is damaged and consult *instructions for use*
	Sterile fluid path
	Sterile fluid path (ethylene oxide)
	Sterile fluid path (irradiation)
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Lower limit of temperature
	Upper limit of temperature
	Temperature limit
	Humidity limitation
	Biological risks
	Do not re-use
	Consult *instructions for use* or consult electronic *instructions for use*
	Caution
	Contains or presence of natural rubber latex
	In vitro diagnostic medical device
	Negative control
	Positive control
	Contains sufficient for <*n*> tests
	For IVD performance evaluation only
	Non-pyrogenic

Symbol	Meaning
	Patient number
	This way up
	Do not stack
	Single sterile barrier system
	Contains or presence of phthalate: combination of bis(2-ethylhexyl) phthalate (DEHP) and benzyl butyl phthalate (BBP)
	Collect separately Indicates separate collection for waste of electrical and electronic equipment required.
	CE marking; Signifies European technical conformity
	Device for near-patient testing
	Device for self-testing
	This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."
	Country of manufacture "CC" shall be replaced by either the two letter or the three letter country code.
	Collection time
	Cut
	Peel here
	Collection date
	Keep away from light
	Hydrogen gas is generated
	Perforation
	Start panel sequence number
	End panel sequence number
	Internal sequence number
	Medical device
	Contains hazardous substances
	Ukrainian conformity mark
	Meets FCC requirements per 21 CFR Part 15
	UL product certification for US and Canada
	Unique device identifier

Becton, Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152 USA

EC REP Becton Dickinson Ireland Ltd.
Donore Road, Drogheda
Co. Louth, A92 YW26
Ireland

CH REP BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins, Switzerland

Australian and New Zealand Sponsors:
Becton Dickinson Pty Ltd.
66 Waterloo Road
Macquarie Park NSW 2113
Australia

Becton Dickinson Limited
14B George Bourke Drive
Mt. Wellington Auckland 1060
New Zealand

BD SurePath™ Collection Vial

For use with the BD PrepStain™ and BD Totalys™ Systems

CE IVD R_X Only 500017013(02) 2019-07

1.1

REF **491452**	BD SurePath™ Collection Vial Kit	Σ	500
REF **491438**	BD SurePath™ Vial and Cervix Brush Kit	Σ	500
REF **491439**	BD SurePath™ Vial and Combi Brush Kit	Σ	500
REF **491440**	BD SurePath™ Vial and Spatula/Brush Kit	Σ	500

INTENDED USE FOR GYNECOLOGIC APPLICATIONS

1.1

The BD SurePath™ Collection Vial is designed for use with the BD PrepStain™ and BD Totalys™ Systems for the processing of BD SurePath Liquid-based Pap Tests. The BD SurePath Collection Vial contains an alcohol-based preservation solution that serves as a transport, preservative and antibacterial medium for gynecologic specimens. Refer to the BD PrepStain or the BD Totalys SlidePrep package inserts for additional information and clinical data regarding the BD SurePath Liquid-based Pap Test.

SUMMARY AND EXPLANATION

Refer to the SAMPLE COLLECTION USING CERVICAL SAMPLING DEVICE(S) WITH DETACHABLE HEAD(S) section of this package insert for instructions on using the BD SurePath Collection Vial.

For information on using the BD SurePath Collection Vial with different platforms, refer to the following documentation:

- BD Totalys SlidePrep Product Insert
- BD Totalys MultiProcessor Instrument User's Manual
- BD PrepMate™ Instrument User's Manual
- BD PrepStain Product Insert
- BD SurePath Manual Method Product Insert

REAGENTS

Materials Provided: Each package of BD SurePath Collection Vials contains: 25 or 500 BD SurePath Collection Vials with 10 mL of BD SurePath Preservative Fluid in each vial.

Materials Required But Not Provided: Specimen collection device.

Use either a broom-type sampling device with detachable head (e.g., Rovers® Cervex Brush®) or a combination endocervical brush/plastic spatula device with detachable head(s) (e.g., Cytobrush Plus® GT and Pap Perfect® spatula).

WARNINGS AND PRECAUTIONS

Cytologic specimens may contain infectious agents. Wear suitable protective clothing, gloves, and eye/face protection. Follow appropriate biohazard precautions when handling samples.

BD SurePath Preservative Fluid contains an aqueous solution of denatured ethanol. The mixture contains small amounts of methanol and isopropanol. Do not ingest.

Warning

H226 Flammable liquid and vapour.

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **P241** Use explosion-proof electrical/ventilating/lighting/equipment. **P280** Wear protective gloves/protective clothing/eye protection/face protection. **P240** Ground/bond container and receiving equipment. **P233** Keep container tightly closed. **P242** Use only non-sparking tools. **P243** Take precautionary measures against static discharge. **P303+P361+P353** IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. **P370+P378** In case of fire: Use for extinction: CO_2, powder or water spray. **P403+P235** Store in a well-ventilated place. Keep cool. **P405** Store locked up. **P501** Dispose of contents/container in accordance with local/regional/national/international regulations.

PRECAUTIONS

1. For *in vitro* Diagnostic Use.
2. Good laboratory practices should be followed and all procedures for use of the BD PrepStain, the BD Totalys SlidePrep, and the BD Totalys MultiProcessor systems should be strictly observed.
3. Avoid splashing or generating aerosols. Operators should use appropriate hand, eye and clothing protection.
4. The preservative fluid contained in the BD SurePath Collection Vial was tested for antimicrobial effectiveness against *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Candida albicans*, *Mycobacterium tuberculosis* and *Aspergillus niger* and found to be effective. BD SurePath samples inoculated with 10^6 CFU/mL of each species yielded no growth after 14 days (28 days for *Mycobacterium tuberculosis*) of incubation under standard conditions. However, universal precautions for safe handling of biological fluids should be practiced at all times.

General precautions on ancillary testing from the BD SurePath Collection Vial

While there is no evidence that removal of an aliquot from the BD SurePath Collection Vial affects the quality of the specimen for cytology testing, rare instances of misallocation of pertinent diagnostic material may occur during this process. Healthcare providers may need to acquire a new specimen if the results do not correlate with the clinical history of the patient. Furthermore, cytology often addresses different clinical questions than molecular testing; therefore, aliquot removal may not be suitable for all clinical situations. If necessary, a separate specimen may be collected for ancillary testing rather than taking an aliquot from the BD SurePath Collection Vial.

Aliquot removal from low-cellularity specimens may leave insufficient material in the BD SurePath Collection Vial for preparation of a satisfactory BD SurePath Liquid-based Pap Test.

FIRST AID

Call a physician immediately. If swallowed, do not induce vomiting. Give plenty of water to drink. Never give anything by mouth to an unconscious person. If inhaled, remove person to fresh air. In case of contact, immediately flush skin with water; immediately flush eyes with plenty of water for at least 15 minutes.

STORAGE AND DISPOSAL

1. Store the BD SurePath™ Collection Vial without cytologic samples at room temperature (15–30 °C) in the vials provided.
2. The BD SurePath Collection Vial preserves cells for up to 6 months at refrigerated temperatures (2–10 °C) or up to 4 weeks at room temperature (15–30 °C). 1.1
3. Do not use the BD SurePath Collection Vial beyond the expiration date printed on the vial.
4. Expired and used supplies and products should be disposed of properly in accordance with institutional and local government regulations.

SAMPLE COLLECTION USING CERVICAL SAMPLING DEVICE(S) WITH DETACHABLE HEAD(S):

NOTE: For specimen collection, use either a broom-type sampling device with detachable head (e.g., Rovers Cervex-Brush) or a combination endocervical brush/plastic spatula device with detachable head(s) (e.g., Cytobrush Plus GT and Pap Perfect spatula).

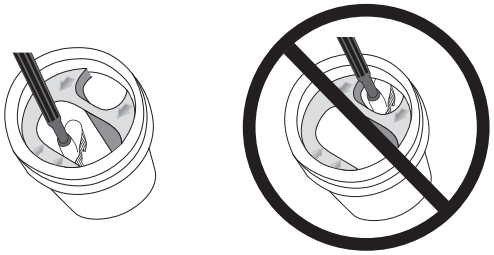
1. Obtain a sample from the cervix according to the standard collection procedure (e.g., CLSI guideline GP15-A3).[1]
2. Holding the collection vial firmly down on a flat surface, insert the head(s) of the collection device(s) into the larger of the two openings in the BD SurePath Collection Vial using one of three methods:

   (1) Using the thumb and forefinger of a gloved hand, disconnect the head of the broom-type device from the handle and deposit into the larger of the two vial openings.

   (2) Insert the head of the broom-type device into the larger of the two vial openings. Rotate the handle of the collection device while gently pulling up to detach the device head from the handle, depositing the device head into the larger of the two vial openings.

   (3) When using combination brush/spatula collection devices with detachable heads, insert the first device so that the break point is above the top of the light blue vial insert and the head is below the insert. Bend the device back and forth until the device breaks, deposting the collection head into the larger of the two vial openings. Repeat for the second device.

   Discard the handle(s) of the sampling device(s). Do not touch the head(s) of the sampling device(s).



   NOTE: Arrows on top of the light blue vial insert point to where the collection device head(s) should be deposited. **Always deposit collection device head(s) into the larger vial opening.**

   DO NOT place collection device head(s) into the smaller vial opening.
3. Cap the vial tightly.

4. Optional: To utilize pre-labeled 2-D barcodes for positive sample identification, remove the upper barcode on the vial label by peeling from the top left corner. Attach the barcode to the requisition form to be sent to the lab. The second barcode remains on the vial, linking the patient sample to the requisition form.
5. Send the specimen containing the head(s) of the sampling device(s), with appropriate paperwork, to the laboratory for processing.

Collection Vial Transport

For domestic and international shipments, specimens should be packaged and labeled in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and etiologic agents/infectious substances. Time and temperature conditions for storage must be maintained during transport.

LIMITATIONS OF THE PROCEDURE

Always use good sampling techniques when collecting specimens. Poor sample collection techniques will produce inadequate preparations. Gynecologic specimens should be collected using a broom-type sampling device or a combination endocervical brush/plastic spatula device with detachable head(s) according to the standard collection procedure provided by the manufacturer. Wooden spatulas should not be used to collect specimens with the BD SurePath Collection Vial. Endocervical brush/plastic spatula devices that are not detachable should not be used with the BD SurePath Collection Vial.

After the first vortex step, a maximum of 0.5 mL of the homogeneous mixture of cells and fluid may be removed for ancillary testing prior to further processing of the BD SurePath Liquid-based Pap Test. Refer to the BD PrepStain, BD Totalys SlidePrep, or Manual Method package inserts or the BD Totalys MultiProcessor Instrument User's Manual for instructions on aliquot removal.

REFERENCE

1. Clinical and Laboratory Standards Institute (CLSI). *Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline – Third Edition.* CLSI document GP15-A3 (ISBN 1-56238-679-4). CLSI 2008.

Technical Information: In the United States contact BD Technical Service and Support at 1.800.638.8663 or www.bd.com.

Change History

Revision	Date	Change Summary
(02)	2019-07	Converted printed instructions for use to electronic format and added access information to obtain the document from BD.com/e-labeling. Updated "Warnings and Precautions" section with new GHS information. Added hazard "P405 Store locked up".

US Customers only: For symbol glossary, refer to www.bd.com/symbols-glossary

Manufacturer / Производител / Výrobce / Fabrikant / Hersteller / Κατασκευαστής / Fabricante / Tootja / Fabricant / Proizvođač / Gyártó / Fabbricante / Атқарушы / 제조업체 / Gamintojas / Ražotājs / Tilvirker / Producent / Producător / Производитель / Výrobca / Proizvođač / Tillverkare / Üretici / Виробник / 生产厂商

Use by / Използвайте до / Spotřebujte do / Brug før / Verwendbar bis / Χρήση έως / Usar antes de / Kasutada enne / Date de péremption / 사용 기한 / Upotrijebiti do / Felhasználhatóság dátuma / Usare entro / Дейін пайдалануға / Naudokite iki / Izlietot līdz / Houdbaar tot / Brukes for / Stosować do / Prazo de validade / A se utiliza până la / Использовать до / Použite do / Upotrebiti do / Använd före / Son kullanma tarihi / Використати до\line / 使用截止日期
YYYY-MM-DD / YYYY-MM (MM = end of month)
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = края на месеца)
RRRR-MM-DD / RRRR-MM (MM = konec měsíce)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutning af måned)
JJJJ-MM-TT / JJJJ-MM (MM = Monatsende)
EEEE-MM-HH / EEEE-MM (MM = τέλος του μήνα)
AAAA-MM-DD / AAAA-MM (MM = fin del mes)
AAAA-KK-PP / AAAA-KK (KK = kuu lõpp)
AAAA-MM-JJ / AAAA-MM (MM = fin du mois)
GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)
ÉÉÉÉ-HH-NN / ÉÉÉÉ-HH (HH = hónap utolsó napja)
AAAA-MM-GG / AAAA-MM (MM = fine mese)
ЖЖЖЖ-АА-КК / ЖЖЖЖ-АА / (АА = айдың соңы)
YYYY-MM-DD/YYYY-MM(MM = 월말)
MMMM-MM-DD / MMMM-MM (MM = mėnesio pabaiga)
GGGG-MM-DD/GGGG-MM (MM = mēneša beigas)
JJJJ-MM-DD / JJJJ-MM (MM = einde maand)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutten av måneden)
RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
AAAA-MM-DD / AAAA-MM (MM = fim do mês)
AAAA-LL-ZZ / AAAA-LL (LL = sfârşitul lunii)
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = конец месяца)
RRRR-MM-DD / RRRR-MM (MM = koniec mesiaca)
GGGG-MM-DD / GGGG-MM (MM = kraj meseca)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutet av månaden)
YYYY-AA-GG / YYYY-AA (AA = ayın sonu)
PPPP-MM-ДД / PPPP-MM (MM = кінець місяця)
YYYY-MM-DD / YYYY-MM (MM = 月末)

Catalog number / Каталожен номер / Katalogové číslo / Katalognummer / Αριθμός καταλόγου / Número de catálogo / Katalooginumber / Numéro catalogue / Kataloški broj / Katalógusszám / Numero di catalogo / Каталог нөмірі / 카탈로그 번호 / Katalogo / numeris / Kataloga numurs / Catalogus nummer / Numer katalogowy / Număr de catalog / Номер по каталогу / Katalógové číslo / Kataloški broj / Katalog numarası / Номер за каталогом / 目录号

Authorized Representative in the European Community / Оторизиран представител в Европейската общност / Autorizovaný zástupce pro Evropském společenství / Autoriseret repræsentant i De Europæiske Fællesskaber / Autorisierter Vertreter in der Europäischen Gemeinschaft / Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα / Representante autorizado en la Comunidad Europea / Volitatud esindaja Euroopa Nõukogus / Représentant autorisé pour la Communauté européenne / Autorizuirani predstavnik u Europskoj uniji / Meghatalmazott képviselő az Európai Közösségben / Rappresentante autorizzato nella Comunità Europea / Европа қауымдастығындағы уәкілетті өкіл /유럽 공동체의 위임 대표 / Įgaliotasis atstovas Europos Bendrijoje / Pilnvarotais pārstāvis Eiropas Kopienā / Bevoegde vertegenwoordiger in de Europese Gemeenschap / Autorisert representant i EU / Autoryzowane przedstawicielstwo we Wspólnocie Europejskiej / Representante autorizado na Comunidade Europeia / Reprezentantul autorizat pentru Comunitatea Europeană / Уполномоченный представитель в Европейском сообществе / Autorizovaný zástupca v Európskom spoločenstve / Autorizovano predstavništvo u Evropskoj uniji / Auktoriserad representant i Europeiska gemenskapen / Avrupa Topluluğu Yetkili Temsilcisi / Уповноважений представник у країнах ЄС / 欧洲共同体授权代表

In Vitro Diagnostic Medical Device / Медицински уред за диагностика ин витро / Lékařské zařízení určené pro diagnostiku in vitro / In vitro diagnostisk medicinsk anordning / Medizinisches In-vitro-Diagnostikum / In vitro διαγνωστική ιατρική συσκευή / Dispositivo médico para diagnóstico in vitro / In vitro diagnostika meditsiiniaparatuur / Dispositif médical de diagnostic in vitro / Medicinska pomagala za In Vitro Dijagnostiku / In vitro diagnosztikai orvosi eszköz / Dispositivo medicale per diagnostica in vitro / Жасанды жағдайда жүргізетін медициналық диагностика аспабы / In Vitro Diagnostic 의료 기기 / In vitro diagnostikos prietaisas / Medicīnas ierīces, ko lieto in vitro diagnostikā / Medisch hulpmiddel voor in-vitro diagnostiek / In vitro diagnostisk medisinsk utstyr / Urządzenie medyczne do diagnostyki in vitro / Dispositivo médico para diagnóstico in vitro / Dispozitiv medical pentru diagnostic in vitro / Медицинский прибор для диагностики in vitro / Medicínska pomôcka na diagnostiku in vitro / Medicinski uređaj za in vitro dijagnostiku / Medicinteknisk produkt för in vitro-diagnostik / İn Vitro Diyagnostik Tıbbi Cihaz / Медичний пристрій для діагностики in vitro / 体外诊断医疗设备

Temperature limitation / Температурни ограничения / Teplotní omezení / Temperaturbegrænsning / Temperaturbegrenzung / Περιορισμοί θερμοκρασίας / Limitación de temperatura / Temperatuuri piirang / Limites de température / Dozvoljena temperatura / Hőmérsékleti határ / Limiti di temperatura / Температураны шектеу /온도 제한 / Laikymo temperatūra / Temperatūras ierobežojumi / Temperatuurlimiet / Temperaturbegrensning / Ograniczenie temperatury / Limites de temperatura / Limite de temperatură / Ограничение температуры / Ohraničenie teploty / Ograničenje temperature / Temperaturgräns / Sıcaklık sınırlaması / Обмеження температури / 温度限制

Batch Code (Lot) / Код на партидата / Kód (číslo) šarže / Batch-kode (lot) / Batch-Code (Charge) / Κωδικός παρτίδας (παρτίδα) / Código de lote (lote) / Partii kood / Numéro de lot / Lot (kod) / Tétel száma (Lot) / Codice batch (lotto) / Топтама коды / 배치 코드(로트) / Partijos numeris (LOT) / Partijas kods (laidiens) / Lot nummer / Batch-kode (parti) / Kod partii (seria) / Código do lote / Cod de serie (Lot) / Код партии (лот) / Kód série (šarža) / Kod serije / Partinummer (Lot) / Parti Kodu (Lot) / Код партії / 批号（亚批）

Contains sufficient for <n> tests / Съдържанието е достатъчно за <n> теста / Dostatečné množství pro <n> testů / Indeholder tilstrækkeligt til <n> tests / Ausreichend für <n> Tests / Περιέχει επαρκή ποσότητα για <n> εξετάσεις / Contenido suficiente para <n> pruebas / Küllaldane <n> testide jaoks / Contenu suffisant pour <n> tests / Sadržaj za <n> testova / <n> teszthez elegendő / Contenuto sufficiente per <n> test / <n> тесттері үшін жеткілікті / <n> 테스트가 충분히 포함됨 / Pakankamas kiekis atlikti <n> testų / Satur pietiekami <n> pārbaudēm / Inhoud voldoende voor “n” testen / Innholder tilstrekkelig til <n> tester / Zawiera ilość wystarczającą do <n> testów / Conteúdo suficiente para <n> testes / Conţinut suficient pentru <n> teste / Достаточно для <n> тестов(а) / Obsah vystačí na <n> testov / Sadržaj dovoljan za <n> testova / Innehåller tillräckligt för <n> analyser / <n> test için yeterli malzeme içerir / Вистачить для аналізів: <n> / 足够进行 <n> 次检测

Consult Instructions for Use / Направете справка в инструкциите за употреба / Prostudujte pokyny k použití / Se brugsanvisningen / Gebrauchsanweisung beachten / Συμβουλευτείτε τις οδηγίες χρήσης / Consultar las instrucciones de uso / Lugeda kasutusjuhendit / Consulter la notice d’emploi / Koristi upute za upotrebu / Olvassa el a használati utasítást / Consultare le istruzioni per l’uso / Пайдалану нұсқаулығымен танысып алыңыз / 사용 지침 참조 / Skaitykite naudojimo instrukcijas / Skatīt lietošanas pamācību / Raadpleeg de gebruiksaanwijzing / Se i bruksanvisningen / Zobacz instrukcja użytkowania / Consultar as instruções de utilização / Consultaţi instrucţiunile de utilizare / См. руководство по эксплуатации / Pozri Pokyny na používanie / Pogledajte uputstvo za upotrebu / Se bruksanvisningen / Kullanım Talimatları’na başvurun / Див. інструкції з використання / 请参阅使用说明

Do not reuse / Не използвайте отново / Nepoužívejte opakovaně / Ikke til genbrug / Nicht wiederverwenden / Μην επαναχρησιμοποιείτε / No reutilizar / Mitte kasutada korduvalt / Ne pas réutiliser / Ne koristiti ponovo / Egyszer használatos / Non riutilizzare / Пайдаланбаңыз / 재사용 금지 / Tik vienkartiniam naudojimui / Nelietot atkārtoti / Niet opnieuw gebruiken / Kun til engangsbruk / Nie stosować powtórnie / Não reutilize / Nu refolosiţi / Не использовать повторно / Nepoužívajte opakovane / Ne upotrebljavajte ponovo / Får ej återanvändas / Tekrar kullanmayın / Не використовувати повторно / 请勿重复使用

Serial number / Сериен номер / Sériové číslo / Serienummer / Seriennummer / Σειριακός αριθμός / Nº de serie / Seerianumber / Numéro de série / Serijski broj / Sorozatszám / Numero di serie / Топтамалық нөмірі / 일련 번호 / Serijos numeris / Sērijas numurs / Serie nummer / Numer seryjny /Número de série / Număr de serie / Серийный номер / Seri numarası / Номер серії / 序列号

For IVD Performance evaluation only / Само за оценка качеството на работа на IVD / Pouze pro vyhodnocení výkonu IVD / Kun til evaluering af IVD ydelse / Nur für IVD-Leistungsbewertungszwecke / Μόνο για αξιολόγηση απόδοσης IVD / Sólo para la evaluación del rendimiento en diagnóstico in vitro / Ainult IVD seadme hindamiseks / Réservé à l'évaluation des performances IVD / Samo u znanstvene svrhe za In Vitro Dijagnostiku / Kizárólag in vitro diagnosztikához / Solo per valutazione delle prestazioni IVD / Жасанды жағдайда «пробирка ішінде»,диагностикада тек жұмысты бағалау үшін / IVD 성능 평가에 대해서만 사용 / Tik IVD prietaisų veikimo charakteristikoms tikrinti / Vienīgi IVD darbības novērtēšanai /Uitsluitend voor doeltreffendheidsonderzoek / Kun for evaluering av IVD-ytelse / Tylko do oceny wydajności IVD / Uso exclusivo para avaliação de IVD / Numai pentru evaluarea performanţei IVD / Только для оценки качества диагностики in vitro / Určené iba na diagnostiku in vitro / Samo za procenu učinka u in vitro dijagnostici / Endast för utvärdering av diagnostisk användning in vitro / Yalnızca IVD Performans değerlendirmesi için / Тільки для оцінювання якості діагностики in vitro / 仅限 IVD 性能评估

For US: "For Investigational Use Only"

Lower limit of temperature / Долен лимит на температурата / Dolní hranice teploty / Nedre temperaturgrænse / Temperaturuntergrenze / Κατώτερο όριο θερμοκρασίας / Límite inferior de temperatura / Alumine temperatuuripiir / Limite inférieure de température / Najniža dozvoljena temperatura / Alsó hőmérsékleti határ / Limite inferiore di temperatura / Температураның төменгі руқсат шеги / 하한 온도 / Žemiausia laikymo temperatūra / Temperatūras zemākā robeža / Laagste temperatuurlimiet / Nedre temperaturgrense / Dolna granica temperatury / Limite mínimo de temperatura / Limită minimă de temperatură / Нижний предел температуры / Spodná hranica teploty / Donja granica temperature / Nedre temperaturgräns / Sıcaklık alt sınırı / Мінімальна температура / 温度下限

CONTROL Control / Контролно / Kontrola / Kontrol / Kontrolle / Μάρτυρας / Kontroll / Contrôle / Controllo / Бақылау / 컨트롤 / Kontrolė / Kontrole / Controle / Controlo / Контроль / kontroll / Контроль / 对照

CONTROL + Positive control / Положителен контрол / Pozitivní kontrola / Positiv kontrol / Positive Kontrolle / Θετικός μάρτυρας / Control positivo / Positiivne kontroll / Contrôle positif / Pozitivna kontrola / Pozitív kontroll / Controllo positivo / Оң бақылау / 양성 컨트롤 / Teigiama kontrolė / Pozitīvā kontrole / Positieve controle / Kontrola dodatnia / Controlo positivo / Control pozitiv / Положительный контроль / Pozitif kontrol / Позитивний контроль / 阳性对照试剂

CONTROL – Negative control / Отрицателен контрол / Negativní kontrola / Negativ kontrol / Negative Kontrolle / Αρνητικός μάρτυρας / Control negativo / Negatiivne kontroll / Contrôle négatif / Negativna kontrola / Negatív kontroll / Controllo negativo / Негативтік бақылау / 음성 컨트롤 / Neigiama kontrolė / Negatīvā kontrole / Negatieve controle / Kontrola ujemna / Controlo negativo / Control negativ / Отрицательный контроль / Negatif kontrol / Негативний контроль / 阴性对照试剂

STERILE EO Method of sterilization: ethylene oxide / Метод на стерилизация: етиленов оксид / Způsob sterilizace: etylenoxid / Steriliseringsmetode: ethylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / Método de esterilización: óxido de etileno / Steriliseerimismeetod: etüleenoksiid / Méthode de stérilisation : oxyde d'éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszere: etilén-oxid / Metodo di sterilizzazione: ossido di etilene / Стерилизация әдici – этилен тотығы / 소독 방법: 에틸렌옥사이드 / Sterilizavimo būdas: etileno oksidas / Sterilizēšanas metode: etilēnoksīds / Gesteriliseerd met behulp van ethyleenoxide / Steriliseringsmetode: etylenoksid / Metoda sterylizacji: tlenek etylu / Método de esterilização: óxido de etileno / Metodă de sterilizare: oxid de etilenă / Метод стерилизации: этиленоксид / Metóda sterilizácie: etylénoxid / Metoda sterilizacije: etilen oksid / Steriliseringsmetod: etenoxid / Sterilizasyon yöntemi: etilen oksit / Метод стерилізації: етиленоксидом / 灭菌方法：环氧乙烷

STERILE R Method of sterilization: irradiation / Метод на стерилизация: ирадиация / Způsob sterilizace: záření / Steriliseringsmetode: bestråling / Sterilisationsmethode: Bestrahlung / Μέθοδος αποστείρωσης: ακτινοβολία / Método de esterilización: irradiación / Steriliseerimismeetod: kiirgus / Méthode de stérilisation : irradiation / Metoda sterilizacije: zračenje / Sterilizálás módszere: besugárzás / Metodo di sterilizzazione: irradiazione / Стерилизация әдici – сәуле түсipy / 소독 방법: 방사 / Sterilizavimo būdas: radiacija / Sterilizēšanas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Steriliseringsmetode: bestråling / Metoda sterylizacji: napromienianie / Método de esterilização: irradiação / Metodă de sterilizare: iradiere / Метод стерилизации: облучение / Metóda sterilizácie: ožiarenie / Metoda sterilizacije: ozračavanje / Steriliseringsmetod: strålning / Sterilizasyon yöntemi: irradyasyon / Метод стерилізації: опроміненням / 灭菌方法：辐射

Biological Risks / Биологични рискове / Biologická rizika / Biologisk fare / Biogefährdung / Βιολογικοί κίνδυνοι / Riesgos biológicos / Bioloogilised riskid / Risques biologiques / Biološki rizik / Biológiailag veszélyes / Rischio biologico / Биологиялық тәуекелдер / 생물학적 위험 / Biologinis pavojus / Bioloģiskie riski / Biologisch risico / Biologisk risiko / Zagrożenia biologiczne / Perigo biológico / Riscuri biologice / Биологическая опасность / Biologické riziko / Biološki rizici / Biologisk risk / Biyolojik Riskler / Біологічна небезпека / 生物学风险

Caution, consult accompanying documents / Внимание, направете справка в придружаващите документи / Pozor! Prostudujte si přiloženou dokumentaci! / Forsigtig, se ledsagende dokumenter / Achtung, Begleitdokumente beachten / Προσοχή, συμβουλευτείτε τα συνοδευτικά έγγραφα / Precaución, consultar la documentación adjunta / Ettevaatust! Lugeda kaasnevat dokumentatsiooni / Attention, consulter les documents joints / Upozorenje, koristi prateću dokumentaciju / Figyelem! Olvassa el a mellékelt tájékoztatót / Attenzione: consultare la documentazione allegata / Абайлаңыз, тиісті құжаттармен танысыңыз / 주의, 동봉된 설명서 참조 / Dėmesio, žiūrėkite pridedamus dokumentus / Piesardzība, skatīt pavaddokumentus / Voorzichtig, raadpleeg bijgevoegde documenten / Forsiktig, se vedlagt dokumentasjon / Należy zapoznać się z dołączonymi dokumentami / Cuidado, consulte a documentação fornecida / Atenţie, consultaţi documentele însoţitoare / Внимание: см. прилагаемую документацию / Výstraha, pozri sprievodné dokumenty / Pažnja! Pogledajte priložena dokumenta / Obs! Se medföljande dokumentation / Dikkat, birlikte verilen belgelere başvurun / Увага: див. супутню документацію / 小心，请参阅附带文档。

Upper limit of temperature / Горен лимит на температурата / Horní hranice teploty / Øvre temperaturgrænse / Temperaturobergrenze / Ανώτερο όριο θερμοκρασίας / Límite superior de temperatura / Ülemine temperatuuripiir / Limite supérieure de température / Gornja dozvoljena temperatura / Felső hőmérsékleti határ / Limite superiore di temperatura / Температураның руқсат етілген жоғарғы шеги / 상한 온도 / Aukščiausia laikymo temperatūra / Augšējā temperatūras robeža / Hoogste temperatuurlimiet / Øvre temperaturgrense / Górna granica temperatury / Limite máximo de temperatura / Limită maximă de temperatură / Верхний предел температуры / Horná hranica teploty / Gornja granica temperature / Övre temperaturgräns / Sıcaklık üst sınırı / Максимальна температура / 温度上限

Keep dry / Пазете сухо / Skladujte v suchém prostředí / Opbevares tørt / Trocklagern / Φυλάξτε το στεγνό / Mantener seco / Hoida kuivas / Conserver au sec / Držati na suhom / Száraz helyen tartandó / Tenere all'asciutto / Құрғақ күйінде ұста / 건조 상태 유지 / Laikykite sausai / Uzglabāt sausu / Droog houden / Holdes tørt / Przechowywać w stanie suchym / Manter seco / A se feri de umezeală / Не допускать попадания влаги / Uchovávajte v suchu / Držite na suvom mestu / Förvaras torrt / Kuru bir şekilde muhafaza edin / Берегти від вологи / 请保持干燥

Collection time / Време на събиране / Čas odběru / Opsamlingstidspunkt / Entnahmeuhrzeit / Ώρα συλλογής / Hora de recogida / Kogumisaeg / Heure de prélèvement / Sati prikupljanja / Mintavétel időpontja / Ora di raccolta / Жинау уақыты / 수집 시간 / Paėmimo laikas / Savākšanas laiks / Verzameltijd / Tid prøvetaking / Godzina pobrania / Hora de colheita / Ora colectării / Время сбора / Doba odberu / Vreme prikupljanja / Uppsamlingstid / Toplama zamanı / Час забору / 采集时间

Peel / Обелете / Otevřete zde / Åbn / Abziehen / Αποκολλήστε / Desprender / Koorida / Décoller / Otvoriti skini / Húzza le / Staccare / Ұстіңгі қабатын алып таста / 벗기기 / Plėšti čia / Atlīmēt / Schillen / Trekk av / Oderwać / Destacar / Se dezlipeşte / Отклеить / Odtrhnite / Oljuštiti / Dra isär / Ayırma / Відклеїти / 撕下

Perforation / Перфорация / Perforace / Perforering / Διάτρηση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Тесік тесу / 절취선 / Perforacija / Perforācija / Perforatie / Perforacja / Perfuração / Perforare / Перфорация / Perforácia / Perforasyon / Перфорація / 穿孔

Do not use if package damaged / Не използвайте, ако опаковката е повредена / Nepoužívejte, je-li obal poškozený / Må ikke anvendes hvis emballagen er beskadiget / Inhal beschädigter Packungnicht verwenden / Μη χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά. / No usar si el paquete está dañado / Mitte kasutada, kui pakend on kahjustatud / Ne pas l'utiliser si l'emballage est endommagé / Ne koristiti ako je oštećeno pakiranje / Ne használja, ha a csomagolás sérült / Non usare se la confezione è danneggiata / Егер пакет бұзылған болса, пайдаланба / 패키지가 손상된 경우 사용 금지 / Jei pakuotė pažeista, nenaudoti / Nelietot, ja iepakojums bojāts / Niet gebruiken indien de verpakking beschadigd is / Må ikke brukes hvis pakke er skadet / Nie używać, jeśli opakowanie jest uszkodzone / Não usar se a embalagem estiver danificada / A nu se folosi dacă pachetul este deteriorat / Не использовать при повреждении упаковки / Nepoužívajte, ak je obal poškodený / Ne koristite ako je pakovanje oštećeno / Använd ej om förpackningen är skadad / Ambalaj hasar görmüşse kullanmayın / Не використовувати за пошкодженої упаковки / 如果包装破损，请勿使用

Keep away from heat / Пазете от топлина / Nevystavujte přílišnému teplu / Må ikke udsættes for varme / Vor Wärme schützen / Κρατήστε το μακριά από τη θερμότητα / Mantener alejado de fuentes de calor / Hoida eemal valgusest / Protéger de la chaleur / Držati dalje od izvora topline / Óvja a melegtől / Tenere lontano dal calore / Салқын жерде сақта / 열을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt no karstuma / Beschermen tegen warmte / Må ikke utsettes for varme / Przechowywać z dala od źródeł ciepła / Manter ao abrigo do calor / A se feri de căldură / Не нагревать / Uchovávajte mimo zdroja tepla / Držite dalje od toplote / Får ej utsättas för värme / Isıdan uzak tutun / Берегти від дії тепла / 请远离热源

Cut / Срежете / Odstřihněte / Klip / Schneiden / Κόψτε / Cortar / Lõigata / Découper / Reži / Vágja ki / Tagliare / Кесіңіз / 잘라내기 / Kirpti / Nogriezt / Knippen / Kutt / Odciąć / Cortar / Decupaţi / Отрезать / Odstrihnite / Iseći / Klipp / Kesme / Розрізати / 剪下

Collection date / Дата на събиране / Datum odběru / Opsamlingsdato / Entnahmedatum / Ημερομηνία συλλογής / Fecha de recogida / Kogumiskuupäev / Date de prélèvement / Dani prikupljanja / Mintavétel dátuma / Data di raccolta / Жинаған тізбекүні / 수집 날짜 / Paėmimo data / Savākšanas datums / Verzameldatum / Dato prøvetaking / Data pobrania / Data de colheita / Data colectării / Дата сбора / Dátum odberu / Datum prikupljanja / Uppsamlingsdatum / Toplama tarihi / Дата забору / 采集日期

µL/test / µL/тест / µL/Test / µL/εξέταση / µL/prueba / µL/teszt / µL/테스트 / мкл/тест / µL/tyrimas / µL/pārbaude / µL/teste / мкл/аналіз / µL/检测

Keep away from light / Пазете от светлина / Nevystavujte světlu / Må ikke udsættes for lys / Vor Licht schützen / Κρατήστε το μακριά από το φως / Mantener alejado de la luz / Hoida eemal valgusest / Conserver à l'abri de la lumière / Držati dalje od svjetla / Fény nem érheti / Tenere al riparo dalla luce / Қараңғыланған жерде ұста / 빛을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt no gaismas / Niet blootstellen aan zonlicht / Må ikke utsettes for lys / Przechowywać z dala od źródeł światła / Manter ao abrigo da luz / Feriți de lumină / Хранить в темноте / Uchovávajte mimo dosahu svetla / Držite dalje od svetlosti / Får ej utsättas för ljus / Işıktan uzak tutun / Берегти від дії світла / 请远离光线

Hydrogen gas generated / Образуван е водород газ / Možnost úniku plynného vodíku / Frembringer hydrogengas / Wasserstoffgas erzeugt / Δημιουργία αερίου υδρογόνου / Producción de gas de hidrógeno / Vesinikgaasi tekitatud / Produit de l'hydrogène gazeux / Sadrži hydrogen vodik / Hidrogén gázt fejleszt / Produzione di gas idrogeno / Газтектес сутегі пайда болды / 수소 가스 생성됨 / Išskiria vandenilio dujas / Rodas ūdeņradis / Waterstofgas gegenereerd / Hydrogengass generert / Powoduje powstawanie wodoru / Produção de gás de hidrogénio / Generare gaz de hidrogen / Выделение водорода / Vyrobené použitím vodíka / Oslobađa se vodonik / Genererad vätgas / Açığa çıkan hidrojen gazı / Реакція з виділенням водню / 会产生氢气

Patient ID number / ИД номер на пациента / ID pacienta / Patientens ID-nummer / Patienten-ID / Αριθμός αναγνώρισης ασθενούς / Número de ID del paciente / Patsiendi ID / No d'identification du patient / Identifikacijski broj pacijenta / Beteg azonosító száma / Numero ID paziente / Пациенттің идентификациялық нөмірі / 환자 ID 번호 / Paciento identifikavimo numeris / Pacienta ID numurs / Identificatienummer van de patiënt / Pasientens ID-nummer / Numer ID pacjenta / Número da ID do doente / Număr ID pacient / Идентификационный номер пациента / Identifikačné číslo pacienta / ID broj pacijenta / Patientnummer / Hasta kimlik numarası / Ідентифікатор пацієнта / 患者标识号

Fragile, Handle with Care / Чупливо, Работете с необходимото внимание. / Křehké. Při manipulaci postupujte opatrně. / Forsigtig, kan gå i stykker. / Zerbrechlich, vorsichtig handhaben. / Εύθραυστο. Χειριστείτε το με προσοχή. / Frágil. Manipular con cuidado. / Õrn, käsitsege ettevaatlikult. / Fragile. Manipuler avec précaution. / Lomljivo, rukujte pažljivo. / Törékeny! Óvatosan kezelendő. / Fragile, maneggiare con cura. / Сынғыш, абайлап пайдаланыңыз. / 조심 깨지기 쉬운 처리 / Trapu, elkitės atsargiai. / Trausls; rīkoties uzmanīgi / Breekbaar, voorzichtig behandelen. / Ømtålig, håndter forsiktig. / Krucha zawartość, przenosić ostrożnie. / Frágil, Manuseie com Cuidado. / Fragil, manipulaţi cu atenţie. / Хрупкое! Обращаться с осторожностью. / Krehké, vyžaduje sa opatrná manipulácia. / Lomljivo - rukujte pažljivo. / Bräckligt. Hantera försiktigt. / Kolay Kırılır, Dikkatli Taşıyın. / Тендітна, звертатися з обережністю / 易碎，小心轻放

R_X Only This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner." / S'applique uniquement aux États-Unis: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner." / Vale solo per gli Stati Uniti: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner." / Gilt nur für die USA: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner." / Sólo se aplica a los EE.UU.: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."

bd.com/e-labeling
KEY-CODE: 500017013

Europe, CH, GB, NO:	**+800 135 79 135**		
International:	**+31 20 794 7071**		
AR	**+800 135 79 135**	**LT**	**8800 30728**
AU	**+800 135 79 135**	**MT**	**+31 20 796 5693**
BR	**0800 591 1055**	**NZ**	**+800 135 79 135**
CA	**+1 855 805 8539**	**RO**	**0800 895 084**
CO	**+800 135 79 135**	**RU**	**+800 135 79 135**
EE	**0800 0100567**	**SG**	**800 101 3366**
GR	**00800 161 22015 7799**	**SK**	**0800 606 287**
HR	**0800 804 804**	**TR**	**00800 142 064 866**
IL	**+800 135 79 135**	**US**	**+1 855 236 0910**
IS	**800 8996**	**UY**	**+800 135 79 135**
LI	**+31 20 796 5692**	**VN**	**122 80297**

BD

Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152 USA

EC REP Benex Limited
Pottery Road, Dun Laoghaire
Co. Dublin, Ireland

Australian Sponsor:
Becton Dickinson Pty Ltd.
4 Research Park Drive
Macquarie University Research Park
North Ryde, NSW 2113
Australia

U.S. Patent Number: 8,617,895.

Rovers® Cervex-Brush® is a trademark of Rovers Medical Devices B.V.
Cytobrush Plus® and Pap Perfect® are trademarks of CooperSurgical, Inc.

1.

BD PrepMate™ Automated Accessory

Operator's Manual

780-08157-00(05) 2015-02
REF 491103,491424

TriPath Imaging, Inc.
7780 Plantation Drive
Burlington, NC 27215 USA

EC REP Benex Limited
Pottery Road, Dun Laoghaire
Co. Dublin, Ireland

Australian Sponsor:
Becton Dickinson Pty Ltd.
4 Research Park Drive
Macquarie University Research Park,
North Ryde, NSW 2113 Australia

Change History

Revision	Pages	Reason
1	All	Update graphics. Updates for new software. General updates. This revision is for FDA review, currently not for sale.
02	All	Update for new print and bind specification sheet.
03	All	Add Australian Representative address. Update EC Rep address. Add LCD display troubleshooting section.
04	All	Changed EC Rep address back to current Shannon, County Clare address. Changed revision format. Changed BD PrepStain density reagent to BD Density Reagent. Changed BD PrepStain Syringes to BD Syringing Pipettes.
05	All	Changed EC Rep address; updated section Loading and Unloading the Specimen Rack; Added user installation instructions.

Table of Contents

Preface 1
- About this manual 1
- Document conventions 1
- Symbol glossary 2
- Advisory information 3

Introduction 5
- Requirements 5

Materials 7
- Materials provided 7
- Materials required but not provided 7
- Equipment required 7

BD PrepMate Automated Accessory Operating Sequence 7
- Operating sequence overview 7
- Operating sequence details 7

Operator Controls 9
- Control key descriptions 9

Operating the BD PrepMate Automated Accessory 11
- Loading/Unloading the specimen rack 11
- BD PrepMate operating instructions 13
- Instrument shut down 14

System Maintenance 14

Operating Messages 15
- Status messages 15
- Error messages 16
- Fault messages 18

Preventative Maintenance 18
- Annual maintenance 18

Troubleshooting 18
- Instrument generated fault messages 18

Repair and Disposal 22

Declaration of Conformity 23
- Warranty information 23

Operational Specifications 24
- Power requirements 24
- Operating conditions 24
- Storage conditions 24
- General 24
- Fusing 24

Appendix: BD PrepMate Automated Accessory Installation Instructions 25

Table of Figures

Figure 1 Voltage warning label 4
Figure 2 BD PrepMate Automated Accessory front view 6
Figure 3 BD PrepMate Automated Accessory rear view 6
Figure 4 BD PrepMate Automated Accessory operator controls 9
Figure 5 Loading the specimen rack 11
Figure 6 Centrifuge tubes loaded into specimen rack 11
Figure 7 BD PrepMate specimen rack to slide tray row & column correspondence 12
Figure 8 Syringe plungers fully seated 12

Preface

About this manual

This manual describes the function, operation, and maintenance of the BD PrepMate™ Automated Accessory. The BD PrepMate Automated Accessory is a component of the BD SurePath™ Liquid-based Pap Test and BD PrepStain™ System; it is not a stand-alone system. Likewise, this insert is not intended to be a stand-alone document; it is a component of the documentation for the BD SurePath Liquid-based Pap Test and BD PrepStain System, and is designed to be included in the three-ring binder for the
BD SurePath Liquid-based Pap Test and BD PrepStain System Operator's Manual.

All questions about the BD PrepMate Automated Accessory should be directed to BD Diagnostics Technical Support. The contact address and phone number can be found in ***Warranty Information*.**

Document conventions

The following conventions are used in this document to identify important information.

- Type like this (**THIS KEY**) indicates a reference to a key to be pressed.
- Type like this (see ***Introduction***) is a reference to text elsewhere in this manual.

There are five notice types used in this manual: three types of warnings, a caution, and a note. The appearance and usage of each type is detailed below:

Warning
Indicates the possibility of severe personal injury or loss of life if instructions are not followed.

Warning
Indicates the possibility of shock and fire potential if instructions are not followed.

Warning
Indicates the possibility of potential exposure to blood and other potentially infectious bodily fluids if instructions are not followed.

Caution
Indicates the possibility of severe equipment damage or invalid results if instructions are not followed.

Note: Gives helpful information about the BD PrepMate Automated Accessory.

Symbol glossary

There are several symbols used on the instrument. Those symbols and their meanings are shown below

	Catalog Number		Manufacturer
	Authorized Representative in the European Community		In Vitro Diagnostic Medical Device
	Consult Instructions for Use		Temperature Limitation
	Biohazard		Caution, risk of electrical shock
	Caution, risk of danger. Consult accompanying documents.		Separate collection of electric and electronic devices according to Directive 2002/96/EC (WEEE). Applies in the countries of the European Union, as well as Norway and Switzerland.
	Alternating current		Protective conductor terminal

Advisory information

Biological and chemical hazards

Warning
Fluids processed by the BD PrepMate Automated Accessory may contain infectious clinical samples and/or toxic or corrosive chemicals. The potential for hazardous exposure exists due to the possibility of spilling these materials. Hand, eye, and clothing protection should be worn at all times.

General Precautions

Good laboratory practices should be followed and all procedures for use of the BD PrepMate Automated Accessory should be strictly observed. Failure to follow recommended procedures as outlined in this manual may compromise performance.

Preparation of samples using the BD PrepMate Automated Accessory should be performed only by persons who have been appropriately trained on the use of the BD PrepMate Automated Accessory.

Specimen Collection and Handling

Warning
Specimen samples may contain potentially infectious agents. Universal precautions should be taken to avoid skin or body fluid contact with specimens.

Warning
If any specimen material spills, the spill should be cleaned up immediately and cleanup materials disposed of properly.

Mechanical Hazards

The BD PrepMate Automated Accessory is a computer controlled device. There is a potential for injury and bodily harm from moving mechanical components when the instrument is in operation. A safety guard cover is provided to prevent accidental contact with any moving components.

Warning
The BD PrepMate Automated Accessory is a computer controlled device. This instrument is designed for hands-off operation. Never reach into the cover when the instrument is operating. As with any moving machinery, there is a possibility of bodily injury. Never reach into the instrument work space while the instrument is operating.

Caution
Federal law restricts the use of this instrument to applications performed on the order of physicians or any other practitioner licensed by the state to order testing associated with the instrument. All users of the instrument and its thin-layer slide products should be appropriately trained and experienced in its use and specific associated tasks.

Caution
This device has been type tested and found to comply with the limits for ISM-Equipment in accordance with the requirements for FCC Part 15 Subpart J, Class A and EN 5011, Class B, which are designed to provide protection against such interference in a residential installation. If the equipment is not used in strict accordance with the manufacturer's instructions, it may cause interference to radio and TV reception or the functionality of other electrical devices.

Note: If it is necessary to interrupt operation of the instrument, press the **STOP** key on the user interface of the BD PrepMate Automated Accessory.

Electrical hazards

The same precautions considered when using any electrical equipment should be observed with this instrument.

The following warning statement is located on the back of the instrument.

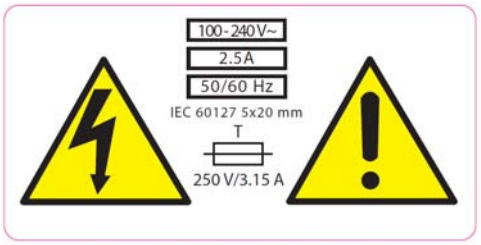


Figure 1 *Voltage warning label*

The rear panel power cord inlet (see *Figure 3*) is considered the main disconnect for the instrument.

Note: If the instrument is used in a manner not specified by BD Diagnostics, the protections provided by this instrument may be impaired and warranty may be voided.

Introduction

1.

1.2

The BD PrepMate Automated Accessory is an accessory to the BD SurePath Liquid-based Pap Test and BD PrepStain System. The BD PrepMate Automated Accessory automates the initial enrichment process of mixing and dispensing the specimen over BD Density Reagent.

The BD PrepMate Automated Accessory mixes and removes the specimen from a BD PrepStain preservative vial. It then layers the specimen onto the density reagent in a centrifuge tube. The automated process handles from one to twelve specimens per cycle.

To reduce the possibility of specimen contamination, the tops of vials are not removed during the process. The BD PrepMate Automated Accessory provides a unique puncture-top process that mixes and dispenses samples from capped vials. Vials, syringes, and tubes are disposable. To eliminate the possibility of specimen contamination, they are not reused.

Requirements

- Gynecologic specimens for preparation using the BD PrepMate Automated Accessory should be collected using an approved sampling device according to the standard collection procedure provided by the manufacturer.
- Training by authorized personnel is a prerequisite for production of BD SurePath slides.
- BD PrepStain supplies must be used. See ***Materials required but not provided*** later in this manual.

Caution
This instrument should be lifted and carried by grasping underneath the base. Do not use either of the blue front panels as a lifting position. Never lift or carry the instrument by the front panel.

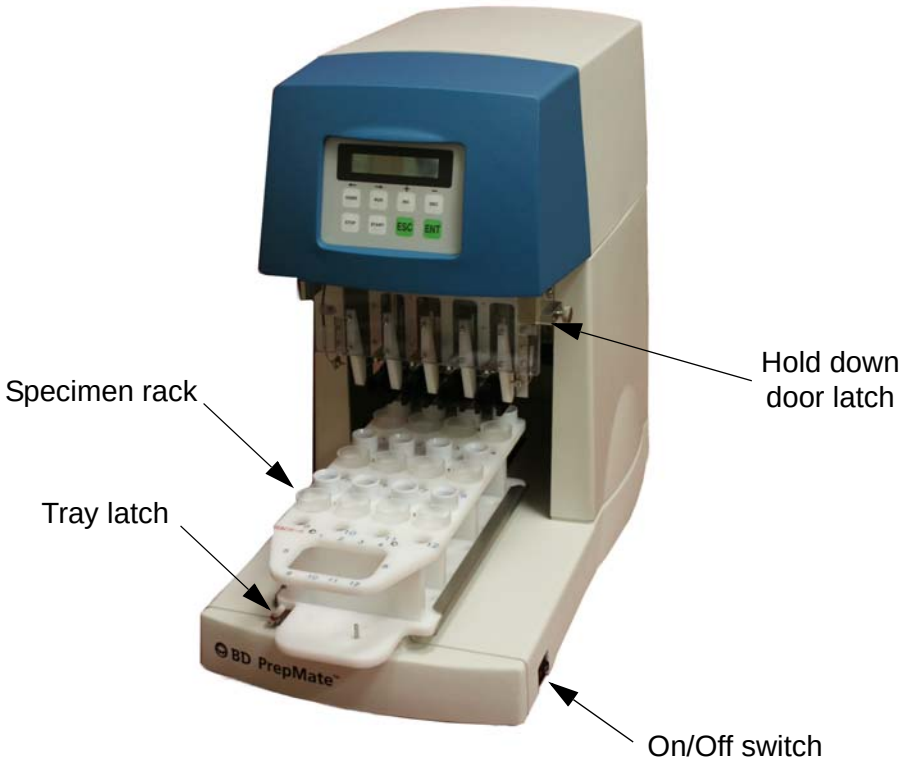


Figure 2 *BD PrepMate Automated Accessory front view*

Figure 3 *BD PrepMate Automated Accessory rear view*

Materials

Materials provided

- BD PrepMate Automated Accessory and power cord(s)
- BD PrepMate specimen racks

Materials required but not provided

The following single-use only materials are available from BD Diagnostics:

- BD PrepMate Consumables Kit
- BD Syringing Pipettes
- BD Centrifuge tubes
- 12-place centrifuge tube holders
- BD SurePath Collection Vials
- BD Density Reagent

Equipment required

- Centrifuge (Various models are available-choose the model most appropriate for your workload.)

BD PrepMate Automated Accessory Operating Sequence

Operating sequence overview

The following steps summarize the BD PrepMate Automated Accessory operating sequence.

1. The user loads the BD PrepMate specimen rack with up to 12 specimens and processing components.
2. The user loads the specimen rack into the BD PrepMate Automated Accessory and presses **START**.
3. The BD PrepMate Automated Accessory mixes, transfers, and layers all specimens. See ***Operating sequence details***. A tone sounds to indicate that this portion of the cell enrichment process is complete.
4. The user unloads the specimen rack and passes the layered specimens on to the centrifugation step.

Operating sequence details

The following steps describe the details of the BD PrepMate Automated Accessory operating sequence.

1. The user powers on and prepares the instrument. See ***BD PrepMate operating instructions***.
2. The first row of syringes is positioned for pickup and is lifted from the specimen rack.

3. The syringe plungers are lifted to a draw level and pushed back down one time while the syringes are being lifted. This pre-mix step improves smoothness of movement of the plunger against the syringe wall during the dispense cycle.
4. The specimen rack is positioned so that the BD SurePath Liquid-based Pap Test preservative vials are directly underneath the syringes.
5. The syringes are lowered so that their tips puncture the seals on the caps of the BD SurePath Liquid-based Pap Test preservative vials and stop near the bottom of each vial.
6. The syringe plungers move up and down for eight cycles to mix the specimen.
7. The plungers are raised to draw the specimen into the syringes.
8. The syringes are raised and the specimen rack is positioned so that the tips are directly over the centrifuge tubes.
9. The syringes are lowered so that their tips rest inside and against the side of the tube containing BD Density Reagent.
10. The specimen is slowly dispensed into the tubes at 3 gradually increased speeds so as not to mix with the BD Density Reagent in the tubes.

    Note: The instrument may be silent and appear to have stopped during this operation.

11. The syringes are then raised and the specimen rack backs up to the original syringe load position.
12. The syringes are lowered back into the specimen rack and the tray backs up to release them.
13. The syringe holder is raised to the top position, completing transfer of the first group of four specimens.
14. Steps 1 - 12 are repeated for the remaining rows until the processing cycle is complete.

Operator Controls

Operator controls are located on the front panel of the instrument. *Figure 4* illustrates these controls.

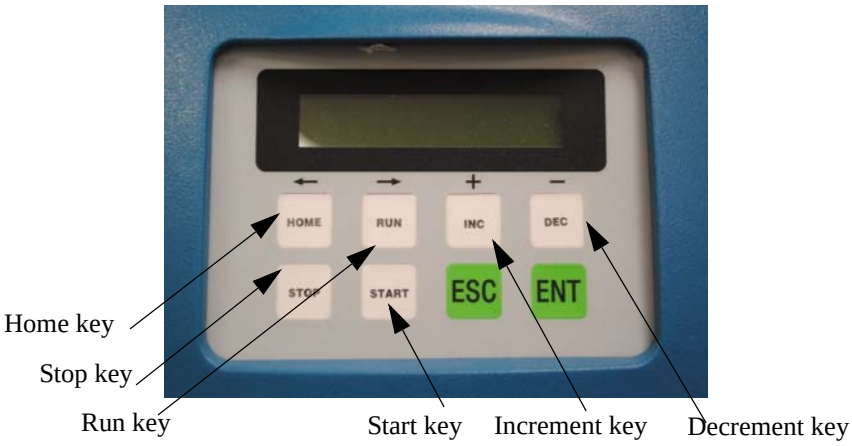


Figure 4 *BD PrepMate Automated Accessory operator controls*

The operator interface is made up of a Liquid Crystal Display (LCD) panel and eight control keys. The LCD panel displays messages to indicate the operating status and prompts when action is required. When a key is pressed, the current message is interrupted for a short period of time to identify the key pressed. Follow the instructions indicated on the LCD panel. In normal operation, these instructions signal the operator to either insert a rack, change a rack, or to press **START**.

Refer to ***Operating Messages*** later in this manual for details on this panel's displays.

Control key descriptions

The control keys are located on the front panel of the instrument (see *Figure 4*). These keys allow control of the BD PrepMate Automated Accessory.

HOME

Use this key to return all BD PrepMate Automated Accessory components to their start-up positions. If a row is being processed when **HOME** is pressed the components do not return to the home position until that row is processed. This key is also used during power up to home the motors.

RUN

Use this key to resume processing after an interruption. When the **RUN** key is pressed the normal processing sequence resumes.

INC

Use this key to increase the number of rows in the processing cycle. This key is needed only if too few rows were selected. Each time a processing cycle completes, the setting returns to the default value (3).

Do not change this setting in the middle of a processing cycle. Wait until a new rack is loaded.

DEC

Use this key to decrease the number of rows in the processing cycle. When there are fewer than twelve vials to process, change the rows to
2 (8 vials) or
1 (4 vials). Each time a processing cycle completes, the setting returns to the default value (3).

Do not change this setting in the middle of a processing cycle. Wait until a new rack is loaded.

STOP

Use this key to interrupt processing. The **STOP** key can be pressed at any time during the cycle.

START

Use this key to begin the processing cycle. After a specimen rack is inserted, removed or replaced, push this key to begin a cycle. Inserting or replacing a rack activates the tray latch. The instrument will not begin operating until the tray is properly latched.

ESC and ENT

These keys are used only at the manufacturing facility. They are used to program the operator interface. These keys do not have a role in the day-to-day use of the product. Do not use these keys.

Operating the BD PrepMate Automated Accessory

Please read this procedure carefully before operating.

Caution
Manually moving metal tray may cause instrument malfunction. Contact BD for assistance with moving the metal tray by hand.

Loading/ Unloading the specimen rack

1. Confirm that the specimen vials and centrifuge tubes are properly accessioned (labeled). Vortex the vials.
2. Insert the specimen vials to be processed into the specimen rack starting at vial row 1 (see *Figure 5*). Fill each row of 4 in order until the rack is full (12 vials), or until all of the vials to be processed are loaded. Make sure that the vials are fully seated in their circular wells. If processing fewer than three rows of vials, start loading vials at vial row 1.

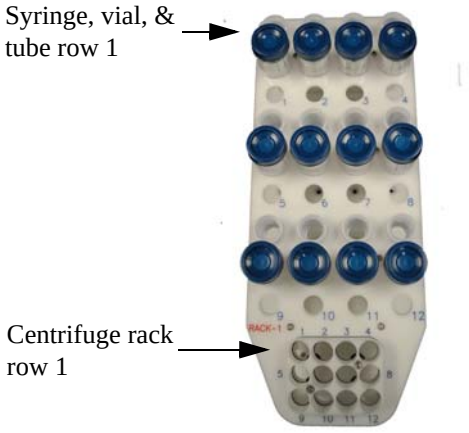


Figure 5 *Loading the specimen rack*

3. Load the centrifuge tubes into the specimen rack. Insert each tube adjacent to its specimen vial, and then pipette 4 mL of BD Density Reagent into each tube.

Figure 6 *Centrifuge tubes loaded into specimen rack*

4. Confirm that each tube is labeled the same as its corresponding specimen vial (i.e., the vial loaded in the same row and column). The correspondence between rows and columns in the specimen rack and the BD PrepStain slide tray is illustrated in *Figure 7*. The illustration identifies the location of Position 1 (row 1, column 1) in three places: the syringe, vial, and tube rows on the BD PrepMate specimen rack; the centrifuge rack rows; and the rows on the slide tray.

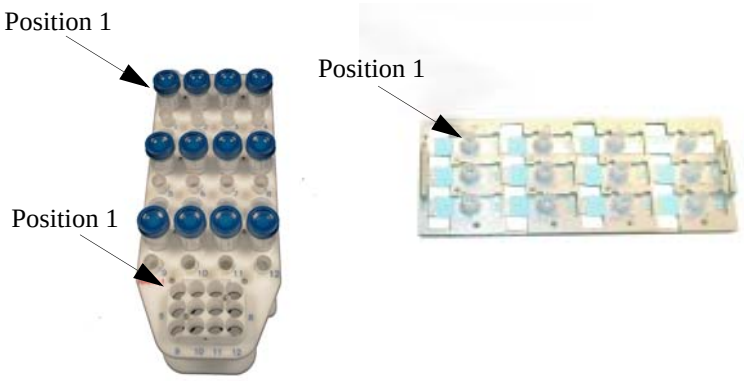


Figure 7 *BD PrepMate specimen rack to slide tray row & column correspondence*

5. Place a syringe into the rack adjacent to each vial. Ensure that the plunger of each syringe is fully seated. The BD PrepMate Automated Accessory will not operate if a plunger is too high.

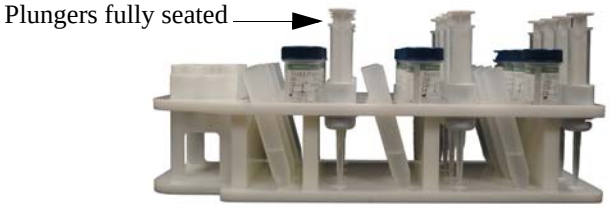


Figure 8 *Syringe plungers fully seated*

6. After the specimen rack has been processed (see ***BD PrepMate operating instructions*** below) carefully unload the rack. Place the tubes containing the cell suspension and density reagent into the centrifuge racks in the same order as they were in the BD PrepMate Automated Accessory. *Figures 5* and *7* illustrate the proper correspondence between the centrifuge racks and the BD PrepMate specimen rack.

7. For each residual specimen vial to be retained, the existing cap should be replaced. (Replacement caps can be ordered from BD.) Handle the punctured caps and open specimen vials with care to avoid cross-contamination. Dispose of the punctured caps properly into a biohazard material container.
8. Remove syringing pipettes and discard. Dispose of the syringes properly into a biohazard material container. The tips of the syringes should not come in contact with the specimen rack.
9. Clean the specimen rack after each use to prevent cross-contamination. See ***System Maintenance*** for the specimen rack cleaning procedure.

Caution
After the specimen sample has been layered onto the density reagent in the tube, samples should be centrifuged within 30 minutes to obtain optimum process results.

Caution
To maintain chain of custody, take care to properly orient the labeled, centrifuge tubes and specimen vials when loading the BD PrepMate specimen rack and when transferring the centrifuge tubes to centrifuge racks.

BD PrepMate operating instructions

1. Make sure the instrument is connected to an AC power source and the side panel power switch is in the **On** position. When the power is first turned on, the LCD panel displays the message **INITIALIZING**. After approximately 15 seconds, the message **READY TO HOME vX.X PRESS HOME** is displayed.
   Press the **HOME** key to complete the initialization process and move all the motors to their start positions.

   Note: This operation is only performed during initial power up of the instrument and is not repeated if the power remains on during regular operation.

   After the initialization sequence is complete, the instrument displays the message **PREPMATE READY, (v X.X) LOAD SPECIMEN RACK** (X.X indicates the current software version).
2. Make sure the vial hold-down door is in the vertical, latched position.
3. Place a prepared specimen rack into the instrument's tray. See ***Loading/Unloading the specimen rack*** for instructions on loading the specimen rack. Slide the specimen rack in from the front until the tray latch at the front left corner of the tray engages (See *Figure 2*).

4. If processing fewer than three rows, press **DEC** to decrease the number of specimen rows to the correct setting before pressing **START**. The number of rows to be processed appears in parentheses as part of the **PRESS START** message. When **DEC** or **INC** is pressed, the display is updated accordingly. If any problems occur, follow the instructions that appear on the display.
5. When a specimen rack processing cycle completes, an audible tone sounds. Replace the finished rack with the next rack to be processed, reset the number of rows if necessary, and press **START**.
6. **Inspect the centrifuge tubes to verify that the correct amount of sample has been transferred.** The dispense action is verified automatically, but a visual inspection for the correct volume level should also be performed in case of a syringe tip clog or system failure. The correct amount of sample in the tube is:
   12 mL ± 1 mL (4 mL of density reagent and 8 mL of sample).

Instrument shut down

Once all daily usage is complete and the instrument is unloaded, press the toggle switch (on the right side of the instrument) to the **OFF** position to shut down the instrument.

System Maintenance

Perform the following system maintenance tasks as necessary.

Caution

- Disconnect power before servicing or cleaning
- Do not remove the cover
- No serviceable parts inside
- Refer servicing to qualified personnel only
- Do not spray with any liquids; excessive moisture may cause an electrical hazard
- Do not allow liquid to enter the horizontal motion slots in the bottom cover and the vent slots located on the rear of the instrument

Clean the specimen racks after every run to prevent cross-contamination.

1. Dampen a wipe with antiseptic solution, such as 5 to 10% bleach solution. Wring wipe of excess liquid.

2. Wipe down the specimen rack using the dampened antiseptic wipe making sure all excess liquid is removed.

   Do not spray the antiseptic solution directly onto specimen racks.

   Do not place specimen racks in a dishwasher.

   Repeat steps 1 and 2 for each specimen rack to be cleaned.
3. Dispose of all wipes by placing them into a biohazard material container.

As needed, wash the specimen racks in soap and warm water to remove any residue or buildup. This type of cleaning does not need to be performed after every run.

Clean the instrument tray and the area under the tray daily.

1. Dampen a wipe with antiseptic solution, such as 5 to 10% bleach solution. Wring wipe of excess liquid.
2. Wipe down the tray using the dampened antiseptic wipe making sure all excess liquid is removed.
3. Dispose of the wipe by placing it into a biohazard material container.

Clean the outer surfaces of the instrument as needed.

1. Wipe the outer surfaces using a mild soap and water solution. If disinfection is required, use isopropyl alcohol.

Plastic disposables may contain infectious material and therefore should be disposed of as a potential biohazard.

Operating Messages

The LCD panel displays a number of status, error and fault messages. The message types are defined below.

- Status messages describe the progress of the processing cycle.
- Error messages describe a problem and what to do to correct it.
- Fault messages describe a problem that requires repair, and advise calling maintenance.

Status messages

The following status messages display during the normal progress of the processing cycle. The messages are listed in alphabetic rather than chronological order.

CHANGE SPECIMEN RACK
PRESS RUN

This message is displayed if **RUN** is pressed after a processing cycle is complete, but before changing the specimen rack.

Remove the specimen rack, slide in the next one, and then press **RUN** to continue processing.

DEC TO # OF SPECIMEN
ROWS (-) PRESS START

This message is displayed as soon as the normal start up sequence is complete and a loaded specimen rack is in place. If the number of rows (indicated in parenthesis) is incorrect, use the **DEC** and **INC** keys to set it correctly. When the number is correct, press **START** to begin the processing sequence.

FINISHED
CHANGE SPECIMEN RACK

This message is displayed when a processing cycle is complete.

Remove the specimen rack, slide in the next one, and then press **RUN** to continue processing.

BD PREPMATE READY v x.x
LOAD SPECIMEN RACK

In this message, "x.x" indicates the current software version. When the normal start up sequence is complete, this message is displayed until a specimen rack is loaded into the instrument.

PROCESSING...STAY
CLEAR WHILE RUNNING

This message is displayed during the normal sequence of operation. No action is required until the processing complete message is displayed and the tone sounds.

Error messages

The following error messages describe a problem and what to do to correct it. The messages are listed in alphabetic order.

CLOSE VIAL HOLD-DOWN
DOOR, PRESS RUN

This message is displayed if the vial hold-down door is not latched. It will continue to display until the latch is closed and the **RUN** button is pressed.

The vial hold-down door secures and prevents the specimen vials from being dislodged by the syringes. The door is hinged to allow access to the syringe grippers if required. A sensor detects the door position and prevents the instrument from operating if the door is not latched. The instrument will not operate until this door is closed.

PIPETTE PLUNGER UP
FIX & PRESS RUN

This message is displayed if the plunger of one of the syringes (pipettes) is not completely seated when you start a run. A through-beam fiber optic sensor located at the bottom of the vial hold-down

door is positioned to shine a beam directly over the top of the syringe plungers. If any of the four plungers in the row is not completely seated before the syringe enters the syringe grippers, the sensor detects it and stops horizontal movement so that the syringe will not be forced into the syringe gripper. The plunger must be pushed down manually before the run can proceed.

SEAT RACK IN TRAY
PRESS RUN

The rack tray contains a pivoting latch at the front left corner. This latch holds the rack in the tray but allows the rack to be removed. A proximity sensor underneath the tray senses whether the latch is open or closed. The instrument is not allowed to run unless the latch is closed. The latch must be opened and re-closed to start operation. Opening and closing the latch indicates a specimen rack has been inserted or changed.

This message occurs if the latch is not seated properly when **START** is pressed or if the latch opens during processing. The latch must be closed before processing can be started or continued.

TRAY ALIGNED, PRESS
RUN TO CONTINUE

This message is displayed when the tray has been repositioned properly. When the tray is in place and this message is displayed, visually confirm that the row of syringes is aligned with the vertical assembly that picks them up, and then press **RUN** to continue. This message is only displayed after the **TRAY MOVEMENT DETECT RE-ALIGN TRAY** message has been displayed, and the tray has been properly repositioned.

TRAY MOVEMENT DETECT
RE-ALIGN TRAY

This message indicates that a tray is out of alignment. This can occur if the tray is bumped out of position. Move the tray gradually forward or backward until the **TRAY ALIGNED, PRESS RUN TO CONTINUE** message is displayed. When the tray is in place, visually confirm that the row of syringes is aligned with the vertical assembly that picks them up, and then press **RUN** to continue. If the message appears again, it indicates a fault with the horizontal sensor. Call BD Diagnostics Technical Support or your authorized distributor.

WRONG DRAW VOLUME
PRESS RUN TO RETRY

The mechanical draw action of the syringes is verified on each draw. This message is displayed if the draw action is insufficient.

The last step of the ***BD PrepMate operating instructions*** is a visual verification of the draw volume. The absence of this error message

indicates only that the mechanical draw action is correct. A visual verification step still needs to be performed.

This problem can be caused by a clog in one of the syringe tips. Retry the draw cycle by pressing **RUN** (this can be repeated as many times as desired.) If the message continues to display after several tries, call BD Diagnostics Technical Support or your authorized distributor.

Fault messages

Fault messages are displayed when the instrument detects that there is a problem that requires repair. All such faults are identified by a **CALL MAINTENANCE** message that also describes the type of failure.

If one of these messages is displayed, contact BD Diagnostics Technical Support or your authorized distributor.

Preventative Maintenance

Caution:
- Disconnect power before servicing or cleaning
- Refer servicing to qualified personnel only
- No serviceable parts inside
- Do not remove the cover

Annual maintenance

- The BD PrepMate Automated Accessory is designed to operate with no routine maintenance other than cleaning. Refer to ***System Maintenance*** for details.
- Annual maintenance must be performed by authorized personnel.

Troubleshooting

Instrument generated fault messages

This section describes messages that indicate an operating fault condition. Following the troubleshooting directions should lead to resolution.

LCD DISPLAY BECOMES SCRAMBLED OR UNREADABLE

If the instrument continues processing a tray after the fault occurs, allow the instrument to finish processing the tray before proceeding with troubleshooting. If the machine ceases to function at the time of the fault, remove the tray and syringes that are being processed to clear any jams and continue to troubleshooting.

Troubleshooting

- Turn the power switch to the **OFF** position for 30 seconds and re-apply power. If the LCD display and instrument appear to be

functioning correctly after reapplying power, continue operation as normal.

- If cycling the power did not clear the fault condition; repeat cycling the power one more time. If the LCD display and instrument appear to be functioning correctly after reapplying power, continue operation as normal.
- If cycling the power does not clear the fault condition or the problem persists, call BD Diagnostics Technical Support.

SEAT RACK IN TRAY
PRESS RUN

This fault message is displayed if the latch that secures the specimen rack in the tray is not seated properly. The rack tray contains a pivoting latch at the front left corner, which holds the rack in the tray, but also allows the rack to be removed. A proximity sensor underneath the tray senses that the latch is closed or open. *The instrument will not run unless the latch is closed. Also, the latch must be opened and re-closed before new processing can begin.*

The latch must be opened and closed to start operation. This indicates a specimen rack has been inserted or changed. This message occurs if the latch is not closed completely when **START** is pressed or if the latch is opened during processing. *The latch must be closed before processing can be started or continued.*

Troubleshooting

- Has the latch been opened and closed?
- Has a specimen rack been removed and/or added to the tray?
- Does the latch rotate freely from open to close position with and without the rack in place?
- Call BD Diagnostics Technical Support if the answer to each of these questions is "yes" and problems persist.

To reset the fault: follow message on the display, verify that the latch is closed and seated, and press the **START** or **RUN** button to continue processing

CLOSE VIAL HOLD-DOWN
DOOR, PRESS RUN

The vial hold-down door must be latched in the down position for the BD PrepMate Automated Accessory to run. Attached to this door are mechanical fingers that engage the top of the specimen vial so that the vial cannot be raised out of the rack when the syringe tip is removed from the vial.

The door can be rotated upward to access the syringe grippers/ pipettes. There is a proximity sensor that senses the position of the door and prevents the
BD PrepMate Automated Accessory from operating if the door is raised or unlatched. This message is displayed any time the door is raised.

If a processing cycle is not in progress, another one cannot be started until the door is closed. If a processing cycle is in progress, it will stop when the door is raised. To restart the cycle close the door, and then press **RUN**.

Troubleshooting

- Is the vial hold-down door latched in place?
- Has the BD PrepMate Automated Accessory been moved?
- Check to see how the cover and hold-down door are mounted on the instrument.
- If problems persist, call BD Diagnostics Technical Support.

**PIPETTE PLUNGER UP,
PRESS RUN**

A through-beam fiber optic sensor is located in front of the vial hold-down door. It is positioned to shine the beam directly over the top of the syringe plungers. If any of the four plungers in the row is not completely down, just before the syringe enters the syringe grippers, the sensor detects it and stops horizontal movement so that the syringe will not be forced into the gripper. This message will be displayed and *the plunger must be pushed down before the run continues*.

Troubleshooting

- Do the optic sensors line up with each other on the door?
- Is there a beam of light being emitted from one sensor to the other sensor?
- Are all plungers pushed down on the syringes?
- Has the specimen rack been re-seated into the tray?
- Are there any plastic pieces (flash) sticking up from the top of the plunger?
- If problems persist, call BD Diagnostics Technical Support.

To reset the fault: follow the message on the display and press the **RUN** button to continue processing.

**TRAY MOVEMENT DETECT,
RE-ALIGN TRAY**

This message indicates that the tray is out of alignment. This can occur if the tray is bumped out of position. If this message appears again after the tray has been realigned, a horizontal out sensor fault is indicated.

Troubleshooting

- Gradually move the tray forward or backward until the **TRAY ALIGNED, PRESS RUN TO CONTINUE** message is displayed.
- Verify that the row of syringes is properly aligned with the current row of syringe holding grippers.
- Push the **RUN** key.
- If the rack was bumped while it was in the rack loading position, pull the rack fully to the front stop and press **RUN.** If the problem is not resolved, a horizontal out sensor fault is indicated. Turn off the BD PrepMate Automated Accessory for a few seconds and then back on to recycle the start position.
- If problems persist, call BD Diagnostics Technical Support.

**WRONG DRAW VOLUME,
PRESS RUN TO RETRY**

The mechanical draw action of the syringes is verified on each draw. This message is displayed if the draw action is insufficient, most likely caused by a clog.

The last step of the ***BD PrepMate operating instructions*** is a visual verification of the draw volume. The absence of this error indicates only that the mechanical draw action is correct. The visual verification step must still be performed.

Troubleshooting

- To reset the fault: the operator is prompted to re-try by pressing **RUN**. The draw can be tried as many times as desired. The mixing cycle will not be repeated if the draw cycle is repeated.
- Run the draw cycle for the current row several times to see if the clog can be cleared. If unable to clear the fault, press **RUN** and when the syringe plunger reaches the bottom of its stroke, press **STOP**. This should allow the vial hold-down door to be raised so that the syringes can be removed for inspection. Only do one syringe at a time. Be careful not to bump the rack to cause a misalignment of the rack to the syringe position. Use good laboratory techniques while performing this operation.

- Visually inspect the removed syringe to determine if a clog can be seen.

  Is the pipette orifice restricted in any way?

  Is there debris in the specimen clogging the pipette tips?

- Replace the syringe if clogged; move to the next syringe and repeat procedure. Once all syringes in the row have been checked, close the vial, hold down door and press **RUN**.
- Are pipette tips resting on the bottom of the vial due to incorrect vertical stopping position?
- If problems persist, call BD Diagnostics Technical Support.

HORIZONTAL IN FAULT

Troubleshooting

- Turn off the instrument. Pull out tray; turn on the instrument again.

HORIZONTAL OUT FAULT

Troubleshooting

- Turn off the instrument. Push in tray; turn on the instrument again.

OTHER FAULTS

Should any of the following faults occur or messages appear on the screen, call BD Diagnostics Technical Support.

- Horizontal Position Fault
- Vertical Top Fault
- Vertical Mid Fault
- Vertical Bottom Fault
- Plunger Driver Fault
- Rear Travel Limit
- Draw Sensor Fault
  - Draw Sensor or Connection Failure
- Plunger Sensor Fault
- Tray accidentally moved to the rear travel position
- Fiber optic sensor heads misaligned
- Vial hold-down door hinge screws loose

Note: If there is a loss of power to the BD PrepMate Automated Accessory, the processor does not retain memory. The operator will need to determine which step the process was in and restart testing at the appropriate step.

Repair and Disposal

Please contact BD Diagnostics Technical Support for guidance should repair or disposal of your BD PrepMate Automated Accessory be required. Support staff will provide a Certificate of Decontamination as part of the Returned Material Authorization Form.

Prior to returning the instrument for repair or replacement, please follow the decontamination procedure below:

1. Wipe down all exterior surfaces with a 5% to 10% bleach solution.
2. Attach signed Certificate of Decontamination.

When disposing of the instrument, the respective statutory rules must be observed. Pursuant to Directive 2002/96/EC (WEEE), all devices supplied after August 13, 2005 may not be disposed as part of domestic waste.
The icon of the crossed-out trash can shows that the device may not be disposed as part of domestic waste. The waste disposal guidelines of the individual EC countries may vary. If necessary, contact your supplier.

Declaration of Conformity

BD Diagnostics certifies that the BD PrepMate Automated Accessory is manufactured in accordance with all applicable standards and regulations.

A full Declaration of Conformity is available upon request. Contact BD Diagnostics Technical Support.

Warranty information

The BD PrepMate Automated Accessory is warranted one year from the date of delivery. For repair or technical support information, contact your authorized distributor, or BD Diagnostics Technical Support.

Technical Support
USA
Technical Service and Support
BD Diagnostics–Diagnostic Systems
www.bd.com/ds
technical_services@bd.com
1-800-638-8663

Service performed by anyone other than BD Diagnostics or its authorized agents may, at the discretion of BD Diagnostics be cause to void this warranty. No other party is authorized to make any warranty or to assume any liability for BD Diagnostics products. No other warranty, either implied or in writing, will be recognized.

Operational Specifications

Power requirements	Rated Voltage: 100–240 VAC, 50–60 Hz Maximum Current: 2.5 A
Operating conditions	Ambient Temperature: 0–36°C, 32–97°F Ambient Humidity: 30% to 85% RH (non-condensing)
Storage conditions	Temperature: 0–50°C, 32–122°F
General	Weight: 80 lbs, 36.3 kg Height: 22” Width: 14” Depth: 23”
Fusing	All fuses are 5x20 mm and are 3.15 A @ 250 VAC time-delay, IEC 60127 rated. The product name plate is located on the rear panel with the power inlet and provides fuse information. Replacement fuses must be the same rating and type (T) as identified. Type T indicates a time-delay acting fuse.

Appendix: PrepMate Installation Instructions

About these instructions

These instructions describe the steps necessary to install the BD PrepMate™ Automated Accessory.

The installer is expected to be either a BD PrepMate Automated Accessory user or an authorized representative of BD Diagnostics. It is also expected that the installer has read and understands the instructions in the BD PrepMate™ Automated Accessory Operator's Manual.

Document conventions

The following conventions are used in this document to identify important information.

- Type like this (**THIS KEY**) indicates a reference to a key that you press.
- Type like this (see ***Introduction***) is a reference to text elsewhere in these instructions.

There are two notice types used in this reference: a caution and a note. The appearance and usage of each type is detailed below.

Caution
Indicates the possibility of severe equipment damage or invalid results if instructions are not followed.

Note: Gives helpful information about the BD PrepMate Automated Accessory.

Advisory information

General Precautions

Caution

- This instrument should be lifted and carried by grasping underneath the base. Do not use either of the blue front panels as a lifting position. Never lift or carry the instrument by the front panel.
- The supplies included in the installation kit are not intended for clinical use. When you complete the verification process, discard any unused supplies.
- Operating the instrument at an improper voltage could result in damage to the instrument.
- Do not operate the system from an AC power outlet without a proper ground connection.
- Installing a power cord with incorrect polarity could create an electrical shock hazard or damage to the instrument.

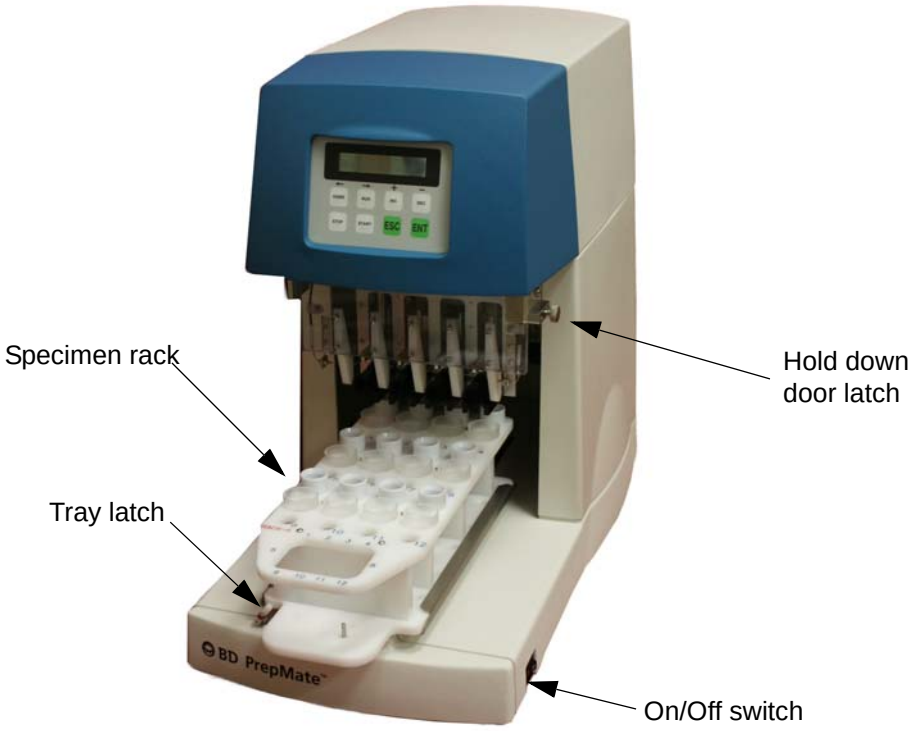


Figure 1 *BD PrepMate Automated Accessory front view*

Figure 2 *BD PrepMate Automated Accessory rear view*

Unpacking the BD PrepMate Automated Accessory

Note: Read all instructions before starting.

1. Unpack all items in the shipping container.
2. Verify that the following components are included in the shipping container:
   - ♦ BD PrepMate Automated Accessory (1)
   - ♦ Power cord (1)
   - ♦ Specimen Racks (4) numbered 1 through 4
   - ♦ Disposable Installation Kit (1) containing:
     - ◆ Syringing pipettes (12)
     - ◆ Empty specimen collection vials (12)
     - ◆ Vial lids (12)
     - ◆ Centrifuge tubes (12)
3. Open the hold-down door and remove the foam packing that supports the gripper framework before attempting any operation.

Initial setup and test run

Before you put the instrument into service, set it up and run a test cycle to confirm proper operation.

Initial setup

1. Carefully inspect the instrument and accessories for any physical damage sustained in transit. If the instrument is received in damaged condition, do not proceed. Call Customer Service.
2. Place the BD PrepMate Automated Accessory on a sturdy workbench. Position the instrument so that the front lower edge is at least six inches back from the front edge of the workbench. This allows the tray to fully extend without protruding past the edge of the working surface. It should not be placed in direct sunlight or near a heat source.
3. Before connecting the power cord, verify that the voltage listed on the rear panel nameplate is compatible with the AC voltage at the operating site. If the voltage available is not compatible, notify BD Diagnostics Technical Support.
4. Connect the AC power cord between the instrument power input module (shown in Figure 2) and the power outlet or uninterruptible power source (UPS).

Note: Use of a UPS (recommended but not supplied) between the power source and the BD PrepMate Automated Accessory is recommended to

prevent interruption of the process in case of a power outage or brown out. The UPS should have a minimum rating of 150 VA for 5 minutes.

Load BD PrepMate Automated Accessory for test run

1. Power up the BD PrepMate Automated Accessory by turning the side panel power switch to the **On** position. The On position is represented by a vertical line (|).
   The LCD panel will light up and display identification messages. If the instrument does not light up, check the fuses and/or the power source for problems. The syringe gripping fingers will move up and the tray will move to the forward position.
2. When the power is first turned on, the LCD panel displays the message **INITIALIZING**. After approximately 15 seconds, the message **READY TO HOME vX.X PRESS HOME** is displayed. Press the **HOME** key to complete the initialization process and move all the motors to their start positions.

   Note: This operation is only performed during initial power up of the instrument and is not repeated if the power remains on during regular operation.

   After the initialization sequence is complete, the instrument displays the message **PREPMATE READY, (v X.X) LOAD SPECIMEN RACK** (X.X indicates the current software version).
3. Use the supplies included in the installation kit to load the specimen rack with 12 capped vials, syringing pipettes (syringes), and centrifuge tubes. Make sure that the vials are fully seated in their circular wells and place a syringe into the rack adjacent to each vial. Make sure that the plunger of each syringe is fully seated.

Note: The BD PrepMate Automated Accessory will not operate if a plunger is too high.

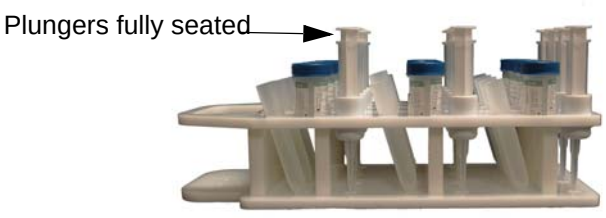


Figure 3 *Syringe plungers fully seated*

Note: For the purposes of this installation procedure, no live patient specimens are used. Refer to the BD PrepMate™ Automated Accessory Operator's Manual for instructions on processing live patient specimens.

4. Load the specimen rack onto the instrument's tray. Slide the specimen rack in from the front until the tray latch at the front left corner of the tray engages (See *Figure 1* for tray latch illustration).

Note: If the tray is not properly latched, the LCD display will not update.

Process a test cycle

1. Once the specimen rack is loaded into the tray, the message **DEC TO # OF SPECIMEN ROWS (-) PRESS START** should be displayed.
2. Make sure the hold-down door is in the vertical, latched position. If the door is not properly latched, the message **CLOSE VIAL HOLD-DOWN DOOR, PRESS RUN** will be displayed. It will continue to display until you close the latch and press **RUN**.
3. Press **START**. The number of rows to be processed appears in parentheses as part of the **PRESS START** message. If any problems occur, follow the instructions that appear on the display.
4. Observe the operating sequence and confirm the following:
   - ♦ The syringe gripping fingers engage and lift the syringes.
   - ♦ The syringes align and puncture the seals on the caps of the empty specimen collection vials and stop near the bottom of each vial.
   - ♦ The syringe plungers are raised and lowered through eight mixing cycles.
   - ♦ The syringe plungers are raised as if drawing preservative fluid into the syringes.
   - ♦ The hold-down fingers retain the vials as the syringes are withdrawn.
   - ♦ The syringes center in the centrifuge tubes and are lowered so that their tips rest inside and against the side of the centrifuge tube before dispensing.
   - ♦ The plungers move slowly into the syringing pipettes as if dispensing into the centrifuge tube.
   - ♦ The syringes are lifted and lowered back into the specimen rack.
5. When a specimen rack processing cycle completes, an audible tone sounds.
6. If the functions in steps 4 are not performed as described, shut down the BD PrepMate Automated Accessory and call Customer Service.

This completes the BD PrepMate Automated Accessory installation. The instrument is now ready for use.

BD PrepMate™ Automated Accessory

Precise Specimen Transfer Directly from BD SurePath™ Collection Vials

BD

Helping all people live healthy lives

The BD PrepMate™ Automated Accessory offers precise automation for BD's unique cellular enrichment process. It mixes, aspirates, and dispenses a defined volume of specimen.

- Eliminates manual cap removal, reducing the risk of contamination
- Flexible, automated process handles 1-12 samples per cycle
- Fast sample processing, taking less than 5 minutes to run 12 samples[1]
- Simple User Interface and small footprint

1.4

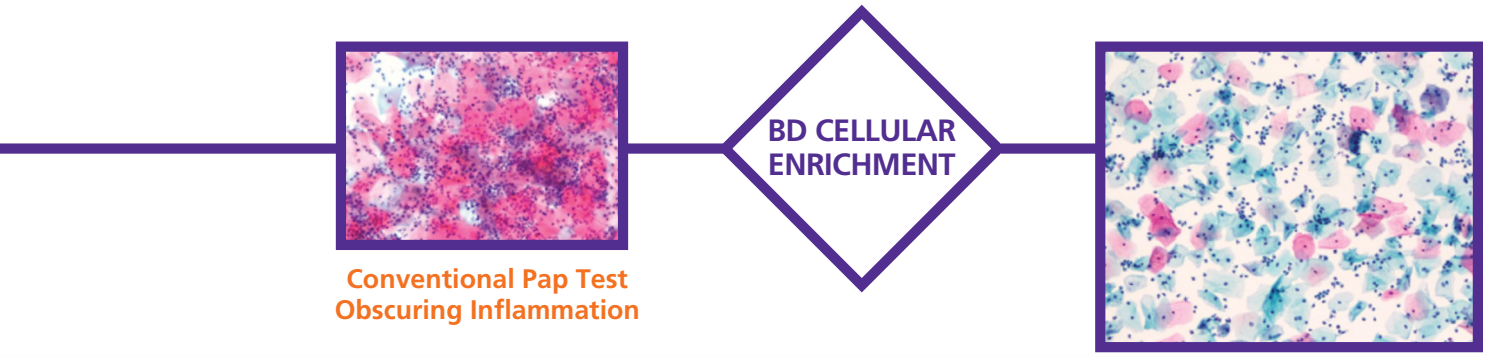
The BD Cellular Enrichment Process

Centrifugal Sedimentation Through BD Density Reagent Helps Remove Non-Diagnostic Components[2]

- Reduces non-diagnostic debris such as excess inflammatory cells, mucus, blood, and lubricants
- Minimizes air-drying artifact and obscuring, overlapping cellular material
- Easier visualization of epithelial cells, diagnostically relevant cells and infectious organisms

Minimizes Unsatisfactory Test Results

- Compared to Conventional Pap Smears BD Sure Path Liquid-based Pap Test reduces the number of unsatisfactory slides and ASCUS results, and provides higher HSIL+ detection.[3]



Conventional Pap Test Obscuring Inflammation

After processing

BD SurePath Liquid-based Pap Test Reduced Inflammation

The BD Cellular Enrichment Process removes non-diagnostic components from specimens, minimizing unsatisfactory test results.

SPECIMEN HANDLING	
Specimen Collection Type:	BD SurePath™ Collection Vial
On-board Sample Capacity:	BD SurePath™ Liquid-based Pap Test: Up to 12 samples
Specimen Transfer and Storage:	BD Syringing Pipettes and BD Centrifuge Tubes

DIMENSIONS	
Height:	55.88 cm (22 in)
Width:	35.56 cm (14 in)
Depth:	58.42 cm (23 in)
Weight:	36.3 kg (80 lbs)

ENVIRONMENTAL REQUIREMENTS	
Ambient Temperature:	0 – 36°C (32 – 97° F)
Ambient Humidity:	30% to 85% RH (non condensing)

ELECTRICAL REQUIREMENTS	
Rated Voltage:	100 – 240 VAC
Maximum Current:	2.5 A
Input Line Frequency:	50 – 60 Hz
Fusing:	Fuses are 5x20 mm, 3.15 A @ 250 VAC time-delay, IEC 60127 rated

Part Number:	491103

1. Data on File
2. Refer to BD SurePath™ Manual Method Product Insert
3. Refer to BD PrepStain™ System Product Insert

BD Diagnostics
7 Loveton Circle
Sparks, MD 21152
800.638.8663
www.bd.com/ds

BD PrepStain™ Slide Processor

User's Manual

Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152 USA

EC REP Benex Limited
Pottery Road, Dun Laoghaire
Co. Dublin, Ireland

Australian Sponsor:
Becton Dickinson Pty Ltd.
4 Research Park Drive
Macquarie University Research Park
North Ryde, NSW 2113 Australia

CE

500005572 (2015-06)(03)

Change History

Revision / Date	Pages	Reason
(01)(2014-11)	All	Manual updated to reflect site transfer from Burlington, NC to Sparks, MD
(02)(2014-12)	All	Corrected catalog number for BD SurePath Precoat Slides
(03)(2015-06)	All	Emphasized the importance of not bumping/hitting the robot. Emphasized the importance of setting up deck correctly (to avoid the robot crashing). Added instructions for keyboard initialization in the case of robotic arm error.

This Operator's Manual describes the function, operation and maintenance of the BD PrepStain™ Slide Processor for use in preparing BD SurePath™ Liquid-Based Pap Test Slides. Training by BD authorized personnel is required before operating the system. Please read this manual before using the BD PrepStain™ Slide Processor using BD SurePath™ reagents. BD SurePath, BD FocalPoint, BD PrepStain, BD Logo, & all other trademarks are property of Becton, Dickinson and Company.

UNIX is a registered trademark of UNIX System Laboratories, Inc.

Hewlett Packard is a registered trademark of the Hewlett Packard Company.

Table of Contents

Table of Contents iii

Preface vii

About this manual vii
Chapter organization vii
Formatting conventions viii

1: System Overview

Installation 1-1
Introduction 1-1
PrepStain components 1-1
Vortexer descriptions 1-1
PrepMate description 1-2
PrepMate specimen rack 1-3
BD Syringing Pipettes 1-3
Centrifuge bucket 1-4
Slides 1-4
Specimen vials 1-4
Centrifuge tubes 1-4
Centrifuge 1-4
Fluid aspiration system 1-5
PrepStain instrument 1-7

2: System Specifications

BD PrepStain™ Slide Processor components 2-1
Multi-vial vortexer (optional) 2-1
Single vial vortexer 2-1
PrepMate specifications 2-2
Centrifuge 2-3
BD PrepStain™ instrument specifications 2-3
PREP system component layout 2-5
Materials required (available from BD) 2-6
Materials required but not provided 2-7
Materials (optional) 2-7
Installation 2-7

3: Principles of Operation

Process overview 3-1
Specimen collection 3-1
Collection vial and devices 3-2
Specimen handling and cell enrichment 3-4
Sample randomization 3-4
BD Density Reagent 3-4
Mixing and layering 3-5
Centrifugation 3-7
Specimen processing with the BD PrepStain™ system 3-7
BD Settling Chamber 3-7
Computer workstation 3-7
PrepStain instrument 3-8
Slide Preparation and staining 3-11
Screening BD SurePath thin-layer preparations 3-15

4: PreProcessing Steps

Preparation of buffered water 4-1
Required materials 4-1
Procedure to make Stock Buffer 4-1
Procedure to make Working Solution of Buffered Water 4-2
Setup for specimen transfer 4-2
Chain of custody 4-2
Prepare slides on slide rack 4-3
PrepStain process procedure 4-4
Reprocessing BD SurePath cell pellets 4-10

5: Gynecologic (GYN) Slide Processing

PrepStain GYN program 5-1
Program overview 5-1
Main Menu screen 5-2
Step in Progress screen details 5-3
Processing gynecologic (GYN) specimens 5-4
Prep only 5-11
Slide Staining 5-12
Change sample/stain parameters 5-15
Scan Barcodes (optional feature) 5-19

6: Maintenance Procedures

Materials required 6-1
Daily preventive maintenance 6-1
Perform system clean up 6-2
Weekly preventive maintenance 6-3
Preparation of 5% cleaning solution 6-3
Flush stain and vacuum lines 6-3
Clean the Z-rod 6-5
Empty gravity and waste containers 6-5
Preventative maintenance 6-5
Monthly preventive maintenance 6-7
Replace Schuco vacuum pump felt silencer 6-7
Clean all water bottles and tubing 6-7

7: Troubleshooting

Error codes and messages 7-1
General error message codes 7-2
..... 7-2
Syringe pump error keys 7-2
..... 7-3
Robot arm error codes 7-3
Problems and solutions 7-4

8: Glossary of terms

9: Setup and Diagnostics

System setup 9-1
Machine setup 9-2
Implement racks 9-3
Computer setup 9-3
Password setup 9-3
Diagnostics 9-4
Keyboard operation 9-5
Random XYZ test 9-5
DiTi Tests 9-7

10: Non-GYN Slide Processing

PrepStain Non-GYN program 10-1
Program overview 10-2
Non-Gyn Main Menu 10-3
Processing non gynecologic (Non GYN) specimens 10-4
Slide arrangements for multiple slides 10-8

Appendix: Ancillary Testing from the BD SurePath Collection Vial

Procedure 11-2
Limitations of Procedure 11-3
General precautions on ancillary testing from BD SurePath Collection Vial 11-4

Symbol Glossary 12-1

Ordering Information 13-1

Preface

About this manual

This manual is designed to be the primary resource for understanding how to use the BD PrepStain™ Slide Processor (PrepStain) to produce BD SurePath™ Liquid-based Pap Test slides (SurePath slides). Users of this manual are expected to have received training by BD-authorized personnel and to have had hands-on experience in processing samples.

Chapter organization

Chapter divisions are organized around the primary tasks associated with processing specimens using the PrepStain system.

- ***Chapter 1***, ***System Overview*** introduces the PrepStain Slide Processor and BD PrepStain system components.
- ***Chapter 2***, ***System Specifications*** details the specifications for each component in the PrepStain system.
- ***Chapter 3***, ***Principles of Operation*** describes the sequence of events in the PrepStain slide preparation work flow.
- ***Chapter 4***, ***PreProcessing Steps*** describes the procedures used to prepare gynecologic specimens for processing by the PrepStain instrument.
- ***Chapter 5***, ***Gynecologic (GYN) Slide Processing*** describes how to use the GYN application to process gynecologic specimen slides.
- ***Chapter 6***, ***Maintenance Procedures*** details the procedures you need in order to properly maintain the PrepStain system
- ***Chapter 7***, ***Troubleshooting*** provides procedures you can use to isolate and resolve problems with the PrepStain system.
- ***Chapter 8***, ***Glossary of terms*** provides definitions of the mechanical components that make up the PrepStain slide processor and the terms used in the process.
- ***Chapter 9***, ***Setup and Diagnostics*** describes how to access and perform the PrepStain instrument’s setup and diagnostic tests.
- ***Chapter 10***, ***Non-GYN Slide Processing*** describes how to use the Non-GYN application to process Non-GYN specimen slides.

CAUTION:

- Federal law restricts this device to sale by or on the order of a physician, or any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device and are trained and experienced in the use of the BD PrepStain™ Slide Processing system.
- This equipment generates and uses radio frequency energy. It has been type tested and found to comply with the limits for ISM-equipment in accordance with the requirements for FCC Part 15 Subpart J, Class A and EN 55011, Class B, which are designed to provide protection against such interference in a residential installation. If the equipment is not used in strict accordance with the manufacturer's instructions, it may cause interference to radio and TV reception or the functionality of other electrical devices.

Formatting conventions

The following types of formatting are used in this document to identify important information.

- Type like this (**This Key**) indicates a reference to a key that you press.
- Type like this (`Type This`) is a reference to a keystrokes that you type.
- Type like this (**`Screen Text`**) is a reference to a text that appears on screen.
- Type like this (see ***Introduction***) is a reference to text elsewhere in this manual.

There are five notice types used in this reference: three warnings, a caution and a note. These notices highlight important information or warn the operator of potentially dangerous situations. The appearance and usage of each type is detailed below:

Warning
Indicates the possibility of severe personal injury or loss of life if instructions are not followed.

Warning
Indicates the possibility of shock and fire potential if instructions are not followed.

Warning
Indicates the possibility of potential exposure to blood and other potentially infectious bodily fluids if instructions are not followed.

CAUTION: Indicates the possibility of equipment damage or invalid results if instructions are not followed.

Note: Gives helpful information about the PrepStain system.

Chapter 1
System Overview

Installation

Installation and initial verification of performance can be performed only by BD-authorized service personnel.

The BD PrepStain™ system arrives in one or more shipping cartons. The remainder of this chapter details the content of these cartons.

Introduction

This chapter introduces the BD PrepStain™ Slide Processor and system components. The components of the system and their functions are described, as are the various consumable items used in processing a BD SurePath Pap test.

Illustrations of each component in the PrepStain process are introduced in the order they would be encountered in the routine laboratory process.

PrepStain components

The following illustrations and descriptions describe the primary components that make up the PrepStain system.

Vortexer descriptions

Figure 1-1: illustrates the single and multi-vial vortexers that are used to mix the specimen so that there is a homogeneous distribution of cells for processing on the BD PrepStain™ Slide Processor instrument

- The single-vial vortexer processes a single specimen vial at a time. It is also used to vortex the centrifuge bucket after the second centrifuge cycle. (This item is not supplied by BD.)
- The multi-vial vortexer allows you to process up to 25 specimen vials at a time. (This item is provided by BD.)

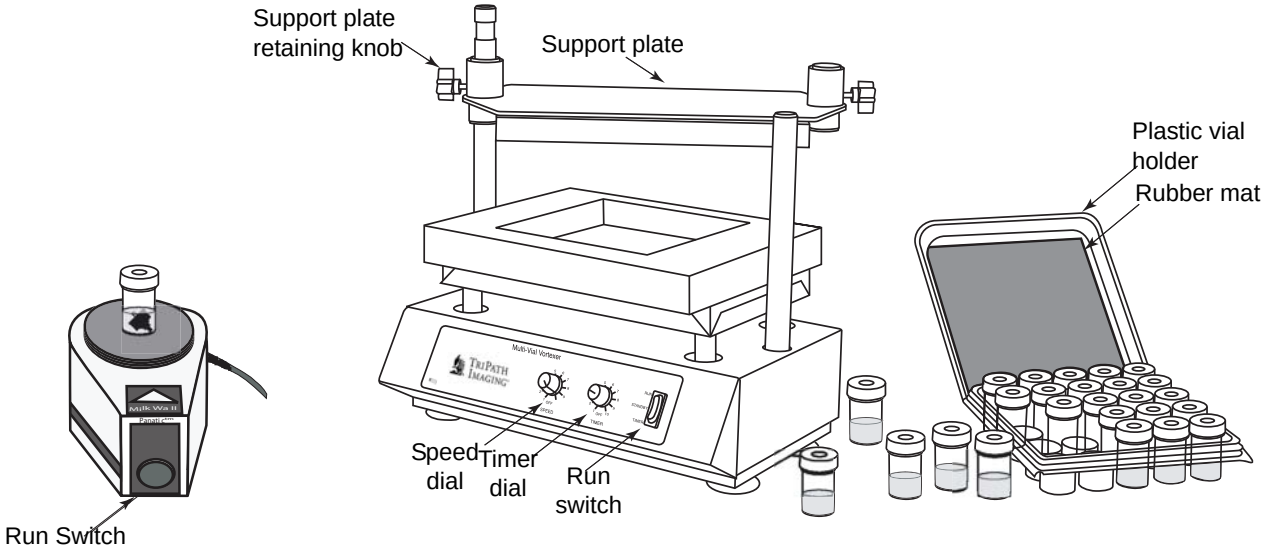


Figure 1-1: *Single and multi-vial vortexers*

PrepMate description

Figure 1-2: illustrates the BD PrepMate Automated Accessory (PrepMate), the specimen processing rack, and the centrifuge bucket. The PrepMate is designed to transfer the cell solution from the BD SurePath Collection Vial (collection vial) to a BD Centrifuge Tube that contains the BD Density Reagent (density reagent).

The specimen rack holds the centrifuge bucket, and up to 12 sets of specimen vials, BD Centrifuge Tubes, and BD Syringing Pipettes (syringing pipettes). The specimen vials contain the detached head of the sampling device, in BD SurePath Preservative Fluid. The centrifuge tubes contain 4 ml of BD Density Reagent (aliquoted into each tube by the user). The syringing pipettes are used to mix and then transfer the specimen solution from the collection vials to the centrifuge tubes. After the transfer, the centrifuge tubes are placed in the centrifuge rack.

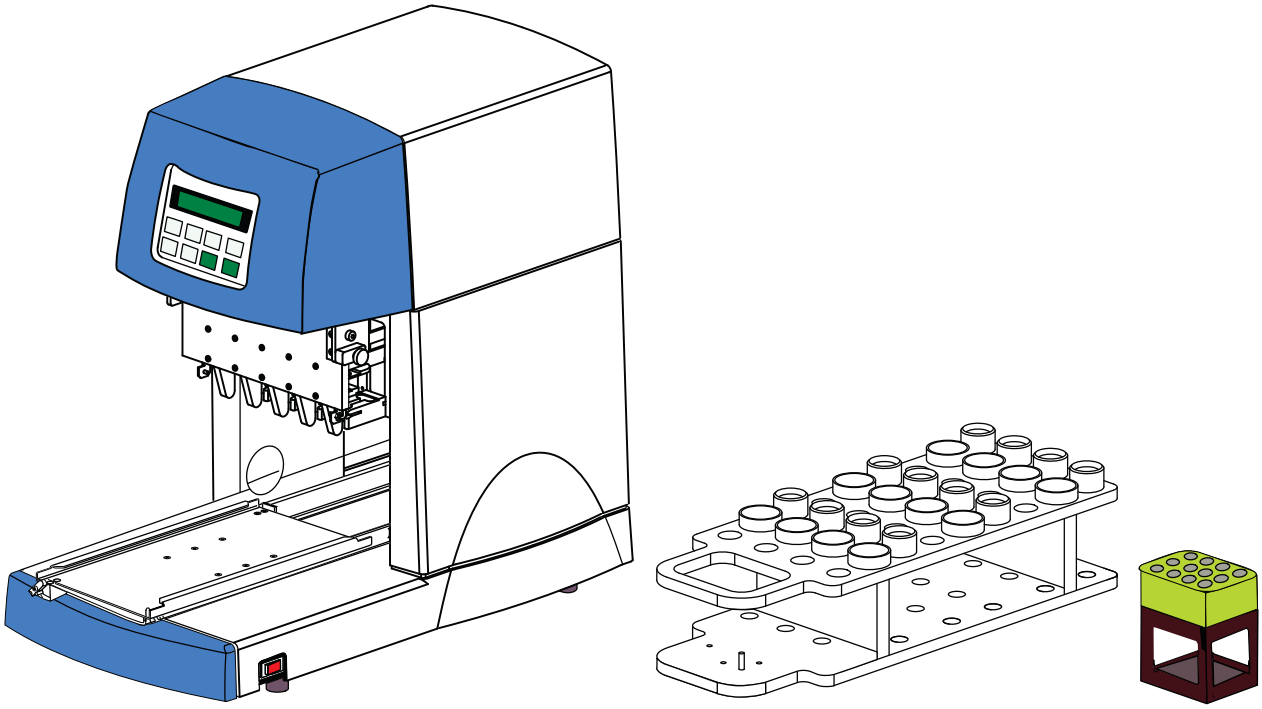


Figure 1-2: *PrepMate, plastic specimen rack, and centrifuge bucket*

PrepMate specimen rack

Figure 1-3: illustrates a PrepMate specimen rack fully loaded with a centrifuge bucket, BD Centrifuge Tubes, specimen vials, and BD Syringing Pipettes.

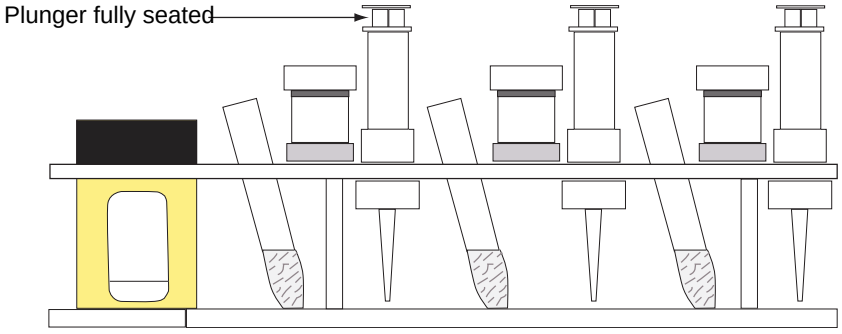


Figure 1-3: *Loaded specimen rack*

BD Syringing Pipettes

The BD Syringing Pipettes (illustrated in *Figure 1-3:*) are plastic syringes that transfer the sample from the specimen vial to the centrifuge tube.

Centrifuge bucket

Figure 1-4: illustrates the centrifuge bucket. As illustrated in figures *1-3*, *1-5*, and *1-13* this component fits into the PrepMate tray, the centrifuge, and the waste station of the PrepStain. It holds the BD Centrifuge Tubes that contain the cell solution and Density Reagent. The bucket holds up to twelve centrifuge tubes at a time through both centrifugation cycles and during processing on the BD PrepStain™ instrument.

Slides

BD SurePath PreCoat Slides are standard 25 by 75 mm microscope slides that have been coated and prepared for use in the BD PrepStain™ System by the manufacturer.

Specimen vials

The BD SurePath Collection Vial (illustrated in figures *1-1* and *1-3*) is used to transport the patient sample.

Centrifuge tubes

The BD Centrifuge Tubes (illustrated in figures *1-4* and *3-11*) are 12 ml plastic test tubes that contain the sample throughout the cell enrichment process.

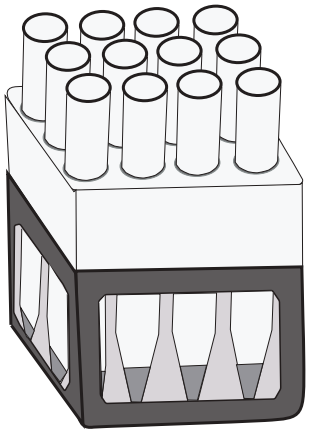


Figure 1-4: *Centrifuge bucket*

Centrifuge

The centrifuge is used to prepare the concentrated cell pellet that is processed on the BD PrepStain™ instrument. This centrifuge provided with the PrepStain system is programmable and includes a variety of safety features. All programs necessary to process specimens on the PrepStain instrument have been pre-programmed at the manufacturer for your convenience. These programs occupy positions numbered 1 through 4 on the centrifuge.

Figure 1-5: illustrates the centrifuge racks being loaded into the centrifuge. The model of centrifuge may vary.

Figure 1-5: *Centrifuging the cell samples*

CAUTION: The centrifuge Operator's Manual is separate from this manual. Please read the centrifuge Operator's Manual before operating the centrifuge.

Fluid aspiration system

Figure 1-6: illustrates the Easy Aspirator (aspirator) block with the tips installed. The aspirator block connects to the vacuum pump by way of a waste bottle that collects the aspirated fluids.

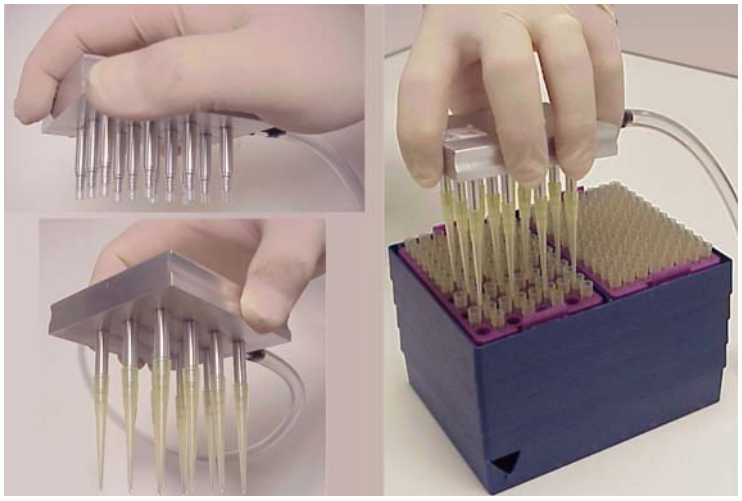


Figure 1-6: *Aspirator with tips*

Figure 1-7: illustrates the vacuum waste bottle with its lid and tubing connections properly secured.

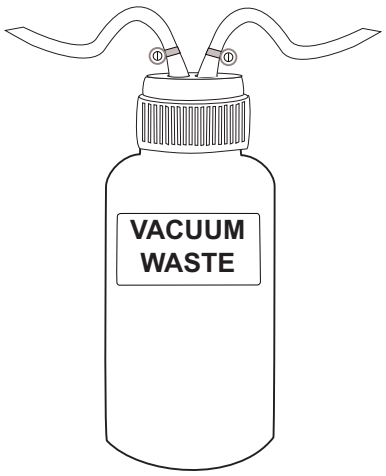


Figure 1-7: *Waste bottle for aspirated fluids*

The vacuum pumps pictured in *Figure 1-8:* and *Figure 1-9:* are used to aspirate excess fluids. There are two of these pumps in a typical BD PrepStain™ system installation. (Either model may be present.)

- One pump is connected to the aspirator block. The tips insert into the BD Centrifuge Tubes, and are used to remove the excess fluids that have been isolated from the cell sample in the first centrifuge cycle.
- The second pump connects to the PrepStain instrument's quad arm. Its function is to aspirate fluids from the BD Settling Chambers.

Figure 1-8: *Vacuum pump (international models may vary)*

Figure 1-9: *KNF pump*

Warning

A potential safety hazard has been identified concerning alcohol vapors that are exhausted from the BD PrepStain vacuum pump (all Schuco and KNF-Neuberger models). The vacuum pump exhausts alcohol vapors during normal operation that could cause a flammable atmosphere if the pump is kept in an enclosed space e.g. cabinet. Remove the vacuum pump from any enclosed spaces that are not well-ventilated. The vacuum pump should be used in a well-ventilated space that is free of ignition sources close to the exhaust.

PrepStain instrument

1. *Figure 1-10:* illustrates the BD PrepStain™ Slide Processsor. The PrepStain instrument transfers cell samples from the BD Centrifuge Tube to a settling chamber mounted on a microscope slide. The PrepStain instrument then automatically stains and rinses each slide.

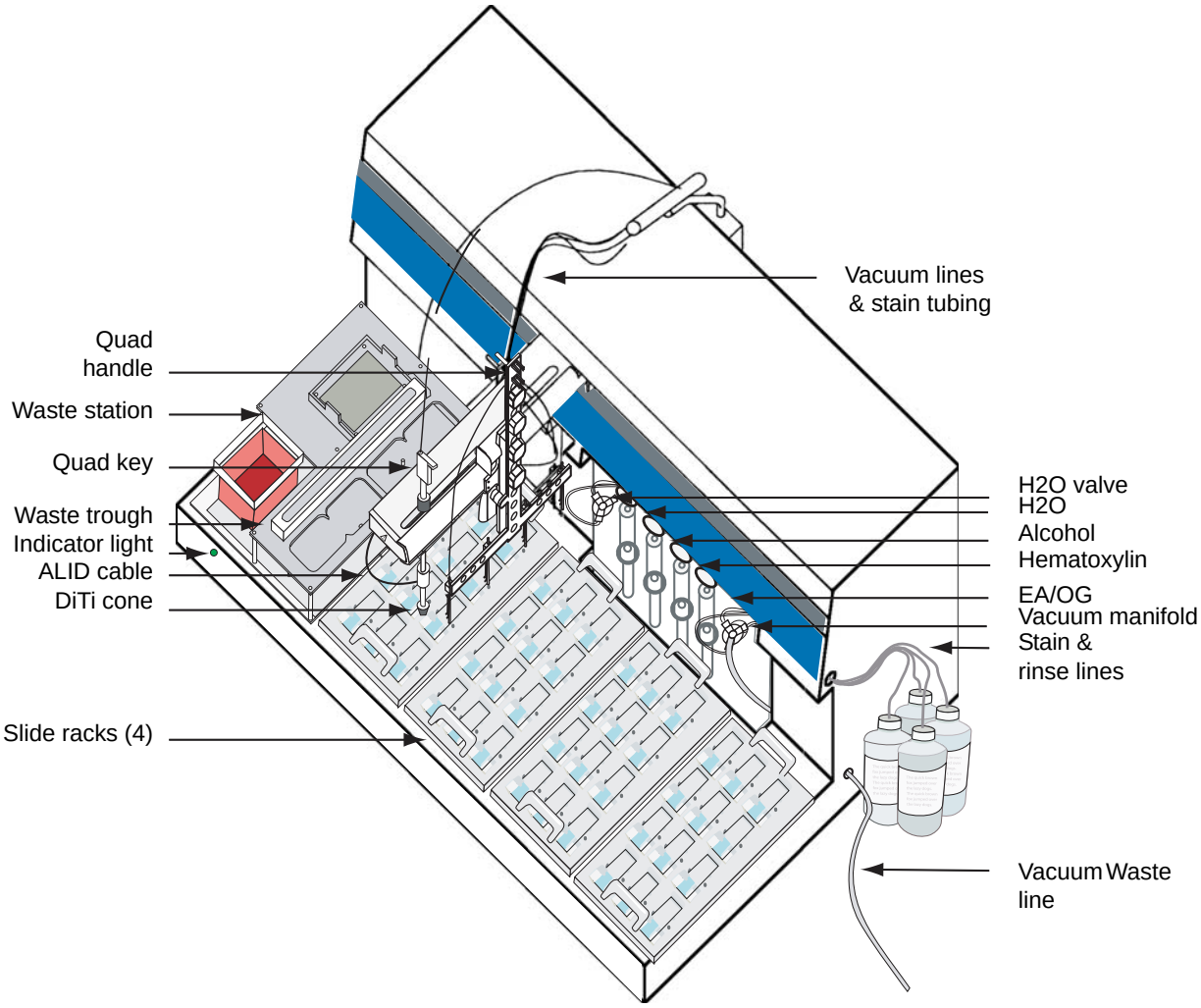


Figure 1-10: *PrepStain instrument, front view*

Warning

- The pipetting instrument is a robotic device that operates under computer control. As with most robotic devices, there is a potential for injury and bodily harm from moving mechanical components whenever the instrument is in operation. The instrument is designed for automatic "hands-off" operation only. Never reach into the instrument work space when the unit is in an operating mode. A safety guard is provided with the instrument to prevent accidental contact with any moving components.
- Bumping the robotic device (Quad arm or DiTi assembly) may result in instrument error.

- If it is necessary to interrupt operation of the instrument, check the screen display for the “User Break” command (the <F-10> key on the computer keyboard. The system will stop after completion of the current command and an option menu will appear on screen.

Warning
This equipment generates, uses and can radiate radio frequency energy, and if not installed and used in accordance with the instructions in this manual, may cause interference to radio communications.

The primary components of the BD PrepStain™ instrument are listed below:

- Robotic processor
- Waste station
- Quad arm
- Disposable Tip (DiTi) Assembly
- Rinsing and staining syringes
- Slide racks

Figure 1-11: illustrates the layout of a typical PrepStain instrument back panel. Refer to this illustration for help locating connections, switches or fuses.

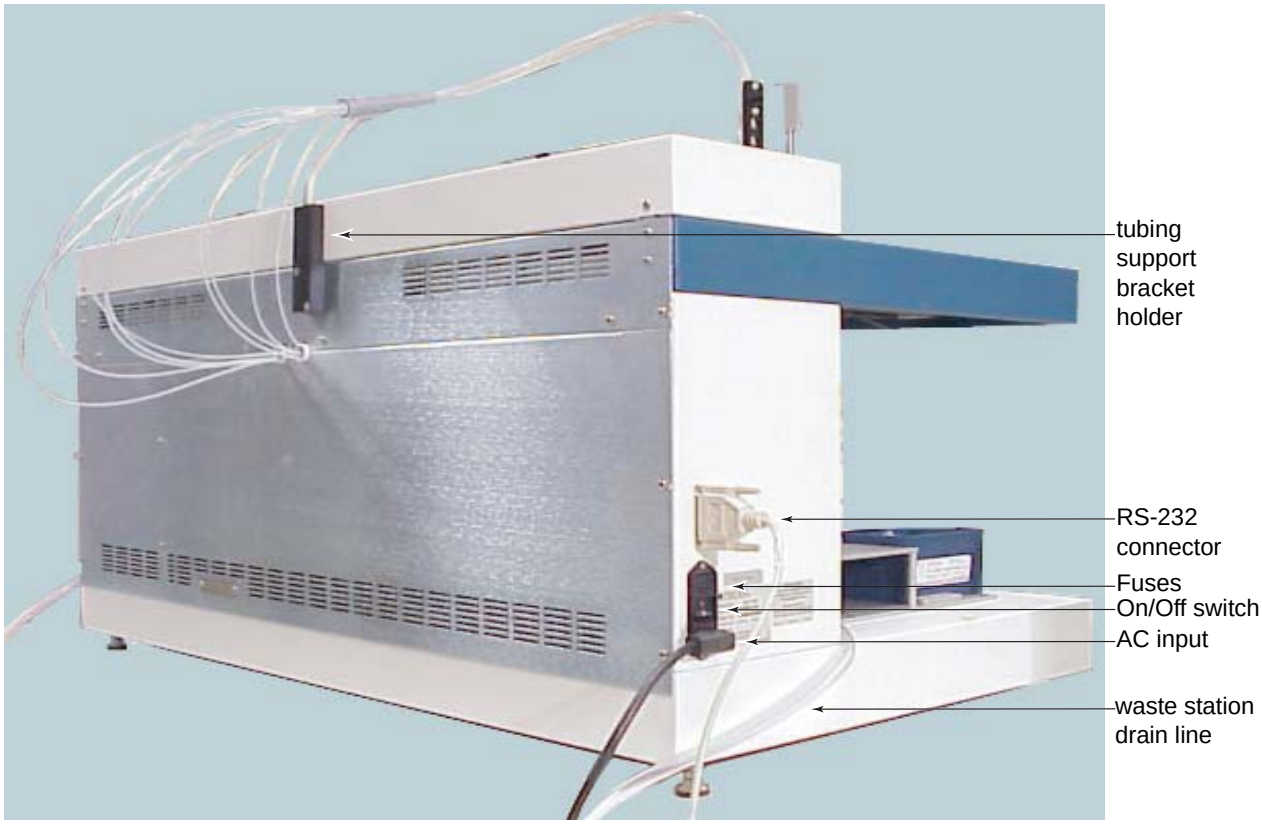


Figure 1-11: *PrepStain instrument, back panel*

Figure 1-12: illustrates the connection layout of the inputs and outputs to the BD PrepStain™ instrument, the PC workstation and monitor, the vacuum pump, the vacuum waste bottle and waste bottle. Refer to this illustration and the following discussion for help in determining if all connections are setup properly.

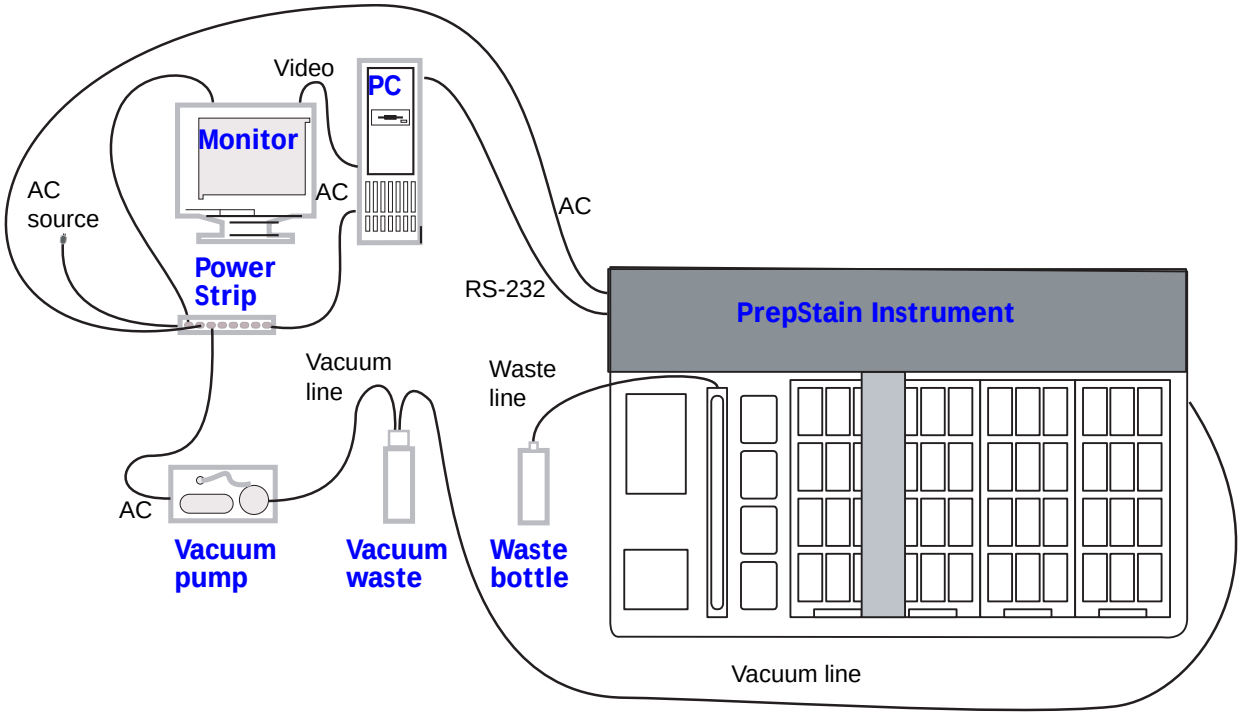


Figure 1-12: *PrepStain system connections*

PrepStain instrument connections

There are two electrical inputs: AC power comes from the power strip and an RS-232 connection provides communication with the PC workstation.

PC workstation connections

Both the workstation and monitor get AC from the power strip. The workstation connects to the PrepStain instrument via an RS-232 cable. The monitor and workstation connect via a standard VGA cable.

Vacuum pump and waste bottle connections

The vacuum pump gets AC from the power strip. A vacuum line connects the pump to the vacuum waste bottle. The other line from the vacuum waste bottle connects to the vacuum manifold on the rear of the PrepStain instrument (refer to *Figure 1-11:*). The waste bottle connects to the waste trough via the waste line tubing.

Figure 1-13: illustrates the primary elements of the waste station. This component slides onto the slide processor as pictured in *Figure 1-10:*.

- The waste container holds discarded tips.
- The tip holder stores unused tips in position for the DiTi arm to pick them up.
- The four centrifuge bucket holders position the BD Centrifuge Tubes so that the pelletized cell samples can be transferred to the BD Settling Chambers.
- The waste trough is used to drain the excess solution that is primed through the DiTi Assembly and reagent pipette bundles.
- The waste tubing drains the waste trough.

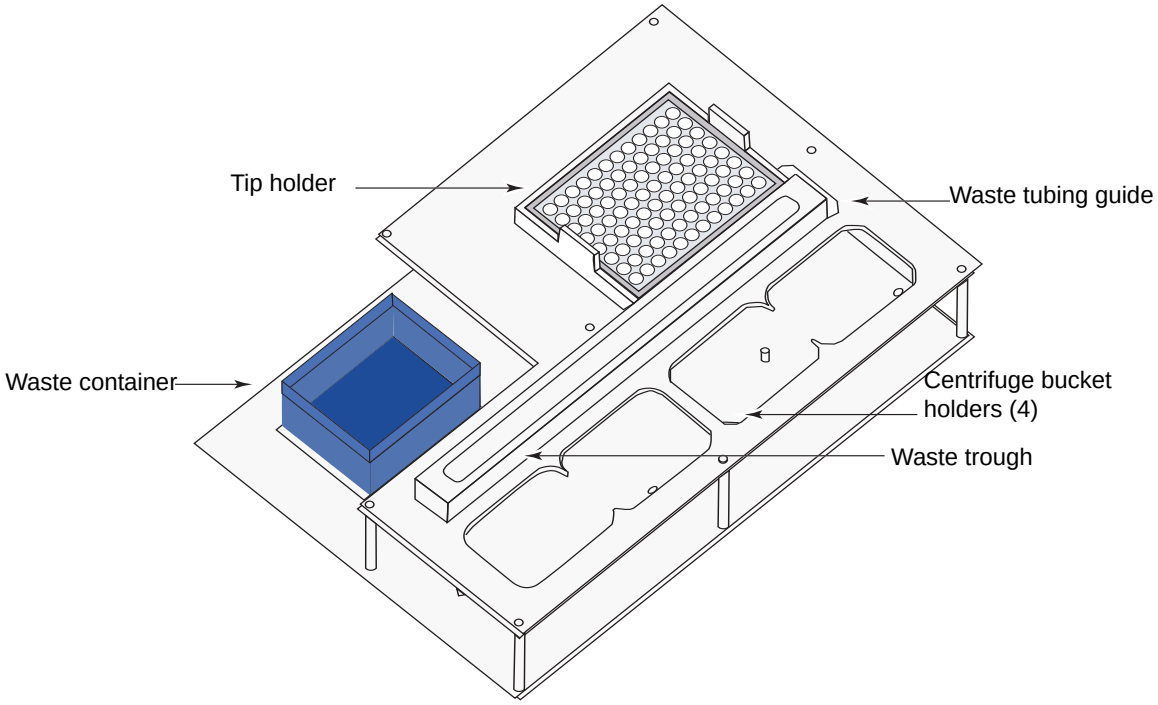


Figure 1-13: *Waste Station*

Figure 1-14: illustrates the quad arm assembly. This assembly mounts to the chassis under the cover plate.

The arm is positioned perpendicular to the work platform and aligns with the slide racks in parallel with the Y axis. The arm's movement is in parallel to the X axis.

Note: The four manifolds correspond to the four reagents used, not to the four bundled sets of pipette tips and aspirator tips. Tubing from each manifold is routed to each bundle.

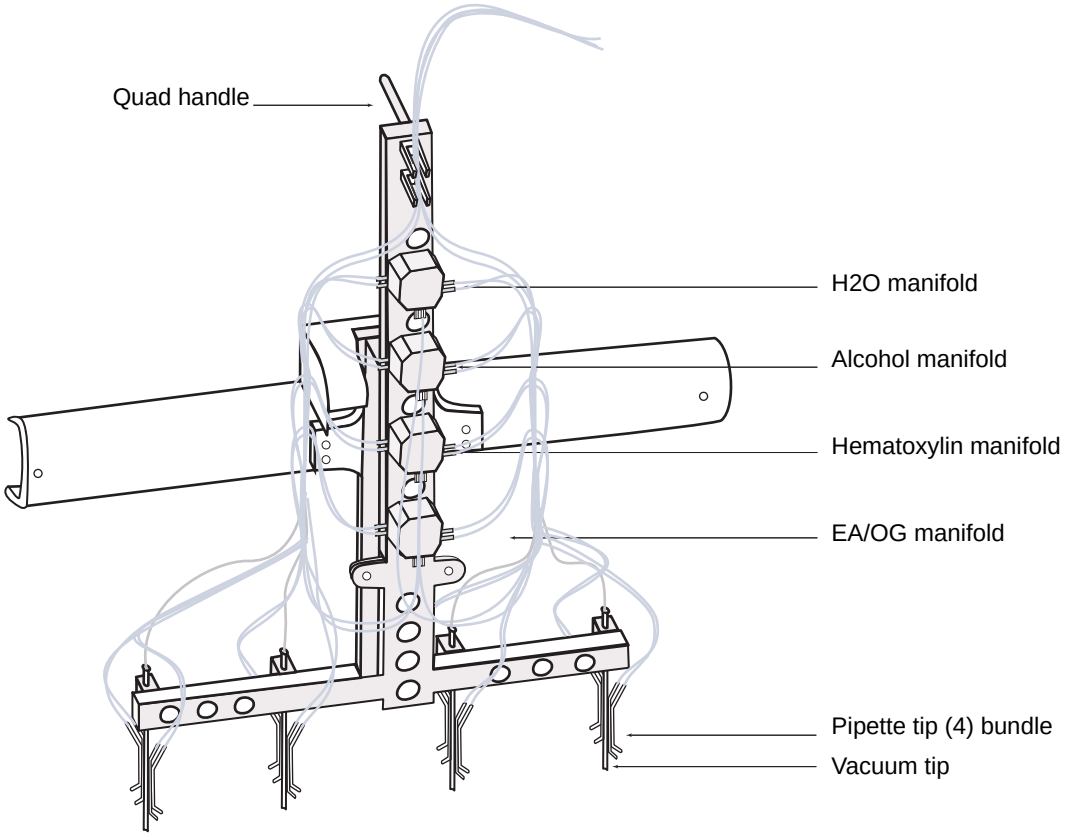


Figure 1-14: *Quad arm with pipette bundles, stain, and vacuum lines*

Figure 1-15: illustrates the key components that make up the disposable tip (DiTi) assembly

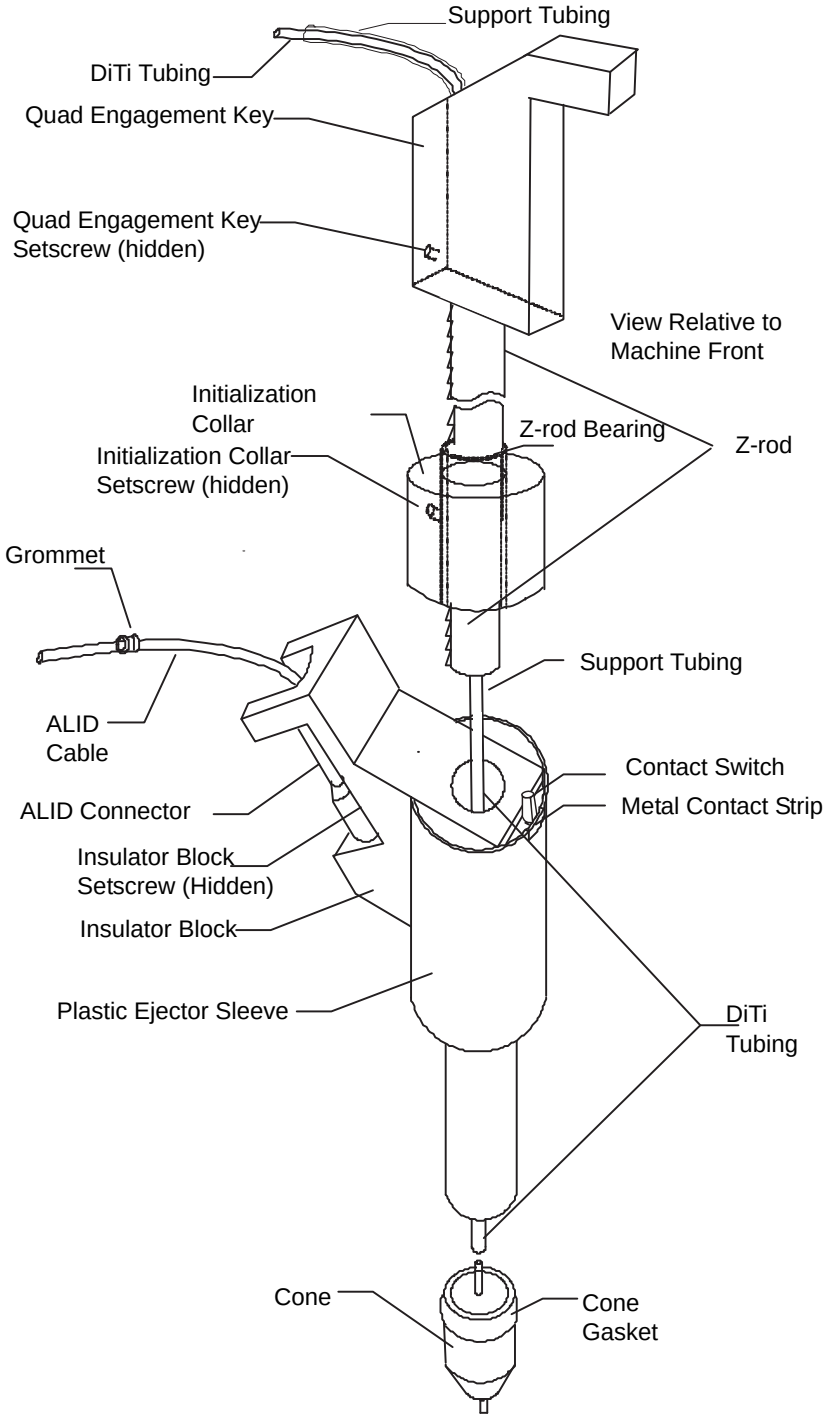


Figure 1-15: *Disposable tip (DiTi) assembly detail*

Figure 1-16: illustrates the 5 ml syringes that are used to pump the rinsing and staining solutions to the quad arm pipette bundles.

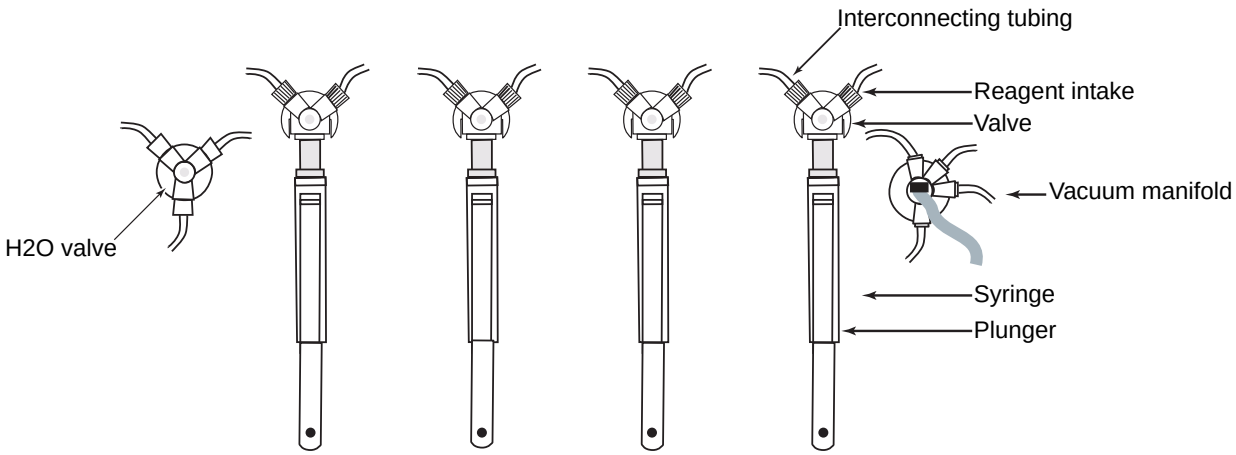


Figure 1-16: *Rinsing and staining syringes*

Figure 1-17: illustrates one of four slide racks. The BD Settling Chambers insert into cutouts and then lock into place with a clockwise twist. Each chamber has a settling chamber seal. This seal keeps the liquid cell solution from seeping out from the settling chamber during processing.

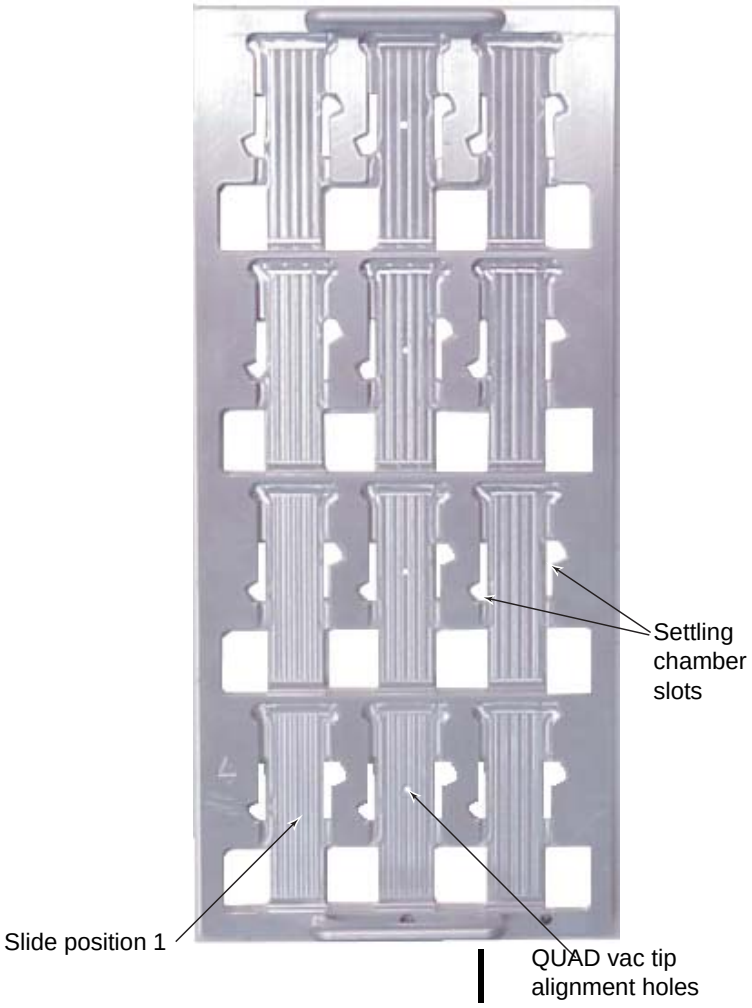


Figure 1-17: *Slide rack with settling chamber slots*

The slide racks insert onto the work platform as illustrated in *Figure 1-18:*. The work platform mounts to the right of the waste station.

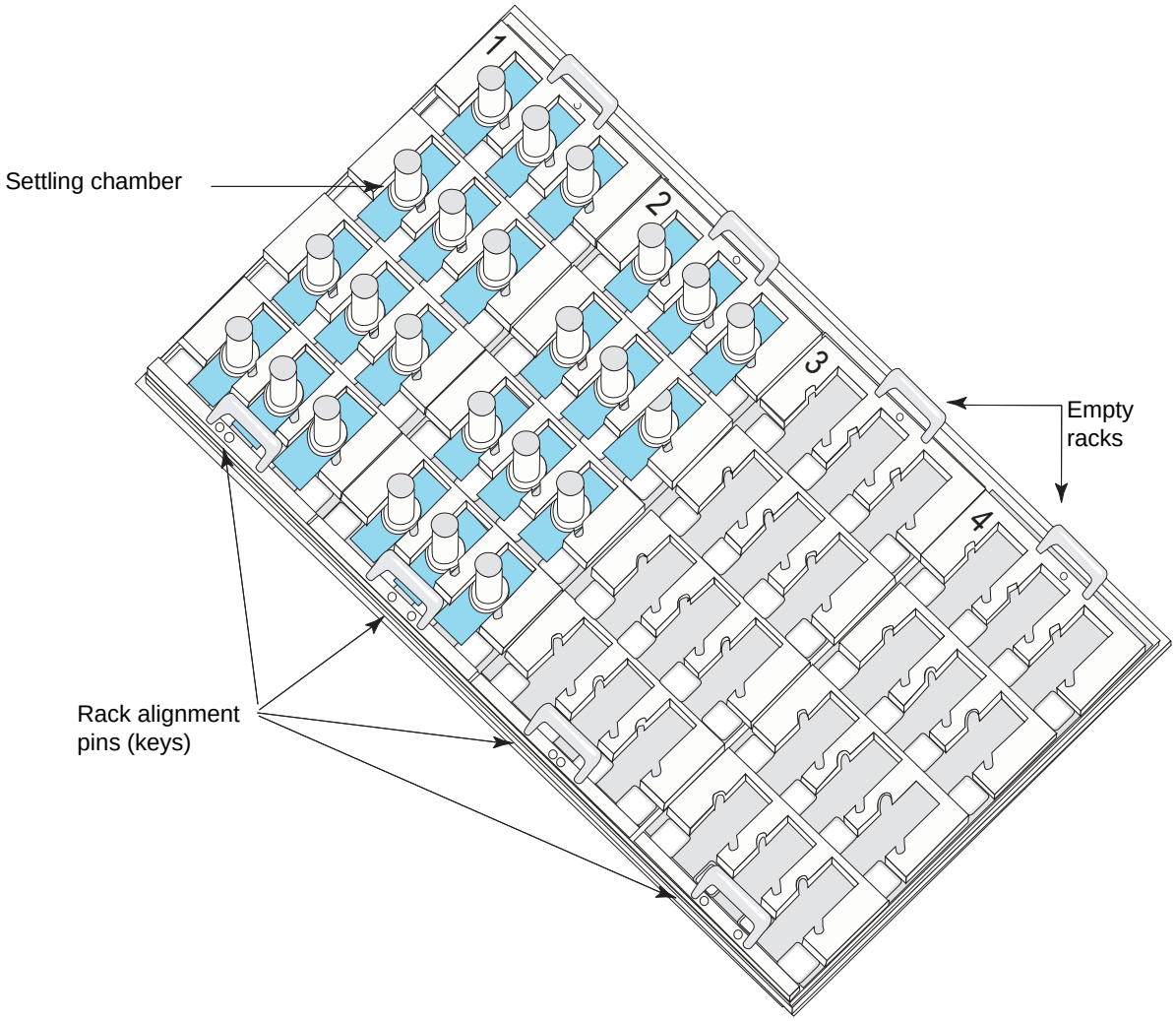


Figure 1-18: *PrepStain slide racks*

Chapter 2
System Specifications

BD PrepStain™ Slide Processor components

Multi-vial vortexer (optional)

The model of multi-vial vortexer you receive depends on the voltage requirements in your area. Specifications for both are provided below:

	490406	490125
VOLTAGE	100 to 120 Volts	220 to 240 Volts
FREQUENCY	50 to 60 Hertz	50 to 60 Hertz
POWER	100 Watts	100 Watts
FUSE	5 Amp quick acting (F) 5mm x 20mm	1 Amp quick acting (F) 5mm x 20mm

Non Operating Storage

Ambient Temperature: -20 to 65° C, -4 to 149° F

Ambient Humidity: 20% - 85% RH, non-condensing

Operating conditions

Indoor Use only

Ambient Temperature: 18 to 33° C, 64 to 91° F

Ambient Humidity: 20% - 85% RH, non-condensing

Altitude: 0 to 6,562 ft. (2000M) above sea level

Installation Category II and Pollution Degree 2 in accordance with IEC 664

General Weight: 36 pounds, 16.3 kG

Width: 15 inches Depth: 12 inches

Single vial vortexer

Required, but not provided, the single vial vortexer must be capable of developing 3000 RPM.

100 to 120 Volts, 50 to 60 Hertz, 40 Watts

PrepMate specifications

		PREPMATE 490410, 490104	PREPMATE 491103
OPERATING CONDITIONS	Rated Voltage	115 or 230 V~	100-240 V~
	Frequency	50/60 Hz	50/60 Hz
	Rated Current	2 Amps	2.5 Amps
	Rated Power	140 VA	150 VA
	Ambient Temperature	0-36° C (32-97° F)	0-36° C (32-97° F)
	Ambient Humidity	30% to 85% RH (non-condensing)	20% to 80% RH (non-condensing)
GENERAL	Weight	80 pounds, 36.3 kG	80 pounds, 36.3 kG
	Height	21 inches	21 inches
	Width	12 ½ inches	12 ½ inches
	Depth	23 inches	23 inches

	PREPMATE 490410, 490104	PREPMATE 491103

FUSING	• All fuses are 5x20 mm and rated 250V~. The product name plate is located on the rear panel with the power inlet and provides fuse information. Replacement fuses must be the same rating and type (F) as identified. Type F indicates a fast acting fuse.
	• The PrepMate has 2 fuses, located in the power entry module. They function as the main power fuse.
	• Main AC Fuse is 2 Amp:
	  • For the 115 V~ model of the PrepMate, use a UL CSA 2 amp fuse for the power entry module.
	  • For the 230 V~ model of the PrepMate, use an IEC 60127 standard fuse for the power entry module.
		• All fuses are 5x20mm and are 3.15 A @ 250 V~ Time Delay, and IEC 60127 rated. The product name plate is located on the rear panel with the power inlet and provides fuse information. Replacement fuses must be the same rating and type (T) as identified. Type (T) indicates a time delay acting fuse.
		• The PrepMate has 2 fuses located in the power entry module.

Centrifuge

Centrifuge specifications vary depending on the model shipped with your system. Values listed below are typical.

Voltage: ..... 120 Volts
Power: ..... 400 Watts
Height: ..... 17 inches
Clearance: ..... 38 inches (full open)
Width: ..... 24 inches

BD PrepStain™ instrument specifications

Weight: ..... 147 lbs (67 kg)
Height: ..... 34 inches (86 cm)
Width: ..... 40 inches (102 cm)
Clearance: ..... 44 inches (112 cm)
Depth: ..... 25 inches (64 cm)
Waste: ..... 408-ml/48 sample run - Transfer and Stain

Operating conditions

Temperature	15-40°C (59-104°F)
Relative Humidity	30-85% at 40°C or below non-condensing
Altitude	up to 4000 m (13,000 ft.)

Storage conditions

Temperature	0-50°C (32-122°F)
Relative Humidity	30-85% at 40°C or below non-condensing
Altitude	up to 10,000 m (32,000 ft.)

Power Requirements

Voltage	100-240 VAC
Frequency	50/60 Hz

Computer

PC 386 or higher or any 100% compatible
At least 4 MB RAM
Serial Asynchronous Interface Adapter (RS 232)
Hard Disk with at least 10 MB of free space
3.5 inch floppy
VGA (640x480) or SVGA display adapter and monitor
MS DOS 6.0 and higher
Voltage: 120 V / 50-60 Hz
Power: 350 W

Monitor

Voltage: 100 - 240 V~ / 6A 50-60 Hz
Power: 25 watts
Height: approx. 24 inches

Warning

- The pipetting instrument is a robotic device that operates under computer control. As with most robotic devices, there is a potential for injury and bodily harm from moving mechanical components whenever the instrument is in operation. The instrument is designed for automatic “hands-off” operation only. Never reach into the instrument work space when the unit is in an operating mode. A safety guard is provided with the instrument to prevent accidental contact with any moving components.
- Bumping the robotic device (Quad arm or DiTi assembly) may result in instrument error.
- If it is necessary to interrupt operation of the instrument, check the screen display for the “User Break” command (the **F-10** key on the computer keyboard. The system will stop after completion of the current command and an option menu will appear on screen.

PREP system component layout

The following table describes the physical layout of a BD PrepStain™ system. How you situate each component in relation to the others depends on your space constraints and workflow.

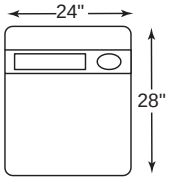
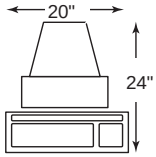
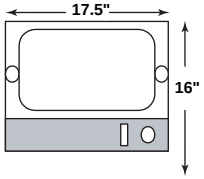
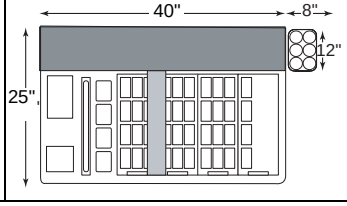
COMPONENT NAME	COMPONENT ILLUSTRATION	CLEARANCE
CENTRIFUGE		Overhead clearance: 38 inches for lid to open fully. However the lid’s stabilizers allow partial opening in tight spaces.
MONITOR & KEYBOARD		Overhead clearance: 24 inches Although the monitor and keyboard do not need to be on the counter, they must be in close proximity to the instrument. (Model may vary.)
MULTI-VIAL VORTEXER		**Note:** to reduce the affects of vibration, consider locating automated components on a counter top that is separate from the one that supports the PrepStain instrument.
PREPSTAIN INSTRUMENT AND STAIN RACK		Rear clearance: 4 inches Overhead clearance: 34 inches **Note:** to reduce the affects of vibration, consider locating automated components on a counter top that is separate from the one that supports the PrepStain instrument.

Table 2-1 PrepStain slide processor counter top space

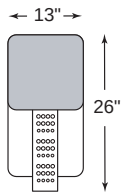
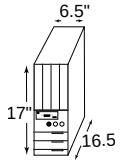
PREPMATE		**Note:** to reduce the affects of vibration, consider locating automated components on a counter top that is separate from the one that supports the PrepStain instrument.
WORKSTATION CPU		Although the CPU does not need to be on the counter, it must be in close proximity to the instrument.

Table 2-1 PrepStain slide processor counter top space

Although there is no clearance specification for the components listed below, make sure there is either floor space below or space above the counter nearby, and that the instrument is operating in a well-ventilated area.

Table 2-2 BD PrepStain™ Slide Processor floor or under counter space

COMPONENT	**FOOTPRINT** (length x depth)
PrepStain instrument Vacuum Pump	12 x 18 inches
PrepStain instrument Waste bottle	7 x 10 inches

In addition, backside clearance is essential for the power cords, vacuum pumps, and the CPU air intake grills.

CAUTION: Do not store in closed, non-ventilated areas as vacuum pump exhausts alcohol vapors that could cause a flammable atmosphere if the pump is kept in an enclosed space, e,g, cabinet.

Materials required (available from BD)

- BD PrepStain™ Slide Processor and accessories
- BD SurePath Collection Vials (includes BD SurePath™ Preservative Fluid)
- Cervical sampling device(s) with detachable head(s)
- BD Density Reagent
- BD Syringing Pipettes
- BD Settling Chambers
- BD Cytology Stain Kit
- BD SurePath PreCoat slides
- BD PrepStain Transfer Tips
- BD Centrifuge Tubes
- BD PrepMate Automated Accessory
- BD Aspirator Tips
- Centrifuge and accessories

Materials required but not provided

- Easy Aspirator Kit
- Vortex Mixer
- Deionized Water
- BD Alcohol Blend Rinse or Isopropanol and Reagent Grade Alcohol
- BD SurePath Preservative Fluid
- Clearing Agent, Mounting Media and Glass Coverslips
- Tris Buffered Saline Packet
- Contrad 70, Decon 90, or bleach

Materials (optional)

- Multi-vial Vortexer
- 4 mL Density Reagent Dispenser

Installation

BD PrepStain™ Slide Processor installation must be performed only by BD–authorized personnel. A service representative will work with key operators and provide verification documentation of correct system installation.

Chapter 3
Principles of Operation

This chapter describes the process used by the BD PrepStain™ system in the preparation of BD SurePath slides. The sequence of tasks and the operating principles used by each component in the process are described as well.

Process overview

The PrepStain system is based on a semi-automated procedure for the preparation of liquid based cervical cell samples.

There are three main phases in the BD SurePath slide preparation process. These phases are listed below:

- Specimen collection
- Cell enrichment
- Slide preparation and staining

Specimen collection

Using the collection device, the specimen is collected at the doctor's office. The device head containing the cervical sample is placed into a vial of BD SurePath Preservative Fluid, and sent to the laboratory.

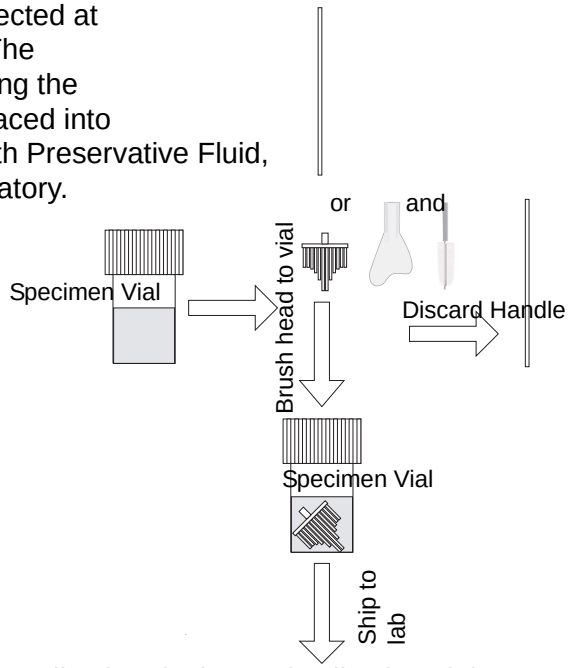


Figure 3-1 *Specimen collection device and collection vial*

Collection vial and devices

The BD SurePath Collection Vial contains a buffered 24% ethanol solution that is similar to other cytologic preservative fluids. The preservative fluid fixes diagnostic cells and is bactericidal for gram negative enterics, gram positive cocci, and fungi.

Detachable head collection devices

A broom-type device and a combination brush/plastic spatula are the two recommended sampling devices for the collection of cervical specimens for the BD SurePath Pap Test. These devices are pictured in *Figure 3-2*.

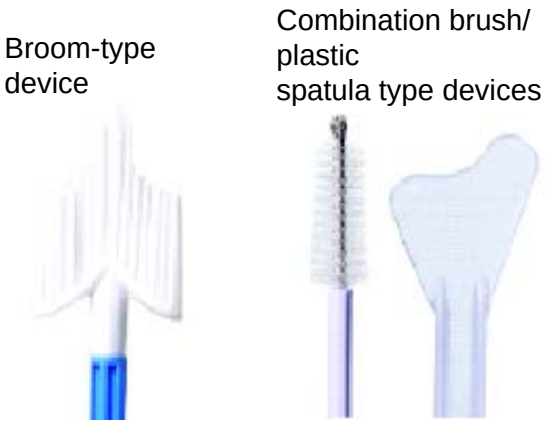


Figure 3-2 *Detachable head collection devices*

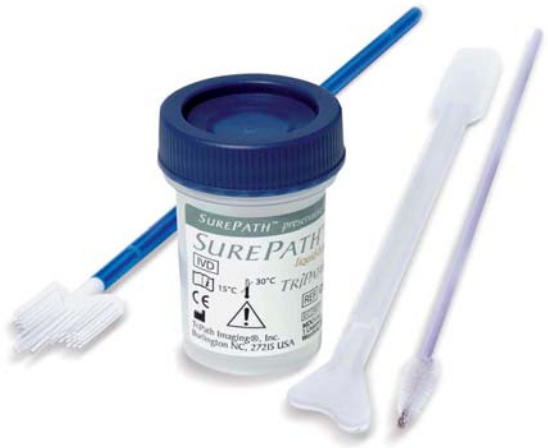
Broom-type device

A broom-type device (e.g., Rovers® Cervex-Brush, Rovers Medical Devices B,V., Oss - The Netherlands) is one of two recommended sampling devices for the collection of cervical specimens for the BD SurePath system. The central bristles of the device are inserted far enough into the cervical os to obtain cells from the endocervix. The side bristles sweep cells from the ectocervix and transformation zone.

Combination brush/plastic spatula device-type device

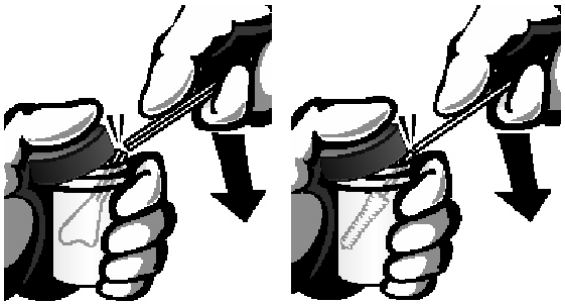
The Pap Perfect® (CooperSurgical Inc., Trumbull, CT) spatula and Cytobrush® Plus GT devices combine to make up the other recommended sampling method for the collection of cervical specimens for the BD SurePath Pap Test.

First, the contoured end of the plastic spatula is inserted into the cervical os and then rotated 360° around the entire exocervix. Next the brush is inserted into the endocervix until only the bottom-most bristles are exposed at the os. Slowly rotate ¼ to ½ turn in one direction.



Once the samples have been obtained, the patient specimen is placed in a vial of preservative fluid and the handle of the device is removed, leaving the head(s) of the device in the collection vial. The vial is capped tightly and transported to the clinical laboratory for

Figure 3-3 *BD SurePath Collection Vial and collection devices*



Drop or snap off the device heads from their handles and drop the detachable heads of the device into the BD SurePath vial. There are several approved methods for removing these heads. The cap-assisted method is pictured here. See product insert for instructions.

Figure 3-4 *BD SurePath Collection Vial and combination devices*

Specimen handling and cell enrichment

During this phase of the BD SurePath slide preparation process, the cervicovaginal samples are randomized and the clinical content of the sample is enriched. In the process, the sample is prepared in a series of manual steps that include vortexing to mix and disaggregate the sample, mixing, layering onto BD Density Reagent, and centrifugation.

1.2

Sample randomization

To start the cell enrichment process, the BD SurePath collection vials are vortexed for 15 ± 5 seconds at 3000 rpm. Shearing forces of the vortex free cells and cell clusters from the specimen collection device and partially disaggregate cell clusters.

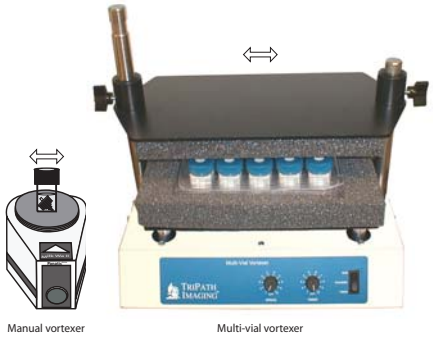


Figure 3-5 *Preparing specimen vials for transfer*

Note: Figures *3-5* and *3-6* illustrate some of the components used to perform these particular tasks.

Note: An aliquot of the specimen (up to 0.5 mL) may be removed from the vial for ancillary testing prior to the BD SurePath Pap test process. See Appendix for more information.

BD Density Reagent

BD Density Reagent is a polysaccharide solution with sodium azide added as a preservative. The cell suspension is centrifuged through the density reagent for 2 minutes ± 15 seconds at 200 rcf ± 25. Small particulates and debris, which are trapped above the interface between the supernatant preservative fluid and the density reagent, are removed, enriching the clinical materials in the sample.

A second centrifugation, at 800 rcf ± 50 for 10 ± 1 minute, concentrates the diagnostic cellular materials in the bottom of the tube. The remaining density reagent is decanted, leaving the resulting enriched pellet of cellular materials in the BD Centrifuge Tube, which is vortexed and placed on the PrepStain instrument for further processing.

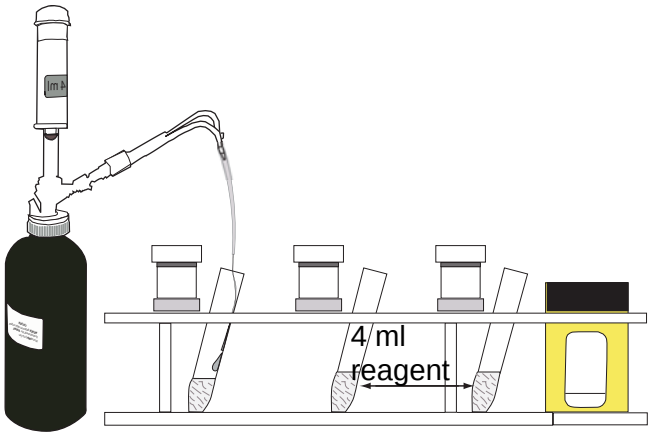


Figure 3-6 *Preparing centrifuge tube for transfer*

Mixing and layering

Samples are mixed and then gradually transferred to a BD Centrifuge Tube that contains BD Density Reagent. This transfer is referred to as layering. This part of the process is accomplished automatically, using the BD PrepMate Automated Accessory. This method is summarized below.

1. The PrepMate is an automated accessory to the PrepStain system. The PrepMate automates the initial enrichment process of mixing and dispensing the specimen over the density reagent.

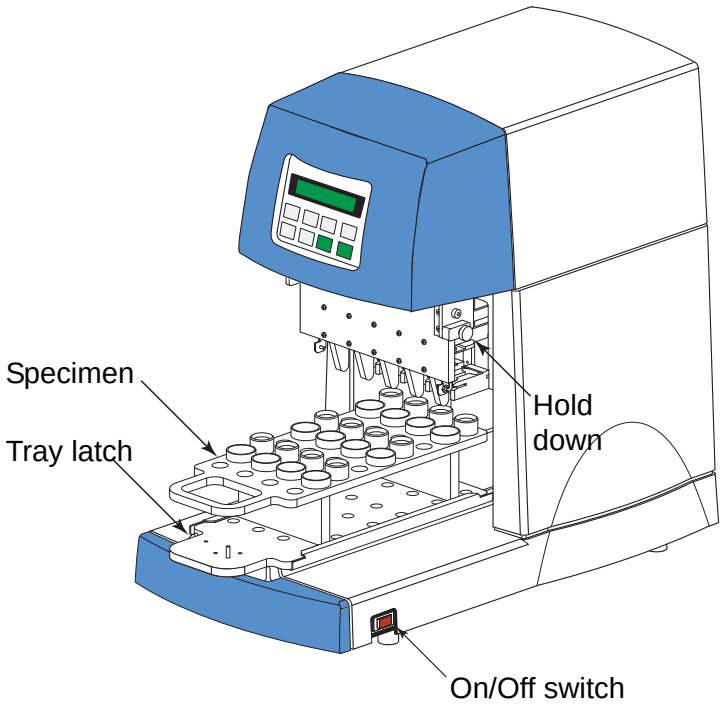


Figure 3-7 *PrepMate front view*

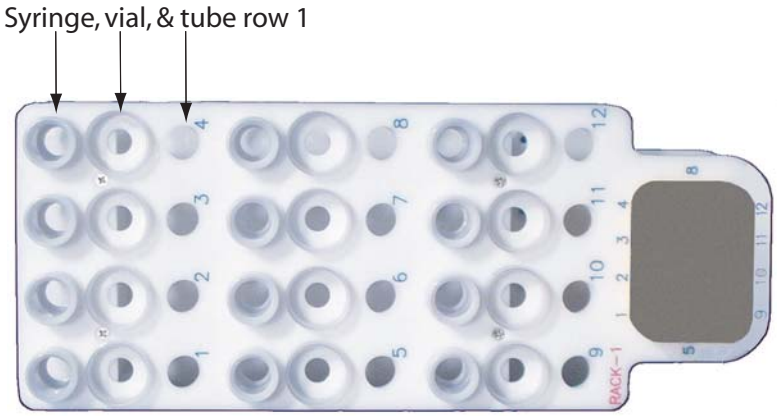


Figure 3-8 *PrepMate processing rack*

The BD PrepMate Automated Accessory mixes and removes the specimen from the preservative vial. It then layers the specimen onto the density reagent in the BD Centrifuge Tube. The PrepMate's automated process handles from one to twelve specimens per cycle.

1.2 To reduce the possibility of specimen contamination, the tops of vials are not removed during the process. The PrepMate provides a unique, puncture-top process that mixes and dispenses with the top on. Vials, syringes, and tubes are disposable. To eliminate the possibility of specimen contamination, they are not reused.

Centrifugation

Centrifugation consists of three steps:

- a “soft spin” pulls cell solution through density reagent
- the Easy Aspirator removes the supernate
- a “hard spin” concentrates diagnostic cellular materials in the bottom of the tube

Specimen processing with the BD PrepStain™ system

1. The PrepStain system performs the automated slide preparation and staining steps for the thin-layer preparation of cytologic materials on a BD SurePath PreCoat Slide.

1.2

1.2 The BD SurePath PreCoat Slide has been coated with a high molecular weight cationic solution. The resulting positive charge allows adhesion of the negatively charged diagnostic cytological material to the slide throughout the slide preparation process.

BD Settling Chamber

1.2 The BD Settling Chamber serves as a vessel to contain the resuspended cellular materials while they settle onto the coated microscope slide. The resulting thin-layer preparation is stained discretely in the same settling chamber.

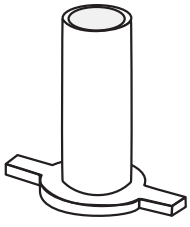


Figure 3-9 *BD Settling Chamber*

Computer workstation

The BD PrepStain™ instrument is linked to a DOS-based computer. The software that runs the sample processor is started by typing a command at the DOS prompt, and then controlled using a series of menus.

Note: Refer to *Chapter 10* ***Non-GYN Slide Processing*** for instructions on using the PrepStain instrument for NonGYN applications.

PrepStain instrument

1.2 The BD PrepStain™ instrument performs the automated sample transfer and staining steps that create a thin-layer preparation of cytologic material on a coated microscope slide.

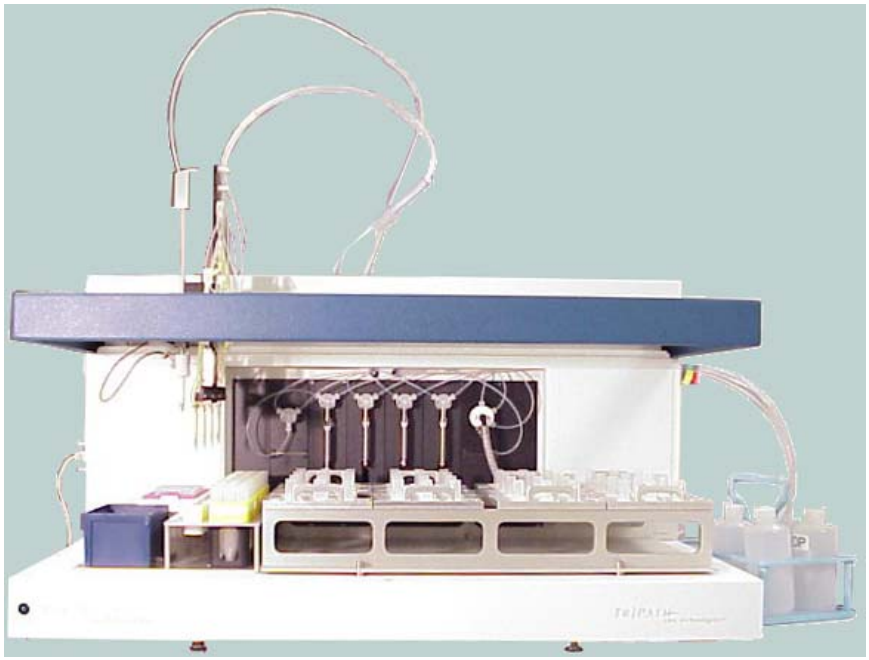


Figure 3-10 *PrepStain instrument*

Robotic sample processor

1. The Tecan robotic sample processor illustrated in *Figure 3-10* is a fully automated sample processor. It is the base instrument of the PrepStain system. The PrepStain instrument is a system of microprocessor-controlled liquid handling components controlled by system software that resides on the hard disk of a computer. An operator controls the mechanical components from the computer keyboard. Special preparation methods, supplied by BD are used for each application.

1.2 The PrepStain instrument resuspends the pelleted cell samples in buffered deionized (DI) water, and transfers aliquots of the cell suspensions to BD Settling Chambers mounted BD SurePath PreCoat slides. An incubation period allows the cells to settle onto the microscope slide surface, and then the processor performs a sequence of washes and staining steps to stain the slide by the

1.2 Papanicolaou method. The sequences, volumes, times, and orientation of the transfer and staining steps are controlled by the computer workstation.

The PrepStain instrument hardware is based on a modular design concept in which each of the major processor functions are performed by an independent component of the instrument. The principle components of the processor are listed below:

- Syringe Pump
- X/Y/Z Movement Mechanism (Arm)
- Disposable Tip (DiTi) Assembly
- Quad Arm
- External Water Valve
- Waste Station
- Slide Racks and Work Platform

Syringe Pump

The Syringe Pump is a microprocessor-controlled syringe with a pump and two-way valve that connects to the quad tubing and a reagent container via tubing. All parts that come into contact with liquid are made of inert materials such as glass, Teflon, or Fluoroethylpropylene (FEP). A stepper motor drives the syringe plunger. Both the valve and the stepper motor are operated by a built-in microprocessor. The BD PrepStain™ instrument has 4 syringe pumps to control aspiration and dispensing of programmed volumes of reagents and samples with high accuracy and at variable speeds.

X/Y/Z movement mechanism (robotic arm)

The robotic arm moves in the X (left-right), Y (forward-backward) and Z (up-down) directions. It has a Z-rod that moves up and down. The DiTi (Disposable Tip) assembly is mounted on the Z-rod, which is raised or lowered (Z-direction) by the Z-stepper motor. The quad arm is mounted on the robotic arm and attached to the safety bar. The arm moves left and right (X-direction), and is driven by the X-stepper motor. The robotic arm must be free of impediments in order to operate correctly. The X, Y, and Z stepper motors are powered and controlled by electronics located inside the board cage of the instrument.

Disposable tip (DiTi) assembly

The PrepStain instrument uses a disposable tip assembly for aspirating and pipetting samples. *Figure 1-15:* illustrates the principle components that make up this assembly.

The instrument uses a fresh BD PrepStain Transfer Tip to mix, aspirate, and transfer each sample. This assures that transfers are free of contamination. Tips are picked up by driving the DiTi cone down into the tip with sufficient force to form an airtight seal about the tip hub. This secures the tip to the cone for pickup and displaces a contact

spring. The PrepStain instrument uses this displacement to detect the presence and proper pickup of a tip. The sample is then transferred (from tube to slide), the tip is discarded and a new tip is picked up for the next transfer.

Quad Arm

The quad arm illustrated in *Figure 1-14:* is a system of BD Syringing Pipettes, tubing, and manifolds that is mounted on the arm of the BD PrepStain™ instrument. The device is self-retracting and remains clear of DiTi operations when not in use. The Z-rod and quad key of the DiTi assembly engage the quad handle so that the arm moves in parallel with the DiTi when it is lowered. This positions the four pipette bundles into four BD Settling Chambers simultaneously.

Each pipette bundle has four dispensing tips mounted about a larger vacuum tip. When lowered to just above the surface of the slide, the vacuum tip empties out the chamber. The dispensing tips can then apply one of four reagents to the chambers. Bundling the dispensing and vacuuming tips in this manner allows simultaneous staining operations to be performed on four samples.

Waste Station

The waste station, which is located on the left side of the instrument is illustrated in *Figure 1-13:*.

During priming or cleaning of the system tubing, excess liquids are dispensed to the waste trough, which drains into a large waste container for safe and easy disposal. After use, BD PrepStain Transfer Tips are discarded into a waste container.

The waste station also includes the BD PrepStain Transfer Tip holder which positions 96 disposable tips for pickup by the DiTi cone. Along the right side of the waste station, four slots hold the centrifuge buckets in position. To help ensure chain of custody, the bucket holders are numbered 1-4 and are uniquely pinned at the base so that each centrifuge bucket can fit into only a single position and orientation.

For example: tube bucket number 1 will fit only into tube holder position 1, and must face the front of the station.

Slide Racks and Work Platform

The work platform illustrated in *Figure 1-18:* holds the slide racks, and mounts to the right of the waste station.

Each slide rack has a 4 row by 3 column array of glass slide positions. The work platform and slide racks are numbered 1-4 and pinned so that each slide rack will fit only into its correspondingly numbered position.

Each slide is mounted on the rack under a settling chamber that locks into place with a clockwise twist. The settling chamber seal and the slide form a barrier that prevents leaking when the chamber is filled with liquid. The sedimentation of cells onto the slide's surface and the subsequent staining takes place in the settling chamber. After staining, the settling chamber is removed and discarded. The slide is cleared and coverslipped to prepare it for screening.

Slide Preparation and staining

The slide preparation, staining, and rinsing process is performed by the BD PrepStain™ instrument. The steps in this process are outlined below:

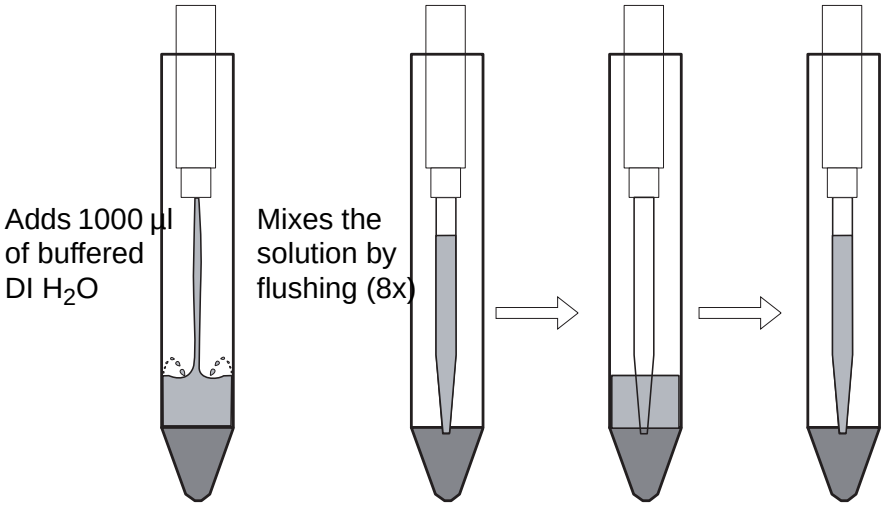


Figure 3-11 *Preparing to transfer the cell pellet*

1.2

- First the instrument adds buffered DI water to the Settling Chamber by the Quad arm pipette bundle.
- Next, the instrument adds 1000ul of buffered DI water to the cell pellet via the DiTi.
- It then picks up a BD PrepStain Transfer Tip and mixes the resulting solution by flushing it in and out of the disposable Pipette Tip 8 times.

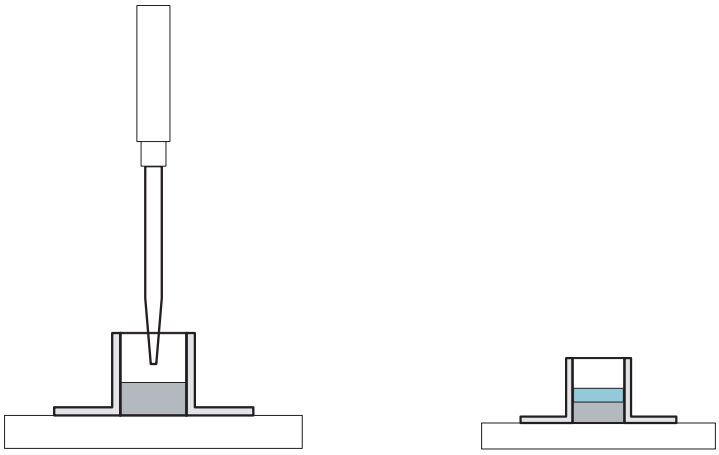


Figure 3-12 *Transferring the sample to the settling chamber*

1.2 • Next, the PrepStain instrument aspirates 200 µl of the sample from the BD Centrifuge Tube and dispenses 200 µl of specimen into the settling chamber. The tube and remaining specimen can be discarded, or retained for adjunctive testing.

Note: If retaining the tube containing specimen, add 2ml of BD SurePath Preservative Fluid to the tube to preserve the cell pellet.

1.2 • The sample is allowed to settle onto the slide for a minimum of 10 minutes. During this time, cells bonding with the BD SurePath PreCoat slide coating form a thin layer of cells.

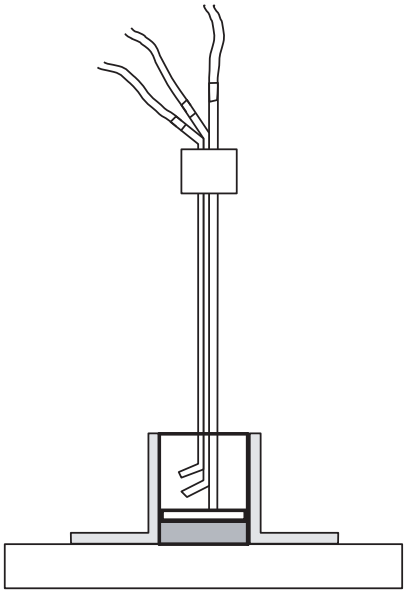


Figure 3-13 *Washing the cell sample*

1.2

- The BD PrepStain™ instrument adds a 600 µl alcohol wash to the sample and evacuates all remaining fluids.
- The sample is then allowed to dry for approximately 60 seconds.
- The last part of the automated processing is a sequence of stain and rinse cycles. Stain and rinse cycles are essentially the same: all that varies from cycle to cycle is the reagent used and the duration of the pause.

Figure 3-14 illustrates a typical stain and rinse sequence.

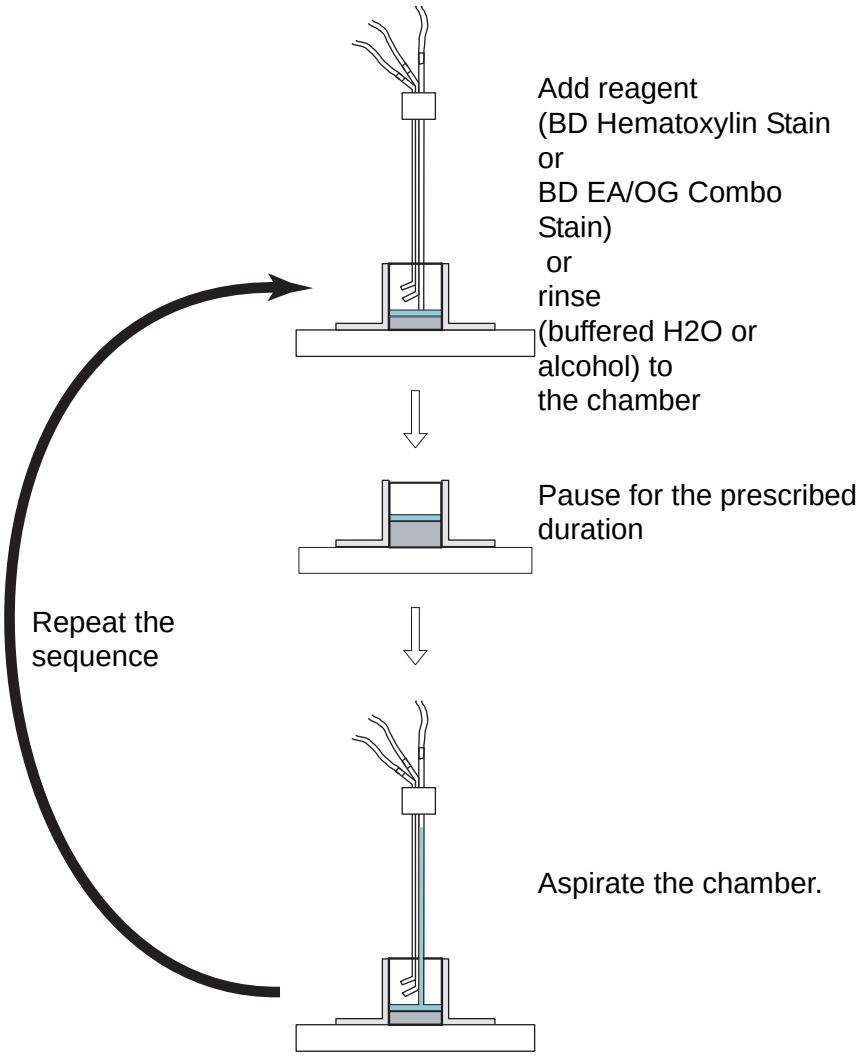


Figure 3-14 *Typical stain or rinse cycle*

1.2

Screening BD SurePath thin-layer preparations

The BD PrepStain™ system produces a uniform layer of stained cells in a 13 mm diameter circle. The sample layer contains single cells or small cell clusters. There is very little mucus and few large clumps of entwined cells.

The entire slide preparation is screened using a 10x objective by scanning across the slide in a serpentine method. It is a good idea to screen each slide twice, moving once horizontally and once vertically across the preparation area, as depicted below.

Figure 3-15 *Serpentine, double screening method*

All diagnostic criteria in current cytology laboratory use for conventional Pap smears are applicable to BD SurePath thin-layer preparations. Standard laboratory procedures are to be followed in reporting results.

Chapter 4
PreProcessing Steps

This chapter provides the procedures used to prepare cervicovaginal specimens for processing by the BD PrepStain™ instrument. These procedures are listed below.

Preparation of buffered water

Required materials

- One (1) liter volumetric flask
- Deionized (DI) or distilled water
- Tris Buffered Saline packet, pH 8.0
- Measuring device, 200 ml
- One (1) 4L bottle

CAUTION: Read this procedure carefully. The stock buffer solution must be prepared before the working solution can be made.

Procedure to make Stock Buffer

1. Fill the 1 liter flask approximately half full with de-ionized (DI) or distilled water.
2. Empty 1 pack of Tris Buffered Saline packet, pH 8.0 into flask and swirl until dissolved.
3. Fill flask to the 1 liter mark and seal the flask with Parafilm.
4. Invert the flask several times to ensure complete mixing.
5. Transfer stock solution to the 1L bottle provided during installation.
6. Label bottle with date prepared and expiration date.
7. The stock solution is stable for four (4) weeks refrigerated (2 - 10ºC). Discard after four weeks. Clean or replace container before making a new batch of stock solution. (See Note following.)

Procedure to make Working Solution of Buffered Water

1. Measure 200 ml of Stock Buffer and pour into a 4L bottle labeled with BD Tris Buffered Water Working Solution..
2. Add 3400 ml of de-ionized (DI) or distilled water.
3. Cap and invert to mix well.
   - Label gallon container with date prepared and expiration date.

The Working Solution is stable for two (2) weeks at room temperature (15 - 30° C). Clean or replace container before making a new batch of working solution. (See Note following.)

Note: Wash containers using appropriate lab wear cleaner (do not use bleach). Rinse container thoroughly with de-ionized (DI) or distilled water after cleaning or before using a new container.

Setup for specimen transfer

CAUTION: Cytologic specimens may contain infectious agents. Wear gloves and follow appropriate biohazard precautions when handling sample vials.

This chapter discusses the PrepMate automated transfer method.

Chain of custody

In order to maintain chain of custody of test samples, all specimen vials, BD Centrifuge Tubes, and glass slides are loaded in their respective racks **front to back** and **left to right**. The correspondence between rows and columns in the PrepMate rack, centrifuge tube rack, and slide rack is illustrated in *Figure 4-1*. The illustration identifies the location of Position 1 (row 1, column 1) in three places: on the PrepMate rack, the centrifuge tube rack, and the slide rack.

Warning
Tubes in centrifuge racks must be carefully oriented with matching slide racks. Correct placement of labeled tubes with correspondingly labeled slides is essential and must be verified by the operator in order to prevent sample mix-ups.

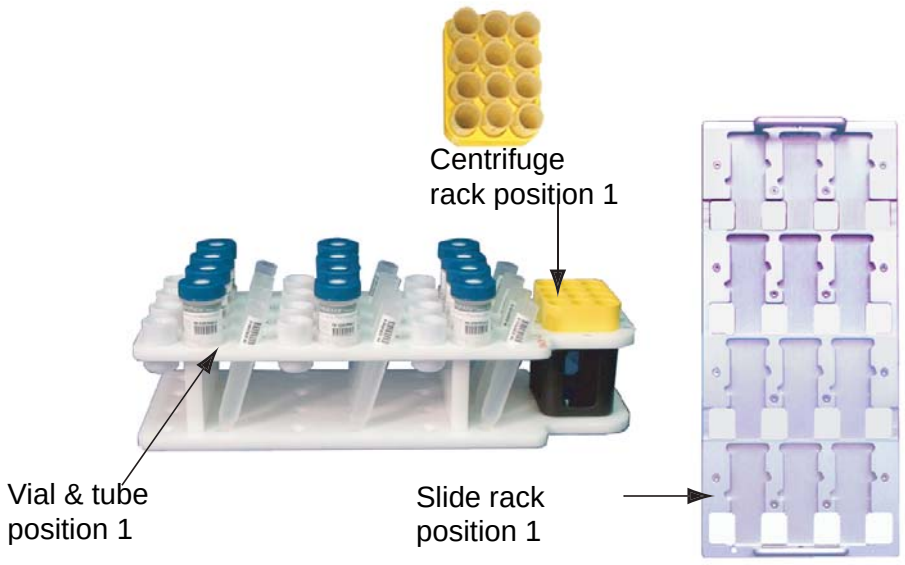
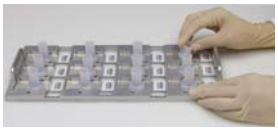


Figure 4-1 *PrepMate rack, centrifuge tube rack, and slide rack row and column correspondence*

Note: Positioning pins on the PrepMate rack and PrepStain instrument help to ensure proper alignment. This ensures the sample from position 1 in the PrepMate rack is deposited on the slide in position 1 on the slide rack.

Prepare slides on slide rack

Slide rack



1. Place BD SurePath PreCoat slides on the slide racks in the same position as the tubes in the centrifuge tube rack. *Be careful not to touch the surface of the slide.*

CAUTION: Slide Coat can be removed from the surface of the slide if it is scratched or touched during the application of the settling chamber which can impact the quality of the slide preparation.

2. Lock the chamber into place over each slide on the slide rack as shown in *Figure 4-2*.
3. If there are less than four specimens in a column, place blank slides and BD Settling Chambers in the corresponding spaces.

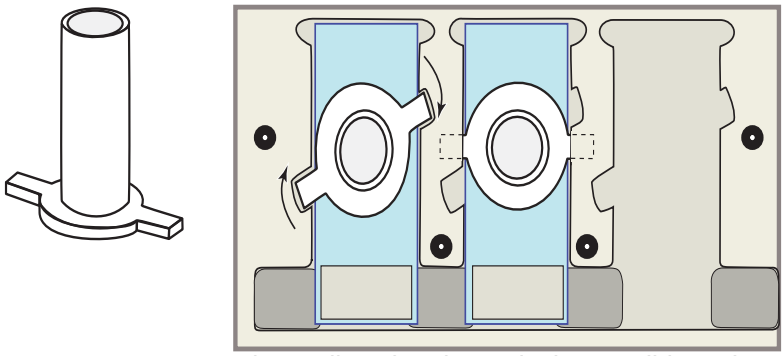


Figure 4-2 *Lock BD Settling Chambers over each slide*

PrepStain process procedure

1. For each sample to be tested, label the test requisition, specimen vial, BD Centrifuge Tube, and a BD SurePath PreCoat Slide with a uniquely identifying label. Use a solvent resistant marker to write on the frosted end of the glass slide or apply a printed label with sample identification.

CAUTION: Recheck labels on collection vials, BD SurePath PreCoat slides, and centrifuge tubes in specific preparation rack positions to ensure that each sample set matches the correct sample.

Vortexer

2. Vortex sample vials for a minimum of 15 ± 5 seconds. The vortex speed must be sufficient to cause a funnel in the collection vial (approximately 3000 rpm). If using the Multi-vial Vortexer, place a rubber liner on top of the vials in the clamshell to secure the vials and prevent spinning which would decrease effectiveness of the vortexing.

PrepMate Rack

3. Place labeled specimen vials and centrifuge tubes into the PrepMate rack in ascending order (proper orientation of the PrepMate rack is with the centrifuge tube rack facing to the right). Reconfirm that each centrifuge tube is labeled the same as it's corresponding specimen vial.

Density Reagent

4. Dispense 4 ± 0.1 ml of BD Density Reagent into each BD Centrifuge Tube.
5. Place a syringing pipette into the rack adjacent to each specimen vial. Make sure the plunger of each syringe is fully seated. The BD PrepMate Automated Accessory will not operate if a plunger is too high. *Figure 4-3* illustrates this point.

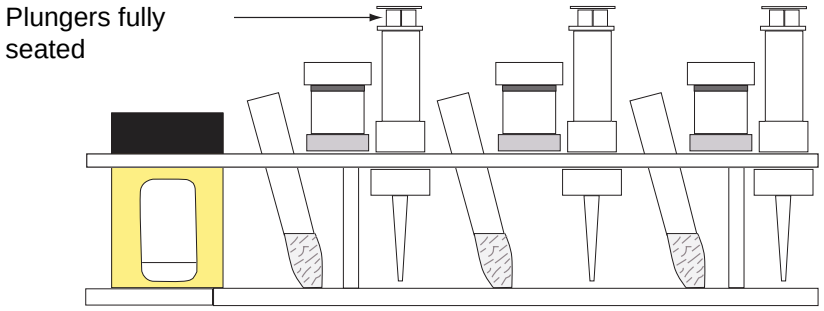


Figure 4-3 *Centrifuge tubes fully seated*

PrepMate

6. Run the PrepMate. (For detailed operation instructions, please consult the BD PrepMate user's manual.
   a. Make sure the PrepMate is connected to an AC power source and the side panel power switch is in the On position. Follow on-screen prompts prior to loading specimen rack. Do not load the specimen rack until the display reads **`PREPMATE READY, (v x.x)LOAD SPECIMEN RACK.`**
   b. Make sure the vial hold-down door is in the vertical, latched position.
   c. Place a loaded specimen rack into the instrument's tray. Slide the rack in from the front until the tray latch at the front left corner of the tray engages. Do not manually move the metal tray, as this may cause instrument malfunction.
   d. If you are processing fewer than three rows, press **`DEC`** to decrease the number of specimen rows to the correct setting before you press **`START`**. The number of rows to be processed appears in parentheses as part of the start message. When you press **`DEC`** or **`INC`**, the display is updated accordingly. If any problems occur, follow the instructions that appear on the display.
   e. When a specimen rack processing cycle completes, an audible tone sounds. Replace the finished rack with the next rack to be processed, reset the number of rows if necessary, and press **`START`**.

f. Inspect the centrifuge tubes to verify that the correct amount of sample has been transferred. The correct amount of sample in the tube is 12 ± 1 ml (4 ml of density reagent and 8 ml of sample).

7. After the specimen rack has been processed, carefully unload the rack from the BD PrepMate Automated Accessory.

Note: The PrepMate specimen racks should be cleaned between runs to prevent cross-contamination. See PrepMate user's manual for more information.

8. Place the tubes containing the cell suspension and density reagent into the centrifuge tube racks in the same order as they were in the PrepMate rack.
9. Remove the syringes and discard.

Tip: Allow the specimen vials to remain in the PrepMate rack (this can be used as a labeling template for the slide rack).

Note: For each residual specimen vial to be retained, the existing cap should be replaced. (Replacement caps can be ordered from BD.) Handle the punctured caps and open specimen vials with care to avoid cross- contamination. Dispose of the punctured caps properly into a biohazard material container.

CAUTION:

- To obtain optimum results, after the specimen sample has been layered onto the density reagent, samples should be centrifuged and the supernatant aspirated within 30 minutes.
- To maintain chain of custody, take care to properly position the BD Centrifuge Tubes and specimen vials when loading the PrepMate rack, and when transferring the centrifuge tubes to the tube rack.

Centrifuge Program 1

10. Ensure centrifuge tubes racks are properly balanced.
    a. If the tube count between the two racks is not matched, add blank tubes and balance with DI water.
    b. Do not reposition tubes to balance the tube racks as this will compromise chain of custody.
11. Centrifuge the tubes at 200 rcf ± 25 for 2 minutes ± 15 seconds using Program #1.

Tube Vac

12. Remove supernatant using the Tube Vac and Easy Aspirator.
    a. Turn on the Tube Vac vacuum pump, adjust vacuum pressure to 8 - 10 in. Hg (Schuco) or 5 - 6 in. Hg / 180-220 mBAR (KNF). Always allow pump come to equilibrium vacuum pressure before beginning aspiration.
    b. Attach a set of Tips with Easy Aspirator Head. With only very moderate pressure, press head downward, squarely and evenly, to attach tips.

Note: Do not bury the post seal so deeply into Tip hub that hub is flush with metal post.

    c. Observe that the twelve BD Aspirator Tips (aspirator tips) are securely attached to the posts on the Easy Aspirator Head.
    d. Slowly lower aspirator tips into supernatant, staying just below the dropping fluid level, until the aspirator head rests evenly across the tops of the BD Centrifuge Tubes. At this point you should hear the tips drawing air.

Note: At this position, the level of the interface fraction at the density reagent should have been penetrated and the majority of supernatant fraction and interface fraction removed.

    e. Carefully withdraw the aspirator head with loaded tips from the tube set.

Note: If tips are used for additional aspirations, rinse the tips with deionized water after each rack of tubes. Replace the tips after aspirating four centrifuge racks (up to 48 samples). Alternately, for one-time tip use, eject and reload as described below.

    f. Hold aspirator head of tip ejector in front of and at same plane as the white Delrin wedge in top of tip ejector. Slide the aspirator head along top of wedge so that posts align into slots.

Note: The tip ejector slots may seem to be a little tight at first. This tightness loosens over time as the white Delrin wedge material wears and adjusts with use.

    g. Sliding the aspirator head should eject all of the tips into the disposal tray (see the note below). Withdraw the head by pulling up and out. If no further specimens are to be aspirated, turn OFF vacuum pump.

Note: To prevent clogs, it is important to run water through the aspirator posts before shutting off the vacuum pump. Perform this rinse after the last tube bucket is aspirated and the tips are still seated on the aspirator posts.

h. Dispose of used tips, as required by local procedures for disposal of hazardous wastes, collected in tip waste container when it becomes half full.

i. After the supernatant has been aspirated, rebalance the tube racks as described in step 10.

Centrifuge Program 2

13. Centrifuge the remaining fluid at 800 rcf ± 50 for 10 minutes ± 1minute using Program #2. This centrifugation concentrates the diagnostic components into a cell pellet.

Decant Tubes

14. Remove the tube racks from the centrifuge. In a single, rapid motion, decant the supernatant by inverting each tube rack 180 degrees so as not disturb the cell pellet. While inverted, carefully blot the mouth of all tubes in the rack with absorbent paper. Turn the rack upright after 3 to 5 seconds.

Hand Vortexer

15. Holding a gloved hand on top of the tubes, vortex the centrifuge tube racks thoroughly for 15 ± 5 seconds. The absorbent material used to blot after decanting may be held in place during hand vortexing.

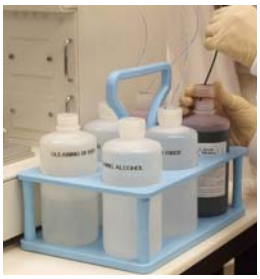
PrepStain

16. Run the BD PrepStain™ Slide Processor:

a. Place the tube racks and slide racks on the PrepStain instrument. Confirm that the position of each labeled slide on the slide rack corresponds to the position of its matching labeled tube in the tube rack. Confirm that all tube racks and slide racks are seated properly on the instrument.

b. Place each labeled intake tubing into its corresponding reagent container (the intake tubing must go all the way to the bottom of the reagent bottle). Confirm there is adequate reagent in each bottle to complete the run.

Reagent containers



c. Place 96 pre-loaded BD PrepStain Transfer Tips onto the DiTi station. Press down firmly on the plastic tip holder so that the front and back tabs snap into place on the station securely.

CAUTION: The pipetting instrument is a robotic device that operates under computer control. As with most robotic devices, there is potential for injury and bodily harm from moving mechanical components whenever the PrepStain is in operation. PrepStain is designed for automatic “hands-off” operation only. If the robotic movement is impeded, this generates an error. To avoid aborting the run, do not obstruct operation of the robotic arm.

---

d. Turn on the PrepStain system. The computer automatically runs the GYN software application.

e. To process and stain slides, select **`Slide Preparation and Staining`** from the Main Menu and follow the instrument prompts. Refer to ***Chapter 5*** in this manual for instructions on operating the software.

f. An alarm sounds as each slide rack has completed the staining process.

17. As each slide rack is completed, remove it from the BD PrepStain™ instrument.
18. Invert the slide rack to decant the residual alcohol. Before returning to an upright position, blot excess alcohol from the BD Settling Chambers. Turn the slide rack right side up.
19. Taking one slide at a time, remove and discard the settling chamber and then coverslip the slide.
    a. Direct a stream of reagent alcohol or 2-propanol above the preparation area on the slide.
    b. Clear each slide by directing a stream of xylene or xylene substitute above the preparation area on the slide.
    c. Using a 24 mm x 30 mm cover glass, coverslip the slide as usual, using a polymer-based mounting medium.

CAUTION:

- When removing the settling chamber, avoid scraping cell circle from slide.
- Do not allow the slides to dry prior to coverslipping. Each slide must be coverslipped one at a time.
- Leaving samples in alcohol for an extended length of time can cause the cells to destain.

20. Remove the tube racks from the PrepStain instrument. Add 2 ml of BD SurePath preservative fluid to each tube. Cap each tube or cover with parafilm. From the date of collection, cell pellets with preservative can be stored for up to 4 weeks at room temperature (15 – 30º C), or 6 months refrigerated (2 –10º C).
21. System clean up and quit:
    a. Select **`Clean Up System`**, and follow the directions displayed on the monitor.
    b. After the clean up procedure is complete, the screen will return to the Main Menu.
    c. Select **`Quit`**.
    d. Turn off the power.

Reprocessing BD SurePath cell pellets

The reprocessing procedure begins with the cell pellet that remains after the initial **`Slide Preparation and Staining`** run.

1. If refrigerated, allow specimen(s) to come to room temperature.
2. Proceed with steps 13 - 19 of the PrepStain process procedure.

1.

Chapter 5

1.1

Gynecologic (GYN) Slide Processing

This chapter provides both instructions and overview information for processing gynecologic specimen slides on the BD PrepStain™ instrument. To jump right to the procedure for processing specimen slides, turn to page 5-4. To familiarize yourself with the screens and controls used to perform this procedure refer to the following discussion.

PrepStain GYN program

Program overview

The GYN program operating principles and its sequence of events are discussed in ***Chapter 3*.*Principles of Operation*** To summarize this sequence, the slide processor transfers the samples and then performs a series of stain and rinse cycles that create a thin-layer preparation of cytologic materials on a BD SurePath PreCoat slide.

Each stain and rinse cycle follows the same pattern: what varies from cycle to cycle is the reagent used and the duration of the pause.

The BD PrepStain™ instrument's functions are controlled using a computer workstation. Three DOS based, menu-driven applications provide access to the programs that run the PrepStain instrument.

Using the workstation menus, you communicate with the instrument and monitor the progress of slide processing.

To access the gynecologic (GYN) slide processing functions, you just turn the workstation on. If the workstation is already running, you can access this and other functions by typing the appropriate command from the DOS prompt and pressing **Enter**. *Table 5-1* lists the commands and their corresponding function.

Table 5-1 PrepStain workstation commands

COMMAND	FUNCTION
GYN	Access the Slide Preparation and Staining, Slide Preparation, and Slide Staining procedures for gynecologic specimens
NONGYN	Access the Slide Preparation and Staining and Slide Staining procedures for non-gynecologic specimens
UTIL	Flush stain and DiTi lines

Figure 5-1 illustrates the welcome and version check screen that displays when you open the GYN program.

Figure 5-1 *GYN Version Check menu*

The screens in the GYN application are divided into three sections as illustrated in *Figure 5-1*.

e. The top (banner) section displays text messages on several lines. These messages tell you what action the system is performing or about to perform.
f. The middle (menu) section displays menu prompts you use to control the system.
g. The bottom (prompt) section displays text messages on a single line. These messages tell you what's happening and what to do next.

Note: Screens pictured are for illustration purposes only. Current display may differ in appearance.

Main Menu screen

After you verify the version, the GYN Main Menu screen is displayed. *Figure 5-2* illustrates this screen.

Figure 5-2 *GYN Main Menu*

This chapter discusses the **`Slide Preparation and Staining`**, **`Slide Preparation`**, and **`Slide Staining`** options. The **`Clean Up System`** option is discussed in ***Chapter 6***. The **`System Setup`** and **`Diagnostics`** options are discussed in ***Chapter 9***. These last two options should only be accessed by (or with the help of) a BD-authorized technician unless specified as part of routine maintenance.

Step in Progress screen details

While processing is underway, the monitor displays the current status of the process using the Step in Progress screen. *Figure 5-3* illustrates this screen.

Figure 5-3 *Step in Progress screen*

As pictured in *Figure 5-3*, the steps in the Sample and Stain process are listed at the top of the screen. The step that the BD PrepStain™ instrument is currently performing is highlighted and blinking.

The lower portion of the screen displays a settling chamber icon for each sample being processed (8 in this example). The sample currently being processed blinks.

The lower right corner displays icons for the reagent syringe pumps. Blinking arrows indicate the reagent(s) in use.

Definitions for each of the steps are listed below:

Resuspend Sample: Buffered water is added to re-suspend the cell pellet in the BD Centrifuge Tube.

Mix Sample: The cell pellet is repeatedly aspirated and dispensed to mix the cell material.

Transfer Sample: The mixed cell suspension is aspirated and dispensed into the Settling Chamber of the corresponding slide position.

Preparation Pause: The PrepStain system pauses for sedimentation of cells, drying, dehydration, rehydration and incubation of stains.

Wash with Water: The Settling Chamber is emptied and then rinsed with deionized water.

Wash with Alcohol: The Settling Chamber is emptied and then rinsed with BD Alcohol Blend Rinse.

Stain with Hematoxylin: The BD Hematoxylin Stain (hematoxylin) is applied, aspirated and reapplied to stain. BD Hematoxylin is the first stain used in the staining process.

Stain with EA/OG: The BD EA/OG Combo Stain (EA/OG) is applied, aspirated, and reapplied to stain. EA/OG is the second stain used in the staining process.

Processing gynecologic (GYN) specimens

Before you can perform this procedure you must first complete the preparation procedures in ***Chapter 4***, ***PreProcessing Steps***.

1. The GYN application runs automatically when starting the BD PrepStain™ instrument workstation.
   If the workstation is already running, but the GYN application is not:
   from the DOS prompt, type in `GYN` and then press **Enter**.
   The GYN Version Check screen is displayed.
2. Select **Run Version 1.3.0.3** from the menu, and then press **Enter**. This brings up the GYN Main Menu. The main menu (*Figure 5-2*) provides access to all functions of the program.

3. Select **Slide Preparation and Staining**, and then press **Enter**. The PrepStain Run Information screen (illustrated in *Figure 5-4*) is displayed.

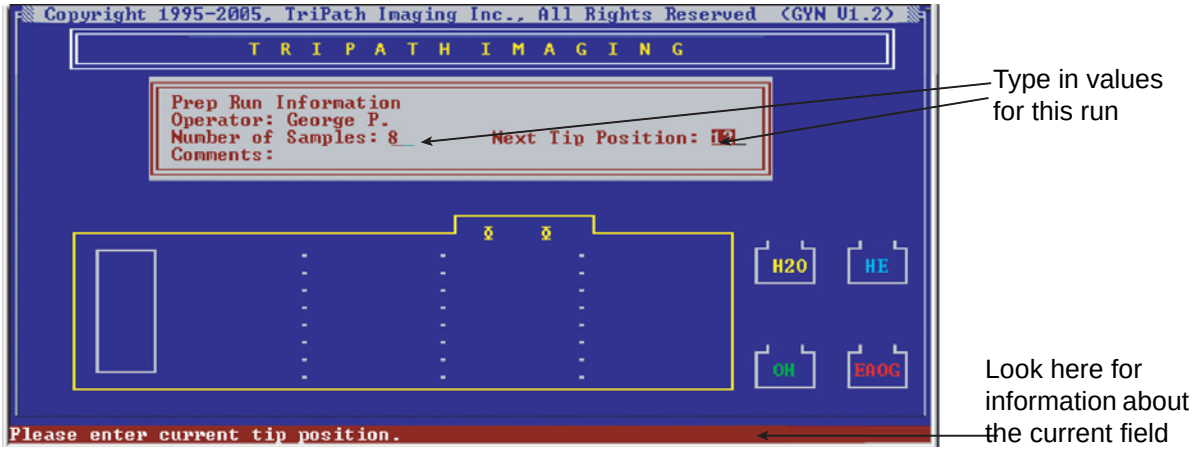


Figure 5-4 *PrepStain Run Information screen*

Note: You can use either the **Tab** or **Enter** keys to move the cursor (navigate) from one field to the next on PrepStain system screens.

4. Navigate to the second field (skip the **`Operator`** field), type in the number of samples to be processed and then press **Enter**. The number of samples must be a multiple of four.

Note: If the number of slides to be processed is not divisible by four, type in the next higher multiple of four, and then add blank slides, BD Settling Chambers, and tubes to the tube rack to make up the difference.

5. Navigate to the next field, and either press **Enter** to confirm that the Next Tip Position is correct; or type in the correct tip position, and then press **Enter** (skip the **`Comments`** field).
6. The **`Reenter Run Information`** prompt is displayed.

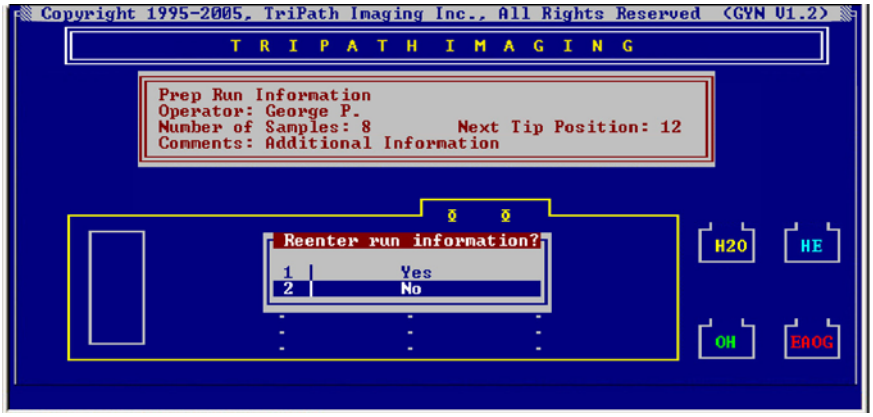


Figure 5-5 *Reenter Run Information menu*

- To change the number of samples or the next tip position, select **Yes**, press **Enter**, and repeat the last two steps.
- To confirm your entries and proceed, select **No** and then press **Enter**.

7. The **`Change Sample/Stain Parameters`** prompt is displayed.

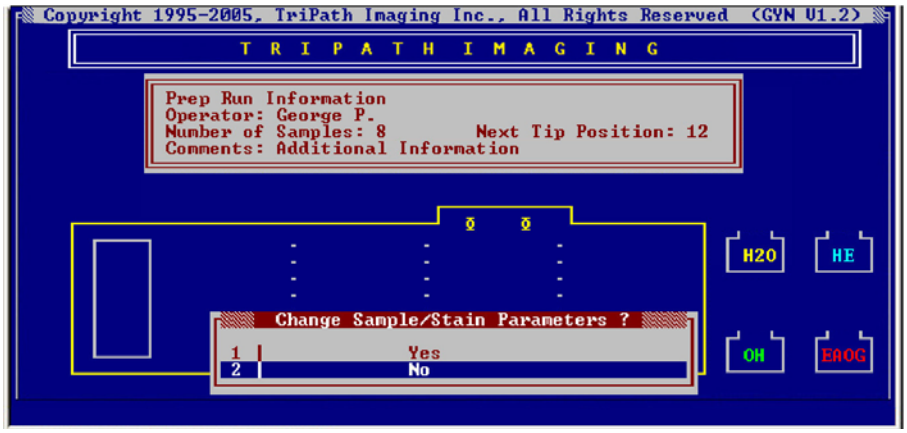


Figure 5-6 *Change Sample/Stain Parameters prompt*

- To change the sample or stain settings, select **Yes** and then press **Enter**. Refer to *Change sample/stain parameters* on page 5-15 for details on how to make these adjustments.
- To use the existing settings and proceed, select **No** and then press **Enter**.

8. The **Scan barcodes?** menu is displayed.

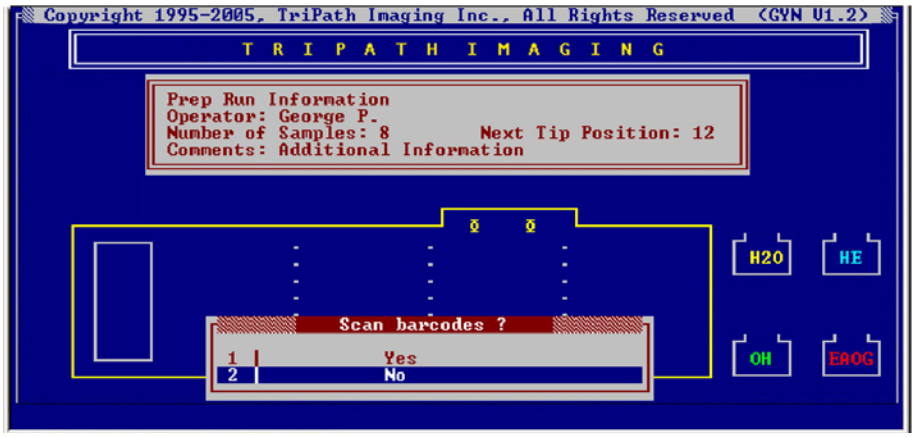


Figure 5-7 *Scan Barcodes menu*

- To use a barcode scanner, select **Yes** and then press **Enter**. Refer to *Scan Barcodes (optional feature)* on page 5-18 for details on using this feature.
- To bypass the barcode program and proceed, select **No** and then press **Enter**.

9. The vacuum prompt is displayed and the alarm sounds. Press any key to silence the alarm.

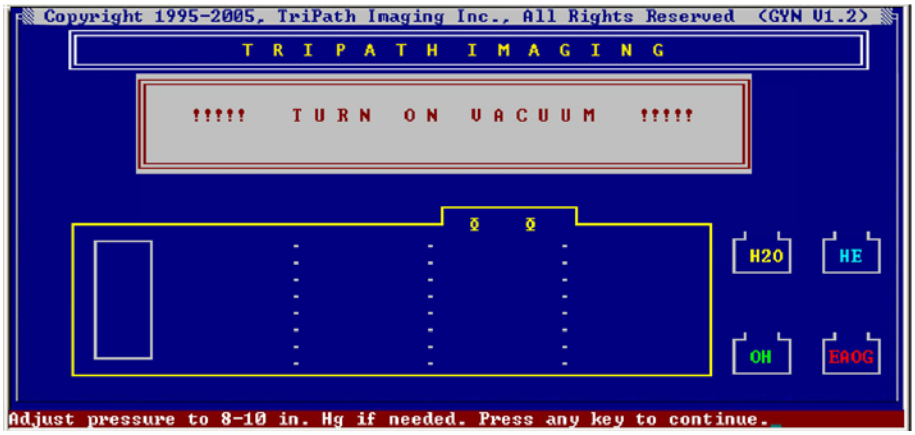


Figure 5-8 *Vacuum Pump Prompt screen*

10. Turn on the vacuum pump, wait a few minutes for it to warm up.
    - If using the Schuco pump, adjust pressure to 8 - 10 inches Hg, and then press any key to continue.
    - If using the KNF pump, adjust the pressure to 5-6 inHg, and then press any key to continue.

Note: The pump pressure setting at the bottom of the screen (8-10) is only for the blue Schuco pump. Use 5-6 inHg if using the KNF pump with pressure gauges in units of inHg. Use 180-220 mBAR if using the KNF pump with pressure gauges in units of mBAR.

11. The **`Prime ALL Tubing?`** prompt is displayed.

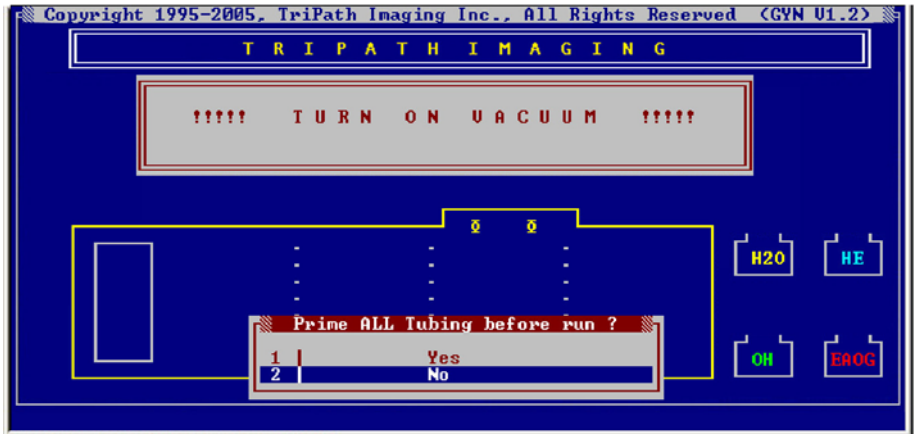


Figure 5-9 *Prime All Tubing menu*

- If this is the first run of the day, select **Yes** and then press **Enter** to prime the system tubing. The system initializes and the syringe pumps pump two full syringe volumes through the quad arm tubing and into the waste station.
- For subsequent runs during the next eight hours, select **No** and then press **Enter** to skip the full priming function.
- Before each run, a single syringe volume is automatically pumped through the tubing to ensure that the system is filled.

While the system is priming, the PrepStain System Priming screen is displayed.

Note: The elapsed time of the sequence displays in the lower left corner. This display is present for each task the PrepStain instrument performs.

Figure 5-10 *PrepStain is Priming screen*

12. When the priming cycle is complete, The screen displays the **Is the PrepStain tubing primed?** prompt.

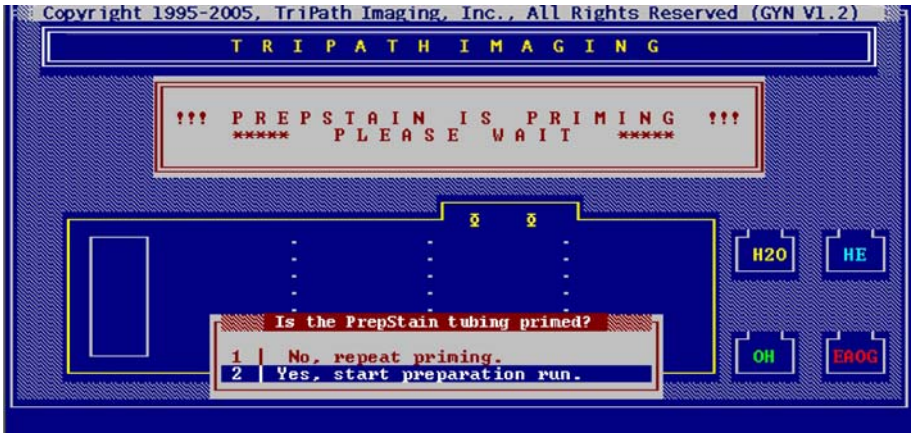


Figure 5-11 *Is the tubing primed?*

- To repeat the priming sequence, select **No** and then press **Enter**.
- To proceed with slide preparation and staining, select **Yes** and then press **Enter**.

Note: Steps 13 - 17 describe the Sample Preparation and Staining process. During this sequence, the Step in Progress screen is displayed. For a description of this screen, refer to *Step in Progress screen details* on page 5-3.

13. The DiTi dispenses buffered water into each BD Centrifuge Tube to re-suspend the cell pellet. Next, the DiTi picks up a disposable tip, and then a sample of the cell suspension is aspirated, carried to its corresponding slide, and deposited into the settling chamber.
14. After samples have been transferred to all racks, the instrument pauses for at least ten minutes while the cells sediment onto the slide.
15. When the sedimentation pause is complete, an alarm alerts the operator that the arm is about to move.

    Staining is performed one slide rack at a time. During each staining cycle, each slide is pre-washed in the appropriate reagent (buffered water for hematoxylin, alcohol for EA/OG Combo Stain) and then stained. Each settling chamber is completely emptied between stains and washes. After the staining is complete, the slide is washed with alcohol.
16. When all of the slides on a rack have been stained, the PrepStain system sounds an alarm, and then continues to stain the next slide rack.

    h. As each slide rack is completed, remove it from the BD PrepStain™ instrument and decant the alcohol from the BD Settling Chambers into a proper receptacle.

CAUTION:

- When removing the settling chamber, avoid scraping cell circle from slide.
- Do not allow the slides to dry prior to coverslipping. Each slide must be coverslipped one at a time.
- Leaving samples in alcohol for an extended length of time can cause the cells to destain.

17. When the PrepStain instrument finishes processing, the **`Sample Preparation Complete`** prompt appears and an alarm sounds. Press any key to silence the alarm and continue.
18. When you complete a Slide Preparation and Staining run, you can either run another batch, exit to DOS, clean the instrument, or simply turn the PC and PrepStain instrument off.

Note: If for any reason it becomes necessary to pause the instrument, press the **F10** key. The PrepStain instrument suspends processing. Follow the screen prompts to resume processing.

Prep only

Before you can perform this procedure you must first complete the preparation procedures in ***Chapter 4***, ***PreProcessing Steps***. Access to the **Slide Preparation** process is via the GYN Version Check and GYN Main menu screens These screens are illustrated in *Figure 5-1* and *Figure 5-2*.

1. The GYN application runs automatically when you start the BD PrepStain™ instrument workstation.
   If the workstation is already running, but the GYN application is not:
   from the DOS prompt, type in GYN and then press **Enter**.
   The GYN Version Check screen is displayed.
2. Select **Run Version 1.3.0.3** from the menu, and then press **Enter**. This brings up the GYN Version Main Menu. The main menu (*Figure 5-2*) provides access to all functions of the program.
3. Select **Slide Preparation**, and then press **Enter**.
   The PrepStain Run Information screen will be displayed.

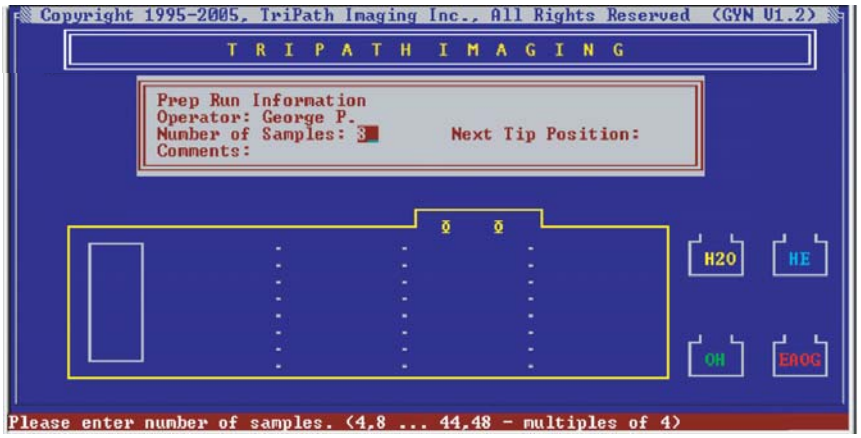


Figure 5-12 *PrepStain Run Information screen*

Note: You can use either the **Tab** or **Enter** keys to move the cursor (navigate) from one field to the next on PrepStain system screens.

4. Load samples, slides, and BD Settling Chambers, and then check the reagent levels. (Note that it is not necessary to place tubing in the hematoxylin and EA/OG reagent containers)
5. Follow instructions as prompted on the screen.
6. The PrepStain instrument will automatically transfer samples to the appropriate slides.
7. The PrepStain instrument sounds an alarm after each rack is finished processing.

8. Remove the finished slide rack from the instrument.
9. Invert the rack to decant the liquid. With the rack still inverted, lightly tap the slide rack on absorbent material to blot excess alcohol from the BD Settling Chambers. Leave the rack inverted for up to a minute to drain any residual rinse agent.
10. Return the rack to an upright position, and then carefully remove the BD Settling Chambers one at a time. Immediately place the slides into a rack submerged in 95 - 100% Ethanol.
11. Repeat steps 8 - 10 for the remaining slide racks.
12. Begin staining procedure.

Slide Staining

Access to the **Slide Staining** process is via the GYN Version Check and GYN Main menu screens These screens are illustrated in *Figure 5-1* and *Figure 5-2*.

1. The GYN application runs automatically when you start the BD PrepStain™ instrument workstation.
   If the workstation is already running, but the GYN application is not:
   from the DOS prompt, type in GYN and then press **Enter**.
   The GYN Version Check screen is displayed.
2. Select **Run Version 1.3.0.3** from the menu, and then press **Enter**. This brings up the GYN Version Main Menu. The main menu (*Figure 5-2*) provides access to all functions of the program.
3. Select **Slide Staining**, and then press **Enter**.
   The PrepStain Run Information screen will be displayed.

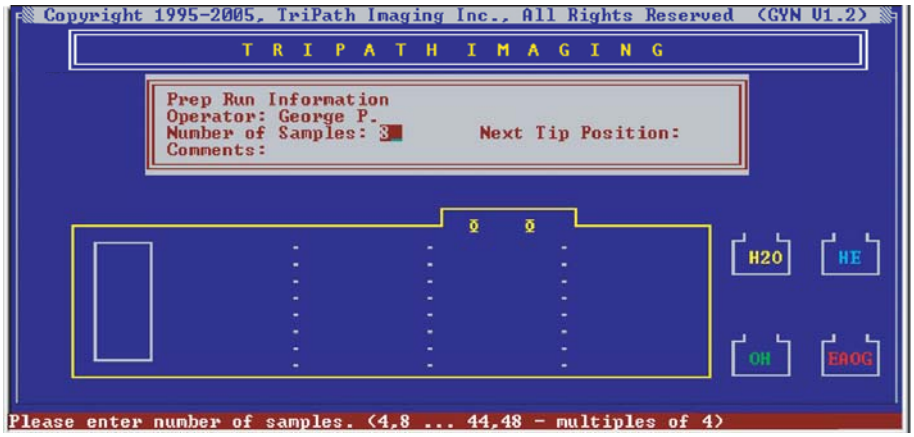


Figure 5-13 *PrepStain Run Information screen*

Note: You can use either the **Tab** or **Enter** keys to move the cursor (navigate) from one field to the next on PrepStain system screens.

4. Navigate to the second field (you can skip the **`Operator`** field), type in the number of samples to be processed and then press **Enter**. The number of samples must be a multiple of four.

Note: If the number of slides to be processed is not divisible by four, type in the next higher multiple of four, and then add an equal number of blank slides and BD Settling Chambers.

5. Press **Enter** again (you can skip the **`Comments`** field), to complete the PrepStain Run Information screen.
6. The **`Reenter Run Information`** prompt is displayed.
   - To change the number of samples, select **Yes**, press **Enter**, and repeat step 4.
   - To confirm your entries and proceed, select **No** and then press **Enter**.
7. The **`Change Sample/Stain Parameters`** prompt is displayed.

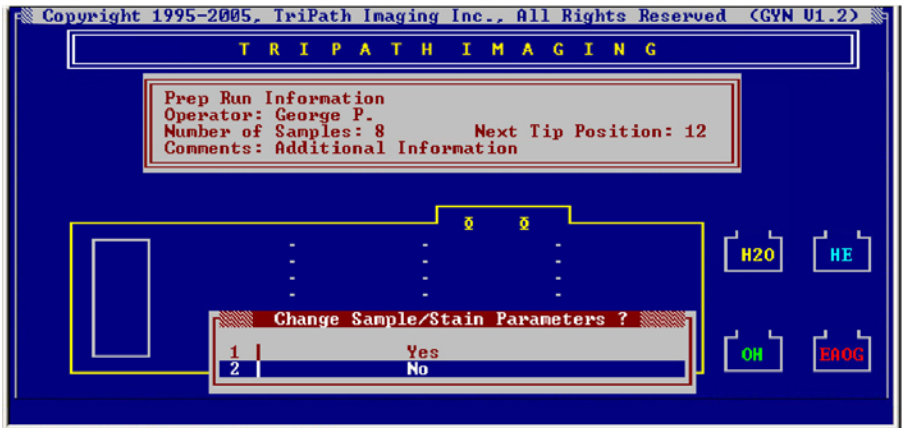


Figure 5-14 *Change Sample/Stain Parameters menu*

   - To change the sample or stain settings, select **Yes** and then press **Enter**.
     Refer to *Change sample/stain parameters* on page 5-15 for details on how to make these adjustments.
   - To use the existing settings and proceed, select **No** and then press **Enter**.
8. The **`Scan Bar Codes?`** prompt is displayed.

- To use a barcode scanner, select **Yes** and then press **Enter**. Refer to *Scan Barcodes (optional feature)* on page 5-18 for details on using this feature.
- To bypass the barcode program and proceed, select **No** and then press **Enter**.

9. The vacuum prompt is displayed and the alarm sounds. Press any key to silence the alarm.
10. Turn on the vacuum pump, adjust the pressure to 8 - 10 inHg for Schuco pump or 5-6 inHg (180-220 mBAR) for KNF pump, and then press any key to continue.
11. The **`Prime ALL Tubing?`** prompt appears.
    - If this is the first run of the day, select **Yes** and then press **Enter** to prime the system tubing. The system initializes and the syringe pumps pump two full syringe volumes through the quad arm tubing and into the waste station.
    - For subsequent runs during the next eight hours, select **No** and then press **Enter** to skip the full priming function.
    - Before each run, a single syringe volume is automatically pumped through the tubing to ensure that the system is filled.
12. When the priming cycle is complete, the **`Is the tubing primed?`** prompt is displayed.
    - To repeat the priming sequence, Select **No** and then press **Enter**.
    - To proceed with slide staining, select **Yes** and then press **Enter**. The Step in Progress screen is displayed.

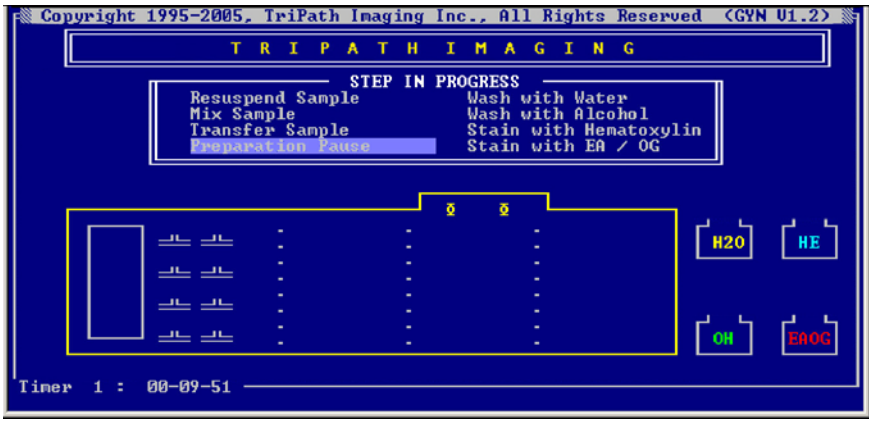


Figure 5-15 *Step in Progress screen*

Note: Steps 13 - 15 describe the Slide Staining process. During this sequence, the Step in Progress screen is displayed. For details on this screen, refer to *Step in Progress screen details* on page 5-3. Note that the first three elements in the list (Resuspend Sample, Mix Sample, and Transfer Sample) do not occur in the Slide Staining sequence.

13. Staining is performed one slide rack at a time. During each staining cycle, each slide is pre-washed in the appropriate reagent (buffered water for hematoxylin, alcohol for EA/OG) and then stained. Each settling chamber is completely emptied between stains and washes. After the staining is complete, the slide is washed with alcohol.
14. When all of the slides on a rack have been stained, the PrepStain system sounds an alarm, and then continues to stain the next slide rack.
    i. As each slide rack is completed, remove it from the PrepStain instrument and decant the alcohol from the BD Settling Chambers into a proper receptacle.

CAUTION:

- When removing the settling chamber, avoid scraping cell circle from slide.
- Do not allow the slides to dry prior to coverslipping. Each slide must be coverslipped one at a time.
- Leaving samples in alcohol for an extended length of time can cause the cells to destain.

15. When the PrepStain instrument finishes processing, the **`Sample Preparation Complete`** prompt appears and an alarm sounds. Press any key to silence the alarm and continue.
16. When you complete a Slide Staining run, you can either run another, exit to DOS, clean the instrument, or simply turn the PC and PrepStain instrument off.

Change sample/ stain parameters

The Change Sample/Stain Parameters function provides the means of adjusting the sampling volumes, staining times and cell sedimentation times. You have the opportunity to access this function when you run a Slide Preparation and Staining, Slide Preparation, or Slide Staining cycle and the **`Change Sample/Stain Parameters`** prompt is displayed. Note, that access to this function is protected by password.

CAUTION: Password access should be limited to authorized individuals only.

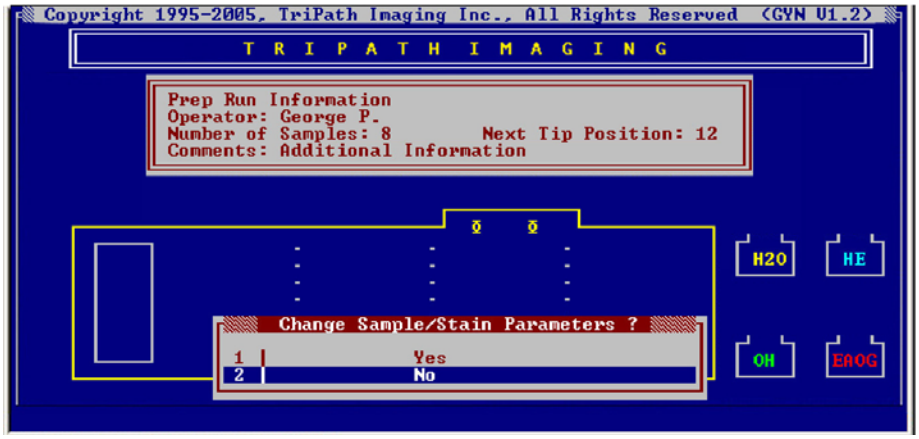


Figure 5-16 *Change Sample/Stain Parameters menu*

This procedure is detailed below:

1. During the PrepStain process, after you specify the number of samples and the next tip position, you have the opportunity to change the stain parameters. To change the parameters that control the staining process, select **Yes** when prompted. The **Password** prompt is displayed.
2. Type in the password.
3. The Sample/Stain Parameters screen (as illustrated in *Figure 5-17*) is displayed so that you can change the parameter settings.

Figure 5-17 *Sample/Stain Parameters screen*

4. The currently active field is highlighted and marked with a flashing cursor. The prompt line at the bottom of the screen displays the range of acceptable values as you move from field to field. Use either the **Tab** or **Enter** keys to navigate to the field you wish to change, and then type in the new values. *Table 5-2* details the parameters you can set using this screen.

Table 5-2 Sample and Stain parameter values

PARAMETER NAME	ACCEPTABLE VALUES	DEFINITION AND DEFAULT VALUES
RESUSPENSION	**0 - 1000** µl	The Resuspension volume is the amount of buffered deionized water added to the cell pellet. The default amount is 1000 µl.
MIX	**100 - 500** µl	The Mix volume is the amount of water pumped in and out of the disposable tip during the re-suspension of the pellet. The default amount is 500 µl.
SAMPLE	**100 - 500** µl	The Sample volume is the amount of sample transferred to the settling chamber. The default amount is 200 µl.
DILUTION	**0 - 1000** µl	The Dilution volume is the amount of buffered deionized water pH (7.5-8.5) added to the sample volume after it is dispensed on the slide. The default amount is 600 µl.
SEDIMENTATION	**0 - 1200 SEC.**	The Sedimentation pause is the amount of time allowed for the cells to settle onto the BD SurePath PreCoat slide. The default amount is 600 sec.
DRYING	**55 - 300 SEC.**	The Drying pause is the amount of time allowed for the cells to dry onto the BD SurePath PreCoat slide. The default amount is 60 sec.
HEMATOXYLIN	**55 - 180 SEC.**	The Hematoxylin incubation is the amount of time allowed for the cells to absorb the stain. The default amount is 85 sec.
EA/OG	**55 - 180 SEC.**	The EA/OG incubation is the amount of time allowed for the cells to absorb the stain. The default amount is 75 sec.
MIX	**1 - 15**	The Mix cycles is the number of times that the diluted sample is pumped in and out of the disposable tip to re-suspend the cell pellet. The default number is 8.
WATER WASH	**1 - 9**	The Water washes is the number of water cycles used to wash the slide after hematoxylin staining is complete The default number is 2 cycles.
ALCOHOL WASH	**1 - 9**	The Alcohol washes is the number of alcohol cycles used to wash the slide after EA/OG staining is complete. The default number is 3 cycles.

Note: Entries of ten (10) or more are rejected as invalid for the number of rinse cycles of both water and alcohol, but there is no audible alarm or onscreen warning to alert you that your entry was rejected. Further, an attempt to enter an invalid value results in only the first digit being accepted. For instance, if you enter **10** the instrument accepts that as **1**, or if you enter **80** the instrument accepts that as **8**.

Restrict entries to the recommended range, and always confirm changed parameters before running and/or saving modified preparation parameters.

5. When the cursor has been to each field, you are presented with 4 options as shown in *Figure 5-18*.

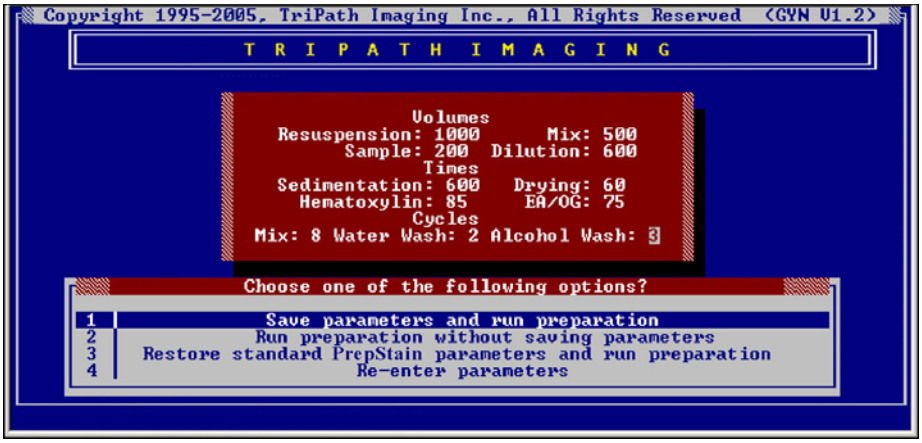


Figure 5-18 *Select a save option*

- Choose the appropriate option, and then press **Enter**.
- When you choose one of the first three options, the change parameters procedure is complete, and the **`Scan Barcodes`** prompt is displayed.
- If you choose option four, return to the previous step.

Scan Barcodes (optional feature)

If barcode labels are in use to accession the centrifuge tubes, specimen vials, and slides, use this procedure to enter the barcode label numbers. This option provides a means of including an additional identity confirmation step to the sample preparation process.

1. To initiate the Scan Barcodes procedure, choose **Yes** at the **`Scan Barcodes`** prompt.
   The Scan Barcodes screen is displayed. As illustrated in *Figure 5-19*, the screen has 24 blank fields; 12 for the active slide rack and 12 for the active tube rack.

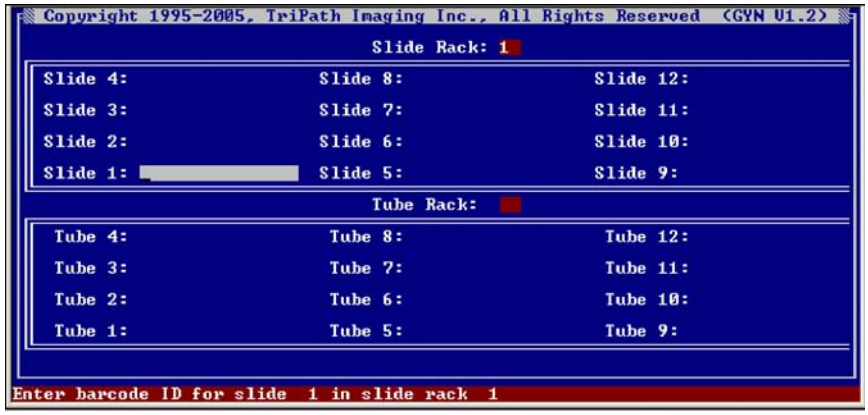


Figure 5-19 *Scan Barcodes screen*

Note: If you are processing less than a full rack of slides, the screen still displays 24 fields (12 positions), but only fields that correspond to the number you are processing are active. That is, the cursor does not go to inactive fields.

2. Use the barcode scanner to scan the label on each slide in the first slide rack. As you scan each label, the cursor moves automatically to the next field.
3. When the labels have been scanned for the slide rack, the cursor moves down to the tube rack. Use the barcode scanner to scan the label on each tube in the first tube rack.

Note: The numbers on the labels for corresponding slides and centrifuge tubes must match. If there is a discrepancy between the numbers, reposition the tubes to correct the correspondence and then re-scan the label(s) to resolve the mis-match. The process cannot continue until you have scanned a correctly oriented tube rack.

4. When you finish scanning the labels in the first tube rack, the screen displays blank fields for the second slide rack and its corresponding tube rack. Repeat steps 2 and 3 for as many additional racks as required. When you finish scanning all racks, return to the PrepStain processing procedure.

Chapter 6
Maintenance Procedures

This chapter details the procedures you need to follow in order to properly maintain the PrepStain system. Proper maintenance is necessary for the BD PrepStain™ Slide Processor system to consistently produce quality slides. If neglected, the instrument's performance will deteriorate over time. BD is not responsible, under warranty or otherwise, for damage due to abuse or neglect.

Materials required

- Shallow (approximately 100 ml) container/beaker
- Deionized (DI) water
- DI water clean up container
- Alcohol
- Alcohol clean up container
- Lint free cloth
- Cleaning solution
- felt silencers (monthly maintenance)

Daily preventive maintenance

Perform daily preventive maintenance at the end of each day or after every eight hours of PrepStain system operation, whichever comes first.

Complete the ***Perform system clean up*** procedure as described below.

- Make sure PrepStain system is turned Off.
- If the instrument is not to be used for more than eight hours, leave the system filled with the deionized water. Place all intake tubing in deionized water. Other solutions can form precipitates, which can shorten the life of the tubing, valves, and syringes and can affect the precision and accuracy of the instrument.
- Remove racks from the instrument surface. Carefully clean and dry the work surface with a soft cloth using cleaning solution.
- Empty tip disposal container into an approved biohazard container.
- Check all syringes and tubing for leaks.
- Empty Vacuum Waste container if needed.
- Wipe pipette bundles with a clean lint-free cloth.
- Wipe DiTi cone with a clean lint-free cloth.
- Wipe racks and work table surface with cleaning solution.

Perform system clean up

Access to the system clean up procedure is via either the GYN or NonGYN applications.

1. As directed on the previous page, have prepared cleaning water and alcohol in the appropriate bottles. Do not remove any of the tubing from the reagent bottles until instructed by the on-screen prompts.
2. The GYN application runs automatically when you start the BD PrepStain™ instrument workstation.
   If the workstation is already running, but the GYN application is not:
   from the DOS prompt, type in `GYN` and then press **Enter**.
   The GYN Version Check screen is displayed.
3. If it's not already running, turn the vacuum pump on. Select **Run Version 1.3.0.3** from the menu, and then press **Enter**.
   The GYN Version Main Menu is displayed. This menu (illustrated in *Figure 5-2*) provides access to all functions of the program.
4. Select **Clean Up System**, and then press **Enter**.
   The PrepStain instrument initializes and then back flushes all reagent lines into their reagent containers.
   The prompt line displays:
   `Please wait for back flushing to complete`.

   The PC workstation sounds an alarm when this step is complete.
5. Press any key to silence the alarm.
   The prompt line displays:
   `Back flushing complete. Press any key to continue clean up.`
6. Put the hematoxylin line in the cleaning water and the EA/OG line into the cleaning alcohol, and then press any key to continue.
   The prompt line displays:
   `Please wait for stain line cleaning to complete.`
7. The PrepStain instrument flushes each stain line with the appropriate solvent, and then sounds an alarm.
8. Press any key to silence the alarm.
   The prompt line displays:
   `Rinsing complete, press any key to continue clean up`.

   Put both the EA/OG and alcohol lines into the DI water. Press any key to continue.
   The prompt line displays:
   `Please wait for lines to fill with DI water.`
9. The PrepStain instrument flushes the tubing and associated syringes with water. When rinsing is complete, all tubing is filled with deionized water.
10. Use stylus to clean inside of the vacuum tips.

11. The PC workstation sounds an alarm and prompts you to hold a container of DI water under each pipette bundle on the Quad arm to flush out the vacuum lines. Press any key to silence the alarm, and then use a small container (approximately a 100 ml) to flush out the vacuum lines for approximately 10 seconds.
    The prompt line displays:
    `Press any key to return to the Main Menu.`
12. When you finish rinsing the pipette bundles, press any key to return to the Main Menu.
13. Turn off the BD PrepStain™ system and vacuum pump.
14. Wipe pipette bundles with a lint-free cloth.
15. Clean the DiTi cone and Grip Tip with a lint-free cloth.
    - Raise the plastic sleeve to expose the DiTi cone and Grip Tip.
    - Using a lint-free cloth, carefully clean the DiTi cone and Grip Tip using a downward motion only.

    This completes the system clean up procedure.

Weekly preventive maintenance

Perform weekly preventive maintenance at the end of each week or after forty hours of operation, whichever comes first. The following materials are required to complete this procedure.

- DI water (at least 1 liter)
- 5% cleaning solution (at least 1 liter)
- 4L container with cap

Weekly maintenance is comprised of the following procedures:

- Flush stain and vacuum lines with cleaning solution
- Clean the Z-rod
- Empty waste containers
- Check tubing connectors and syringes for tightness
- XYZ Test

Preparation of 5% cleaning solution

1. Add 180 ml of Contrad 70, Decon 90, or bleach to a 1-gallon container.
2. Fill 4L container to 3600 mlwith DI or distilled water.
3. Cap and invert gently to mix.

Flush stain and vacuum lines

This procedure flushes the stain and vacuum lines with a 5% cleaning solution followed by a water rinse. The BD PrepStain™ instrument's Utilities program automates this process.

1. Prepare bottles with cleaning solution and fresh DI water for the rinse.

2. The GYN application runs automatically when you start the PrepStain instrument workstation. Exit this application to access a DOS prompt so that you can display the PrepStain Utilities Version Check screen (*Figure 6-1*). This screen provides access to the cleaning process.
   - If the workstation is running the GYN application, select **Quit** to display the DOS prompt, type in `UTIL`, and then press **Enter**. The PrepStain Utilities Version Check screen is displayed.
   - If the workstation is already displaying the DOS prompt, type in `UTIL` and then press **Enter**.
     The PrepStain Utilities menu is displayed.

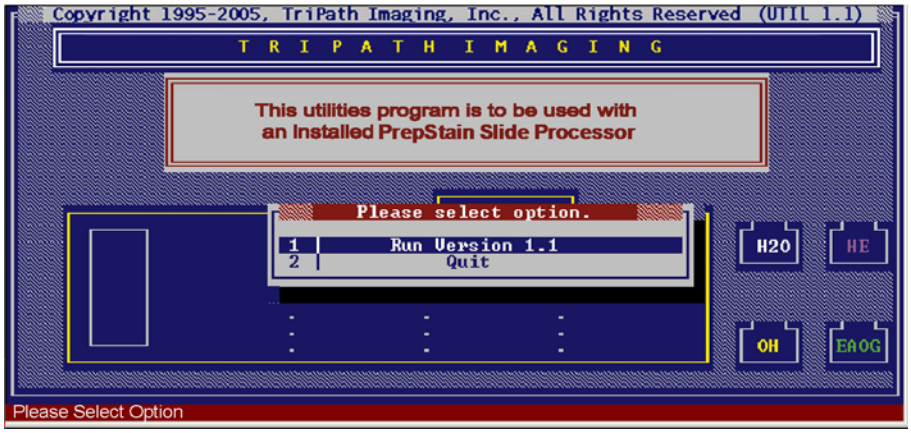


Figure 6-1 *Utilities menu*

3. If it's not already running, turn the vacuum pump on. From the PrepStain Utilities menu, select **Run Utility Version 1.1** and press **Enter**.
   The Utilities menu will be displayed.
4. Select **Flush Tubing With Cleaning Solution**, and then press **Enter**.
   The PrepStain instrument initializes; then the prompt line displays:
   `Place ALL Reagent Intake tubing into cleaning solution. Press any key to begin flushing PREP.`
5. Move all four lines into the cleaning solution container, and then press any key to continue.
   The PrepStain instrument initializes, and then flushes the intake tubing with cleaning solution.
   The prompt line displays:
   `Please wait for cleaning solution flush to finish.`
6. When the flush is complete, the PC workstation sounds an alarm and prompts you to press any key to silence it.
7. Press any key to silence the alarm.
   The prompt line displays:
   `Place All Reagent Intake tubing into fresh, clean DI water. Press any key to begin.`

8. Move all four lines into the DI water container, and then press any key to continue.
   The BD PrepStain™ instrument flushes all lines with DI water, and displays the prompt:
   `Please wait for DI water flush to finish`.
9. When the flush is complete, the PC workstation sounds an alarm and The prompt line displays:
   `Clean up complete, press any key to silence alarm`.
10. Press any key to silence the alarm, and then hold a small container of cleaning solution under each vacuum tip for approximately 10 seconds to flush the vacuum lines with cleaning solution.
11. Rinse each vacuum line by holding a small container of DI water under each vacuum tip for 10 seconds.
    The prompt line displays:
    `Clean up complete, press any key to return to the Utility Menu.`
12. When you finish rinsing the pipette bundles, wipe off the pipette bundles with a clean, lint free cloth, and then press any key to return to the Main Menu.
13. Turn off the vacuum pump. This completes the flush stain and vacuum lines procedure.

Clean the Z-rod

Clean the Z-rod with a lint-free tissue. Do not use oil or solvents to clean the Z-rod.

Empty gravity and waste containers

Depending on your lab volume, this task may be required daily.

Empty the vacuum and gravity waste containers into an approved biohazard container.

Note: When re-attaching waste bottle, make sure the vacuum hoses are properly connected and the cap is tightened.

Preventative maintenance

Running the random X, Y, Z test is required every week. Refer to ***Chapter 9, Setup and Diagnostics*** for details.

The BD PrepStain™ Slide Processor should not be used to prepare patient specimens if more than a week has passed since the last successful random XYZ test. Failure to confirm proper motion control function with this test may result in mis-delivery of patient specimen.

This completes the weekly cleaning process.

Monthly preventive maintenance

Perform the following preventive maintenance routine once a month.

Replace Schuco vacuum pump felt silencer

Note: This section only applies to the blue Schuco pump.

To replace the felt silencer on the vacuum pump:

1. On the vacuum pump, locate the chrome air exhaust fitting.
2. Unscrew the exhaust fitting.
3. Replace the felt silencer pad.
4. Replace the exhaust fitting.

Clean all water bottles and tubing

Using a 5% bleach or Contrad 70 or Decon 90 solution, clean all water bottles thoroughly. Rinse all bottles until all cleaning solution is gone with warm tap water and then rinse with DI water. Using ~100ml straight bleach, clean vacuum bottle; add water and let stand until clean. Rinse with tap water.

This completes the monthly cleaning process.

BD PrepStain™ Slide Processor Maintenance Log

Department_____Month_____

Serial # _____

Please initial each space. If a problem is found take appropriate steps to resolve. For further assistance, call BD Technical Support at: 1-800-638-8663.

DAILY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Perform system clean up																															
Leave tubing in DI water overnight																															
Empty tip disposal and waste containers																															
Check syringes and tubing for leaks																															
Clean pipette bundles and DiTi cone																															
Wipe racks and work table surface with cleaning solution																															
Use stylus to clean inside of vacuum tips																															

Steps for each of these procedures are provided earlier in this chapter.

WEEKLY	WEEK 1 (/ /)	WEEK 2 (/ /)	WEEK 3 (/ /)	WEEK 4 (/ /)	WEEK 5 (/ /)
Run the Utility program flush procedure					
Clean the Z-rod with a lint-free tissue					
Run the Random X, Y, Z test					
Empty vacuum and gravity waste containers (as needed, may be required daily, depending on lab volume)					
Check tubing connectors and syringes for tightness.					

MONTHLY	(/ /)
Replace the felt silencer and filter (if applicable) on the vacuum pump	
Replace water bottles or clean with disinfecting solution	
Clean tubing with the disinfecting solution using Utilities software	

Type text here

Chapter 7 Troubleshooting

This chapter provides procedures you can use to isolate and resolve problems with the BD PrepStain™ Slide Processor system.

Using the information in this chapter, many of the operating problems that can occur with the PrepStain system can be corrected by the operator. By taking note of the error codes and messages that appear on the computer screen and working with the Problems and Solutions table you can often resolve the problem on your own. When calling BD Technical Support, please have a precise description of the problem available, including error code information and attempted corrective action. BD Technical Support: 800-638-8663, or contact your local BD representative.

Error codes and messages

There are a number of errors that the PrepStain instrument can detect. When one of these errors is detected, the PC monitor displays an error message as illustrated in *Figure 7-1*.

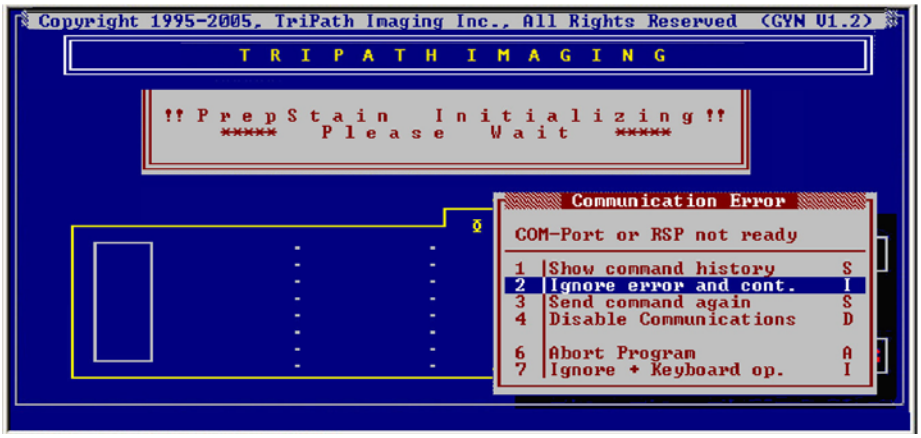


Figure 7-1 *Error message display screen*

The following tables list the error codes that can be displayed. If one of these codes is displayed, note the code, call BD Technical Support.

General error message codes

Table 7-1 General error message codes

CODE #	MESSAGE
1	Initialization Error
2	Invalid Command
3	Invalid Operand
4	Invalid Command Sequence
5	Device Not Implemented
6	Time-out Error
7	Device Not Initialized
8	Command Overflow
9	Plunger Overload/No Liquid Detected
10	Valve Blocked/Z-position Overrun
11	Not Enough For Liquid Sampling
12	No Liquid Detected
13	Not Enough Liquid Detected
17	Arm Collision Avoided
20	Step loss detected on X-axis
21	Step loss detected on Y-axis
22	Step loss detected on Z-axis
24	ALIDUM pulse time out

Syringe pump error keys

The following error codes can be triggered by the syringe pumps. If one of these codes is displayed, note the code, call BD Technical Support.

Table 7-2 Syringe pump error keys

ERROR	POSSIBLE CAUSES
1	Defective diluter valve Defective syringe Valve drive faulty Plunger faulty
2	Software problem Wrong string command
3	Wrong setup Program problem Wrong operand in string command

Table 7-2 Syringe pump error keys

ERROR	POSSIBLE CAUSES
4	Software problem
5	Diluter is faulty CPU87 is faulty
6	Valve is worn out Diluter is faulty
7	Device is not initialized Diluter is faulty
8	Too many commands used on one line
9	Syringe is too tight Valve is blocked Diluter speed is too fast Diluter is faulty
10	Initialization Error

Robot arm error codes

The following error codes can be triggered by problems with the robot arm. If one of these codes is displayed, see Keyboard initialization for arm errors. For more information, note the code and call BD Technical Support.

Table 7-3 Robot arm error codes

ERROR	POSSIBLE CAUSES
1	Setup is not correct Arm is blocked
2	Software problem
3	Wrong setup Software problem
4	Software problem
7	Device is not initialized
8	Too many commands used on one line
9	Syringe is too tight Valve is blocked Diluter speed is too fast Diluter is faulty
17	Arm is not initialized
21	X step loss detected
22	Y step loss detected
23	Z step loss detected
24	ALIDUM connection or ADRI board failure

Keyboard initialization for arm errors

1. Select option `Ignore + Keyboard op`. See Figure 7-1 for example, where it is option 7 in the list.(May not always be option 7.)
2. A new window will open. At the `Command` prompt, type `LOAD` and press `Enter`.
3. A new window will open. In the pop-up box, select `APS Liquid Sys`.
4. At the next `Command` prompt, type `SETUP` and press `Enter`.
5. At the next `Command` prompt, press the F8 button and type `PI`. (Screen will read `#18PI`.) Hit `Enter` to reset the arm.
6. Press Esc key to continue operation from where the error occurred.

Problems and solutions

The following table describes situations that can occur during processing with the BD PrepStain™ instrument. If one of these problems should occur, trying the suggested solutions before calling BD Technical Support will help more quickly resolve the problem.

Table 7-4 *Troubleshooting suggestions*

SYMPTOM	LIKELY CAUSE(S)	CORRECTIVE ACTION SEQUENCE
ALL BD SETTLING CHAMBERS DO NOT EMPTY	• The vacuum pump is not on.	Turn on the vacuum pump.
	• The cap on the vacuum waste bottle is loose.	1. If you just changed the vacuum waste bottle, check that the lid is on securely. 2. Check that all tubing connections are secure.
	• The vacuum pressure is too low.	1. Check all connections from the vacuum manifold. Adjust the vacuum pressure to 8 - 10 inHg for Schuco pump or 5-6 inHg (180-220 mBar) for KNF pump. 2. Call BD Technical Support for assistance.
	• The vacuum line is clogged.	1. Isolate the vacuum line that is causing the obstruction. 2. Use a stylus to unclog the vacuum line. 3. If the clog is not cleared, call BD Technical Support.
	• The waste manifold is clogged.	Call BD Technical Support for assistance.

Table 7-4 *Troubleshooting suggestions*

SYMPTOM	LIKELY CAUSE(S)	CORRECTIVE ACTION SEQUENCE
DOUGHNUTTING Macroscopically visible holes on slide.	• Vacuum bundle touching slide surface.	Call BD Technical Support.
	• Vacuum pressure is too high.	Adjust pressure to between 8 - 10 inHg for Schuco pump or 5-6 inHg (180-220 mBar) for KNF pump.
DROPS FORM AT THE END OF THE DiTi TIP OR PIPETTE STAINING BUNDLE		1. Tighten all liquid connections. 2. If air is observed in the tubing, tighten the tubing connections. 3. Tighten the syringe connection. 4. Call BD Technical Support.
FAILURE TO PICK UP A TIP		Call BD Technical Support.
HYPOCELLULARITY (TOO FEW CELLS)	The Tris buffered water is out of date	Make up a new batch of Tris buffered water.
	BD SurePath PreCoat slides were not used.	Use only BD SurePath PreCoat slides for optimal results.
	An inappropriate fixative was used to fix the specimen.	For optimal results, use BD SurePath Preservative Fluid.
	The vacuum pressure is too high.	Adjust to 8 - 10 inches Hg for Schuco pump or 5-6 inHg (180-220 mBAR) for KNF pump.
	The BD SurePath PreCoat slides are out of date.	Discard out of date BD SurePath PreCoat slides. Use only BD SurePath PreCoat slides that are within expiration date limits.
NUCLEUS IS TOO DARK	An inappropriate fixative was used to fix the specimen.	For optimal results, use BD SurePath Preservative Fluid.
	The hematoxylin staining time was too long.	Decrease the number of seconds for staining.
	Drying artifact	The settling chamber was removed and the cell surface dried before the mounting media and cover glass was added.
OBSTRUCTION	One of the vacuum tips is clogged.	1. Isolate the vacuum tip that is causing the obstruction. 2. Use a stylus to unclog the vacuum tip. 3. Clean the outside of the tip with an alcohol wipe. 4. If the clog is not cleared, call BD Technical Support.

Table 7-4 *Troubleshooting suggestions*

SYMPTOM	LIKELY CAUSE(S)	CORRECTIVE ACTION SEQUENCE
ONE SETTLING CHAMBER DOES NOT EMPTY	Vacuum line pops off of the stain bundle.	Replace the line and then call BD Technical Support.
	This usually is caused by a clog in the vacuum pipette.	1. Isolate the vacuum pipette that is causing the obstruction. 2. Use a stylus to unclog the vacuum pipette. 3. Clean the outside of the pipette with an alcohol wipe. 4. If the clog is not cleared, call BD Technical Support
ONE SETTLING CHAMBER DOES NOT FILL	This is caused by a clog in the manifold or a dispensing pipette.	1. Isolate the manifold or pipette that is causing the obstruction. 2. Use a stylus to unclog it. 3. Clean the outside of the manifold or pipette with an alcohol wipe. 4. If the clog is not cleared, call BD Technical Support.
PINK SPOTS	Z-max of the Slide Quad is too high.	Call BD Technical Support for adjustment.
	The dispense tips are dripping.	Check all tubing connections.
PIPETTE TIP MISSES TARGET		1. Check that the slide rack is properly seated on the worktable and adjust, if necessary. 2. Call BD Technical Support. 3. Perform **Slide Preparation and Staining** or **Slide Preparation**, and confirm that pipette tip is picked up.
RIMMING (SIMILAR TO DOUGHNUTTING) Most of the cells are located on the outer edge of the 13mm circle.	An inappropriate fixative was used. Only for NonGYN.	For optimal results, use BD SurePath Preservative Fluid.
	The settling chambers are not sealed on the slide.	Use only BD SurePath PreCoat slides and do not re-use the settling chambers.
	BD SurePath PreCoat slides were not used.	Use only BD SurePath PreCoat slides.
	The Z dispense setting is incorrect.	Call BD Technical Support.
	The pipette bundle position is incorrect.	Call BD Technical Support.
STAIN QUALITY IS INCONSISTENT	One of the pipettes in the pipette bundle is clogged.	1. Isolate the pipette that is clogged. 2. Use a stylus to unclog it. 3. Clean the outside of the pipette with an alcohol wipe. 4. If the clog is not cleared, call BD Technical Support.
	One or more of the Reagent bottles is too low	Check the levels of all reagent bottles prior to slide processing.
STAINING INTERRUPTIONS		Remove the partially stained rack. Since the system stains one rack at a time, there should be only one such rack.

Table 7-4 *Troubleshooting suggestions*

SYMPTOM	LIKELY CAUSE(S)	CORRECTIVE ACTION SEQUENCE
TIP IS NOT EJECTED		Call BD Technical Support.
TIP FALLS OFF DURING TRANSPORT		Call BD Technical Support.
TRANSFER INTERRUPTION		1. Remove the centrifuge tubes that contain the samples that have not been transferred. 2. Replace “odd” slides (slides in excess of the next highest multiple of four). 3. Wait ten minutes for all the cells to settle onto the slide. 4. Select Slide Staining and process the transferred specimens. 5. Replace the specimens not transferred onto the PrepStain trays. 6. Change the resuspension volume to 10 µl. Refer to *Change sample/stain parameters* on page 5-15 for details. 7. Run **Slide Preparation and Staining** for these specimens. placing blank slides and BD Settling Chambers in the “odd” slide locations.
VOLUME OF DISPENSED REAGENT VARIES		1. If you can see air bubbles in the tubing, tighten the tubing connections. 2. Check the levels in the reagent containers. 3. Call BDTechnical Support.

Chapter 8
Glossary of terms

Refer to the following descriptions as a guide to the mechanical components that make up the BD PrepStain™ Slide Processor and the terms used in the process.

Term	Description / function
Bar Code Reader	• An option only. • Scans and reads labels with barcodes. • Used to verify slide and tube position; that is, it does not enter patient information.
Base Unit	• Robotic sample processor • A system of microprocessor-controlled liquid handling components.
BD EA/OG	• One component of the cytoplasmic Papanicolaou stain. • The mixture contains a modified Eosin-50 and Orange G.
BD Hematoxylin Stain	• Designed specifically for use on the PrepStain instrument • Compatible for use with slides to be processed on the FocalPoint slide profiler. • Water based, nuclear stain used as part of the Papanicolaou staining process.
BD Settling Chambers	• Fastens onto the slide in the slide rack. • Holds samples and other liquids during processing.
BD SurePath Preservative Fluid	• A proprietary fluid used to collect and preserve gynecologic samples.
Centrifugation	• A process to separate fluid(s) and solid(s) using centrifugal force.
Centrifuge	• The PrepStain waste station and the PrepMate specimen rack are designed to fit the shape of the centrifuge buckets.
Centrifuge Bucket Lids	• A safety lid that snaps over the top of the small centrifuge bucket to prevent spills or creation of aerosols during centrifugation.

Term	Description / function
Computer (CPU)	• Hardware component that stores software applications (programs) and data.
Computer Monitor	• Monitor that displays program screens that guide the user through the application.
Decant	• Pouring off supernatant (liquid).
DiTi (**Di**sposable **Ti**p) assembly	• A plastic pipette that is used to mix and distribute the cell solution onto the glass slide.
Easy Aspirator	• A 12-position block connected to a vacuum pump used to aspirate fluid from the centrifuge tubes. • Disposable pipette tips are used.
Microscope Slides	• Clear glass slides of a prescribed size and precoated with a high molecular weight cationic film. Uses brand name known as BD SurePath PreCoat slides. • Cell samples are deposited onto the slide's surface.
Mounting Media	• Toluene or xylene based solution used to adhere the coverglass to the microscope slide.
Pipette Bundle	• Located on the quad arm. • Consists of four dispensing tips mounted around a larger vacuum tip. • Dispenses stains, alcohol, and water.
Quad Arm	• A system of pipette bundles, tubing and manifolds mounted on the arm of the BD PrepStain™ Slide Processor. • Allows staining operations to be performed on four samples at once. • Reagents are dispensed through four pipettes, and waste is removed through a vacuum pipette. • Engaged to move by the quad engagement key on the Z-rod handle. See *Figure* 1-14.
Quad Engagement Key	• Engages the quad handle.
Quad Manifold	• Four plastic housings mounted on the quad arm. • Tubing from syringes to pipette bundles.

Term	Description / function
Slide Rack	• A metal rack fabricated with twelve rectangular cut-outs designed specifically to hold microscope slides. • Each cut-out has a slotted track used to hold a settling chamber on top of the slide surface. • Four racks fit on the work platform of the BD PrepStain™ Slide Processor. • Holds up to 12 glass slides in a 4 x 3 array.
Solvent Resistant Marker	• A pen/marker with ink that will not dissolve in alcohol, water or xylene/xylene substitutes.
Syringe Pump	• A microprocessor-controlled pump with syringe and 2-way valve.
Syringes	• A device used to aspirate and then expel a liquid solution. • On the BS PrepStain™ instrument, 4 syringes are used to move water, alcohol, hematoxylin, and EA/OG (Eosin-50 and Orange G). • The BD PrepMate Automated Accessory uses twelve syringes to first mix and then deposit cell sample solution onto a BD Density Reagent.
Tube Bucket	• A centrifuge bucket capable of holding either: 2, 50 ml centrifuge tubes or 12, 12 ml centrifuge tubes in a 3 x 4 format.
Vacuum Pump	• An electric pump that must be turned on for aspiration to occur. • PVC tubing lines must be securely attached for proper use.
Vortexer	• An electric vibrating device used to agitate the cell pellets in the test tubes and centrifuge tube racks.
Waste Containers	• Bottles used to collect waste liquids used during sample processing.
Waste Station	• Consists of the waste trough, waste tip container, tip holder, and centrifuge bucket holder. See *Figure* 1-13. • When priming or cleaning, any excess liquid is dispensed to the trough. • Trough is emptied to a waste container via drain tubing.
Work Platform	• An adjustable rectangular metal plate on the deck of the PrepStain slide processor. • Holds the slide racks.
Z-Rod	• A vertical toothed rack that is raised or lowered by the Z-stepper motor. • Holds the DiTi assembly components. • Z movement mechanism.

Chapter 9
Setup and Diagnostics

This appendix describes how to access and perform the BD PrepStain™ instrument's setup and diagnostic tests.

CAUTION: Only use the BD PrepStain System as directed. Passwords may be required for certain functions. This section will only be used when directed by service personnel or as indicated for routine use and maintenance.

System setup

Access to the System Setup functions, is via the System Setup option on the GYN Main menu.

1. Select **System Setup** from the GYN Main Menu as shown in *Figure B-1*.

Figure B-1*Main Menu screen*

2. When you choose System Setup, the Enter Password screen is displayed.

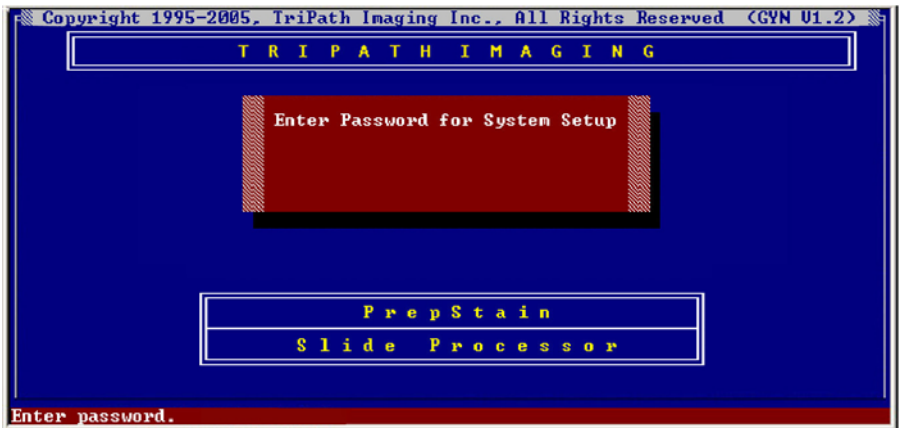


Figure 2-2 *Enter Password screen*

3. Type in your password and then press **Enter**. The System Setup screen is displayed.

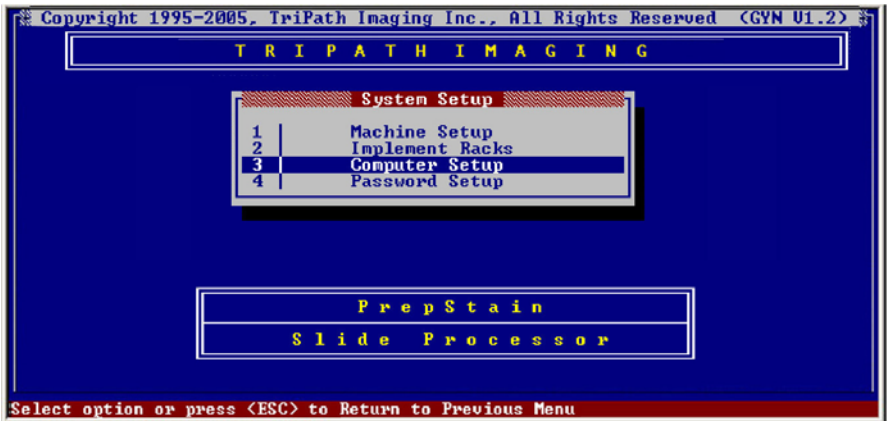


Figure 2-3 *System Setup screen*

4. From the System Setup screen, you have access to the **`Machine Setup`**, **`Implement Racks`**, **`Computer Setup`**, and **`Password Setup`** functions. All but the last option should be used only under the guidance of a BD service representative.

Machine setup

Sets the robotic parameters of the BD PrepStain™ instrument. These parameters are set by a BD service representative prior to or during installation.

Note: Incorrect parameter settings will cause instrument error if there is improper contact between the Quad arm or DiTi assembly and the DiTi Tips, Centrifuge tubes, or Settling Chambers.

Implement racks

Sets the robotic parameters of the BD PrepStain™ instrument. These parameters are set by a BD service representative prior to or during installation.

Note: Incorrect parameter settings will cause instrument error if there is improper contact between the Quad arm or DiTi assembly and the DiTi Tips, Centrifuge tubes, or Settling Chambers.

Computer setup

Sets up the PC workstation, monitor, and printer and assigns a subdirectory location for stored data. These parameters are set by a BD service representative prior to or during installation.

Password setup

This screen allows you to change the password. The password is required to change parameters and enter the System Setup menu. Before you can create a new password, you must provide the current password. Please contact a BD service representative if assistance is required.

1. Select **Password Setup** and press **Enter**. The Password Setup screen will be displayed.

Figure 2-4 *Password Setup screen*

2. In the **Current Password** field, type in the current password for the BD PrepStain™ system, and then press **Enter**. Characters you type appear as asterisks.

3. The screen prompts you to provide the new password.
   In the **New Password** field, type in the new password.
   The PrepStain system password must be precisely 8 keystrokes long and must be comprised entirely of numbers. No letters or other characters are allowed.
4. In the **Confirm New Password** field, type in the new password again to verify that you typed in what you intended.
   - If you mistype, the screen prompts to type in the password again.
   - When you correctly confirm the new password, the Confirm password change menu is displayed.

Figure 2-5 *Confirm Password change menu*

5. Choose the appropriate option:
   - To replace the existing password with the just-specified password, select **Change to new password,** and then press **Enter**.
   - To specify a different password to replace the existing password, select **Enter another password**, and then press **Enter**.
   - To keep the existing password and discard the just-specified password, select **Keep old password**, and then press **Enter**.

This completes the change password procedure.

Diagnostics

The Diagnostic menu provides access to the Keyboard Operation, Random XYZ Test, and DiTi Tests.

To access the Diagnostics menu, from the GYN Main menu, choose **Diagnostics** and then press **Enter**. The Diagnostics menu is displayed.

Figure 2-6 *Diagnostics menu*

Keyboard operation

This utility should be used only under the guidance of a BD representative or authorized personnel.

Random XYZ test

The Random XYZ Test automatically drives the robotic arm to random locations within the instrument worktable, simultaneously recording information about errors, skipped steps, and the parameters of the current test cycle.

Additionally, this test is used during weekly maintenance. See Chapter 6 for details.

1. From the Diagnostics menu, select **Random XYZ Test** and press **Enter**. The Random XYZ test screen will appear.

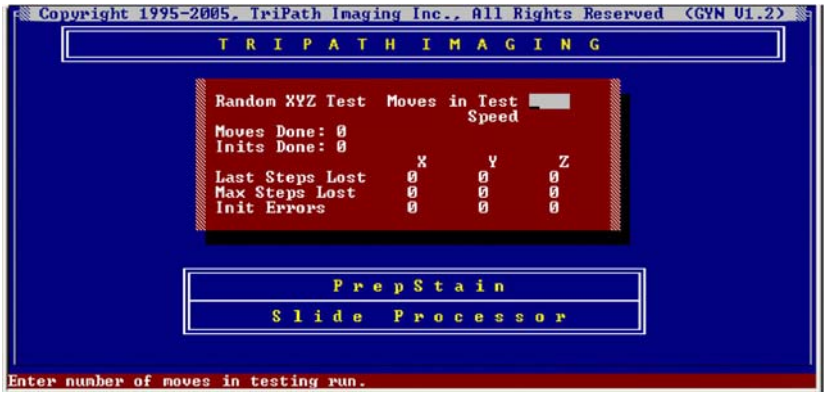


Figure 2-7 *Random XYZ: Number of Moves screen*

2. The screen prompts you to enter the number of moves for the test. 540 moves is the recommended number for a significant test. Type in the desired number of moves, and then press **Enter**. The select test speed menu is displayed.

Figure 2-8 *Random XYZ: Select test speed screen*

3. Select **Normal** and then press **Enter**. The system sounds an alarm and prompts you to check the DiTi for a disposable tip. Remove if present, and then press **Enter** to start the test.
4. The system runs the Random XYZ Test and then displays the results on screen.

Figure 2-9 *Random XYZ: Results screen*

5. *Figure 2-9* illustrates a typical Results screen. Listed below are the acceptable test values for each parameter.

PARAMETER	ACCEPTABLE RESULTS
MOVES DONE	The total number of moves completed by the arm. At least 540 moves should be completed in a random test.
INITS DONE	The total number of initializations the arm has performed. A minimum of twenty initializations is recommended for a meaningful run.
LAST STEPS LOST	The number of steps lost between two initializations. This number must not exceed three.
MAX STEPS LOST	The maximum number of steps lost during the entire test. This number must not exceed three.
INIT ERRORS	The number of errors occurring during an initialization cycle. This number must be zero.

6. The BD PrepStain™ Slide Processor should not be used to prepare patient specimens if there are any initialization errors. Contact BD Technical Support to resolve the failed test. Only after a successful test of at least 540 moves should the device be used for a period of one week. At that point and every week thereafter, the test should be run again to assure continued function of the three motion drives. Failure to confirm proper motion control function with this test may result in mis-delivery of patient specimen.

This completes the Random XYZ Test.

DiTi Tests

The DiTi tests are used to evaluate the performance of the DiTi and its components. There are three tests: Tip handling, Z-rod recovery, and Contact Spring Recovery. To display the DiTi Test menu, select **DiTi Test** from the Diagnostics menu.

Tip handling test

The Tip Handling test records the step losses associated with tip pickups and drop-offs.

1. From the Diagnostics menu, select **DiTi Tests** and press **Enter**. The DiTi Test screen will display the DiTi Test Options menu.

Figure 2-10 *DiTi Test Options*

2. From the DiTi Tests menu. select **Tip Handling** and then press **Enter**. The Tip Handling Test screen is displayed.

Figure 2-11 *DiTi Tip Handling Test*

3. The cursor starts in the **Tips Tested** field. Type in the number of tip pickups for this test, and then press **Enter**. The cursor moves to the **First Test Tip** field.
4. Type in the position number of the first tip for pickup, and then press **Enter** to start the test.
   The system picks up a disposable tip, starting with the first test tip, and then drops it in the Tip Waste container. The DiTi performs a test to detect step losses after each drop off. Step loss should be 8 or less.

5. When the test is complete, the repeat Test option menu is displayed with the test results. You can either repeat the test or quit and return to the DiTi Tests menu.

Z-Rod recovery

The Z-Rod Recovery test checks the recovery of the Z-rod spring after extension.

1. From the Diagnostics menu, select **DiTi Tests** and press **Enter**. The DiTi Test screen will display the DiTi Test Options menu.

Figure 2-12 *DiTi Test Options*

2. From the DiTi Tests menu. select **Z Rod Recovery** and then press **Enter**. The Z Rod Recovery screen is displayed.

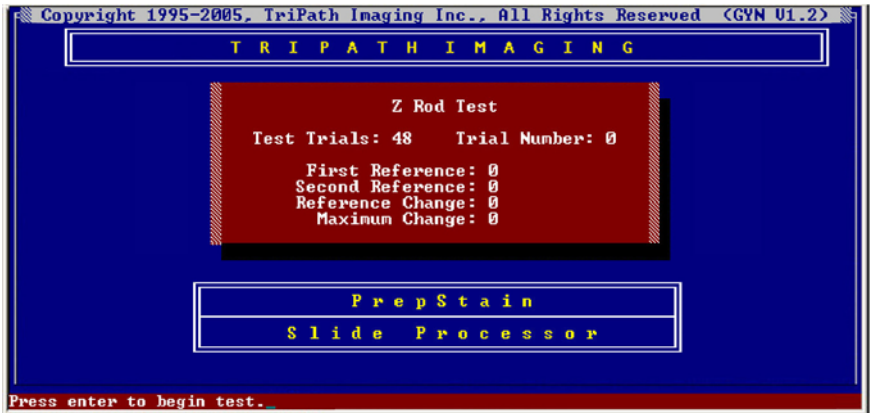


Figure 2-13 *Z Rod Recovery Test Start*

3. Type in the number of Test Trials for this test, and then press **Enter** to start the test.

4. The system performs the test, and then displays the test results and the Repeat Test Option Menu.

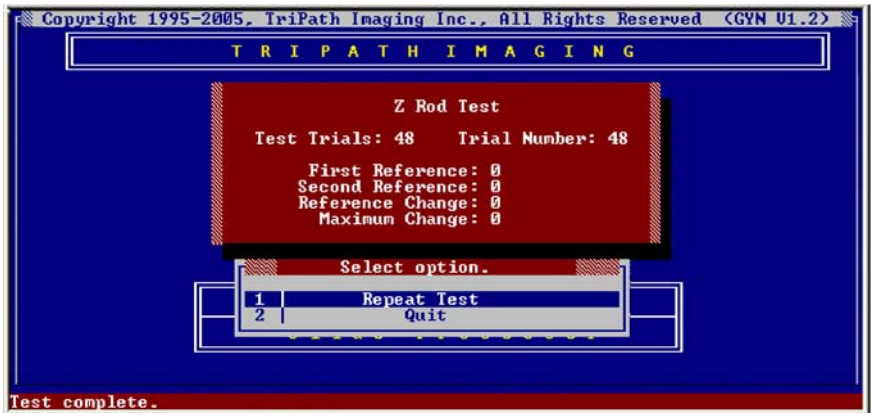


Figure 2-14 *Z Rod Recovery Test Start*

5. Maximum change should be 5 or less. This completes the Z Rod Recovery test.

Contact spring recovery

The Contact Spring Recovery test checks that the contact spring on the DiTi recovers its position after compression.

1. From the Diagnostics menu, select **DiTi Tests** and press **Enter**. The DiTi Test screen will display the DiTi Test Options menu.

Figure 2-15 *DiTi Test Options*

2. From the DiTi Tests menu. select **Contact Spring Recovery** and then press **Enter**. The Contact Spring Recovery screen is displayed.

Figure 2-16 *Contact Spring Recovery Test Start*

3. Press **Enter** to start the test. The screen prompts you to manually raise the DiTi plastic sleeve and allow it to freely drop to its original position five times.

Figure 2-17 *Manually Compress Spring prompt*

After you have done the five drops, press Enter to continue the test. The DiTi will re-initialize the Z-axis to check for step losses.

4. When the test is complete, the results and the Repeat Test Option menu will be displayed.

Figure 2-18 *Repeat Test Option menu*

5. Select **Repeat Trial** to test the contact spring again. Select **Quit** to exit to the DiTi Tests Menu. This completes the Contact Spring Recovery test.

When you select the **Quit** option from one of the DiTi test results screens, the DiTi Tests Menu is displayed. To exit this screen press the **Esc** key. The Diagnostics Menu is displayed. To exit back to the Main Menu, press the **Esc** key again. To exit back to the DOS prompt, either select **Quit** and press **Enter** or press the **Esc** key again.

1. Chapter 10 Non-GYN Slide Processing

1.1 PrepStain Non-GYN program

All of the BD PrepStain™ instrument's functions are controlled using a computer workstation. Access to the programs that run the PrepStain instrument is via three DOS based, menu-driven applications.

Using the workstation menus, you communicate with the instrument, and monitor the progress of slide processing. This chapter describes how to use the Non-GYN application to process Non-GYN specimen slides.

Program overview

Figure C-1 illustrates the initial welcome and version check screen that displays when you open the Non-GYN program.

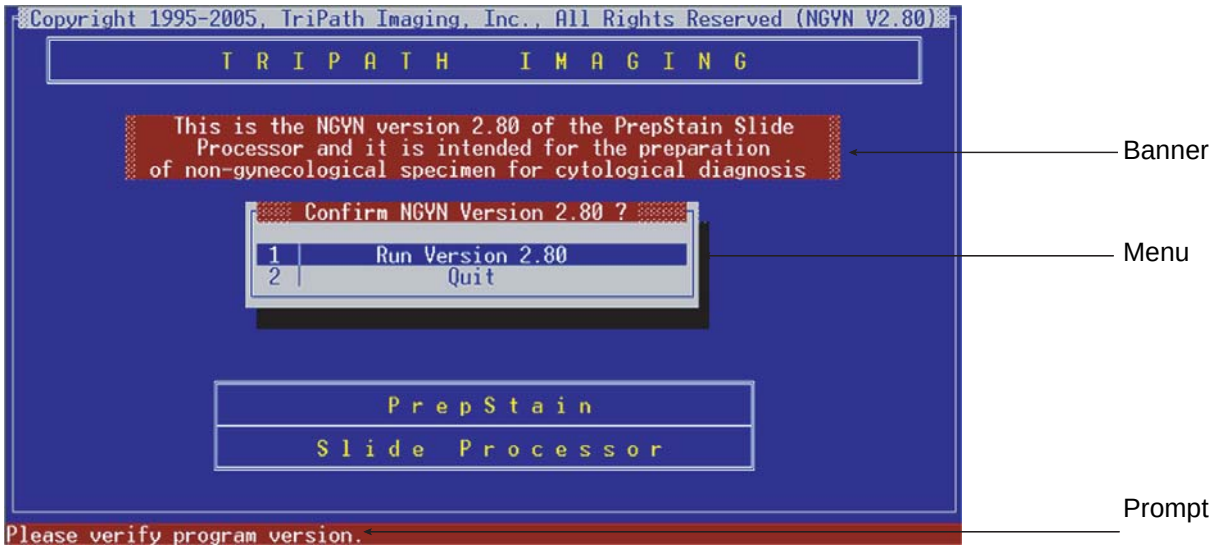


Figure C-1*PrepStain System Non-GYN Version Menu*

The screens in the Non-GYN application are divided into three sections as illustrated in *Figure C-1*.

- The top (banner) section displays text messages on several lines. These messages tell you what action the system is performing or about to perform.

- The middle (menu) section displays menu prompts you use to control the system.
- The bottom (prompt) section displays text messages on a single line. These messages tell you what's happening and what to do next.

Non-Gyn Main Menu

When you choose the first option in the Non-GYN Version menu, the Non-GYN Main Menu is displayed. This screen is illustrated in *Figure 3-2*.

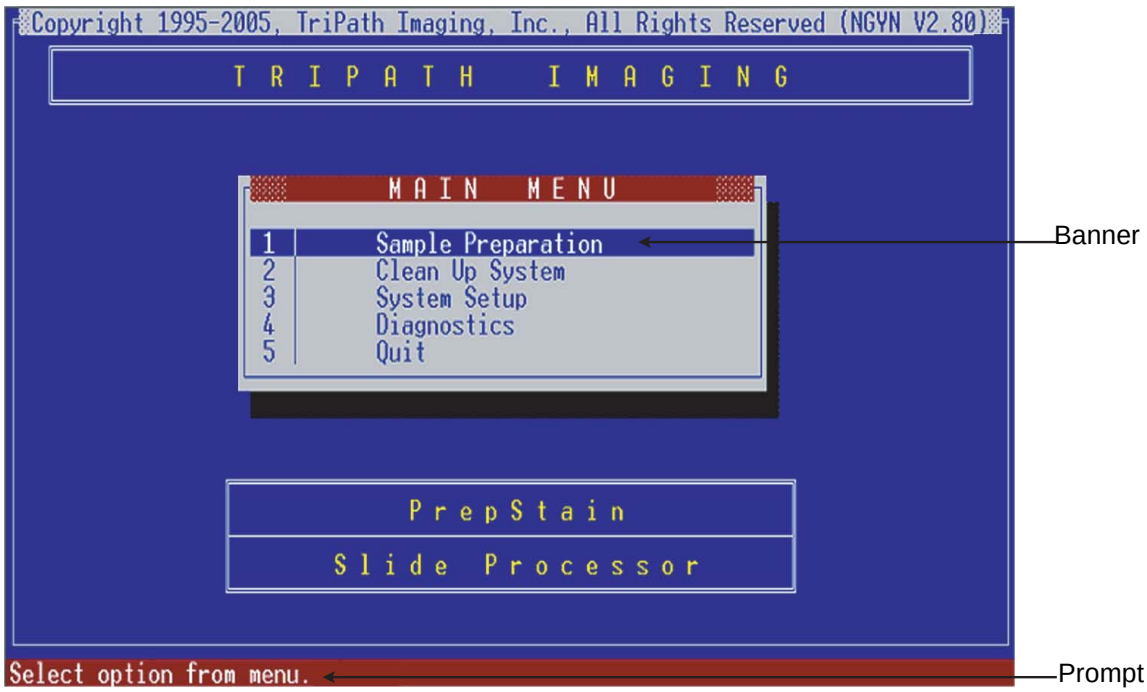


Figure 3-2 *Non-GYN Main Menu*

This appendix provides details on how to use the **`Sample Preparation`** option. For details on how to use the **`Clean Up System`** option, refer to ***Maintenance Procedures*** in *Chapter 6* . For details on how to use the **`System Setup`** and **`Diagnostics`** options, refer to ***Setup and Diagnostics*** in *Chapter 9* .

Processing non gynecologic (Non GYN) specimens

1. The GYN application runs automatically when you start the BD PrepStain™ instrument workstation. Exit this application to access a DOS prompt so that you can display the Non-GYN Version Check menu (*Figure C-1*). This screen provides access to all functions of the program.
   - If the workstation is running the GYN application, select **Quit** to display the DOS prompt, type in `NONGYN`, and then press **Enter**. The Non-GYN Version Check menu (*Figure 3-2*)is displayed.
   - If the workstation is already displaying the DOS prompt, type in `NONGYN` and then press **Enter**.
     The Non-GYN Version Check menu is displayed.
2. Select **Run Version 2.80** from the menu, and then press **Enter**. This brings up the Non-GYN Version 2.80 Main Menu. The main menu (*Figure 3-2*) provides access to all functions of the program.
3. Select **Sample Preparation**, and then press **Enter**.
   The Number of Samples screen (illustrated in *Figure 3-3*) is displayed.

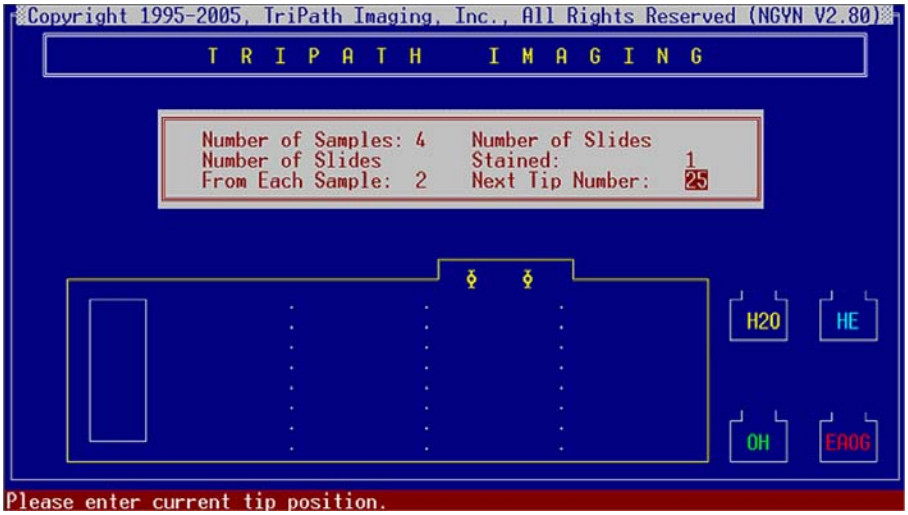


Figure 3-3 *Number of Samples screen*

Note: On this and all other PrepStain system screens, you can use either the **Tab** or **Enter** keys to move the cursor (navigate) from one field to the next.

4. In the first field, type in the number of samples to be processed, and then press **Enter**. The number of samples must be a multiple of four.

Note: If the number of slides to be processed is not divisible by four, type in the next higher multiple of four, and then add blank slides, settling chambers, and tubes to the slide tray to make up the difference.

5. Go to the next field and type in the number of slides you want created for each sample. For example, you might want to create three slides from each sample centrifuge tube.
6. Navigate to the next field and type in the number of slides that you want stained for each sample. For example, if you were creating three slides for each sample, you might only want one of them stained using the current sample and stain settings.
7. Navigate to the next field, and either press **Enter** to confirm that the **`Next Tip Position`** is correct; or type in the correct tip number, and then press **Enter**.
8. The **`Reenter Run Information`** prompt is displayed.
   - To change any of your entries: select **Yes**, press **Enter**, and then repeat the last three steps.
   - To confirm your entries and proceed: select **No** and then press **Enter**.
9. The **`Change Sample/Stain Parameters`** prompt is displayed.
   - To change the sample or stain settings, select **Yes** and then press **Enter**.
     Refer to **Change sample/stain parameters** on page 5-15 for details on how to make these adjustments.
   - To use the existing settings and proceed, select **No** and then press **Enter**.
10. The Turn on Vacuum screen (illustrated in *Figure 3-4*) is displayed.

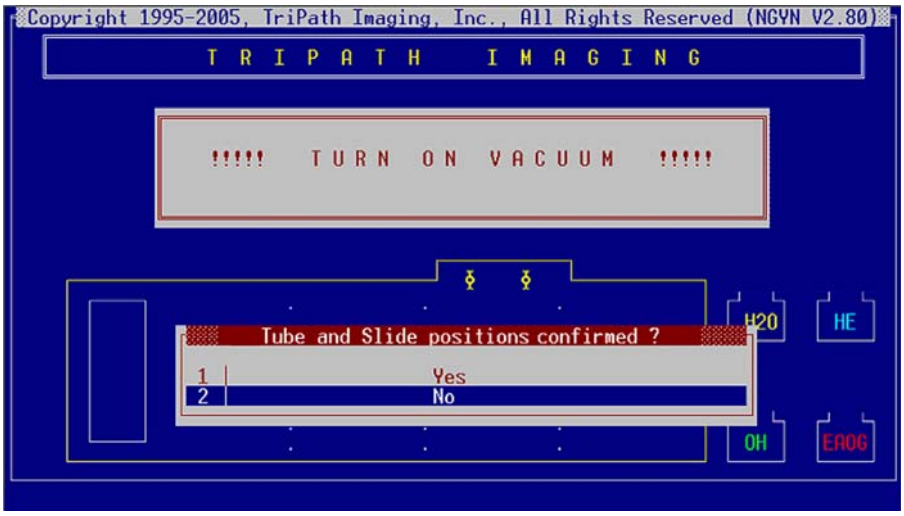


Figure 3-4 *Turn on Vacuum screen*

- Confirm that the position of the sample tubes and their corresponding slides match.
- Select **Yes** and then press **Enter**.

11. The vacuum prompt is displayed and the alarm will sound. Press any key to silence the alarm.
12. Turn on the vacuum pump, wait a few minutes for it to warm up, adjust pressure to 8 - 10 inHg for Shuco pump or 5-6 inHg (180-220 mBAR) for KNF pump, and then press any key to continue.
13. The **`Prime ALL Tubing?`** prompt will appear.
    - If this is the first run of the day, select **Yes** and then press **Enter** to prime the system tubing. The system initializes and the pumps dispense reagents through the quad arm tubing and into the waste station.
    - For subsequent runs during the next eight hours, select **No** and then press **Enter** to skip the full priming function.
    - Before each run, a single syringe volume is automatically pumped through the tubing to ensure that the system is filled.
14. When the priming cycle is complete, the **`Is the tubing primed?`** prompt is displayed.
    - To repeat the priming sequence, select **No** and then press **Enter**.
    - To proceed with slide preparation and staining, select **Yes** and then press **Enter**.
15. The DiTi dispenses buffered water into each BD Centrifuge Tube to re-suspend the cell pellet. Next, the DiTi picks up a disposable tip, and then a sample of the cell suspension is aspirated, carried to its corresponding slide, and deposited into the settling chamber.

16. After a sample is transferred, the BD PrepStain™ instrument dispenses an additional amount of buffered water. When samples have been transferred to all racks, the instrument pauses for ten minutes while the cells sediment onto the slide.
17. When the sedimentation pause is complete, an alarm alerts the operator that the arm is about to move.

    Staining is performed one slide rack at a time. During each staining cycle, each slide is pre-washed in the appropriate reagent (buffered water for hematoxylin, alcohol for EA/OG) and then stained. After the staining is complete, the slide is washed with alcohol. Each settling chamber is completely emptied between stains and washes.
18. When all of the slides on a rack have been stained, the BD PrepStain™ system sounds an alarm, and then continues to stain the next slide rack.
    - As each slide rack is completed, remove it from the PrepStain instrument and decant the alcohol from the BD Settling Chambers into an appropriate receptacle.

CAUTION:

- When removing the settling chamber, avoid scraping cell circle from slide.
- Do not allow the slides to dry prior to coverslipping. Each slide must be coverslipped one at a time.
- Leaving samples in alcohol for an extended length of time can cause the cells to destain.

19. When the BD PrepStain™ instrument finishes processing, the **`Sample Preparation Complete`** prompt is displayed and an alarm sounds. Press any key to silence alarm and continue.
20. When you complete a Sample and Stain run, you can either run another batch, clean up the instrument, or exit to DOS so you can start one of the other PrepStain applications.

1.5

Slide arrangements for multiple slides

1.5

When you process multiple slides for each sample (just as when you process a single slide for each tube), the first sample from each tube is delivered to the corresponding slide on the first available rack, beginning at the front left corner of that rack and moving toward the back. Subsequent samples created from that tube are delivered to the corresponding slide in the next available rack. Some examples are shown in Figures *3-5*, *3-6*, and *3-7*.

Two slides from eight samples

1.5

To process 8 samples, making 2 slides for each sample, the Steps in Progress screen looks like *Figure 3-5*. As an example, a sample from tube 6 would be transferred to two places: slide position 6 on Rack 1, and slide position 6 on Rack 2.

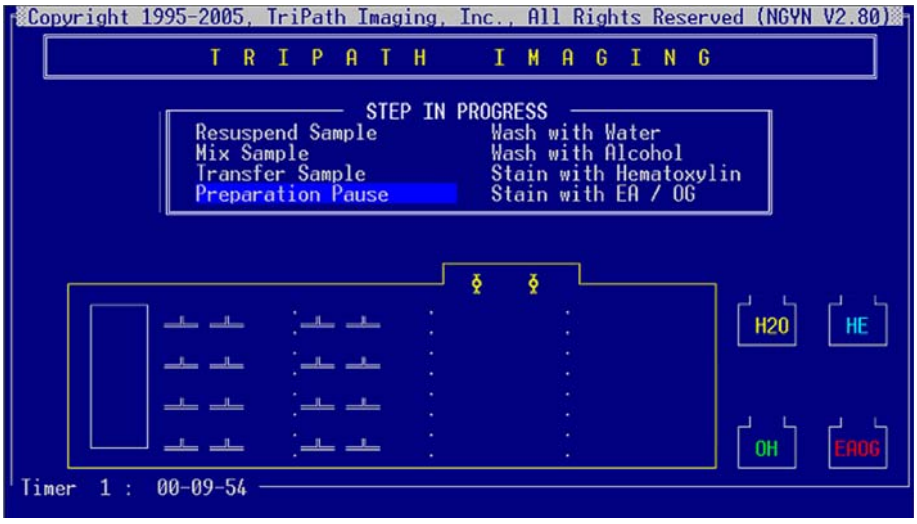


Figure 3-5 *Two slides from eight samples*

Three slides from eight samples

To process 8 samples, making 3 slides for each sample, the Steps in Progress screen looks like *Figure 3-6*. As an example, a sample from tube 6 would be transferred to three places: slide position 6 on Rack 1, slide position 6 on Rack 2, and slide position 6 on Rack 3.

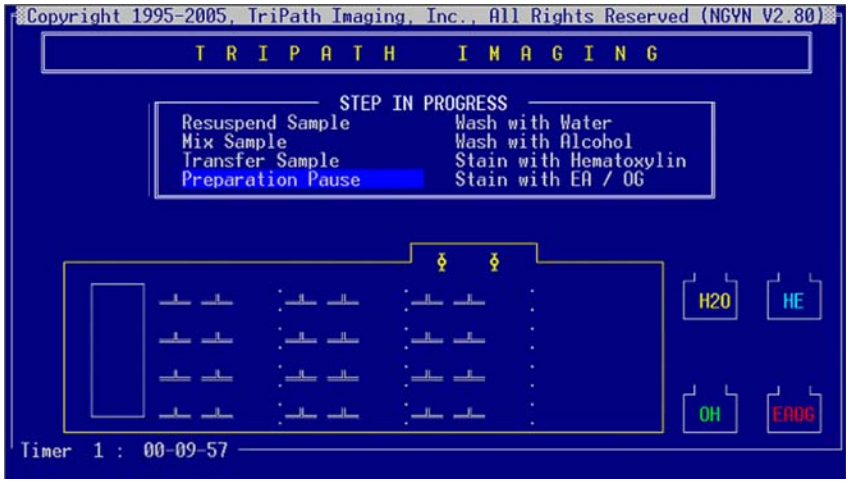


Figure 3-6 *Three slides from eight samples*

Two slides from sixteen samples

To process 16 samples, making 2 slides for each sample, the Steps in Progress screen looks like *Figure 3-7*. In this case there are too many samples being made from each tube to transfer the second copy to rack 2, so the second set of slides is created beginning in the next available rack. In this case that is rack 3.

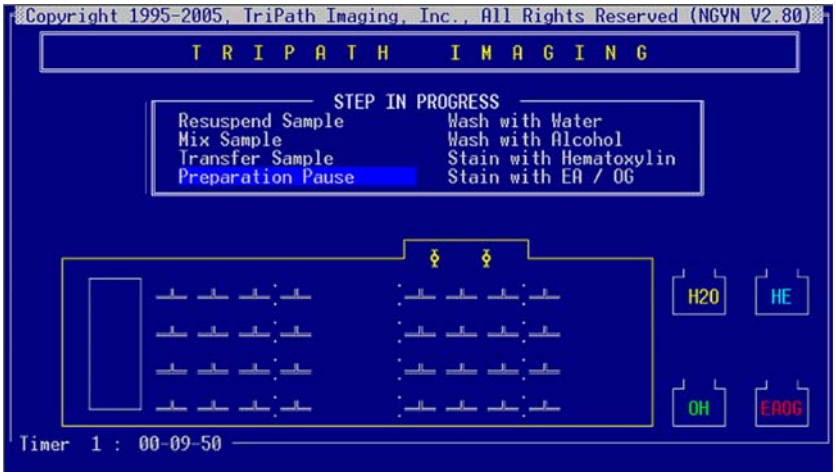


Figure 3-7 *Two slides from sixteen samples*

You can make 2 slides per sample for up to 24 samples per run. You can make up to 4 slides per sample for 12 samples or less.

Appendix: Ancillary Testing from the BD SurePath Collection Vial

An aliquot of the specimen (up to 0.5 mL) may be removed from the BD SurePath Collection Vial for ancillary testing *prior* to the BD SurePath Pap test process.

In order to perform *Chlamydia trachomatis (CT)* and/or *Neisseria gonorrhoeae (GC)* testing using BD ProbeTec™ *Chlamydia trachomatis* (CT) Q^x and *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assays out of the BD SurePath Collection Vial, specific processing steps must be followed as detailed in this section.

Procedure

Note: Sufficient volume is available in the BD SurePath Collection Vial to allow removal of up to 0.5 mL of homogenous mixture of cells and fluid for ancillary testing, while still being able to perform a Pap test using the BD PrepStain system (requires 8.0 ± 0.5 mL).

Note: A maximum of 0.5 mL aliquot may be removed prior to processing the BD SurePath™ Pap test. Only one aliquot may be removed from the BD SurePath Collection Vial prior to performing the Pap test, regardless of the volume of the aliquot.

1. In order to ensure a homogenous mixture, the BD SurePath Collection Vial must be vortexed for 10-20 seconds and the 0.5 mL aliquot must be removed within one minute of vortexing.
2. A polypropylene aerosol barrier pipette tip that is sized appropriately for the volume being withdrawn must be used for aliquot removal. *Note:* Serological pipettes should not be used. Good laboratory practices must be followed to avoid introducing contaminants into the BD SurePath Collection Vial or the aliquot. Aliquot removal should be performed in an appropriate location outside an area where amplification is performed.
3. Visually check the aliquot material in the pipette for evidence of large gross particulates or semi-solids. Evidence of such material encountered while withdrawing the aliquot material should prompt return of all the material to the specimen vial and disqualify the specimen for ancillary testing prior to performing the Pap test.

4 For instructions on processing the aliquot using the BD ProbeTec™ *Chlamydia trachomatis* (CT) Q*x* and *Neisseria gonorrhoeae* (GC) Q*x* Amplified DNA Assays, refer to the Package Inserts provided by the assay manufacturer.

Limitations of Procedure

A volume of 8.0 ± 0.5 mL of the gynecologic specimen collected in the BD SurePath Collection Vial is required for processing the BD SurePath Pap test in the laboratory.

General precautions on ancillary testing from BD SurePath Collection Vial

While there is no evidence that removal of an aliquot from the BD SurePath Collection Vial affects the quality of the specimen for cytology testing, rare instances of misallocation of pertinent diagnostic material may occur during this process. Healthcare providers may need to acquire a new specimen if the results do not correlate with the clinical history of the patient. Furthermore, cytology addresses different clinical questions than sexually transmitted disease (STD) testing; therefore, aliquot removal may not be suitable for all clinical situations. If necessary, a separate specimen may be collected for STD testing rather than taking an aliquot from the BD SurePath Collection Vial. Aliquot removal from low-cellularity specimens may leave insufficient material in the BD SurePath Collection Vial for preparation of a satisfactory BD SurePath Pap test.

Symbol Glossary


Manufacturer


Use by


Catalog number


Authorized Representative in the European Community


In Vitro Diagnostic Medical Device


Temperature limitation


Batch Code (Lot)


Contains sufficient for <n> tests


Consult Instructions for Use


Do not reuse


Serial number


For IVD Performance evaluation only / For US: “For Investigational Use Only”


Lower limit of temperature


Control


Positive control

Negative control

Method of sterilization: ethylene oxide

Method of sterilization: irradiation


Biological Risks


Caution, consult accompanying documents


Upper limit of temperature


Keep dry


Collection time


Peel


Perforation


Do not use if package damaged


Keep away from heat


Cut


Collection date


µL/test


Keep away from light

Hydrogen gas generated

Patient ID number

Ordering Information

Below is a list of components and kits for use with the BD PrepStain™ System.

Product Description	Catalog Number
BD PrepStain Slide Processor	490100
BD PrepMate Automated Accessory	491103
BD Aspirator Tips, 96/box	490510
BD PrepStain Transfer Tips, 96/box	490513
BD Centrifuge Tubes, 480/bag	490515
Tris Buffered Saline Packet	490518
BD Alcohol Blend Rinse, 1700 mL	491121
BD SurePath PreCoat Slides, 96/box	491248
BD PrepStain Slide Library Kit *Contains:* 491248 BD SurePath PreCoat Slides, 96/box 491329 BD Settling Chambers, 96/bag 490513 BD PrepStain Transfer Tips, 96/box	491267
BD PrepStain Consumables Kit *Contains:* 491248 BD SurePath PreCoat Slides, 5 x 96/box 491330 BD Settling Chambers, 2 x 240/bag 490513 BD PrepStain Transfer Tips, 5 x 96/box	491311
BD PrepMate Consumables Kit *Contains:* 491332 BD Density Reagent, 4 x 480 mL 490515 BD Centrifuge Tubes, 480/bag 491331 BD Syringing Pipettes, 2 x 240/box 490510 BD Aspirator Tips, 5 x 96/box	491313
BD Settling Chambers, 96/bag	491329
BD Settling Chambers, 240/bag	491330
BD Syringing Pipettes, 240/box	491331
BD Density Reagent, 480 mL	491332

Product Description	Catalog Number
BD Cytology Stain Kit *Contains:* 491338 BD Hematoxylin Stain 0.75, 480mL 491328 BD EA/OG Combo Stain, 480 mL	491334
BD SurePath Preservative Fluid, 3600 mL	491337
Handheld Barcode Reader - 1D / 2D	491340
BD Dispenser, 4 mL	490516
BD Clamshell, 88/box	490625

Additional components or kits for Non-Gynecological use with the BD PrepStain System.

Product Description	Catalog Number
BD CytoRich Clear Preservative	490719
BD PrepStain Non-GYN Test Kit *Contains:* 490514 BD Centrifuge Tubes, 2 x 96/bag 491248 BD SurePath PreCoat Slides, 2 x 96/box 491329 BD Settling Chambers, 2 x 96/bag 490513 BD PrepStain Transfer Tips, 2 x 96/box	491303
BD Non-GYN Stain Kit *Contains:* 491327 BD Hematoxylin Stain 0.5, 480 mL 491328 BD EA/OG Combo Stain, 480 mL	491333
BD CytoRich Blue Preservative, 3600 mL	491335
BD CytoRich Red Preservative, 3600 mL	491336

1.

BD PrepMate™ automated accessory

Precise specimen transfer directly from BD SurePath™ Collection Vials

1. The BD PrepMate™ Automated Accessory offers precise automation for BD's unique cellular enrichment process. It mixes, aspirates, and dispenses a defined volume of specimen.

1.4
- Eliminates manual cap removal, reducing the risk of contamination
- Flexible, automated process handles 1-12 samples per cycle
- Fast sample processing, taking less than 5 minutes to run 12 samples [1]
- Simple user interface and small footprint

BD

1.3

The BD Cellular Enrichment Process

1.2

Centrifugal sedimentation through BD Density Reagent helps remove non-diagnostic components [2]

- Reduces non-diagnostic debris such as excess inflammatory cells, mucus, blood, and lubricants
- Minimizes air-drying artifact and obscuring, overlapping cellular material
- Easier visualization of epithelial cells, diagnostically relevant cells and infectious organisms

Minimizes unsatisfactory test results

- Compared to conventional cytology the BD SurePath™ Liquid-based Pap test reduces the number of unsatisfactory slides and ASCUS results, and provides higher HSIL+ detection.[3]

1.4

Specimen Handling	
Specimen Collection Type	BD SurePath™ Collection Vial
On-board Sample Capacity	Up to 12 samples
Specimen Transfer and Storage	BD Syringing Pipettes and BD Centrifuge Tubes

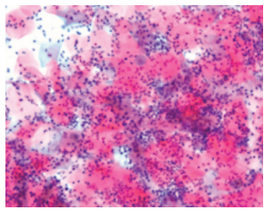
Dimensions	
Height	55.9 cm (22 in)
Width	35.5 cm (14 in)
Depth	58.4 cm (23 in)
Weight	36.3 kg (80 lbs)

Operating conditions	
Ambient Temperature	0 – 36°C (32 – 97° F)
Ambient Humidity	30% to 85% RH (non condensing)

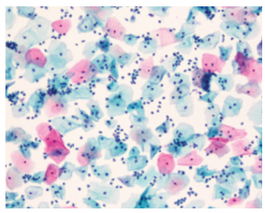
Electrical Requirements	
Rated Voltage	100 – 240 VAC
Maximum Current	2.5 A
Input Line Frequency	50 – 60 Hz
Fusing	Fuses are 5x20 mm, 3.15 A @ 250 VAC time-delay, IEC 60127 rated

Part Number	491103

Conventional Pap Test Obscuring Inflammation



BD CELLULAR ENRICHMENT

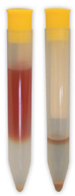


After processing

BD SurePath™ Liquid-based Pap Test Reduced Inflammation

1.2

BD's unique cellular enrichment process removes non-diagnostic components from specimens, minimizing unsatisfactory test results.



1. Data on File
2. Refer to BD SurePath™ Manual Method Product Insert
3. Refer to BD PrepStain™ System Product Insert

BD - Europe, Terre-Bonne Park - A4, Route de Crassier 17, 1262 Eysins, Switzerland

bd.com

1.1

Product Sheet Rovers® Cervex-Brush® Sterile 1.1

Product Name: Rovers® Cervex-Brush® Sterile
Article number: 380100331
Produced by: Rovers Medical Devices B.V.; Lekstraat 10; 5347 KV Oss, The Netherlands

Quality Certificate: Nr. 44 221 121392 , issued by TÜVNORD, Essen, Germany
CE-Conformity Certificate: Nr. 44 232 121392 , issued by TÜVNORD, Essen, Germany

Packaging: 1 Rovers® Cervex-Brush® per bag
100 bags per white box
20 white boxes per transport box

Materials used:		
	Brush:	Polyethylene
	Handle:	Polypropylene
	Bag:	Polyethylene / Polyamide + gridlacq medical paper: 264 x 42 mm
	White box:	Carton 297 x 165 x 100 mm
	Transport box:	Carton 715 x 305 x 545 mm Thickness: 10,2 mm; Burst pressure: approx 2000 kPa;

1.1 The Rovers® Cervex-Brush® product consists of a blue handle (length 175 mm, diameter approx. 4 mm) and a white brush (l x w x h = 32 mm x 19 mm x 6 mm) with hairs.

The sterilisation is performed with ETO. The expiry period is three years after date of production. All this information can be found on each individual bag.
The sterilisation has been validated in line with the requirements of the European Medical Device Directive.

BD

Helping all people live healthy lives

Immunocyto-chemistry

Liquid-based cytology

Computer guided screening

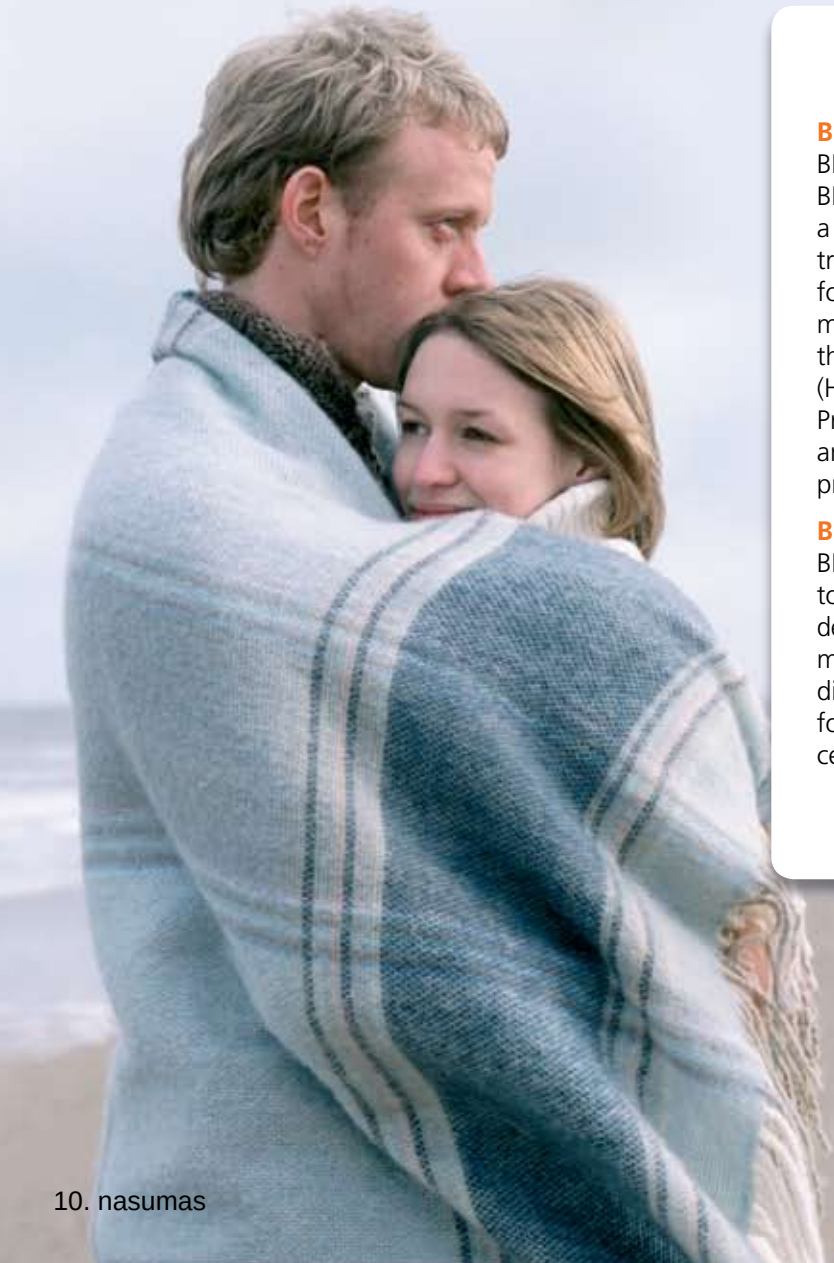
Early detection and clinical management of cancer

Solutions for advanced cytology

Helping all people live healthy lives

BD, a leading global medical technology company that manufactures and sells medical devices, instrument systems and reagents, is dedicated to improving people's health throughout the world. BD is focused on improving drug therapy, enhancing the quality and speed of diagnosing infectious diseases, and advancing research and discovery of new drugs and vaccines. The Company's capabilities are instrumental in combating many of the world's most pressing diseases.

Founded in 1897 and headquartered in Franklin Lakes, New Jersey, United States, BD employs more than 25,000 people in approximately 50 countries throughout the world. The Company serves healthcare institutions, life science researchers, clinical laboratories, industry and the general public.



BD Diagnostics

BD is organized into 3 segments, BD Medical, BD Diagnostics and BD Biosciences. BD Diagnostics is a leading provider of products for the safe collection and transport of diagnostic specimens and of instrumentation for quick, accurate analysis for a broad range of microbiology and infectious disease testing, including the growing problem of healthcare-associated infections (HAIs). The segment is composed of two operating units: Preanalytical Systems, a world leader in sample collection, and Diagnostic Systems, a leader in microbiology testing products and molecular assays.

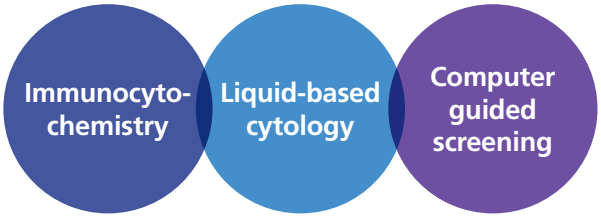
BD Diagnostics - TriPath

BD's TriPath product platform creates innovative solutions to improve the clinical management of cancer, including detection, diagnosis, staging, and treatment. These oncology management tools are intended to span cancer screening, diagnosis, prognosis and therapy monitoring, especially for cancers affecting women's health, including breast, cervical and ovarian.

Redefining the early detection of cancer

We provide integrated cervical cytology screening solutions that offer substantial value to laboratory customers, doctors, patients and third-party payors worldwide in screening for cervical cancer.

SOLUTIONS FOR ADVANCED CYTOLOGY



BD SurePath™ with ProEx C | BD SurePath™ | BD FocalPoint™ GS

Proven Performances

TriPath has had a presence worldwide since its origin:

- BD SurePath™ liquid-based technology was officially approved through the FDA in the US in 1999.
- After a study from NICE in 2004, BD SurePath™ Pap Test has been officially approved in England and Wales.
- More than 120 scientific and clinical studies support TriPath's liquid-based technology.
- 12 European countries are covered by a highly trained distribution network.
- TriPath's proprietary technology is protected by over 100 patents.
- Over 7 million cytology slides processed worldwide every year using the BD FocalPoint™ Imaging System technology.

TriPath products are focused on next-generation clinical solutions for patients through the development of novel molecular oncology products. In cancers of the cervix, breast, ovary, prostate and skin, the proprietary reagents that we develop will be used:

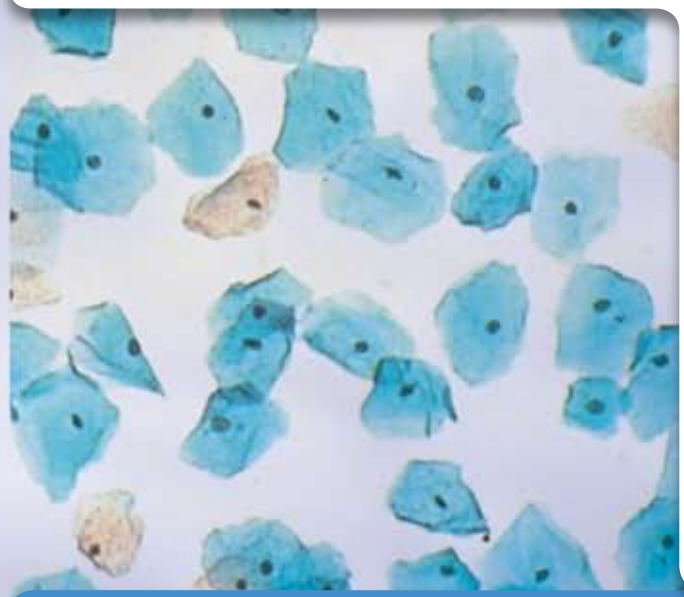
- **to screen and assist in the diagnosis of the presence of disease,**
- **to assess patient prognosis and outcome more accurately,**
- **to guide therapeutic selection in the management of cancers,**
- **to monitor for disease recurrence.**

Immunocyto-chemistry | Liquid-based cytology | Computer guided screening

Reducing risks and optimizing

Simple
Standardized
Efficient

Product availability to be confirmed with our local representative



BD SurePath™ Liquid-Based Pap Test

BD SurePath™ liquid-based Pap Test gives you more confidence in results

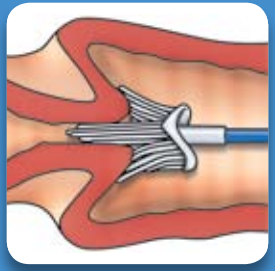
- BD SurePath™ liquid-based Pap Test demonstrates a significant reduction, 43%[1] – 81%[2], in unsatisfactory cases versus conventional Pap tests, reducing the need for unnecessary repeat testing. BD SurePath™ Pap Test is FDA approved and showed a 64.4% increase in HSIL+ detection.[3]
- On average, 37% of cellular material is lost when the collecting device is discarded.[4] BD SurePath™ Pap Test is the only FDA approved liquid-based Pap test that can ensure 100% of the collected sample is sent to the laboratory for processing. No swish, no swirl, no loss of diagnostically relevant cells during sample transfer.
- 2/3 of Pap smear false negatives are the result of cells not being collected on sampling device and collected cells not being transferred to the slide.[5]
- Cervical samples can be collected using broom-like devices or combination broom/spatula with detachable heads.[6] The Rovers Cervex-Brush Combi targets sampling of the transition zone resulting in two- to three-fold increase in harvest of endocervical cells.[7]

One sample: multiple significant tests

Disease examples	Technology examples
HPV[8-10]	Hybrid Capture[8-10]
CT/NG[11][12]	PCR[14][15]
Trichomonas[13]	ISH[16]
	Genotyping[14]

- The residual patient sample can also be used for additional immunocytochemistry tests (BD SurePath™ with ProEx C Immunocytochemical Test).
- Additional BD SurePath™ slides (at least 5) can be processed from the BD SurePath™ enriched cell pellet.

Simple sample collection



1 Collect

2 Drop

3 Send

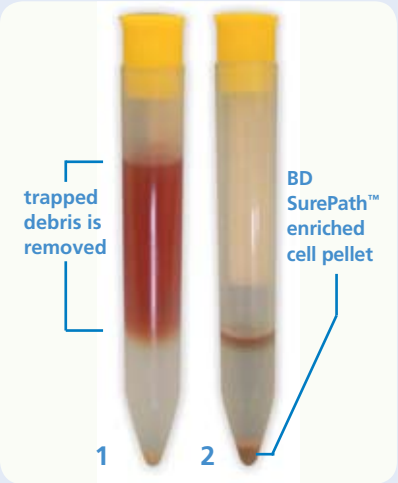
100% of the collected sample is sent to the laboratory every time

the diagnosis

BD SurePath™ Pap Test Proprietary Cell Enrichment Process

The BD SurePath™ Pap Test proprietary Cell Enrichment process separates and reduces obscuring debris (e.g. blood, mucous) and inflammatory cells, preserving background interpretation and providing better and quicker visualization of clinically relevant cells. There is no need for extra processing steps dedicated to bloody or mucoïd samples, leading to a greater standardization of sample processing and clarity of results[17,18].

The BD SurePath™ Pap Test proprietary Cell Enrichment process separates and reduces obscuring debris, thus reducing the unsatisfactory rates[17,18].



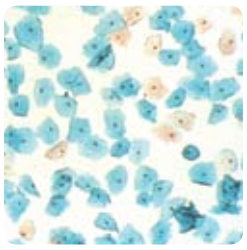
Bring more automation, standardization and productivity into your laboratory

With BD SurePath™ liquid-based Pap Test:

- Slide processing and staining are automated to provide high quality and standardized results.
- Screening time can be significantly reduced and Pap test turnaround times significantly improved compared to conventional Paps.[2]
- Visualization and interpretation of diagnostically relevant cells is easier and quicker.
- High throughput processing (96 slides per 64 minutes without staining, 48 slides per hour with staining) improves laboratory capacity.
- The processor used to prepare BD SurePath™ cervical slides is also used to prepare non-gynecological samples to meet all your cytology needs (e.g. Fine Needle Aspirations, body cavity fluids, urine).

1.4

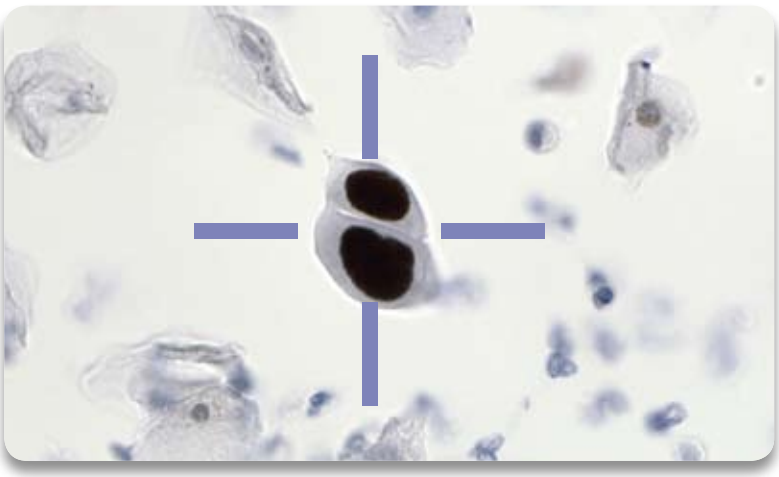
Conventional Slide
Inflammation



BD SurePath™ liquid-based Pap test
Same sample after Cell Enrichment

Immunocyto-chemistry | Liquid-based cytology | Computer guided screening

Confirming the diagnosis



Improved identification of underlying high-grade disease

See the difference

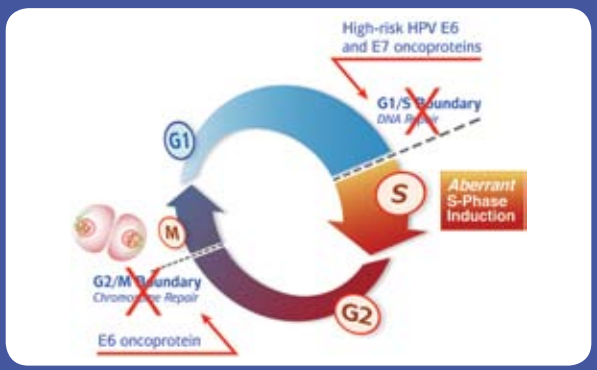
BD SurePath™ with ProEx C is an immunocytochemical test intended to aid in the identification of high-grade cervical disease (CIN2+) in routinely collected BD SurePath™ specimens.[19,20]

This test:

- Produces a nuclear staining pattern that is easy to read, compatible with morphology and current cytopathology classification.
- Provides adjunctive information for cytology diagnosis.
- Designed for manual staining or use with automated staining platforms such as the SMS 3600™ Molecular Stainer.

Detecting Aberrant S-Phase Induction in Cervical Dysplasia

BD SurePath™ with ProEx C Immunocytochemical Test targets key proteins that are over-expressed during Aberrant S-Phase Induction, including Minichromosome maintenance proteins (MCM) and Topoisomerase II alpha (TOP2A).



In Cervical Neoplasia, HPV disrupts both the G1/S and the G2/M cell-cycle checkpoints.

HPV oncoprotein E7 inactivates the G1/S cell cycle checkpoint and accelerates the cell into Aberrant S-Phase Induction.

Measuring Aberrant S-Phase Induction is important

BD SurePath™ with ProEx C Immunocytochemical Test:

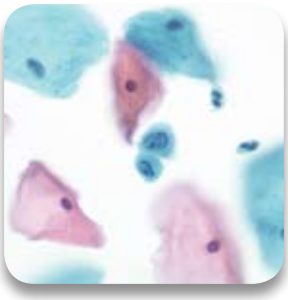
- Provides additional information that assists in morphological classification of high-grade disease (CIN2+).[21]
- Identifies cells that are characteristic of cervical disease and its pre-malignant precursors.[19,20,22-24]
- Detects molecular consequences arising from persistent HPV infection.[19,20,22,23]

Performance is the difference

When it comes to reporting results, your customers expect accurate information. BD SurePath™ with ProEx C Immunocytochemical Test:

- Provides adjunctive information to assist the clinician in more accurate triaging of women with ASC-US+ cytology.[25]
- Research studies have shown increases in the detection rate of underlying high-grade disease (CIN2+) without increasing the false positive rate.[20,25]

BD SurePath™ liquid-based Pap Test



Cytology specimen collected in BD SurePath™ preservative fluid using a BD SurePath™ Papanicolaou stain.

BD SurePath™ with ProEx C Immunocytochemical Test

Cytology specimen from the same patient stained positive for high-grade cervical disease.

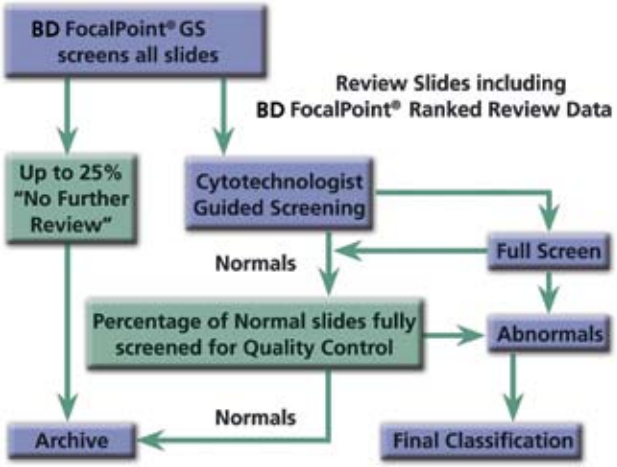
Immunocyto-chemistry | Liquid-based cytology | Computer guided screening

Providing benefits in your daily

BD Focal Point™ GS Imaging System

The BD FocalPoint™ GS Imaging System improves the quality of slide reading by directing the cytotechnologist's attention to slides most likely to contain abnormality. All conventional or BD SurePath™ Pap Test slides from the laboratory are screened on the BD FocalPoint™ system. The BD FocalPoint™ system classifies the slides into "Review" and optional "No Further Review" groups and then ranks Review slides into five quintiles (1=highest risk, 5=lowest risk) helping cytotechnologists to understand the risk inherent in each slide. This information is also used to help the laboratory efficiently perform their Quality Control (QC) process. The BD FocalPoint™ GS Imaging System operates as an aid to the cytotechnologist by automatically relocating areas of interest in a prioritized order. These specific areas on the slide are most likely to contain abnormal cells or information of diagnostic interest. The cytotechnologist then has the interactive capability to electronically mark the area of interest, move to another location on the slide manually, make annotations and track the progress of the marked slide areas during slide review. Once the BD FocalPoint™ system screens all the slides, a cytotechnologist is directed to the Fields of View most likely to contain abnormal cells.

- Each slide has a barcode for better sample tracking.
- The motorized stage of the microscope enables pre-selected Fields of View as well as Fields of View selected by the cytotechnologist for greater flexibility.



BD FocalPoint™ GS cytology Screening Workflow

Each slide is scanned by the BD FocalPoint™ GS system. Hundreds of cell features are measured and translated into an anomaly score.
Each slide is ranked, based on this anomaly score. Slides that are designated as 'Review' are prioritized based on the risk for abnormality (ranking), to aid the cytotechnologist and the pathologist in diagnosis and quality control.

practice of cervical cancer screening

BD FocalPoint™ GS Imaging System showed[26-28]

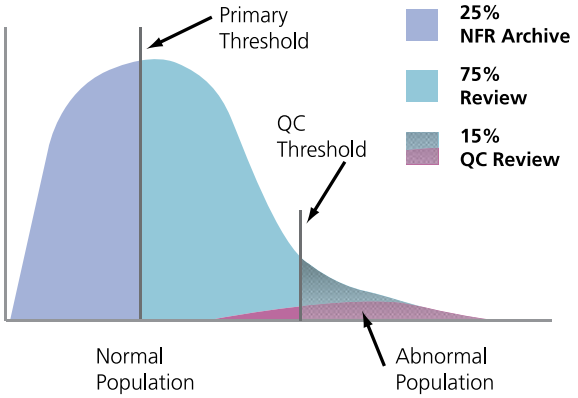
- Numerically more detection of HSIL+ slides for BD SurePath™ liquid-based cytology and conventional Pap smears as compared to the existing practice.[26]
- Statistically improved LSIL+ detection on conventional slides.[26]
- Improved sensitivity and specificity.[26,28-30]
- References to the literature on the BD FocalPoint™ GS Imaging System indicates clinical performance data shows good sensitivity for various levels of cervical disease,
  1) 89.5% for ASC-US, 95.7% LSIL and 98.1% HSIL[29] and,
  2) statistically superior detection of slides with HSIL+ comparing BD FocalPoint™ GS system to manual screening.[27]
- A feasibility study indicated sensitivity of 85.4% for ASC-US/atypical glandular cells of undetermined significance (AGUS), 98% for LSIL, and 100% for cancer.[31]
- By using the BD FocalPoint™ GS system in the cytology laboratory, there is the potential that FOV review may guide the examiner to fields containing significant abnormalities that may otherwise go undetected on human review alone.[32]
- Assessment of No Further Review slides indicated that women in this category can safely return to periodic screening.[33]
- Quality control measures such as rapid review or full manual reading of a random sample are probably not necessary.[33]

BD FocalPoint™ GS Imaging System maximizes laboratory efficiency and productivity

- The BD FocalPoint™ GS system with location guided screening is an important productivity tool in the potentially understaffed cytology laboratory.[27,31,34]
- "The AutoPap with LGS (BD FocalPoint™ GS Imaging System) can significantly speed the examination of Pap smears without lowering the detection rate of clinically important lesions, thus helping alleviate the cytotechnologist shortage."[35]
- The BD FocalPoint™ GS system can result in a substantial reduction in interpretation time.[36]

Annual capacity on a single BD FocalPoint™ GS system is 65.000 conventional slides or 90.000 BD SurePath™ slides (based on 250 working days per year).

- Individual slide screening time will be reduced because the cytotechnologist concentrates on a limited number of Fields of View.
- Total number of slides to screen is reduced by up to 25% if using the "No Further Review" option.



Automated ranking
Ranking of slide anomaly

Offers a reliable and modular tool

- Automatic self-test ensures highest integrity.
- Remote service capability allows fastest possible support.
- Networking capability.
- User-friendly software compatibility with Laboratory Information System (LIS).
- Barcode reading for rapid data retrieval.

Summary Statements

- The BD FocalPoint™ GS Imaging System is effective as a method to improve the accurate practice of cervical cytology.[27]

Supporting our customers

Our training and technical center located near Brussels, as well as our network of highly trained distributors, will provide your laboratory personnel with optimal support for successful integration of our cervical cytology and non-gyn cytology solutions in your laboratory.

Regular training sessions throughout the year

- Morphology training for BD SurePath™ liquid-based cytology
  - **participants:** pathologists, cytotechnologists
  - **objective:** training to screen and diagnose.

  A two-days training with certificate of completion.
- Product operator training for equipment and disposables (BD SurePath™ liquid-based technology, BD FocalPoint™ GS Imaging System, BD SurePath™ with ProEx C immunocytochemical tests)
  - **participants:** pathologists, cytotechnologists, laboratory technicians
  - **objective:** to provide theoretical and practical expertise on the products.

  The training includes 1 or 2 days hands on tutorial with numerous practical exercises in the laboratory.

Showroom

A fully-operational laboratory to perform or assist customers in evaluations and product trials using the customer's samples.

Remote maintenance and technical support

The team offers our customers:

- Remote monitoring of the BD FocalPoint™ GS system installed in your laboratory from our center in Belgium. 24 Hour intervention during working days when necessary.
- Technical assistance and support.
- Updates of the proprietary software.
- On-site revision and maintenance.

References:
(1) Evolution of Pap Testing at a Community Hospital – A Ten Year Experience. Nance K. (*Diagnostic Cytopathology*, Vol 35, No 3:148-153, 2007).
(2) Use of a Liquid-Based, Thin-Layer Pap Test in a Community Hospital: Impact on Cytology Performance and Productivity. Sass M. (*Acta Cytol.* 48:17-22, Jan – Feb 2004).
(3) BD PrepStain™ System Product Insert.
(4) Keeping Collecting Device in Liquid Medium Is Mandatory to Ensure Optimized Liquid-Based Cervical Cytologic Sampling. Bigras G., Rieder M., Lambercy J., Kunz B., Chatelain J., Reymond O., and Cornaz D. (*J Low Genit Tract Dis.* 7:168-174, 2003).
(5) Homogenous Sampling Accounts for the Increased Diagnostic Accuracy Using the ThinPrep™ Processor. Hutchinson M., Isenstein L., Goodman A., Hurley A., Douglass K., Mui K., Patten F., and Zahniser D. (*Am J Clin Pathol.* 101:215-219, 1994).
(6) Liquid-Based Cytology for Cervical Cancer Screening. Bentz J. (*Expert Rev Mol Diagn.* 5:857-871, 2005).
(7) Improved Endocervical Sampling and HPV Viral Load Detection by Cervex-Brush® Combi. Depuydt C., Benoy I., Bailleul E., Vandepitte J., Vereecken A., and Bogers J. (*Cytopathology* 17:374-381, 2006).
(8) Ko V., Tambouret RH., Kuebler DL., Black-Schaffer WS., Wilbur DC., Human Papillomavirus Testing Using Hybrid Capture II With SurePath Collection Initial Evaluation and Longitudinal Data Provide Clinical Validation for This Method. (*Cancer Cytopathology* 2006 108(6); 468-474).
(9) Atypical Squamous Cells of Undetermined Significance in Liquid-Based Cytologic Specimens. Levi A., Kelly D., Rosenthal D., and Ronnett B. (*Cancer* 99:191-197, 2003).
(10) Age-Related Performance of Human Papillomavirus Testing Used as an Adjunct to Cytology for Cervical Carcinoma Screening in a Population with a Low Incidence of Cervical Carcinoma. Petignat P., Faltin D., Goffin F., Billieux M., Stucki D., Sporri S., and Vassilakos P. (*Cancer* 105:126-132, 2005)
(11) Detection of Chlamydia trachomatis and Neisseria gonorrhoeae Infections in North American Women by testing SurePath™ Liquid-Based Pap Specimens in APTIMA Assays. Chernesky M., Freund G., Hook III E., Leone P., D'Ascoli P., Martens M. (*J Clin Microbiol,* 2007 Aug. 45 (8): 2434-8).
(12) Feasibility of Using TriPath Imaging, inc. SurePath™ Preservative Fluid with the BD ProbeTec ET CT/GC Amplified DNA Assays. Martinaitis C., Poth T., Williams K., Welborn C., Shank D., Hellyer T. (*Clinical Viral Symposium* 2005).
(13) The Diagnosis of Trichomonas vaginalis in Liquid-Based Pap Tests: Correlation with PCR. Aslan D., Gulbahce H., Stelow E., Setty S., Brown C., McGlennen R., and Pambuccian S. (*Diagn Cytopathol.* 32:341-344, 2005).
(14) Thin-Layer Liquid-Based Cervical Cytology and PCR for Detecting and Typing Human Papillomavirus DNA in Flemish Women. Depuydt C., Vereecken A., Salembier G., Vanbrabant A., Boels L., Herck E., Arbyn M., Segers K., and Bogers J. (*Br J Cancer.* 88:560-566, 2003).
(15) Adequacy of BD SurePath™ Cytology Samples for DNA-Based Applications: HPV Detection, Identification, and Quantification. Avissar P., Harrison M., Li H., and Malinowski D. (*Acta Cytol.* 48:698, 2004).
(16) Bewtra C., Xie Q., Soundararajan S., Gatalica Z., Hatcher L. Genital Human Papillomavirus Testing by in situ Hybridization in Liquid Atypical Cytologic Materials and Follow-up Biopsies. (*Acta Cytologica*, March-April 2005; 49(2):127-131).
(17) Comparison of the Effectiveness of Two Liquid-Based Papanicolaou Systems in the Handling of Adverse Limiting Factors, Such As Excessive Blood. Sweeney B., Haq Z., Happel J., Weinstein B., and Schneider D. (*Cancer* 108:27-31, 2006)
(18) Direct-to-Vial Experience with AutoCyte PREP in a Small New England Regional Cytology Practice. Marino J., Fremont-Smith M. (*J of Reprod Med*; April 2001, 46(4):353-358).
(19) BD SurePath™ with ProEx C Immunocytochemical Test Product Insert.
(20) Data on file at BD Diagnostics – TriPath.
(21) Shroyer K., Homer P., Heinz D., and Singh M. Validation of a Novel Immunocytochemical Assay for Topoisomerase IIα and Minichromosome Maintenance Protein 2 Expression in Cervical Cytology. (*Cancer Cytopathology*, October 25, 2006; 108(5): 324-330).
(22) Molecular Diagnostic Assays for Cervical Neoplasia: Emerging Markers for the Detection of High-Grade Cervical Disease. Malinowski D. (*BioTechniques* Suppl:17-23, 2005).
(23) Detection of Cervical High-Grade Squamous Intraepithelial Lesions from Cytologic Samples Using a Novel Immunocytochemical Assay (ProEx™ C). Kelly D., Kincaid E., Fansler Z., Rosenthal D., Clark D. (*Cancer* 108:494-500, 2006)
(24) Multiple biomarkers in molecular oncology. I. Molecular diagnostics applications in cervical cancre detection. Malinowski D.; Expert Review Molecular Diagnostics 7(2), 117-131 (2007) (*Future Drugs*, 2007).
(25) Parker M., Sampson S., Hessling J., Chatterjee A., Prpic D., Hall L, Wingate S., Taylor A., and Fischer T. Evaluation of Molecular Biomarkers for the Detection of High Grade Cervical Disease (CIN2+) in Routinely Collected Cervical Samples (2005). (*Cancer Cytopathology*; 105: 322). (Platform Presentation 4; Data on file at BD Diagnostics - TriPath).
(26) BD FocalPoint™ Imaging System Slide Profiler Product Insert.
(27) Wilbur DC., Parker EM., Foti JA. Location-Guided Screening of Liquid-Based Cervical Cytology Specimens. A Potential Improvement in Accuracy and Productivity is Demonstrated in a Preclinical Feasibility Trial. (*American Journal of Clinical Pathology* 2002;118:399-407).
(28) Evaluation of the FocalPoint GS System Performance in an Italian Population-Based Screening of Cervical Abnormalities. Passamonti B., Bulletti S., Camilli M., D'Amico M., Di Dato E., Gustinuchi D., Martinelli N., Malaspina M., Spitta N. (*Acta Cytologica,* 51(0) 2007).
(29) Huang TW., Lin TS., Lee JS. Sensitivity studies of the AutoPap System Location Guided Screening of cervical-vaginal cytologic smears. (*Acta Cytologica*. 43, 363-368, 1999).
(30) Bentz JS. Liquid-based cytology for cervical cancer screening. (*Future Drugs* 2005; 5(6), 857-871).
(31) Lee JS., Kuan L., Oh S., Patten F., Wilbur DC. A feasibility study of the AutoPap System Location Guided Screening. (*Acta Cytologica* 1998 42(1): 226-6).
(32) Kardos T. The FocalPoint System: FocalPoint slide profiler and FocalPoint GS. (*Cancer Cytopathology.* Dec 2004).
(33) Troni G., Cariaggi M., Bulgaresi P., Houssami N., and Ciatto S. Reliability of Sparing Papanicolaou Test Conventional Reading in Cases Reported as No Further Review at AutoPap-Assisted Cytological Screening. (*Cancer* 111:93-98, 2007).
(34) Primary Screening for Cervical Cancer Precursors by the Combined Use of Liquid-Based Cytology, Computer-Assisted Cytology, and HPV DNA Testing. Vassilakos P., Petignat P., Boulvain M., and Campana A. (*Br J Cancer.* 86:382-388, 2002).
(35) Chang AR., Lin WF., Chang A., Chong KS. Can Technology Expedite the Cervical Cancer Screening Process? A Hong Kong Experience Using the AutoPap Primary Screening System with Location Guided Screening Capability. (*American Journal of Clinical Pathology* 2002 March;117(3)437-43).
(36) Ronco G., Vinels C., Montanari G., Orlassino R., Parisio F., Arnaud S., Berardengo E., Fabbrini T., and Segnan N. Impact of the Autopap (Currently FocalPoint) Primary Screening System Location guided Use on Interpretation time and diagnosis. (*Cancer Cytopathology.* April 25, 2003. Vol. 99 (2): 83-88).

XEUR5081-08

BD Diagnostics
TriPath
Erembodegem-dorp 86
9320 Erembodegem, Belgium
www.bd.com/TriPath

For Europe, Middle East and Africa:
Phone: +32 53 720 211
Email: TriPathEurope@BD.com

For use outside the US only.

Operating Instructions

ROTINA 46 S
ROTINA 46 RS

Please enter the following details:	
Stock no.	.....
Monitoring no.	.....
Location	.....

This operating instruction has to be used for the centrifuges bearing the following Manufacturing Nos. :
(the Manufacturing No. of a centrifuge can be see from its name plate)

Type of centrifuge	Voltage	Article No.	Manufacturing No.
ROTINA 46 S	208-240 V	4606	XXXX-01-00
ROTINA 46 S	110-127 V	4606-01	XXXX-02-00
ROTINA 46 RS	220-240 V	4611	XXXX-01-00
ROTINA 46 RS	110-127 V	4611-01	XXXX-01-00
ROTINA 46 RS	208-240 V	4611-07	XXXX-01-00
ROTINA 46 RS	220-240 V	4611-50	XXXX-01-00
ROTINA 46 RS	110-127 V	4611-51	XXXX-01-00

 Order no. AB075-01GB

CE

Certificate of EU - Conformity

as defined by the EU regulations

- for machines 89/392/EWG
- for electro-magnetic compatibility 89/336/EWG, amended by regulations 91/263/EWG, 92/31/EWG and 93/68/EWG
- for low voltage 73/23/EWG, amended by regulation 93/68/EWG

We, Messrs. Andreas Hettich
Gartenstraße 100
D-78532 Tuttlingen,

hereby certify that centrifuge model(s)

ROTINA 46S, ROTINA 46 RS

is (are) manufactured in accordance with the following standards and regulations:

EN 61010 part 1 and 2
EN 55011

in addition the following national standards and regulations are applied:

VBG 1	DIN 58970
VBG 4	BS 4402
VBG 7z	
VBG 20	

Tuttlingen 11.06.2007 Hettich Zentrifugen

ppa. H. Eberle

Contents

1 Intended application 1
2 Notes on safety 1
3 Warning symbols 3
4 Delivery checklist 3
5 Manufacturer's address 3
6 Technical specifications 4
7 Diagrams of operating conditions 6
8 Initial operation 7
9 Installing the rotor and fitting attachments 8
10 Control and display elements 9
10.1 Control elements 9
10.2 Status display 10
10.3 Data fields 10
10.3.1 Data field 1 10
10.3.2 Data field 2 10
10.3.3 Data field 3 10
10.3.4 Data field 4 10
10.3.5 Data field 5 10
11 Entering centrifuging data 11
11.1 Data field 1 11
11.2 Data field 2 12
11.3 Data field 3 12
11.3.1 Run up with preset level from 1 - 9 12
11.3.2 Run up with preset time, adjustable in the predefined time range 13
11.3.3 Run down with preset level from R0-R9 13
11.3.4 Run down with preset time, adjustable in the predefined time range 13
11.3.5 Run down with brake release 13
11.4 Data field 4 14
11.5 Data field 5 14
11.6 Programming notes 15
11.6.1 Retrieving a program: 15
11.6.2 Modifying a program and storing it under the same number 15
11.6.3 Modifying and then starting a program 16
12 Making changes while the centrifuge is running 16
13 Calculating RCF or RPM 16
13.1 RCF 16
13.2 RPM 16
14 How to gain rapid access when switching on 17

14.1 Centrifuging program after switching on 17
15 Acoustic signal 17
16 Retrieving the number of operating hours 18
17 Time / date retrieval 18
18 Sedimentation effect 18
19 Centrifuging 19
19.1 - with the speed RPM parameter 19
19.2 - with the RCF parameter 19
19.3 - with a program 20
19.4 - with temperature preselection (cooled centrifuge) 20
19.5 - of denser substances 20
20 EMERGENCY STOP 21
21 Changing the rotor 21
22 Rotor identification 21
23 Emergency release 22
24 Care / maintenance 22
24.1 Supporting lugs 22
25 Faults 23
25.1 Note on faults 23
25.2 Fault table 23
26 Repairs 24
27 Customer Services / Servicing 24
28 Acceptance of the centrifuges for repair 24
29 Appendix 25
29.1 Option: Key-operated switch 25
29.2 Option: Programs being run in sequence 25
29.2.1 Program sequence with simultaneous keying-in of program data 25
29.2.2 Entering a sequence of previously stored programs 26
29.2.3 Retrieving a program sequence 27
29.2.4 Running a program sequence 27
29.2.5 Changing a program sequence 27
29.2.6 Deleting a program sequence 27
30 Rotors and accessories 28
31 S e r v i c e 1

1 Intended application

The centrifuge is used for separating substances or mixtures with a density of up to max. 1.2 kg/dm³.
Through the production of centrifugal force it can separate mixtures or alter the proportions in a mixture.
If the substance or mixture to be centrifuged is denser than 1.2 kg/dm³, the rated speed should be reduced (see section “Centrifuging of denser substances”).

2 Notes on safety

- This centrifuge is a state-of-the-art piece of equipment which is extremely safe to operate.
  - However, it can lead to danger for users or others if used by untrained staff, in an inappropriate way or for a purpose other than that it was designed for.
- Before the initial operation of your centrifuge you should read and pay attention to the operating instructions.
- Along with the operating instructions and the legal regulations on accident prevention, you should also follow the recognised professional regulations for working in a safe and professional manner.
  These operating instructions should be read in conjunction with any other instructions concerning accident prevention and environmental protection based on the national regulations of the country where the device is to be used.
- The centrifuge should be installed on a good, stable base.
- When setting the equipment up you should pay attention to the following points:
  - A 300 mm safety zone must be established around the centrifuge in accordance with IEC 1010-2-2.
  - This safety zone must be kept clear of both people and hazardous substances at all times when the centrifuge is in operation.
  - According to the laboratory instrument standards EN 61010-2-20 an emergency switch to separate power supply in the event of a failure must be installed in the building electrical system.
    This switch has to be placed remote from the centrifuge, prefered outside of the room in which the centrifuge is installed or near by the exit of this room.
- Do not place any object in front of the ventiduct.
  - Keep a ventilation area of 300 mm around the ventiduct.
- The centrifuge should always be loaded evenly.
- Centrifuge containers must not be filled beyond the capacity specified by the manufacturer.
  - Centrifuge containers should only be filled outside the centrifuge.
- Standard centrifuge containers of glass will not stand RCF values exceeding 4000 (DIN 58970, pg. 2)
- No attachments should be used other than those authorised by the manufacturer.
- Centrifuge containers may only be centrifuged with accessories (reducing adapters, frames, suspensions, etc.) authorised by the manufacturer (see section "Rotors and accessories).
- The centrifuge may only be operated when the balance is within the bounds of acceptability.

- The centrifuge must not be operated in areas subject to danger of explosions.
- The centrifuge must not be used with:
  - inflammable or explosive materials
  - materials that react with one another producing a lot of energy.
- If users have to centrifuge hazardous materials or compounds contaminated with toxic, radioactive or pathogenic micro-organisms, they must take appropriate measures. Without additional proceedings (like an additional bioseal between bucket and lid of bucket or angle rotor with a special bioseal between rotor and lid) a centrifuge is not a biosafety system in accordance to the regulation EN 61010-2-20. In the case of material belonging to risk group II (see the World Health Organisation's "Laboratory Biosafety Manual") they should employ a biosafety system. Under this system small drips and aerosols are prevented from escaping by a bioseal (packing ring) located between the hanger and the lid. Centrifuge containers with special screw caps, as obtainable through trade suppliers, can also be used for hazardous substances.
  In the case of materials from the higher risk groups greater safety provision is required than the arrangements described above. In a biosafety system, centrifuge containers with special screw caps must be used.
- For further details of available biosafety systems see section "Rotors and accessories". If in doubt, you should obtain relevant information from the manufacturer.
- The centrifuge must not be operated with highly corrosive substances which could impair the mechanical integrity of rotors, hangers and accessories.
- Any rotors, hangers or accessories showing clear signs of corrosion or mechanical defects must not be used for centrifuging.
- In order to prevent corrosion developing through cleaning or disinfectant agents, it is most important that any specific instructions from the manufacturers of such agents should be followed carefully.
  Before applying any cleaning or disinfecting procedure other than those recommended by the manufacturer, the user should contact the manufacturer to make sure that the planned process will not damage the equipment.
- Only original spare parts and authorised original accessories may be used.
- In case of fault or emergency release, never touch the rotor before it has stopped turning.
- This centrifuge is classified in Germany as a Group 3 device according to the *Medizinische Geräteverordnung MedGV* (the regulations on medical equipment).
- It conforms to safety regulations based on:
  IEC 1010-1/-2
  DIN - EN61010 Parts 1and 2
- The safe operation and reliability of the centrifuge can only be guaranteed if:
  - the centrifuge is operated in accordance with the operating instructions,
  - repairs are carried out by engineers approved by the manufacturer,
  - the electrical installation on the site where the centrifuge is installed conforms to the demands of IEC stipulations,
  - prescribed tests to UVV-VBG7z are carried out by an expert.
- With centrifuges for robotic use please pay attention to the notes of the key operated switch.

No claim under guarantee will be considered by the manufacturer unless the above instructions have been adhered to.

3 Warning symbols

Caution! Follow instructions carefully.

Load centrifuge rotor evenly.
All positions on rotor must be filled.

Do not fill centrifuge containers inside the centrifuge.

4 Delivery checklist

The following items and accessories are delivered with the centrifuge:

1	Connecting cable	230 V
		115 V
1	Fuse	T 2 AL; 250 V
1	Square spanner	
1	Release pin	
1	Lubricating grease for supporting lugs	
1	Operating instructions	
1	Rotor instructions	

Rotina 46 S
1 Notes on moving the equipment safely
Rotina 46 RS
1 Notes on moving the equipment safely

The rotor(s) and associated accessories are included in the delivery in the quantity ordered.

5 Manufacturer’s address

Hettich Zentrifugen GmbH & Co. KG
Gartenstraße 100
D-78532 Tuttlingen
Germany
Telephone ## 49 7461 705-0, Fax ## 49 7461 705-125
e-mail Info@HettichLab.com
http:\\www.HettichLab.com

6 Technical specifications

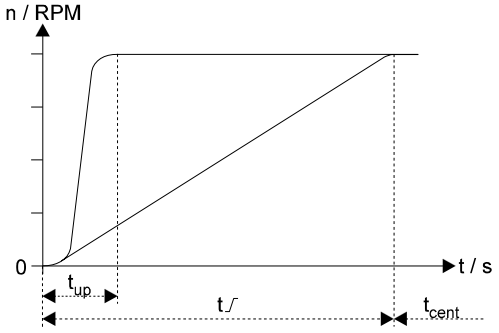
Manufacturer	Hettich Zentrifugen D-78532 Tuttlingen			
Model	ROTINA 46 S		ROTINA 46 RS	
Product no.	4606	4606-01	4611	4611-01
Mains voltage (± 10%)	208-240 V 1~	110-120 V 1~	220-240 V 1~	110-127 V 1~
Mains frequency	50 - 60 Hz	50-60 Hz	50 Hz	60 Hz
Connected load	1200 VA	1100 VA	1700 VA	2000 VA
Current consumption	5.5 A	11 A	7.5 A	16.5 A
Power consumption	850 W	880 W	1350 W	1600 W
Refrigerant	------		R 404a	
Max. capacity Max. density Speed RPM Force RCF Kinetic energy Obligatory inspection	4 x 400 ml 1.2 kg/dm^3 11000 13800 35000 Nm yes			
Environment – Ambient temperature – Relative humidity	5°C up to 40°C max. 80% up to 31°C, descending in a linear pattern down to 50% at 40°C			
Sample overtemp.	≤ 15 K		-----	
Class of protection	I			
EMC – Emission (Radio interference suppression) – Immunity	ISM (Industrial Science Medicine) EN 55011 Class B	FCC Class B	EN 55011 Class B	FCC Class B according to EN 50082-1
Noise level (dependent on rotor)	≤ 66 dB(A)		≤ 66 dB(A)	
Dimensions • Width • Depth • Height	 580 mm 690 mm 410 mm		 815 mm 690 mm 410 mm	
Weight approx.	55 kg		88 kg	

Manufacturer	Hettich Zentrifugen D-78532 Tuttlingen		
Model	ROTINA 46 RS	ROTINA 46 RS	
Product no. Mains voltage (± 10%) Mains frequency Connected load Current consumption Power consumption	4611-07 208-240 V 1~ 60 Hz 1800 VA 8.5 A 1500 W	4611-50 220-240 V 1~ 50 Hz 1700 VA 7.5 A 1350 W	4611-51 110-127 V 1~ 60 Hz 2000 VA 16.5 A 1600 W
Refrigerant	R 404a	R 404a	
Max. capacity Max. density Speed RPM Force RCF Kinetic energy Obligatory inspection	4 x 400 ml 1.2 kg/dm^3 11000 13800 35000 Nm yes		
Environment – Ambient temperature – Relative humidity	5°C up to 40°C max. 80% up to 31°C, descending in a linear pattern down to 50% at 40°C		
Sample overtemp.	-----	-----	
Class of protection	I		
EMC – Emission (Radio interference suppression) – Immunity	ISM (Industrial Science Medicine) FCC Class B according to EN 50082-1	EN 55011 Class B	FCC Class B
Noise level (dependent on rotor)	≤ 66 dB(A)	≤ 66 dB(A)	
Dimensions • Width • Depth • Height	815 mm 690 mm 410 mm		
Weight approx.	88 kg		

7 Diagrams of operating conditions

Diagram 1

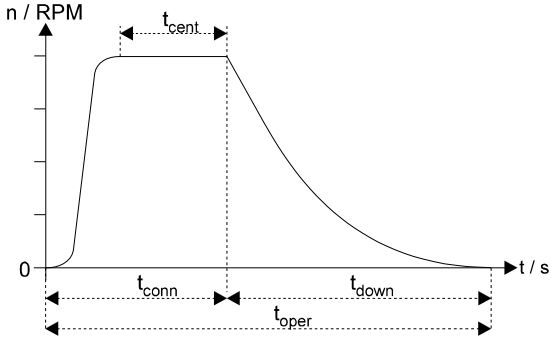
Run-up charateristics



t_{up} = not selectable current-controlled run-up (run-up period dependent on the rotor)
$t_{\nearrow}$ = selectable speed-regulated run-up
t_{cent} = selectable centrifuging time

Diagram 2

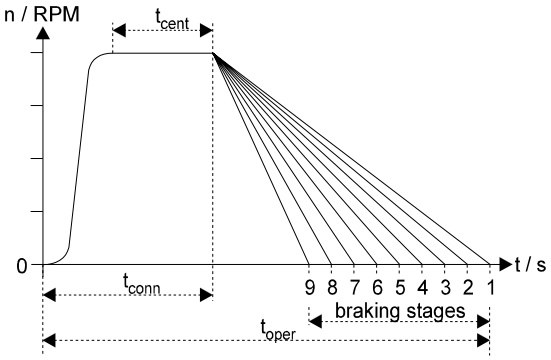
Operating characteristics



t_{conn} = selectable power-on time $t_{conn} = t_{up} + t_{cent}$
t_{down} = not susceptible slow-down time (depend. on the rotor)
t_{oper} = operating time $t_{oper} = t_{conn} + t_{down}$
t_{cent} = selectable centrifuging time

Diagram 3

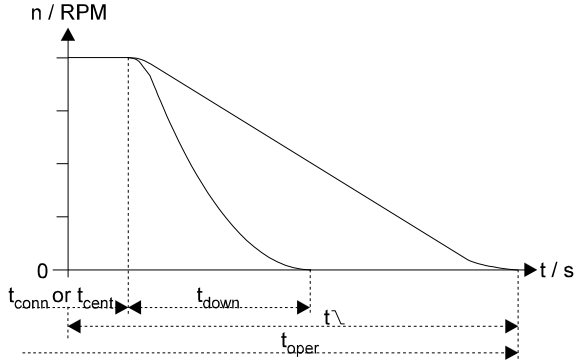
Operating time with braked slow-down (braking stages 1 - 9)



t_{conn} = selectable power-on time
t_{oper} = operating time
t_{cent} = selectable centrifuging time

Diagram 4

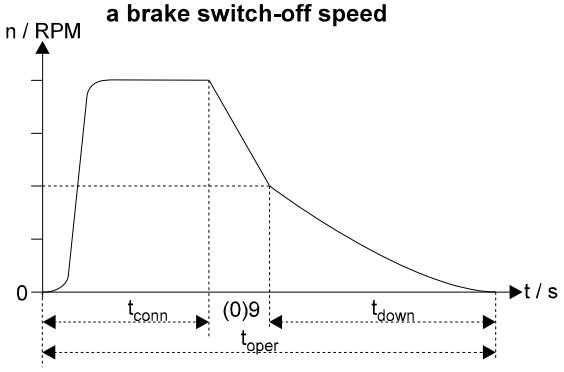
characteristics with speed-regulated and unbraked slow-down (braking stage 0)



t_{conn} = selectable power-on time
t_{cent} = selectable centrifuging time
t_{down} = not susceptible slow-down time (depend. on the rotor)
$t_{\searrow}$ = selectable speed-regulated slow-down

Diagram 5

Characteristics in case of entering a brake switch-off speed



t_{conn} = selectable power-on time
(0)9 = braking stage (e.g. 9)
t_{oper} = operating time
$n^{(0)}$ / RPM = 2000
t_{down} = not susceptible slow-down time (depend. on the rotor)

8 Initial operation

- According to the laboratory instrument standards EN 61010-2-20 an emergency switch to separate power supply in the event of a failure must be installed in the building electrical system.
  This switch has to be placed remote from the centrifuge, prefered outside of the room in which the centrifuge is installed or near by the exit of this room.
- The amount of space required is given under dimensions in the “Technical specifications” section.
- The centrifuge should be set up in a suitable position on a good, firm surface. When setting up the equipment, care should be taken to provide the required safety area of 300 mm around the centrifuge in accordance with IEC 1010-2-2.

The safety area must be clear of all persons and hazardous substances at all times when the centrifuge is in operation.

- Do not place any object in front of the ventiduct.
  – Keep a ventilation area of 300 mm around the ventiduct.
- You should check that the mains voltage corresponds to that stipulated on the model plate.
- Using the connecting cable provided, the centrifuge should be connected to a standard mains socket.
- Mains switch “**ON**” - switch position “**I**”.
  The following information will be displayed on the screen:
  1. Centrifuge type.
  2. The rated speed “n-max-Rotor” acquired most recently through rotor identification.
  3. The version number corresponding to the model.
  4. The entry field containing centrifuge data as used in the last run or entered as parameters.
- If the symbol is displayed in the top left-hand corner, this means that the lid is locked.
  Rotate the turning handle on the front panel to the left. The symbol will change to .
- Open the lid.

The lid can only be opened when the centrifuge is switched on and the rotor is at rest. If it cannot be opened under these circumstances, see the section on “Emergency release”.

- Remove the transport safety device (see instruction sheet on “Moving the equipment safely.”).

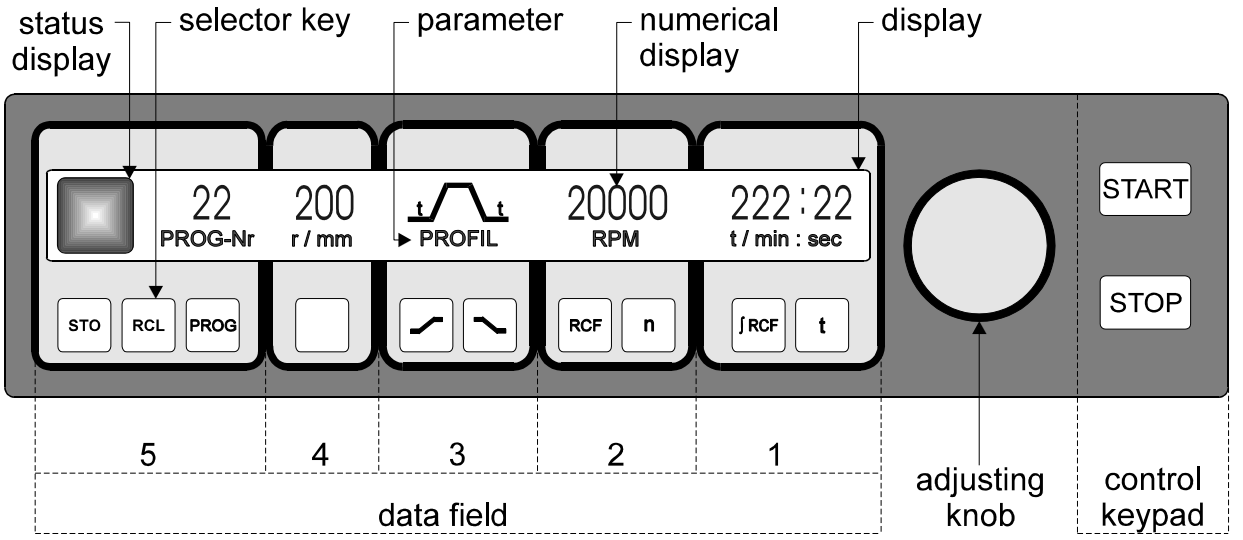
9 Installing the rotor and fitting attachments

See Rotor Instructions B032 or the section “Changing the rotor”.

- All spaces must be filled on rotors with free-swinging hangers. No empty rotor positions are permitted.
- Always fill the centrifuge containers outside the centrifuge.
- Check by eye that each container is filled to the same level.
- Loads must be equal between opposing positions.
  For details of allowable combinations see the section "Rotors and accessories" in the appendix.
- Close the lid. Turn the handle on the front panel to the right. The 〓 symbol must be visible.

The centrifuge can only be started when the 〓 symbol is visible.

10 Control and display elements



10.1 Control elements

Selector key — Key for selecting the parameters.

Press key until the numerical field above the selected parameter is displayed in reverse (dark background).

> Data can only be entered into an reverse numerical field.
> An reverse numerical field will be cleared automatically after 10 secs.

Adjusting knob — For setting the key data in the numerical field.

START — Start centrifuging.

The rotation light will come on in the display.

STOP — Stop centrifuging.

The run-down will be performed in a manner laid down in advance.
If braking level 1-9 has been set, the rotor decelerate with braking level 9 (the shortest run-down time).
If braking level 0 has been set, the rotor does not decelerate with braking level 9 but with a reduced braking force.

10.2 Status display

Lid locked. Start centrifuge or open lid.
 symbol flashing, centrifuging finished

Lid not locked. Centrifuge can not be started.
Lid can be opened or locked.

Rotation light is on from the moment the start command is issued until the rotor comes to rest.

STOP After a timed switch-off or after STOP key pressed.
After an EMERGENCY STOP the display light flashes.

LOCK 1, LOCK 2 Switch setting of the key-operated switch (only with centrifuges with key-operated switch).

10.3 Data fields

10.3.1 Data field 1

- adjustable:
  - Switch-on time
  - Operating time
  - Centrifuging time
  - Long run

∫RCF Query the effect of sedimentation
(see the section "Sedimentation effect")

10.3.2 Data field 2

- adjustable:
  - Operating speed RPM
  - Relative centrifugal force RCF

10.3.3 Data field 3

- adjustable:
  - Run-up using different levels - with a preset time
  - Run-down using different levels - with a preset time
  - Free run-down
  - Run-down with brake switched off

10.3.4 Data field 4

- adjustable:
  - Radius for determining the RPM or RCF
  - Temperature (in cooled centrifuges)

10.3.5 Data field 5

- adjustable: Program number
  Keys for
  – input STO
  – output RCL

11 Entering centrifuging data

Before each entry:

1. Use the selector key to select the reverse numerical field above the parameter.
2. Press the selector key as many times as necessary to bring the required parameter onto the screen with an reverse numerical field.
3. Adjust the number using the adjusting knob in the reverse numerical field.
4. Enter all the parameters following the above steps.

An reverse numerical field will be cleared automatically after 10 secs.

Data set once and used the last time the centrifuge ran always reappear when the rotor is stationary.

11.1 Data field 1

Time — Parameter **t / min : sec**
Input **999 : 59**

Numerical field **t / min :** or **t / : sec** → selectable using key [t] .

Adjustable times:

Connect time t_{conn} = Run-up time t_{up} + centrifuging time t_{cent}

t_{conn} : is the time from when the [START] key is pressed until the expiry of the time in numerical field **t / min : sec**.
The connect time t_{conn} must always be longer than the run-up time t_{up}.
If connect time t_{conn} is less than run-up time t_{up} the device will cut out during the run-up time. The set speed is not attained.

Operating time t_{oper} = Run-up time t_{up} + centrifuging time t_{cent} + run-down time t_{down}
or
t_{oper} = Connect time t_{conn} + run-down time t_{down}

t_{oper} : is the time from pressing the [START] key until the rotor comes to rest.

Centrifuging time t_{cent} = Connect time t_{conn} - Run-up time t_{up}

t_{cent} : is the time without run-up time t_{up} and without run-down time t_{down} .

Long run ---:-- Set the parameter **t / min :** → using the key [t] .
Using the adjusting knob, select the message **" 00 "** in the reverse numerical field.

Set the parameter **t / : sec** → using the key [t] .
Using the adjusting knob, select the message **"- - -"** in the reverse numerical field.

When the long run parameter is set, connection time is displayed once the centrifuge has started.
A long run can only be stopped by pressing the [STOP] key.

Sedimentation effect

∫RCF parameter → can be selected with the ∫RCF key.
The numerical value corresponds to the area of the squares of speed and operating time. The numerical value can only be retrieved (see the section "Sedimentation effect").

11.2 Data field 2

Speed

Parameter **RPM** → select using the n key.

Enter in increments of 10.
Lowest allowable speed 50 RPM.

Any speed (operating speed) can be set between 50 and **n-max-Rotor** (rated speed). **n-max-Rotor** can be retrieved using the n key. Press the n key repeatedly until the **n-max-Rotor** parameter appears on the screen. Hold the n key down.
n-max-Rotor is the last speed detected by the rotor identification sensor and is exactly the same as the speed rating displayed on the rotor. This speed cannot and must not be exceeded.

Relative centrifugal force (g-value)

Parameter **RCF** → select using the RCF key.

Enter in increments of 1.
Only an RCF value can be entered here, corresponding to the speed in the numerical field **RPM** and to the radius in the numerical field **r / mm** in data field 4
(see section on calculating RCF or RPM).

11.3 Data field 3

Run up, run down and brake cut-out

Profile symbol parameter → can be selected with key or .

The selected run-up and run-down modes can be seen at any time from the symbol above the **PROFILE** parameter.
Run-up level 1-9 or run-up time t . Run-down level 0-9 or run-down time t.

The run up or run down can be selected within a specific time range. This time range is determined by **n-max-Rotor**. It varies according to the speed setting.

11.3.1 Run up with preset level from 1 - 9

1-9
1 = long run up
9 = short run up

The maximum run up (level 9) cannot be shortened. It can only be extended up to level 1.

The level required should be set with the adjusting knob after selecting the reverse numerical field above the parameter 1-9.

The time corresponding to the set level can be seen after the parameter t min:sec has been selected in the numerical field.

11.3.2 Run up with preset time, adjustable in the predefined time range

t min:sec

The time required should be set using the adjusting knob after selecting the reverse numerical field above the parameter t min:sec.

The time range for run-up time can be retrieved using the adjusting knob in the numerical field above the parameter t min:sec.
The run-up level corresponding to the set time can be seen after the parameter 1-9 in the numerical field has been selected.
If the set time lies between two run-up levels, this can be seen above the parameter t and by pressing the key.
The time set must be shorter than the time setting in data field 1.

11.3.3 Run down with preset level from R0-R9

0-9

R0 = free run down
R1 = long run down
R9 = short run down

The free run-down is determined by kinetic energy and friction. The shortest run-down is achieved through level R9 (the greatest braking force).
The required level should be set after selecting the reverse numerical field above the parameter 0-9.
The time corresponding to the set level can be seen after the parameter t min:sec has been selected with the key.
Brake levels R1-R9 are linear (see diagram 3 in chapter "Diagrams of operating conditions").

11.3.4 Run down with preset time, adjustable in the predefined time range

t min:sec

The time required should be set using the adjusting knob after selecting the reverse numerical field above the parameter t min:sec using the key.

The time range can be retrieved using the adjusting knob in the numerical field above the parameter t min:sec.
The run-down level corresponding to the set time can be seen above the parameter 0-9 by pressing the key.
If the set time lies between two run-down levels, this can be seen above the parameter t and by pressing the key.

11.3.5 Run down with brake release

A time-oriented run down cannot be selected after setting or preselecting a rotational speed for brake cutoff. If a time-oriented run down has already been selected, it functions until the set rotational speed is reached.

$n^{(0)}$ RPM

The required speed should be set after selecting the reverse numerical field above the **$n^{(0)}$ RPM** parameter with the key.

The brake-release speed must be lower than the operational speed **RPM** stored in data field 2.
Once the period of time stored in data field 1 has expired, run down commences at the pre-selected level or time until the set speed is reached. Once this speed is reached, the brake is released and the run-down continues without any further braking until the rotor comes to rest.

11.4 Data field 4

Temperature

Parameter **T / °C** → can be selected with key □ .
adjustable from -20° to +40°C.

The lowest attainable temperature is reached after 1 hour of running time, see the “Rotor and accessories” table in the appendix. It is possible to attain lower temperatures by reducing the rotational speed. Such values must be established empirically.

First select the reverse numerical field above the **T / °C** parameter and then set the required temperature using the adjusting knob. The lid should next be locked because cooling cannot take place while the symbol is displayed.

Once the START key has been pressed, the ACTUAL temperature is displayed.
If the difference between SET and ACTUAL temperatures is greater than 5°C the display will flash. Once a temperature 2 °C below the SET temperature has been reached the cooling system is switched off; it is switched back on again only when the SET temperature is reached. This pattern continues until the lid is unlocked.

Radius

Parameter **r / mm** → can be selected with key □ .

Smallest radius that can be set = 10 mm. Radius values are shown in the table “Rotor and accessories” in the appendix.

First select the reverse numerical field above the **r / mm** parameter and then set the required radius using the adjusting knob.
A radius value must be entered in order to determine

1.the RCF
2.RPM

For further details see section "Calculating RCF or RPM".

11.5 Data field 5

Programming

Parameter **PROG no** → can be selected with the PROG key.

Storage locations 1 - 89	available
Storage locations 1 - 99	retrievable
Storage location 0	used internally. Data can, however, be modified.

First select the reverse numerical field above the parameter **PROG no**., then set storage locations 1-89.

Press the STO key.
The key data entered and selected on the screen will be stored under the current program no. alternatively,

press the RCL key.
The key data stored under the current program no. will be shown on the screen.

11.6 Programming notes

When the reverse numerical field above the parameter **PROG no.** flashes on and off, this signifies:

Number flashing in field	→	Storage location occupied
"**- - - -**" flashing in field	→	Temporary storage location occupied

Programs cannot be deleted, they can only be overwritten.

When "**- - - -**" is displayed above the parameter **PROG no.** and the START key is pressed, the key data displayed will be stored. This key data is stored until a change is made.

When a change is made by pressing the START key, the contents of the memory locations are relocated or shifted.

> The data from temporary storage location "**- - - -**" is now in storage location 90, and the modified data is in temporary storage location "**- - - -**".

This relocation is repeated for each change until storage location 99 is reached, after which the data is lost,

e.g. centrifuging at 500 RPM

		Change						
Description		1	2	3	-	9	10	11
RPM entry in numerical field	500	600	700	800	-	1400	1500	1600
Press START key	X	X	X	X	-	X	X	X
Temporary storage location "**- - - -**"	500	600	700	800	-	1400	1500	1600
Storage location 90		500	600	700	-	1300	1400	1500
Storage location 91			500	600	-	1200	1300	1400
Storage location 92				500	-	1100	1200	1300
"	-	-	-	-	-	-	-	-
Storage location 98					-	500	600	700
Storage location 99					-		500	600

Storage locations 1-99 can only be retrieved when the rotor is stationary.

11.6.1 Retrieving a program:

1. Select the reverse numerical field above parameter **PROG no.**
2. Set the program no.
3. Press the RCL key.

11.6.2 Modifying a program and storing it under the same number

1. Retrieve the program as per section "Retrieving a program".
2. Make the required changes.
3. Select program no. again using the PROG key (reverse display).
4. Program no. will flash. **Press the STO key twice**.
   The modified program is now stored.

11.6.3 Modifying and then starting a program

1. Retrieve program as per section “Retrieving a program”.
2. Make the required changes.
3. Press the START key.

Pressing the START key will clear the program no. It is replaced by the display “**- - - -**”. The modified program is now in the temporary storage location “**- - - -**” and will reappear on the screen when the rotor stops turning.

12 Making changes while the centrifuge is running

Select the appropriate parameter while the centrifuge is running. The numerical value must be displayed inverted.
Change the number, then press the START key. Every change must be confirmed by pressing the START key. It is not possible to make any changes during the run-down phase.
When a program is altered, the program no. is cleared when the rotor stops turning. The modified data is stored in location “**- - - -**“ . The program must be retrieved again.

13 Calculating RCF or RPM

The calculation can only be performed when **RPM** is in a range between 50 and **n-max-Rotor**. See section on "Data field 2" .
For each calculation the radius must be entered in mm.
The radius is the distance from the centre of the rotor axle to the bottom of the centrifuge container or to the point in the centrifugal product furthest from the axle (DIN 58970, Part 1). The radius measurement can be found from the table “Rotor and accessories” in the appendix.

13.1 RCF

Input:	1.Rotational speed	see “Data field 2” section
	2.Radius	see “Data field 4” section

When radius is entered, the RCF is updated simultaneously on the screen with the RCF light flashing at the same time.

Input: 1.Radius
2.Rotational speed

When speed is entered, the RCF is updated simultaneously but not displayed on the screen. The RCF can be retrieved using the RCF key, during which process the radius light will flash.

13.2 RPM

Input: 1.Radius
2.RCF

When the RCF is entered, the speed RPM is updated simultaneously but not displayed on the screen; the radius light flashes at the same time. The speed RPM can be retrieved using the key n.

Input: 1.RCF
2.Radius

When radius is entered, the RCF is updated simultaneously on the screen with the RCF light flashing at the same time.

14 How to gain rapid access when switching on

The following procedure will allow the input screen to displayed more quickly:

- Switch mains ON,
- Immediately after the first visual change on the screen (an reverse display), simply press any selector key.

14.1 Centrifuging program after switching on

After switching on, the screen displays data from program 1 or from the last program to run. This can be set initially as follows:

1. Lid unlocked, symbol .
2. Mains switch ON.
   After the first visual change on the screen (a reverse display),
3. Press the STOP key; this will produce the following message on the screen:

   PROGRAM 1
   LAST PROGRAM

4. Select the required option using the adjusting knob.
5. Press the START button; this will produce the message ***** OK *****.

15 Acoustic signal

Options:

OFF	Signal off.
ON 1	Signal at 30 sec. interval when rotor is stationary.
ON 2	as **ON1**, but also when any key is pressed.

Setting:

- With lid lock off, hold down the t key for 8 secs.
- After 8 secs. **SOUND/BELL ON1** is displayed inverted.
- Choose the required setting with the adjusting knob.
- Confirm the setting by pressing the START key.
- ***** OK ***** should now appear on the screen.

16 Retrieving the number of operating hours

When the lid is not locked, symbol ,press key [t] and hold it down for 8 secs.
Once the message **SOUND/BELL ON 1** has appeared on the screen, press the [t] key again.
You should see:

CONTROL: XX h (X = operating hours)

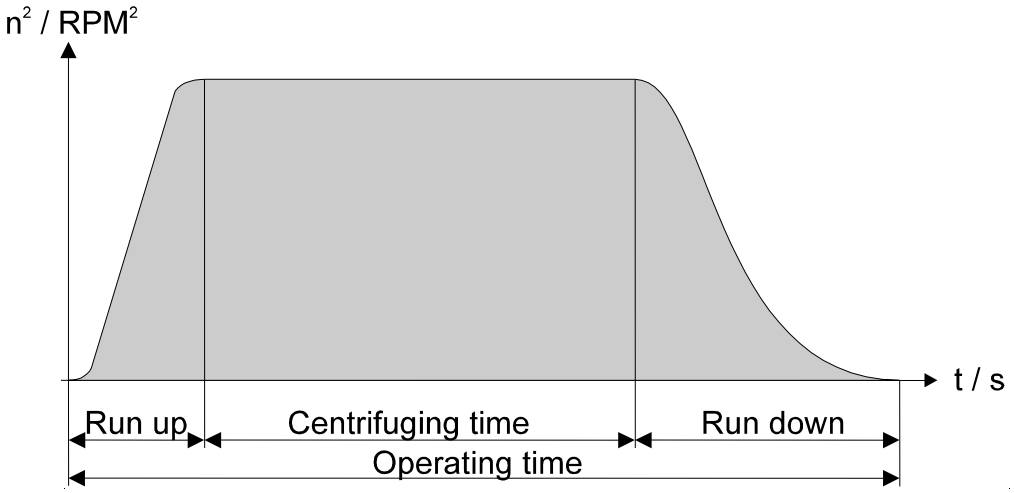
17 Time / date retrieval

As when retrieving the number of operating hours,
press the [t] key again.
The following will appear on the screen:

DATE and TIME

These can be set using the [ ] key and the adjusting knob.
Use the [START] key to confirm a change.

18 Sedimentation effect



The alteration of speed with the integral $\int \mathbf{n^2\ dt}$ must be taken into account when ascertaining the effect of sedimentation during the centrifuge run-up and run-down time. This integral is evaluated using an integrator. The numerical value above the parameter **∫RCF** corresponds to the cross-hatched area of the square formed by speed and operating time. This number can only be retrieved. Changing the time or speed will also have the effect of changing this value.

19 Centrifuging

19.1 - with the speed RPM parameter

- Enter numerical values:
  - Time — t / min : sec
  - Speed — RPM (less than or equal to n-max-Rotor)
  - Run-up level / run-up time — 1-9 or t
    Run-up time is less than time in t / min : sec
  - Run-down ramp / run-down time — 0-9 or t
  - Temperature in cooled centrifuge — T / ° C
- Press the START key.
- Once the time has expired or the STOP key has been pressed, the drive switches off.
- The centrifuge will run down at the selected braking level or run-down time.
- After the rotor has stopped, the message **" OPEN OEFFNEN "** will appear in the display.
- Open the lid.
  Further user operation is only possible after opening the lid once.

19.2 - with the RCF parameter

- Enter numerical values
  - Time — t / min : sec
  - Run-up level / run-up time — 1-9 or t
    Run-up time is shorter than time in t / min : sec
  - Run-down ramp / run-down time — 0-9 or t
  - Radius — r / mm
    For numerical value see table “Rotors and accessories”.
  - RCF — RCF
  - Temperature in cooled centrifuge — T / ° C
- Press the START key.
- Once the time has expired or the STOP key has been pressed, the drive switches off.
- The centrifuge will run down at the selected braking level or run-down time.
- After the rotor has stopped, the message **" OPEN OEFFNEN "** will appear in the display.
- Open the lid.
  Further user operation is only possible after opening the lid once.

19.3 - with a program

- Select program no. on the screen: **PROG-No XX**
- Press the RCL key.
- Press the START key.
- Once the time has expired or the STOP key has been pressed, the drive switches off.
- The centrifuge will run down at the selected braking level or run-down time.
- After the rotor has stopped, the message **" OPEN OEFFNEN "** will appear in the display.
- Open the lid.
  Further user operation is only possible after opening the lid once.

19.4 - with temperature preselection (cooled centrifuge)

Temperature can be set through a range from - 20 ° to + 40 ° C.
For the lowest temperature achievable by the rotor, attained after 1 hour of run time, see the table “Rotor and accessories”.

Temperature behaviour

- If the rotor is stationary and the lid is locked, cooling is in progress.
- If the rotor is stationary and the lid is unlocked, cooling is not in progress.

19.5 - of denser substances

The rotors are designed to centrifuge substances up to a maximum mean homogenous density of 1.2 kg/dm^3 when rotating at the stated speed.
Denser substances must be centrifuged at lower speed.

The permissible speed can be calculated using the following formula:

$$\text{Reduced speed } (n_{red}) = \sqrt{\frac{1.2}{\text{Greater density}}} \times \text{Rated speed}$$

e.g.: RPM 4000, density 1.6 kg/dm^3

$$n_{red} = \sqrt{\frac{1.2}{1.6}} \times 4000 = 3464 \text{ RPM}$$

If in doubt you should obtain clarification from the manufacturer.

20 EMERGENCY STOP

- Press STOP key twice.
- If a braking level R1-R9 or B1-B9 or a run-down time has been set, the rotor decelerates with braking level R9 (shortest run-down time).
- If braking level R0 has been set, the rotor does not decelerates with braking level R9 but with a reduced braking force.
- After the rotor has stopped, the message **" OPEN OEFFNEN "** will appear in the display.
- Open the lid.
  Further user operation is only possible after opening the lid once.

21 Changing the rotor

- Open the lid.
- Loosen the rotor tensioning nut by turning it counter-clockwise with the appropriate spanner (see delivery checklist) until the release point is reached. Once this point is passed, the rotor frees itself from the motor-shaft cone. Continue turning the nut until the rotor can be lifted off the motor shaft.
- Clean the motor shaft and then lightly grease.
- Place the new rotor vertically on the motor shaft. The motor-shaft carrier pin must be located in the groove on the rotor.
- Tighten the tensioning nut.
- Check that the rotor is seated securely.

22 Rotor identification

- Each time a centrifuging run is started, the centrifuge recognises the rotor code of the installed rotor with the help of a sensor. This means that the nominal speed of the installed rotor cannot be exceeded.
- After the identification of a newly installed rotor the drive will cut off and its speed rating will be displayed.
- Afterwards the message " OPEN OEFFNEN " will appear in the display.
- Open the lid.
  Further user operation is only possible after opening the lid once.
- If the speed rating of the newly installed rotor is lower than the last speed entered, the speed rating of the newly installed rotor will be displayed.
  If the speed rating of the newly installed rotor is higher than the last speed entered, the last speed entered will be displayed.
- Close the lid and press the START key.
- Any speed up to the rated speed of the rotor can be entered while the centrifuge is running.

23 Emergency release

If loss of current or a centrifuge fault occurs while the centrifuge is running, the lid remains locked.

To release in an emergency, unplug the centrifuge from the mains.
Wait for the rotor to stop turning before opening the lid.

Insert the release pin (see delivery checklist) horizontally into the drill hole right in the middle of the front panel. Insert the release pin up to the point at which the turning knob can be rotated to the left when the pin is pushed downwards. Open the lid.

24 Care / maintenance

Before applying any cleaning or disinfecting procedure other than those recommended by the manufacturer, the user should contact the manufacturer to make sure that the planned process will not damage the equipment.

- The centrifuge should be cleaned regularly for reasons of hygiene, and if necessary should also be cleaned with soap or a mild cleaning agent.
- Any adherent impurities should be removed as they can cause corrosion.
- Humidity in the air or centrifuge containers with no hermetic seal can lead to condensation. The centrifuge chamber should therefore be cleaned regularly with a cloth or similar.
- For instructions on how to clean the rotor and accessories see the rotor instructions B032.
- In the case of glass breakage, the fragments of glass along with any spilt centrifuge product should be removed carefully from the centrifuge chamber, the containers or container drill holes.

After a glass breakage the rubber inserts for the containers must be replaced because any residual glass fragments in these inserts can cause further glass breakage.

- If any infectious material should find its way into the centrifuge chamber it should be disinfected immediately.
- When a biosafety system is in use (see section “Rotors and accessories”), the bioseal (packing ring) between the hangers and the lid must be checked and cleaned regularly. This routine should be performed at least once a week.
  The packing ring should be replaced as soon as any signs of tears, brittleness or wear are shown.

24.1 Supporting lugs

The supporting lugs on the rotor must always be well lubricated (use Hettich lubricating grease no. 4051). Only when the supporting lugs are lubricated can it be guaranteed that the hangers will swing out evenly and that the centrifuge will not cut out during operation.

25 Faults

25.1 Note on faults

- If any fault or defect should arise, this is indicated by a symbol on the screen, while at the same time an acoustic signal is emitted at 3 sec. intervals.
- The drive cuts out. Depending on the error message the run-down is either with or without braking. After the rotor has come to rest, clearance for opening the lid is issued.

  MAINS RESET: - Mains switch OFF for longer than 10 secs.
  - Mains switch ON.

If the fault cannot be rectifield by following the troubleshooting guide and if the error message reappears after performing a MAINS RESET, you should contact Customer Services.

25.2 Fault table

Message / fault		Cause	Remedy
No display	---	– No voltage. – Overvoltage protection tripped out.	– Check supply voltage. – Mains switch ON.
TACHO - ERROR	01	– Faulty speedometer.	– Open lid. – Turn rotor manually. – MAINS-RESET (see section of notes on faults), when power is switched on, rotor should turn.
	02	– No rotor installed. – Defective motor, frequency converter or drive.	
IMBALANCE	---	Imbalance about motor axis through weight differential in rotor assembly.	– Open lid. – Correct imbalance.
CONTROL - ERROR	04, 06 - 09	Error in lid locking or lid closure.	– Open lid. – MAINS-RESET, (see section of notes on faults).
N > MAX	05	Rotation too fast	
N < MIN	13	Rotation too slow	
ROTORCODE	10	Incorrect rotor coding	
MAINS INTERRUPT	---	Power failure, centrifuging not completed	– Open lid. – Push START button.
VERSIONS-ERROR	12	Mismatch between electronic components	– Open lid. – MAINS-RESET, (see section of notes on faults).
SER I/O - ERROR	30 - 38	Error / defective interface	
° C * - ERROR	50 - 56	Error / defective cooling	
LOCK - ERROR	57	Error / defective program locking	
FU / CCI - ERROR	60 - 83	Error / defective motor control	
CONTROL-ERROR	90 - 95 97 - 99	Error / defective control unit	
N > ROTOR-MAX	96	Nominal speed higher than permitted rotor speed	Check the set speed Reduce the set speed

26 Repairs

Repairs must only be carried out by personnel authorised to do so by the manufacturer.

27 Customer Services / Servicing

Should your centrifuge break down or develop a fault, it should not be touched by anyone except an engineer authorised by the manufacturers.

In such a case you should contact Hettich Customer Services.

Before contacting our Customer Services department you should make a note of the following:

1. Centrifuge model
2. The factory number

Both of these numbers can be found on the centrifuge's model plate.

Note down any problems experienced.

You must follow the steps above in order to return to normal operation as quickly as possible.

28 Acceptance of the centrifuges for repair

If the centrifuge is returned to the manufacturer for repair, it must be decontaminated and cleaned to protect persons, environment and material.

We reserve the right to accept contaminated centrifuges.

Costs incurred for cleaning and disinfection are to be charged to the customer.

We ask for your understanding in this matter.

29 Appendix

29.1 Option: Key-operated switch

In order to safeguard against deletion of stored programs and/or the unintentional execution of programs, the key-operated switch can be used to select program locking.

To choose the required mode of program locking the key must first be inserted in the key-operated switch and the required setting selected on the screen by turning the key to the corresponding position.

A change in the program can only be made in keyswitch position 3.

The key-operated switch has the following three positions:

Position 1: Display → **LOCK 1** setting

Previously entered programs can be called up and run but not modified.

Position 2: Display → **LOCK 2** setting

Only the designated program can be run.
The designated program can not be modified.

Position 3: Display → no display

No program locking.

29.2 Option: Programs being run in sequence

The optional running of programs in a sequence can only be executed after a change or modification to the program control.
Contact the manufacturer or the relevant Hettich service department.

With the optional running of programs in a sequence, centrifugation sequences can be performed with different parameters, e.g. different speeds, in a particular order.

A number of programs can be executed in sequence by:

- The program sequence is keyed in, with the individual program data being keyed in at the same time.
- The program sequence of programs which have already been stored is keyed in.

Programs can only be linked if the run-up and the run-down are preselected at stages 1-9 or 0-9. Storing is not possible if startup is time-managed

29.2.1 Program sequence with simultaneous keying-in of program data

1. Call up the parameters in the display, and key in the desired centrifuging data. Parameters ⌐ and ¬ must be set to a stage from 1-9 or 0-9.
2. Select the **PR-Part** parameter using the PROG key.
3. Use the adjusting knob in the reversed numerical panel to select the desired program sequence number for starting of program sequences.

4. Press the STO key.
   - If program sequence number for starting of program sequences is flashing, STO key must be pressed once more.
   - After the STO key is pressed, the program sequence number increases by 1 and is displayed as follows: " **+ X +** ".
   - Storing is not possible, if a numerical panel appears in reverse in the display.
5. Enter further data required for centrifuging and repeat step 4.
6. To stop the program sequences the desired run-down stage and/or the brake force cut-off speed should be verified by the parameter ⌥ and the PROG key is to be pressed. The program sequence no. decrements by 1. The end of the program sequence is indicated by " **+ X** ".

29.2.2 Entering a sequence of previously stored programs

Before a program sequence is keyed in, a range must be stipulated which is outside the programs already stored, for example:

- Desired program sequence with the programs: 1 - 3 - 4 - 5 - 8
- Range for the program sequence which has already been stored: 10 + 11 + 12 + 13 + 14

1. Determine the number of programs in the program sequence.
2. Select in the display the first program for the starting of program sequences, and press the RCL key.
3. Use the PROG key to select the **PR-Part** parameter, and set the adjusting knob to a number outside the programs which have already been stored (see above).
4. Press the STO key.
   - If program sequence number for starting of program sequences is flashing, STO key must be pressed once more.
   - After the STO key is pressed, the program sequence number increases by 1 and is displayed as follows: " **+ X +** ".
5. Press the RCL key. For this purpose the numerical panel must appear in reverse.
6. Use the adjusting knob to select the next program to be stored in the sequence of programs, and again press the RCL key. The centrifuging data of the program selected will then appear in the display.
7. Repeat steps 4 - 6.
8. To stop the program sequences the desired run-down stage and/or the brake force cut-off speed should be verified by the parameter ⌥ and the PROG key is to be pressed. The program sequence no. goes back by 1. The end of the program sequence is indicated by " **+ X** ".

Combinations of sections 29.2.1 and 29.2.2 are possible.

29.2.3 Retrieving a program sequence

A program sequence can be retrieved as follows:

- Select the numerical panel above the **PROG-Nr** or **PR-Part** parameter until the display appears in reverse.
- The individual programs in the sequence are retrieved using the adjusting knob.

  Start of program sequence: " **X +** "
  Duration of program sequence: " **.... + X + ... + X +....** "
  End of program sequence: " **+ X** ".

29.2.4 Running a program sequence

A program sequence can be run as follows:

- Select the **PR-Part** parameter, and set adjusting knob to program sequence No. " **X +** ".
- Press the RCL key.
- Press the START key.

When a program which is being run is started up, the program sequence number " **X** + " **must** appear in the display, but **may not** appear in reverse.

29.2.5 Changing a program sequence

From program version 2.007 it is possible to make changes to a program sequence. When changing a program the link in the program sequence is deleted. The remaining programs are retained in the memory. After any changes the program must be re-linked (see Chapter 29.2.2).

e.g. change of numerical values in program sequence no. +12+
program sequence position +12+ corresponds to PROG-No. 4 (see example in Chapter 29.2.2).

1. Using the PROG key call up inverse number field via **PROG-No** or **PR-PART**.
2. Using the knob select program sequence no."**+12+**".
3. Press the RCL key.
4. Change required numerical values.
   This change deletes the link.
5. Press the STO key.

Replace the link for program sequence 10 - 14 in accordance with Chapter 29.2.2 (Point 2 to Point 8):

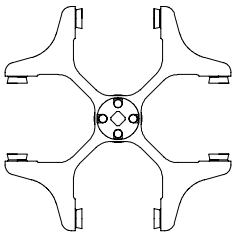
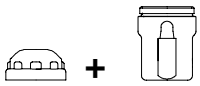
The change has no effect on PROG-No. 4. This data is retained.

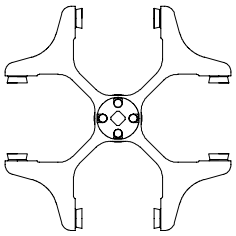
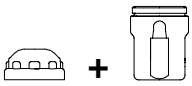
29.2.6 Deleting a program sequence

A program sequence can be deleted as follows:

- Select the parameter **PR-Part**, then use the adjusting knob to set program sequence no. to " **X +** " .
- Press the STO key twice.
- Press the PROG key.

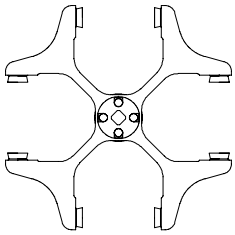
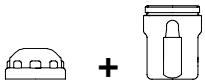
30 Rotors and accessories

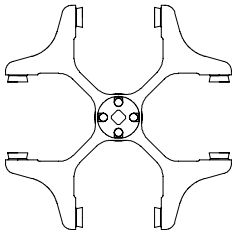
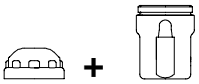
Order no. 4624		4631 + 4630							
Swing out rotor 4-times 									
		Frame							
			4631	4641		4632	4633	4634	4635
		Bottle				**Tubes**			
		0510	0511 without lid	5127					
Capacity	ml	580	650	250		250	100	50	25
Dimensions ∅ x L	mm	87 x 147	87 x 161	62 x 135		65 x 115	40 x 115	34 x 100	24 x 100
Number p. Frame		1	1	1		1	2	3	7
Number p. Rotor		4	4	4		4	8	12	28
RPM	RPM	4000	4000	4000		4000	4000	4000	4000
RCF		3578	3578	3578		3399	3363	3363	3363
Radius	mm	200	200	200		190	188	188	188
Run-up time (97%)	sec	50	50	50		50	50	50	50
Run-down time	sec	50	50	50		50	50	50	50
	sec	445	445	445		445	445	445	445
Temperature	°C [1]	- 5	- 5	- 5		- 5	- 5	- 5	- 5

Order no. 4624		4631 + 4630							
Swing out rotor 4-times 									
		Frame							
		4636	4637	4636	4636	4637	4637	5264	4636
		Tubes							
				Vacutainer					Sarstedt
Capacity	ml	15	7	8,5 - 10	8	1,6 – 5	4 – 7	4,0 – 7,0	9 – 10
Dimensions ∅ x L	mm	17 x 100	12 x 100	16 x 100	16 x 125	13 x 75	13 x 100	16 x 75	16,5 x 92
Number p. Frame		13	19	19	13	19	19	12	13
Number p. Rotor		52	76	76	52	76	76	48	52
RPM	RPM	4000	4000	4000	4000	4000	4000	4000	4000
RCF		3399	3399	3399	3399	3399	3399	3399	3399
Radius	mm	190	190	190	190	190	190	190	190
Run-up time (97%)	sec	50	50	50	50	50	50	50	50
Run-down time	sec	50	50	50	50	50	50	50	50
	sec	445	445	445	445	445	445	445	445
Temperature	°C [1]	- 5	- 5	- 5	- 5	- 5	- 5	- 5	- 5

braked slow-down (9)
unbraked slow-down (0)

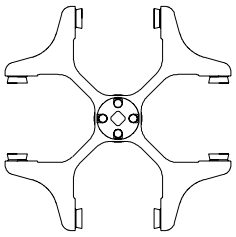
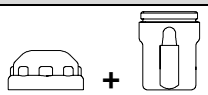
1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)

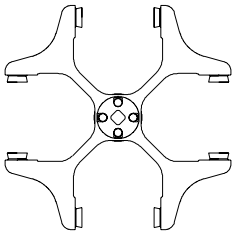
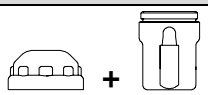
Order no. 4624		4631 + 4630							
Swing out rotor 4-times 									
		Frame							
		4636	4637	4637	4637	4637	4637	5264	5262
Capacity	ml	7,5 – 8,2	4,9	2,6 – 2,9	4,5 – 5	2,0 – 3,0	1,1 – 1,4	4 – 5,5	100
Dimensions ∅ x L	mm	15,3 – 92	13 x 90	13 x 65	11,5 x 92	11,5 x 66	8 x 60	15 x 75	44 x 100
Number p. Frame		13	19	19	19	19	19	12	1
Number p. Rotor		52	76	76	76	76	76	48	4
RPM	RPM	4000	4000	4000	4000	4000	4000	4000	4000
RCF		3399	3399	3399	3399	3399	3399	3399	3220
Radius	mm	190	190	190	190	190	190	190	180
Run-up time (97%)	sec	50	50	50	50	50	50	50	50
Run-down time	sec	50	50	50	50	50	50	50	50
	sec	445	445	445	445	445	445	445	445
Temperature	°C [1]	- 5	- 5	- 5	- 5	- 5	- 5	- 5	- 5

Order no. 4624		4630 + 4631							
Swing out rotor 4-times 									
		Frame							
		5249	5243	5242	5248	5247	5227	5257	5281
		Tubes							
		Sarstedt							
Capacity	ml	100	50	25	15	7	6	1,5 – 2,2	1,5 – 2,2
Dimensions ∅ x L	mm	40 x 115	34 x 100	24 x 100	17 x 100	12 x 100	12 x 82	Reaction tubes	Reaction tubes
Number p. Frame		1	2	5	12	20	20	40	16
Number p. Rotor		4	8	20	48	80	80	160	64
RPM	RPM	4000	4000	4000	4000	4000	4000	4000	4000
RCF		3220	3256	3256	3256	3274	3274	2433/3327	3077
Radius	mm	180	182	182	182	183	183	136 / 186	172
Run-up time (97%)	sec	50	50	50	50	50	50	50	50
Run-down time	Sec	50	50	50	50	50	50	50	50
	Sec	445	445	445	445	445	445	445	445
Temperature	°C [1]	- 5	- 5	- 5	- 5	- 5	- 5	-5	- 5

braked slow-down (9)
unbraked slow-down (0)

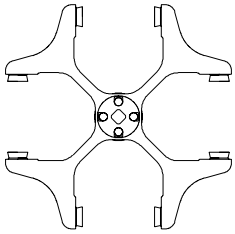
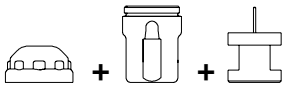
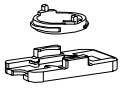
1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)

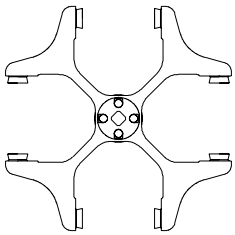
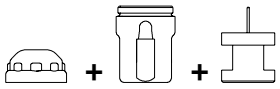
Order no. 4624		4631 + 4630							
Swing out rotor 4-times 									
		5266	5258	5265	5247	5264	5227	5259	6306
		Tubes							
		Sarstedt						Falcon, Corning	
Capacity	ml	25	9 – 12	5	4,5 – 5	3,2 – 6	2 – 4	50	15
Dimensions ∅ x L	mm	25 x 92	16,5 x 92	16,5 x 57	11,5 x 92	15,3 x 57	11,5 x 66	29 x 116	17 x 120
Number p. Frame		5	11	11	20	12	20	2	7
Number p. Rotor		20	44	44	80	48	80	8	28
RPM	RPM	4000	4000	4000	4000	4000	4000	4000	4000
RCF		3256	3256	3345	3256	3274	3274	3327	3381
Radius	mm	182	182	187	182	183	183	186	189
Run-up time (97%)	sec	50	50	50	50	50	50	50	50
Run-down time	sec	50	50	50	50	50	50	50	50
	sec	445	445	445	445	445	445	445	445
Temperature	°C [1]	- 5	- 5	- 5	- 5	- 5	- 5	- 5	- 5

Order no. 4624		4631 + 4630							
Swing out rotor 4-times 									
		5248	5264	6301	5268	5267	4638	4639	4643
		Vacutainer					Falcon	Falcon	Universal-container
Capacity	ml	12	8	7	5	2	15	50	
Dimensions ∅ x L	mm	15,5 x 105	15,5 x 81	12 x 105	12 x 81	10 x 52	17 x 120	29 x 115	
Number p. Frame		12	12	12	12	20	10	4	5
Number p. Rotor		48	48	48	48	80	40	16	20
RPM	RPM	4000	4000	4000	4000	4000	4000	4000	4000
RCF		3256	3274	3256	3309	3238	3506	3506	3345
Radius	mm	182	183	182	185	181	196	196	187
Run-up time (97%)	sec	50	50	50	50	50	50	50	50
Run-down time	sec	50	50	50	50	50	50	50	50
	sec	445	445	445	445	445	445	445	445
Temperature	°C [1]	- 5	- 5	- 5	- 5	- 5	- 5	- 5	- 5

braked slow-down (9)
unbraked slow-down (0)

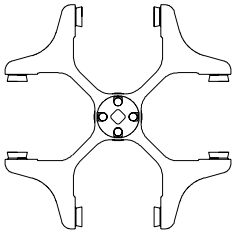
1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)

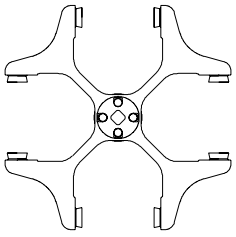
Order no. 4624		4631 + 4630 + 5280							
Swing out rotor 4-times 									
		1662						1670	
								 2)	
		1663	1664	1665	1666	1667	1668	1663	1664
									
Filter Cards		1675	1675	1675	1676	1677	1678	1692	1692
Capacity	ml	1	2	4	8	3 x 2	4 x 1	1	2
Dimensions ∅ / A	mm^2	6,2 / 30	8,7 / 60	12,4 / 120	17,5 / 240	8,7 / 60	6,2 / 30	6,2 / 30	8,7 / 60
Number p. Frame		1 / 2	1 / 2	1 / 2	1 / 2	1 / 2	1 / 2	2 / 4	2 / 4
Number p. Rotor		4 / 8	4 / 8	4 / 8	4 / 8	4 / 8	4 / 8	8 / 16	8 / 16
RPM	RPM	4000	4000	4000	4000	4000	4000	4000	4000
RCF		2236/3238	2236/3238	2236/3238	2236/3238	2236/3238	2236/3238	2236/3238	2236/3238
Radius	mm	125/181	125/181	125/181	125/181	125/181	125/181	125/181	125/181
Run-up time (97%)	sec	50	50	50	50	50	50	50	50
Run-down time	sec	50	50	50	50	50	50	50	50
	sec	410	410	410	410	410	410	410	410
Temperature	°C 1)	- 5	- 5	- 5	- 5	- 5	- 5	- 5	- 5

Order no. 4624		4631 + 4630 + 5280							
Swing out rotor 4-times 									
		1670							
		 2)							
		1665	1666	1667	1668				
									
Filter Cards		1692	1691	1694	1693				
Capacity	ml	4	8	3 x 2	4 x 1				
Dimensions ∅ / A	mm^2	12,4 / 120	17,5 / 240	8,7 / 60	6,2 / 30				
Number p. Frame		2 / 4	2 / 4	2 / 4	2 / 4				
Number p. Rotor		8 / 16	8 / 16	8 / 16	8 / 16				
RPM	RPM	4000	4000	4000	4000				
RCF		2236/3238	2236/3238	2236/3238	2236/3238				
Radius	mm	125/181	125/181	125/181	125/181				
Run-up time (97%)	sec	50	50	50	50				
Run-down time	sec	50	50	50	50				
	sec	410	410	410	410				
Temperature	°C 1)	- 5	- 5	- 5	- 5				

braked slow-down (9)
unbraked slow-down (0)

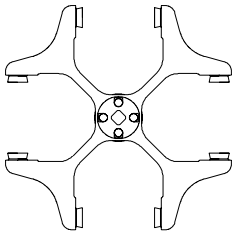
1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)
2) Object carrier will not stand RCF values exceeding 1100

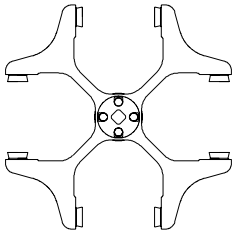
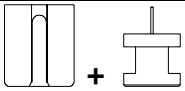
Order no. 4354		4396							
Swing out rotor 4-times 									
		Frame							
		5249	5262	5243	5242	5248	5247	5227	5257
		Tubes							
Capacity	ml	100	100	50	25	15	7	6	1,5 – 2,2
Dimensions ∅ x L	mm	40 x 115	44 x 100	34 x 100	24 x 100	17 x 100	12 x 100	12 x 82	Reaction tubes
Number p. Frame		1	1	2	5	12	20	20	40
Number p. Rotor		4	4	8	20	48	80	80	160
RPM	RPM	5000	5000	5000	5000	5000	5000	5000	5000
RCF		4276	4276	4332	4332	4332	4332	4360	4047/ 4416
Radius	mm	153	153	155	155	155	155	156	109/158
Run-up time (97%)	sec	32	32	32	32	32	32	32	32
Run-down time	sec	35	35	35	35	35	35	35	35
	sec	306	306	306	306	306	306	306	306
Temperature	°C [1]	0	0	0	0	0	0	0	0

Order no. 4354		4396							
Swing out rotor 4-times 									
		Frame							
		5281	5266	5258	5247	5264	5227	5266	5258
		Tubes							
			Sarstedt					Falcon,Corning	
Capacity	ml	1,5- 2,2	25	5	4,5 – 5	3,2 – 6	2 – 4	50	15
Dimensions ∅ x L	mm	Reaction tubes	16,5 x 92	16,5 x 92	11,5 x 92	15,3 x 75	11,5 x 66	29 x 115	17 x 120
Number p. Frame		10	11	11	20	12	20	2	7
Number p. Rotor		40	44	44	80	48	80	8	28
RPM	RPM	5000	5000	5000	5000	5000	5000	5000	5000
RCF		4304	4332	4472	4332	4360	4360	4444	4528
Radius	mm	145	155	160	155	156	156	159	162
Run-up time (97%)	sec	32	32	32	32	32	32	32	32
Run-down time	sec	35	35	35	35	35	35	35	35
	sec	306	306	306	306	306	306	306	306
Temperature	°C [1]	0	0	0	0	0	0	0	0

braked slow-down (9)
unbraked slow-down (0)

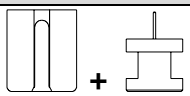
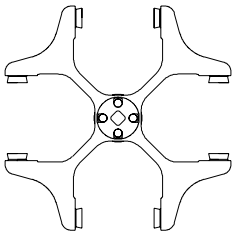
1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)

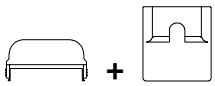
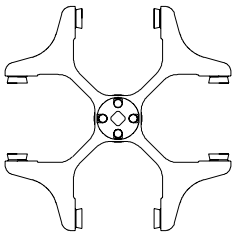
Order no. 4354		4396							
Swing out rotor 4-times 									
		5248	5264	6301	5268	5267			
		Tubes							
		Vacutainer							
Capacity	ml	12	8	7	5	2			
Dimensions ∅ x L	mm	16 x 100	16 x 75	13 x 100	13 x 75	10 x 52			
Number p. Frame		12	12	12	12	20			
Number p. Rotor		48	48	48	48	80			
RPM	RPM	5000	5000	5000	5000	5000			
RCF		4332	4360	4432	4416	4304			
Radius	mm	155	156	155	158	154			
Run-up time (97%)	sec	32	32	32	32	32			
Run-down time	sec	35	35	35	35	35			
	sec	306	306	306	306	306			
Temperature	°C [1]	0	0	0	0	0			

Order no. 4354		4396 + 5280							
Swing out rotor 4-times 									
		1662						**1670**	
								 [2]	
		1663	1664	1665	1666	1667	1668	1663	1664
									
Filter Cards		1675	1675	1675	1676	1677	1678	1692	1692
Capacity	ml	1	2	4	8	3 x 2	4 x 1	1	2
Dimensions ∅ / A	mm^2	6,2 / 30	8,7 / 60	12,4 / 120	17,5 / 240	8,7 / 60	6,2 / 30	6,2 / 30	8,7 / 60
Number p. Frame		1 / 2	1 / 2	1 / 2	1 / 2	1 / 2	1 / 2	2 / 4	2 / 4
Number p. Rotor		4 / 8	4 / 8	4 / 8	4 / 8	4 / 8	4 / 8	4 / 8	4 / 8
RPM	RPM	5000	5000	5000	5000	5000	5000	5000	5000
RCF		2711/4220	2711/4220	2711/4220	2711/4220	2711/4220	2711/4220	2711/4220	2711/4220
Radius	mm	97/151	97 / 151	97 / 151	97 / 151	97 / 151	97 / 151	97 / 151	97 / 151
Run-up time (97%)	sec	32	32	32	32	32	32	32	32
Run-down time	sec	35	35	35	35	35	35	35	35
	sec	306	306	306	306	306	306	306	306
Temperature	°C [1]	0	0	0	0	0	0	0	0

braked slow-down (9)
unbraked slow-down (0)

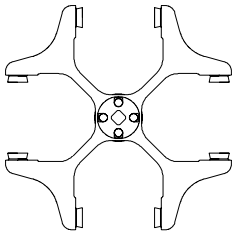
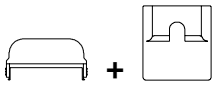
1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)
2) Object carrier will not stand RCF values exceeding 1100

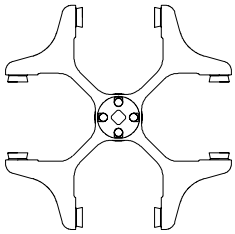
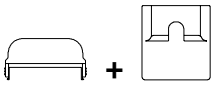
Order no. 4354		4396 + 5280							
Swing out rotor 4-times									
		1670							
		 2)							
		1665	1666	1667	1668				
									
Filter Cards		1692	1691	1694	1693				
Capacity	ml	4	8	3 x 2	4 x 1				
Dimensions ∅ / A	mm^2	12,4 / 120	17,5 / 240	8,7 / 60	6,2 / 30				
Number p. Frame		2 / 4	2 / 4	2 / 4	2 / 4				
Number p. Rotor		8 / 16	8 / 16	8 / 16	8 / 16				
RPM	RPM	5000	5000	5000	5000				
RCF		2711/4220	2711/4220	2711/4220	2711/4220				
Radius	mm	97 / 151	97 / 151	97 / 151	97 / 151				
Run-up time (97%)	sec	32	32	32	32				
Run-down time 【●】	sec	35	35	35	35				
【○】	sec	306	306	306	306				
Temperature	°C 1)	0	0	0	0				

Order no. 4394		5095 + 5091							
Swing out rotor 4-times									
		Frame							
		5262	5249	5243	5242	5248	5247	5227	5257
		Tubes							
Capacity	ml	100	100	50	25	15	7	6	1,5 – 2,2
Dimensions ∅ x L	mm	44 x 100	40 x 115	34 x 100	24 x 100	17 x 100	12 x 100	12 x 82	Reaction tubes
Number p. Frame		1	1	2	5	12	20	20	40
Number p. Rotor		4	4	8	20	48	80	80	160
RPM	RPM	4000	4000	4000	4000	4000	4000	4000	4000
RCF		2755	2755	2773	2773	2773	2773	2791	1968 / 2844
Radius	mm	154	154	155	155	155	155	156	110/159
Run-up time (97%)	sec	32	32	32	32	32	32	32	32
Run-down time 【●】	sec	34	34	34	34	34	34	34	34
【○】	sec	265	265	265	265	265	265	265	265
Temperature	°C 1)	- 6	- 6	- 6	- 6	- 6	- 6	- 6	- 6

【●】 braked slow-down (9)
【○】 unbraked slow-down (0)

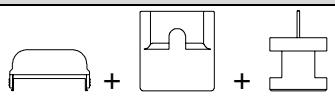
1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)
2) Object carrier will not stand RCF values exceeding 1100

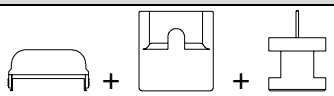
Order no. 4394	5095 + 5091							
Swing out rotor 4-times 								
	Frame							
	5281	5266	5258	5265	5247	5264	5227	5259
	Tubes							
		Sarstedt						Falcon, Corning
Capacity ml	1,5 – 2,2	25	9 – 12	5	4,5 – 5	3,2 – 6	2 – 4	50
Dimensions ∅ x L mm	Reaction tubes	25 x 92	16,5 x 92	16,5 x 57	11,5 x 92	15,3 x 75	11,5 x 66	29 x 115
Number p. Frame	16	5	11	11	20	12	20	2
Number p. Rotor	64	20	44	44	80	48	80	8
RPM RPM	4000	4000	4000	4000	4000	4000	4000	4000
RCF	2612	2773	2773	2880	2773	2791	2791	2844
Radius mm	155	155	155	161	155	156	156	159
Run-up time (97%) sec	32	32	32	32	32	32	32	32
Run-down time sec	34	34	34	34	34	34	34	34
Run-down time sec	265	265	265	265	265	265	265	265
Temperature °C [1]	- 6	- 6	- 6	- 6	- 6	- 6	- 6	- 6

Order no. 4394	5095 + 5091							
Swing out rotor 4-times 								
	Frame							
	6306	5248	5264	6301	5268	5267		
	Vacutainer							
	Falcon, Corning	Vacutainer						
Capacity ml	15	12	8	7	5	2		
Dimensions ∅ x L mm	17 x 120	16 x 100	16 x 75	12 x 100	12 x 75	10 x 52		
Number p. Frame	7	12	12	12	12	20		
Number p. Rotor	28	48	48	48	48	80		
RPM RPM	4000	4000	4000	4000	4000	4000		
RCF	2916	2773	2791	2773	2826	2755		
Radius mm	163	155	156	155	158	154		
Run-up time (97%) sec	32	32	32	32	32	32		
Run-down time sec	34	34	34	34	34	34		
Run-down time sec	265	265	265	265	265	265		
Temperature °C [1]	- 6	- 6	- 6	- 6	- 6	- 6		

braked slow-down (9)
unbraked slow-down (0)

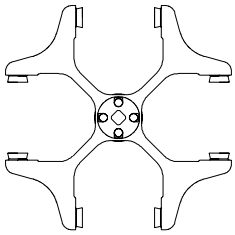
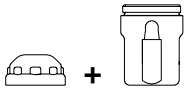
1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)

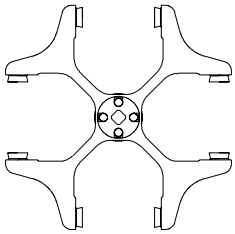
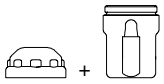
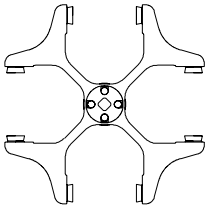
Order no. 4394		5095 + 5091 + 5280							
Swing out rotor 4-times									
		1662						1670	
								 2)	
		1663	1664	1665	1666	1667	1668	1663	1664
									
Filter Cards		1675	1675	1675	1676	1677	1668	1692	1692
Capacity	ml	1	2	4	8	3 x 2	4 x 1	1	2
Dimensions ∅ / A	mm^2	6,2 / 30	8,7 / 60	12,4 / 120	17,5 / 240	8,7 / 60	6,2 / 30	6,2 / 30	8,7 x 60
Number p. Frame		1 / 2	1 / 2	1 / 2	1 / 2	1 / 2	1 / 2	2 / 4	2 / 4
Number p. Rotor		4 / 8	4 / 8	4 / 8	4 / 8	4 / 8	4 / 8	8 / 16	8 / 16
RPM	RPM	4000	4000	4000	4000	4000	4000	4000	4000
RCF		1735/2701	1735/2701	1735/2701	1735/2701	1735/2701	1735/2701	1735/2701	1735/2701
Radius	mm	97 / 151	97 / 151	97 / 151	97 / 151	97 / 151	97 / 151	97 / 151	97 / 151
Run-up time (97%)	sec	32	32	32	32	32	32	32	32
Run-down time	sec	34	34	34	34	34	34	34	34
	sec	256	256	256	256	256	256	256	256
Temperature	°C 1)	- 6	- 6	- 6	- 6	- 6	- 6	- 6	- 6

Order no. 4394		5095 + 5091 + 5280							
Swing out rotor 4-times									
		1670							
		 2)							
		1665	1666	1667	1668				
									
Filter Cards		1692	1691	1694	1693				
Capacity	ml	4	8	3 x 2	4 x 1				
Dimensions ∅ / A	mm^2	12,4 x 120	17,5 x 240	8,7 / 60	6,2 / 30				
Number p. Frame		2 / 4	2 / 4	2 / 4	2 / 4				
Number p. Rotor		8 / 16	8 / 16	8 / 16	8 / 16				
RPM	RPM	4000	4000	4000	4000				
RCF		1735/2701	1735/2701	1735/2701	1735/2701				
Radius	mm	97 / 151	97 / 151	97 / 151	97 / 151				
Run-up time (97%)	sec	32	32	32	32				
Run-down time	sec	34	34	34	34				
	sec	256	256	256	256				
Temperature	°C 1)	- 6	- 6	- 6	- 6				

braked slow-down (9)
unbraked slow-down (0)

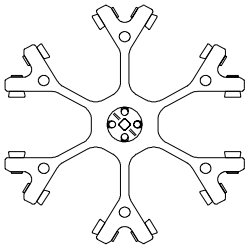
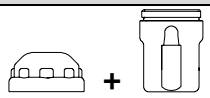
1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)
2) Object carrier will not stand RCF values exceeding 1100

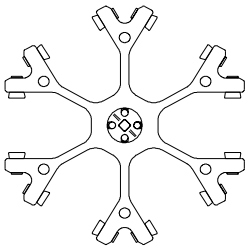
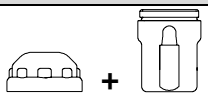
Order no. 4394		5093 + 5092							
Swing out rotor 4-times 									
		Frame							
		5126	5125	5124	5122	5121	5120	5128	5129
		Tubes							
									Falcon
Capacity	ml	100	100	50	25	15	7	6	15
Dimensions ∅ x L	mm	40 x 115	44 x 100	34 x 100	24 x 100	17 x 100	12 x 100	12 x 82	17 x 120
Number p. Frame		1	1	1	4	7	12	12	7
Number p. Rotor		4	4	4	16	28	48	48	28
RPM	RPM	4000	4000	4000	4000	4000	4000	4000	4000
RCF		2952	2952	2969	2898	3005	3005	3005	3095
Radius	mm	165	165	166	162	168	168	168	173
Run-up time (97%)	sec	32	32	32	32	32	32	32	32
Run-down time	sec	34	34	34	34	34	34	34	34
	sec	265	265	265	265	265	265	265	265
Temperature	°C [1]	- 6	- 6	- 6	- 6	- 6	- 6	- 6	- 6

Order no. 4394		5093 + 5092		5092		Order no. 4624		4625
Swing out rotor 4-times 						Swing out rotor 4-times 		
		Reduction						Frame
		5123	support ring with rubber inlay 1057	6319				Microtiter-plates
		Tubes		Bottle				
		Falcon	0530	5127				
Capacity	ml	50	250	250				
Dimensions ∅ x L	mm	29 x 115	65 x 115	62 x 135				
Number p. Frame		2	1	1				3
Number p. Rotor		8	4	4				12
RPM	RPM	4000	4000	4000				4000
RCF		3095	2952	3095				3290
Radius	mm	173	165	173				184
Run-up time (97%)	sec	32	32	32				50
Run-down time	sec	34	34	34				50
	sec	265	265	265				345
Temperature	°C [1]	- 6	- 6	- 6				- 5

braked slow-down (9)
unbraked slow-down (0)

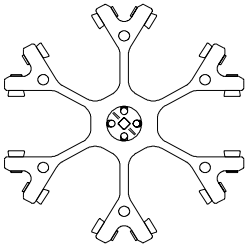
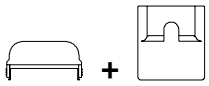
1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)

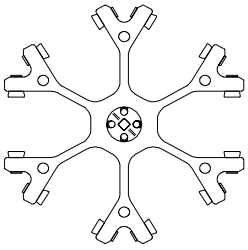
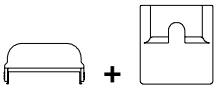
Order no. 4296		5093 + 5092							
Swing out rotor 6-times 									
		Frame							
		5126	5125	5124	5123	5122	5121	5120	5128
		Tubes							
					Falcon				
Capacity	ml	100	100	50	50	25	15	7	6
Dimensions ∅ x L	mm	40 x 115	44 x 100	34 x 100	29 x 115	24 x 100	17 x 100	12 x 100	12 x 82
Number p. Frame		1	1	1	2	4	7	12	12
Number p. Rotor		6	6	6	12	24	42	72	72
RPM	RPM	4000	4000	4000	4000	4000	4000	4000	4000
RCF		3488	3488	3506	3631	3434	3542	3542	3542
Radius	mm	195	195	196	203	192	198	198	198
Run-up time (97%)	sec	50	50	50	50	50	50	50	50
Run-down time	sec	55	55	55	55	55	55	55	55
	sec	443	443	443	443	443	443	443	443
Temperature	°C [1]	- 3	- 3	- 3	- 3	- 3	- 3	- 3	- 3

Order no. 4296		5093 + 5092		5092	5095 + 5091				
Swing out rotor 6-times 									
		Reduction			**Frame**				
		5121-93	support ring with rubber inlay 1057	6319	5262	5249	5243	5242	5248
			Tube	**Bottle**					
		Vacutainer	0530	5127					
Capacity	ml	-	250	250	100	100	50	25	15
Dimensions ∅ x L	mm	16 x 75	65 x 115	62 x 135	44 x 100	44 x 115	34 x 100	24 x 100	17 x 100
Number p. Frame		7	1	1	1	1	2	5	12
Number p. Rotor		42	6	6	6	6	12	30	72
RPM	RPM	4000	4000	4000	4000	4000	4000	4000	4000
RCF		3542	3388	3631	3291	3291	3309	3309	3309
Radius	mm	198	195	200	184	184	185	185	185
Run-up time (97%)	sec	50	50	50	50	50	50	50	50
Run-down time	sec	55	55	55	55	55	55	55	55
	sec	443	443	443	443	443	443	443	443
Temperature	°C [1]	- 3	- 3	- 3	- 3	- 3	- 3	- 3	- 3

braked slow-down (9)
unbraked slow-down (0)

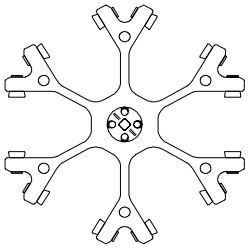
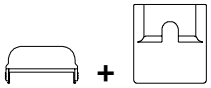
1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)

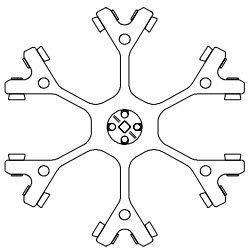
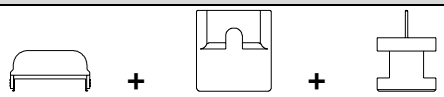
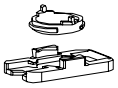
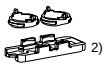
Order no. 4296		5095 + 5091							
Swing out rotor 6-times 									
		Frame							
		5247	5227	5257	5248-91	5247-91	5266	5258	5265
		Tubes							
				Reaction tubes	With Decanteraid		Sarstedt		
Capacity	ml	7	6	1,5-2,2	15	7	25	9-12	5
Dimensions ∅ x L	mm	12 x 100	12 x 82	-	17 x 100	12 x 100	25 x 92	16,5 x 92	16,5 x 57
Number p. Frame		20	20	40	12	20	5	11	11
Number p. Rotor		120	12	240	72	120	30	66	66
RPM	RPM	4000	4000	4000	4000	4000	4000	4000	4000
RCF		3309	3327	2504 above 3381 below	3309	3309	3309	3309	3417
Radius	mm	185	186	140 above 189 below	185	185	185	185	191
Run-up time (97%)	sec	50	50	50	50	50	50	50	50
Run-down time	sec	55	55	55	55	55	55	55	55
	sec	443	443	443	443	443	443	443	443
Temperature	°C [1]	- 3	- 3	- 3	- 3	- 3	- 3	- 3	- 3

Order no. 4296		5095 + 5091							
Swing out rotor 6-times 									
		Framee							
		5247	5264	5227	5259	6306	5248	5264	
		Tubes							
		Sarstedt			Falcon, Corning		Vacutainer		
Capacity	ml	4,5-5	3,2-6	2-4	50	15	12	8	
Dimensions ∅ x L	mm	11,5 x 92	15,3 x 75	11,5 x 66	29 x 115	17 x 120	16 x 100	16 x 75	
Number p. Frame		20	12	20	2	7	12	12	
Number p. Rotor		120	72	120	12	42	72	72	
RPM	RPM	4000	4000	4000	4000	4000	4000	4000	
RCF		3309	3327	3327	3381	3452	3309	3327	
Radius	mm	185	186	186	189	192	185	186	
Run-up time (97%)	sec	50	50	50	50	50	50	50	
Run-down time	sec	55	55	55	55	55	55	55	
	sec	443	443	443	443	443	443	443	
Temperature	°C [1]	- 3	- 3	- 3	- 3	- 3	- 3	- 3	

braked slow-down (9)
unbraked slow-down (0)

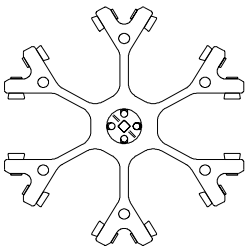
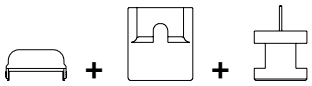
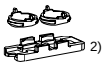
1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)

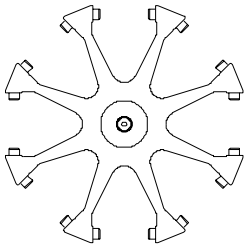
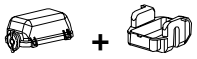
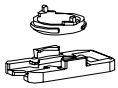
Order no. 4296	5095 + 5091							
Swing out rotor 6-times 								
	Frame							
	6301	5268	5267	5281				
	Vacutainer							
Capacity ml	7	5	2	1,5 – 2,2				
Dimensions ∅ x L mm	12 x 100	12 x 75	10 x 52	Reaction tubes				
Number p. Frame	12	12	20	16				
Number p. Rotor	72	72	120	96				
RPM RPM	4000	4000	4000	4000				
RCF	3300	3363	3291	3148				
Radius mm	185	188	184	176				
Run-up time (97%) sec	50	50	50	50				
Run-down time ■ sec	55	55	55	55				
Run-down time 【○】 sec	443	443	443	443				
Temperature °C 1)	- 3	- 3	- 3	- 3				

Order no. 4296	5095 + 5091 + 5280							
Swing out rotor 6-times 								
	1662						**1670**	
							 2)	
	1663	**1664**	**1665**	**1666**	**1667**	**1668**	**1663**	**1664**
								
Filter Cards	1675	1675	1675	1676	1677	1678	1692	1692
Capacity ml	1	2	4	8	3 x 2	4 x 1	1	2
Dimensions ∅ / A mm^2	6,2 / 30	8,7 x 60	12,4 x 120	17,5 x 240	8,7 x 60	6,2 x 30	6,2 x 30	8,7 x 60
Number p. Frame	2	2	2	2	2	2	4	4
Number p. Rotor	12	12	12	12	12	12	24	24
RPM RPM	4000	4000	4000	4000	4000	4000	4000	4000
RCF	2272/3238	2272/3238	2272/3238	2272/3238	2272/3238	2272/3238	2272/3238	2272/3238
Radius mm	127/181	127/181	127/181	127/181	127/181	127/181	127/181	127/181
Run-up time (97%) sec	50	50	50	50	50	50	50	50
Run-down time ■ sec	55	55	55	55	55	55	55	55
Run-down time 【○】 sec	443	443	443	443	443	443	443	443
Temperature °C 1)	- 3	- 3	- 3	- 3	- 3	- 3	- 3	- 3

■ braked slow-down (9)
【○】 unbraked slow-down (0)

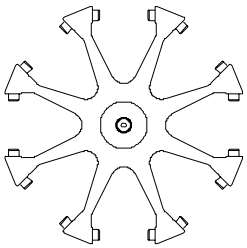
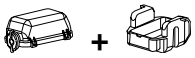
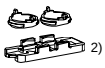
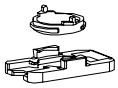
1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)
2) Object carrier will not stand RCF values exceeding 1100

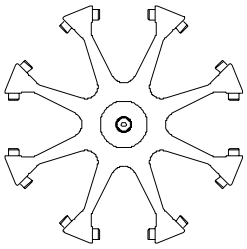
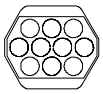
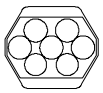
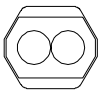
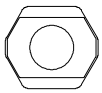
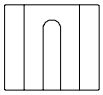
Order no. 4296	5095 + 5091 + 5280							
Swing out rotor 6-times 								
	1670							
	 2)							
	1665	1666	1667	1668				
								
Filter Cards	1692	1691	1694	1693				
Capacity ml	4	8	3 x 2	4 x 1				
Dimensions ∅ / A mm^2	12,4 x 120	17,5 x 240	8,7 x 60	6,2 x 30				
Number p. Frame	4	4	4	4				
Number p. Rotor	24	24	24	24				
RPM RPM	4000	4000	4000	4000				
RCF	2272/3238	2272/3238	2272/3238	2272/3238				
Radius mm	127/181	127/181	127/181	127/181				
Run-up time (97%) sec	50	50	50	50				
Run-down time ◧◯◨ sec	55	55	55	55				
Run-down time 【◯】 sec	443	443	443	443				
Temperature °C 1)	- 3	- 3	- 3	- 3				

Order no. 4618	1661 + 1660							
Swing out rotor 8-times 								
	1662						1670	
							 2)	
	1663	1664	1665	1666	1667	1668	1663	1664
								
Filter Cards	1675	1675	1675	1676	1677	1678	1692	1692
Capacity ml	1	2	4	8	3 x 2	4 x 1	1	2
Dimensions ∅ / A mm^2	6,2 x 30	8,7 x 60	12,4 x 120	17,5 x 240	8,7 x 60	6,2 x 30	6,2 x 30	8,7 x 60
Number p. Frame	1	1	1	1	1	1	2	2
Number p. Rotor	8	8	8	8	8	8	16	16
RPM RPM	3800	3800	3800	3800	3800	3800	3800	3800
RCF	2179	2179	2179	2179	2179	2179	2179	2179
Radius mm	135	135	135	135	135	135	135	135
Run-up time (97%) sec	40	40	40	40	40	40	40	40
Run-down time ◧◯◨ sec	40	40	40	40	40	40	40	40
Run-down time 【◯】 sec	150	150	150	150	150	150	150	150
Temperature °C 1)	- 10	- 10	- 10	- 10	- 10	- 10	- 10	- 10

◧◯◨ braked slow-down (9)
【◯】 unbraked slow-down (0)

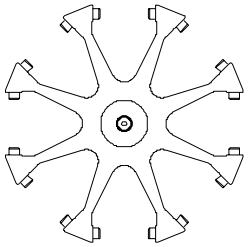
1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)
2) Object carrier will not stand RCF values exceeding 1100

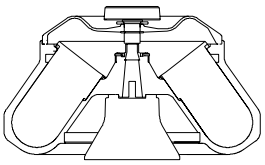
Order no. 4618	1661 + 1660				1660	1680		
Swing out rotor 8-times 								
	1670				1285	1662		
	 2)				 without Lid 1661			
	1665	1666	1667	1668		1671	1672	1673
								
Filter Cards	1692	1691	1694	1693		[1] 1696 [2] 1676	[1] 1696 [2] 1676	[1] 1696 [2] 1676
Capacity ml	4	8	3 x 2	4 x 1	Object Slide	[1] 0,3 [2] 1,5	[1] 0,3 [2] 1,25	[1] 0,3 [2] 0,75
Dimensions ∅ / A mm^2	12,4 x 120	17,5 x 240	8,7 x 60	6,2 x 30	26 x 76	6,2 / 30	8,7 / 60	12,4 / 120
Number p. Frame	2	2	2	2	6	1	1	1
Number p. Rotor	16	16	16	16	48	8	8	8
RPM RPM	3800	3800	3800	3800	3800	3800	3800	3800
RCF	2179	2179	2179	2179		2002	2002	2002
Radius mm	135	135	135	135		124	124	124
Run-up time (97%) sec	40	40	40	40		40	40	40
Run-down time ◧◯ sec	40	40	40	40		40	40	40
Run-down time 【◯】 sec	150	150	150	150		150	150	150
Temperature °C 1)	- 10	- 10	- 10	- 10		- 10	- 10	- 10

Order no. 4618	1741	1742	1745	1746	1366			
Swing out rotor 8-times 								
	Frame							
	0701 Rubber inlay				1326	1327	1328	1329
	Tubes							
Capacity ml	9	15	25	50	4	3	1	1,5 / 2,2
Dimensions ∅ x L mm	14 x 100	17 x 100	24 x 100	34 x 100	12 x 60	10 x 60	6 x 45 Rhesus	Reaction tubes
Number p. Frame	10	7	2	1	12	12	30	9
Number p. Rotor	80	56	16	8	96	96	240	72
RPM RPM	3800	3800	3800	3800	3800	3800	3800	3800
RCF	2827	2906	2906	2906	2398	2398	2414	2414
Radius mm	178	180	180	180	151	151	152	152
Run-up time (97%) sec	40	40	40	40	40	40	40	40
Run-down time ◧◯ sec	40	40	40	40	40	40	40	40
Run-down time 【◯】 sec	205	205	205	205	205	205	205	205
Temperature °C 1)	- 2	- 2	- 2	- 2	- 2	- 2	- 2	- 2

◧◯ braked slow-down (9)
【◯】 unbraked slow-down (0)
[1] One-step method [2] Two-step method

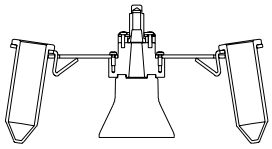
1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)
2) Object carrier will not stand RCF values exceeding 1100

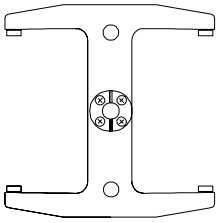
Order no. 4618		1308	1345	1346	1369	1369-91	1369-92	1370	1372
Swing out rotor 8-times 									
		Tubes							
Capacity	ml	50	45	20	15	5	7	9	5
Dimensions ∅ x L	mm	34 x 100	31 x 100	21 x 100	17 x 100	12 x 75	12 x 100	14 x 100	12 x 75
Number p. Frame		1	1	2	4	4	4	10	17
Number p. Rotor		8	8	16	32	32	32	40	136
RPM	RPM	3800	3800	3800	3800	3800	3800	3800	3800
RCF		2732	2906	2780	2669	2669	2780	2780	2605
Radius	mm	172	180	175	168	168	175	175	164
Run-up time (97%)	sec	40	40	40	40	40	40	40	40
Run-down time	sec	40	40	40	40	40	40	40	40
	sec	205	205	205	205	205	205	205	205
Temperature	°C [1]	- 2	- 2	- 2	- 2	- 2	- 2	- 2	- 2

Order no. 4315									
Angle rotor 									
		Reduction							
		---	1446	1447	1451	1451	1448	1449	
		Tubes							
						Sarstedt			
Capacity	ml	85	50	25 ml 30 ml	15	10	10	1,5/2,0	
Dimensions ∅ x L	mm	38 x 106	29 x 107	24 x 100 26 x 95	17 x 100	16,5 x 92	16x 80	Reaction tubes	
Number p. Frame		1	1	1	1	1	2	4	
Number p. Rotor		6	6	6	6	6	12	24	
RPM	RPM	11000	11000	11000	11000	11000	11000	11000	
RCF		13800	13250	12580	12980	12980	12980	13250	
Radius	mm	102	98	93	96	96	96	98	
Run-up time (97%)	sec	65	65	65	65	65	65	65	
Run-down time	sec	65	65	65	65	65	65	65	
	sec	596	596	596	596	596	596	596	
Temperature	°C [1]	0	0	0	0	0	0	0	

braked slow-down (9)
unbraked slow-down (0)

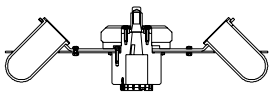
1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)

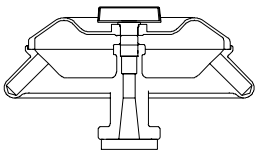
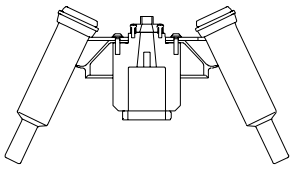
Order no. 4312		E818							
Swing out rotor 									
		Reduction							
		---	1462						
		Tubes							
		Falcon							
Capacity	ml	50	15						
Dimensions ∅ x L	mm	29 x 115	17 x 120						
Number p. Frame		1	1						
Number p. Rotor		12	12						
RPM	RPM	4500	4500						
RCF		4000	4000						
Radius	mm	177	177						
Run-up time (97%)	sec	26	26						
Run-down time	sec	43	43						
	sec	340	340						
Temperature	°C [1]	- 5	- 5						

Order no. 4322		4325							
Swing out rotor 2-times 									
		Frame							
		4326 with Lid 4327	4328 with Lid 4329	4331 with Lid 4332	4333 with Lid 4334	4335	4336	4337	
		Tubes							
Capacity	ml	15	15	15	Hitachi-Racks	LBK-Racks	Microtiter-plates	6	
Dimensions ∅ x L	mm	17 x 100	17 x 120	29 x 115	---	---	---	12 x 82	
Number p. Frame		32	12	8	2	4	3	50	
Number p. Rotor		64	24	16	4	8	6	100	
RPM	RPM	4000	4000	4000	4000	4000	4000	4000	
RCF		2665	2755	2755	2755	2415	2361	2665	
Radius	mm	169	154	154	154	135	132	149	
Run-up time (97%)	sec	38	38	38	38	38	38	38	
Run-down time	sec	45	45	45	45	45	45	45	
	sec	474	474	474	474	474	474	474	
Temperature	°C [1]	- 5	- 5	- 5	- 5	- 5	- 5	- 5	

braked slow-down (9)
unbraked slow-down (0)

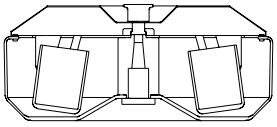
1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)

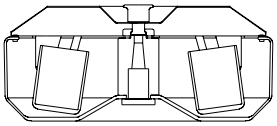
Order no. 4316		Schlenkrohr							
Angle rotor 									
		Reduction							
			4317						
				---					
Capacity	ml	50	25	1,5 - 2,2					
Dimensions ∅ x L	mm	38 x 148,5	24 x 146,5	Reaction tubes 2078					
Number p. Frame		1	1	---					
Number p. Rotor		6	6	30					
RPM	RPM	2000	2000	11000					
RCF		805	783	12715					
Radius	mm	180	175	94					
Run-up time (97%)	sec	17	17	30					
Run-down time	sec	21	21	35					
	sec	286	286	95					
Temperature	°C [1]	- 16	- 16	- 5					

Order no. 4622		Reduction				Order no. 4621	
Angle rotor 			2023	2024		Angle rotor 	
Capacity	ml	1,5 – 2,2	0,5 0,8	0,4			30
Dimensions ∅ x L	mm	Reaction tubes 2078	Reaction tubes Bect.-Dick.	Beckman tubes			Chromium-bath tubes **VK 0508** Skal. 1µl-35µl, 5ml, 30ml **VK 0529** Skal. 10µl-350µl, 15ml, 30ml
Number p. Frame							1
Number p. Rotor		30	30	30			6
RPM	RPM	11000	11000	11000			2000
RCF		12715	12715	12715			917
Radius	mm	94	94	94			205
Run-up time (97%)	sec	30	30	30			17
Run-down time	sec	35	35	35			21
	sec	95	95	95			286
Temperature	°C [1]	- 5	- 5	- 5			- 5

braked slow-down (9)
unbraked slow-down (0)

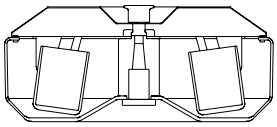
1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)

Order no. 4324		Frame							
Swing out rotor 		5262	5249	5243	5242	5248	5247	5227	5257
		Tubes							
Capacity	ml	100	100	50	25	15	7	6	1,5 – 2,2
Dimensions ∅ x L	mm	44 x 100	40 x 115	34 x 100	24 x 100	17 x 100	12 x 100	12 x 82	Reaction tubes
Number p. Frame		1	1	2	5	12	20	20	40
Number p. Rotor		4	4	8	20	48	80	80	160
RPM	RPM	6000	6000	6000	6000	6000	6000	6000	6000
RCF		6440	6440	6480	6480	6480	6480	6520	4669 / 6641
Radius	mm	160	160	161	161	161	161	162	166 / 165
Run-up time (97%)	sec	95	95	95	95	95	95	95	95
Run-down time	sec	165	165	165	165	165	165	165	165
	sec	935	935	935	935	935	935	935	935
Temperature	°C [1]	3,5	3,5	3,5	3,5	3,5	3,5	3,5	3,5

Order no. 4324		Frame							
Swing out rotor 		5281	5266	5258	5265	5247	5264	5277	
		Tubes							
			Frames for Sarstedt						
Capacity	ml	1,5-2,2	25	9-12	5	4,5 – 5	3,2 – 6	2 – 4	
Dimensions ∅ x L	mm	Reaction tubes	25 x 92	16,5 x 92	16,5 x 57	11,5 x 92	15,3 x 57	11,5 x 66	
Number p. Frame		16	5	11	11	20	12	20	
Number p. Rotor		64	20	44	44	80	48	80	
RPM	RPM	6000	6000	6000	6000	6000	6000	6000	
RCF		6118	6480	6480	6721	6480	6520	6520	
Radius	mm	152	161	161	167	161	162	162	
Run-up time (97%)	sec	95	95	95	95	95	95	95	
Run-down time	sec	165	165	165	165	165	165	165	
	sec	935	935	935	935	935	935	935	
Temperature	°C [1]	3,5	3,5	3,5	3,5	3,5	3,5	3,5	

braked slow-down (9)
unbraked slow-down (0)

1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)

Order no. 4324		Framee für Vacutainer, Falcon, Corning						
Swing out rotor 		5259	6306	5248	5264	6301	5268	5267
		Tubes						
		Tubes						
		Falcon						
Capacity	ml	50	15	12	8	7	5	2
Dimensions ∅ x L	mm	29 x 116	17 x 120	15,5 x 105	15,5 x 81	12 x 105	12 x 81	10 x 52
Number p. Frame		2	7	12	12	12	12	20
Number p. Rotor		8	28	48	48	48	48	80
RPM	RPM	6000	6000	6000	6000	6000	6000	6000
RCF		6541	6802	6480	6520	6480	6601	6440
Radius	mm	165	169	161	162	161	164	160
Run-up time (97%)	sec	95	95	95	95	95	95	95
Run-down time	sec	165	165	165	165	165	165	165
	sec	935	935	935	935	935	935	935
Temperature	°C [1]	3,5	3,5	3,5	3,5	3,5	3,5	3,5

Standard-centrifuge containers of glass will not stand RCF values exceeding 4000 (DIN 58970 Part 2)

braked slow-down (9)
unbraked slow-down (0)

1) The lowest possible temperature during the highest revolutions and 1 hour running time (only in a cooled centrifuge)

31 Service

01.02

Europa / Europe		**☎ / FAX / E-mail**
D / Deutschland	Hettich Service Gartenstr. 100 D – 78532 Tuttlingen	07461 705 112 / 705 185 07461 705 125 Hr. Crombach, Hr. Platzer Info@HettichLab.com
B / Belgique/ België	Dèpex B.V. Leuvenselaan 172-2 B – 3300 Tienen	0032 16 823687 0032 16 823569 info@depex.com www.depex.com/ www.depex.nl/ www.depex.be
DK / Danmark	Hettich Labinstrument ApS Hvidovrevej 274 DK - 2650 Hvidovre	
SF / Suomi	ORIOLA OY Prolab Orionintie 5 / P.O. Box 8 SF – 02200 Espoo	00358 9 42999 00358 9 4293117 ilari.vaalavirta@oriola.fi www.oriola.fi
F / France	ODIL SA 3 rue Pierre Gauthier F-10002 Troyes Cedex	0033 3 8056 5232 0033 3 8058 1677 odil21@aol.com
	Fisher Scientific S.A. 12, rue Gay Lussac BP 2 F-78990 Elancourt Cédex	0033 1 30132400 0033 1 30132424 ventes@fr.fishersci.com
GR / Hellas / Grèce	Pascal E. Strouza S.A. 42, Karaiskaki St. GR-143 43 N.Chalkidona - Athens	0030 1 08547774 0030 1 08547041 ps@pascalstrouza.gr
GB / Great Britain (without Northern Ireland)	Sartorius Limited Longmead Business Centre Blenheim Road GB – Epsom, Surrey KT19 9QN	0044 1 3727 37102 0044 1 3727 20799 a.hack@sartorius.co.uk

		☎ / FAX / E-mail
IRL / Ireland	Lennox Laboratory Supplies Ltd. P.O. Box No. 212 A J.F. Kennedy Drive, Naas Rd. IRL – Dublin 12	00353 1 455 2201 00353 1 450 7906 sales@lennoxlabs.com www.lennoxlabs.com
	Mason Technology Thomas H. Mason & Sons Ltd. 228 South Circular Road IRL – Dublin 8	00353 1 453 44 22 00353 1 415 44 92 sc@masontec.ie
I / Italia	SENECO S.R.L. Via M. Prestinari, No. 4 I – 20158 Milano	0039 2 39313031 0039 2 39313044 Info@seneco.it / senes2@iol.it www.seneco.it
HR / Hrvatska	JOS Instrumenti d.o.o. Instrumenti Rebar 24 HR - 10000 Zagreb	00385 1 234 6567 00385 1 234 7867 jos-instrumenti@zg.tel.hr
	META-LAB III Ravnice 29 HR - 10000 Zagreb	00385 1 230 0497 00385 1 230 0498 META-LAB@ZG.TEL.HR
M / Malta	Vivian Commercial Corp. Ltd Sanitas Bldg.Tower Street M-Msida MSD 06	00356 344 610 00356 341 087 vc@vol.net.mt www.vivian.com
NL / Nederland	Dépex B.V. Nieuweweg 224 NL – 3905 LT Veenedaal	0031 318 547234 0031 318547199 laboratory@depex.com www.depex.com / www.depex.nl / www.depex.be
N / Norge	Dipl. ing. HOUM AS Boks 83 Gretsen N-0409 Oslo	0047 2209 4000 0047 2209 4040 firmapost@houm.no

		☎ / FAX / E-mail
A / Österreich / Austria	GLINIK GmbH Diagnostik- und Laborbedarf Laudonstraße 39 A – 9020 Klagenfurt	0043 463 41675 0043 463 4167515 glinik@happynet.at
	Fischerlehner & Kucera & Co.KG Andreas Hofer Str. 3 A – 6020 Innsbruck	0043 512 582 083 0043 512 582 08320 g.rudigier@tirol.com
	Josef Gratzl Medizintechnik Wilhelmfeldstr. 30 A-4060 Linz-Leonding	0043 732 387 334 0043 732 387 33430 office@gratzl-medizintechnik.com
	Laborpartner Laborbedarf Handelsges.m.b.H. Linzer Str. 451A A-1140 Wien	0043 1 576 600 0043 1 576 6020 info@laborpartner.at www.laborpartner.at
	Merck Eurolab Ges.mbH Zimbagasse 5 A-1147 Wien	0043 1 576 000 0043 1 557 3370 merck-wien@merck.at www.merckeurolab.at
PL / Polen	Labo Baza sc ul. Topolowa 5, Jelonek k/Poznania PL-62-002 Suchy Las	0048 618 125 745 0048 618 125 725 info@pl.fishersci.com www.pl.fishersci.com
	Spectro-Lab ul. Motokowska 51/53 PL-00-542 Warszawa	0048 22 675 2567 0048 22 811 9818 spectlab@pol.pl
	S. Witko ul. Pilsudskiego 143/A2 PL-92-332 Lódz	0048 42 676 3435 0048 42 676 3443 info@witko.com.pl
P / Portugal	LaboControle Lda. Largo Prof. Fernando Fonseca 5 B P-2795 Linda-a-Velha	00351 21 419 7945 00351 21 415 1430 email@labocontrole.pt www.labocontrole.pt
	Dario Correia Lda. Rua Duque del Pamela 25-2° P-1250-097 Lisboa	00351 21 351 3490 00351 21 351 3499 dariocorreia@mail.telepac.pt

		☎ / FAX / E-mail
S / Sverige	Hettich Labinstrument AB Nyponvägen 2 S-19144 Sollentuna	0046 8 7520030 0046 8 7520390 tommy.engstrom@hettichlabinstrument.se www.hettichlabinstrument.se
CH / Schweiz / Suisse	Hettich AG Seestr. 204a CH – 8806 Bäch	0041 1 786 8020 0041 1 786 8021 mail@hettich-ag.ch www.hettich-ag.ch
E / Espãna	AFORA S.A. Aribau 240 E – 08006 Barcelona	00349 3 306 9800 00349 3 241 4323 marketing@afora.com www.afora.com
	GENESYS Instrumentacion S.L. Almedro 4 E-28820 Coslada / Madrid	00349 1 674 1022 00349 1 669 7711 genesys@moebius.es www.moebius.es/genesys
CZ / Czech. Republic	Schoeller Pharma Prague s.r.o. Kyjovska 1984/3 CZ-14200 Praha 4	00420 2 6171 1765/66 00420 2 4447 0745 info@pharma.cz / servis@pharma.cz www.pharma.cz
TR / Turkey	Kutay Laboratuar Cihazlari Tic. A.S. Kovacilar Caddesi 9/2 TR – 34230 Fatih Istanbul	0090 2 125323436 0090 2 125313820 kutaydis@superonline.com
H / Hungary	EUROLAB Kft. Hungaria krt. 109 H – 1143 Budapest	0036 1 363 1459 0036 1 252 9962 Hr. Nastev
CY / Cyprus	Medisell Co. Ltd. P.O. Box 28318 CY – 2093 Strovolos / Lefkosia	00357 2 494300 00357 2 311362 info@medisell.com.cy

		☎ / FAX / E-mail
North and South America		
RA / Argentina	Proveeduria Medica S.R.L. Humberto 1° 2011/13 RA – 1229 Buenos Aires	0054 1 9415491 0054 1 9415575 pmed@promail.com.ar
	La Quimica Quirurgica S.A.C.I. Saavedra 247 RA – 1083 Buenos Aires	0054 114 953 9500 0054 114 952 6593 laqq@relay2.impsat1.com.ar www.laqq.com
BR / Brazil	Merck S.A. Ind. Quimicas Estr. dos Bandeirantes 1099 BR-22710-571 Rio de Janeiro	005521 444 2281 005521 444 2132 veriss@merck.com.br www.merck.com.br
	UNISCIENCE do Brasil Ltda.Av. Candido Portinari 933/937 BR-05114-001 Sao Paolo SP	0055 11 3622 2320 0055 11 3622 2323 sergio.joelsons@uniscience.com www.uniscience.com
RCH / Chile	Merck Química Chilena, Soc. Ltda. Casilla 48-D RCH-Santiago de Chile	0056 2 340 0320 0056 2 340 0259 e.sebik@merck.cl www.merck.cl
C / Cuba	Merck Centroamericana S.A. R. Nautico 3a A no. 15209 e/152 y 154 C-Habana	0053 7 337 645 0053 7 287 686 galano@ip.etecsa.cu
EC / Ecuador	Merck Ecuador C.A. Casilla 2574 EC-Quito	00593 2 981 677 00593 2 981 644 jlarrea@merck.com.ec

		☎ / FAX / E-mail
GCA / Guatemala	Merck Centroamericana S.A. Km 13.5 Carretera Roosevelt Apartado 1651 GCA-Ciudad de Guatemala	0050 2 592 2111 0050 2 594 2954 julio.lujan@merck.com.gt
CO / Colombia	Schott Colombiana S.A. Avendia 22 No. 39-71 Bogotá D.C	0057 1 335 0100 0057 1 368 3223 schott-co@schott.com.co
MEX / México	Comerzializadora en Diagnóstico y Analítica S.A. de C.V. Primera Cerrada de Alfalfares No. 6 Col. Granjas Coapa, Deleg. Tlalpan MEX – 14330 México, D.F.	0052 5 603 4700 0052 5 673 3743 dayana88@.df1.telmex.com.mx
	Schott Mexicana S.A. de C.V. Col. Santa Catarina Coyoacán Av. Mig. Angel de Quevedo 496 B MEX – 04010 México, D.F.	0052 5 554 1295 0052 5 658 8592 jldj@mxmex.schott.net
PE / Peru	Merck Peruana S.A. Ate-Vitarte, Av. Los Frutales #220 Casilla 4331 PE-Lima 1	0051 1 437 5427 0051 1 437 2955 m.schoenfeld@merck.com.pe/ rtisza@merck.com.pe
CDN / Canada	ESBE Scientific 80 McPherson St. CDN – Markham, Ont. L3R 3V6	001 905 4758232 001 905 4755688 dhamilto@esbe.com www.esbe.com
U.S.A	REVPRO Inc. 99 Willenbrock Road USA - 06478 Oxford, CT	001 203 267 4600 001 203 267 4606 prosci@aol.com
	HELMER 15425 Herriman Boulevard USA-Noblesville, IN 46060	001 800 743 5637 001 317 773 9082 service@helmerinc.com

		☎ / FAX / E-mail
YV / Venezuela	Celtek Tecnologias C.A. Edificio Versalles 3° Avenida de los Palos Grandes YV-1060A Caracas	0058 212 285 2590 0058 212 283 6672 rosales@celtek.com.ve www.celtek.com.ve
	Laboratorios Dai, C.A. Edif. Frangiu La Trinidad, Edo. Miranda Calle Bolivar, #27 YV-1080 Caracas	0058 212 945 6903 0058 212 945 7964 labdai@telcel.net.ve
Africa		
ET / Egypt	DELTA Scientific Service 14, Faculty of Medicine Street ET – Ramleh Station, Alexandria	00203 48 46 156 00203 48 71 489 dss@cns-egypt.com
ZA / South Africa Botswana, Lesotho. Namibia, Swaziland, Zimbabwe	Labotec Pty. Ltd. P.O. Box 6553 Halfway House 1685 ZA – Johannesburg, R.S.A.	0027 11 3155434 0027 11 3155882 sales@labotec.co.za
Australia and Asia		
AUS / Australia	HD Scientific Supplies Pty. Ltd. P.O.Box 6044 AUS – Blacktown Business Centre N.S.W. 2148	0061 29 6216955 0061 29 6712293 hdscient@hdscientific.com.au
BRN / Bahrain	General Medicals W.L.L P.O. Box 56 BRN – Manama	00973 727 600 00973 728 274 intercpd@batelco.com.bh
PRC / China	Hua Yue Enterprise 26/F Taikang Cheng Square No. 111, Taikang Road 510115 Guangzhou	0086 20 83221308 0086 20 83220408 infm@huayueco.com www.huayueco.com
HK / Hong Kong	Hua Yue Enterprise Rm. 1613A, 16/F Park-In Comm. Centre 56 Dundas Street Mong Kok, Kowloon, Hong Kong	00852 2770 3628 00852 2751 1904 huayuehk@netvigator.com www.huayueco.com

		☎ / FAX / E-mail
IND / India	Care Biomedicals CB-House, Shrinath-I Jaydeep Nagar, Bhandup (E) IND-Mumbai 400 042	0091 22 562 3150 0091 22 562 3149 carebio@vsnl.com
	Wheecon Instruments In. 95, III Street, Karpagam Avenue R.A. Puram Chennai 600 028	0091 44 493 92 74 0091 44 494 07 68 wheecon@giasmd01.vsnl.net.in
RI / Indonesia	P.T. Transindotama Sinar Perkasa Perkantoran Plaza Pacific Blok A4 No. C83&C85 Jl. Raya Barat Blvd. (Samping Makro) Kelapa Gading Permai RI – Jakarta 14240	0062 21 45840670 0062 21 45840675 transit@dnet.net.id
IRQ / Irak	Karl Kolb KG Im Steingrund 3 D-63303 Dreieich	06103 6030 06103 603101 karlkolb@t-online.de
IR / Iran	Parsel Co. Ltd. No. 90, Ramsar Street Enghelab-E-Eslami Ave. P.O. Box 14155-1944 IR – 15819 Tehran	0098 21 830 4791-2 0098 21 830 4788 pars.ir3@www.dci.co.ir
IL / Israel	Lemico Instrumentation (1988) Ltd. P.O. Box 662/2 Haprat Str. IL-Yavne 81106	00972 8 932 2444 00972 8 932 2252 lemico@netvision.net.il
JOR / Jordan	A.M.S.A.-Arab Medical and Scientific Alliance P.O. Box 208 JOR – Amman 11118	00962 6 552 8009 00962 6 553 2358 amsa@ads.com.jo
KWT / Kuwait	Al-Essa Medical & Scientific Equipment Co. W.L.L. P.O. Box 3562 KWT-Safat 13036	00965 483 3051 00965 245 6386 alessa@ncc.moc.kw
RL / Lebanon	Bioteck S.A.L. Jal EL-Dib Oscar Center P.O. Box 60-247 RL-Beirut	00961 4 713 410 00961 4 721 164 bioteck@-net.com.lb

		☎ / FAX / E-mail
SUL / Oman	Ebin Rushed Pharmacy Co. LLC P.O. Box 169 SUL-Muscat 113	00968 793 741 00968 701 547 erplssb@gto.net.om
AAP/ Palestine	SITTCO - Medipharm Palestine St. 48/P.O. Box 3 AAP-Nablus – West Bank	00972 9 238 7421 00972 9 238 7422 haytham@sittco.com
RP / Philippines	Levin's International Corp. 3rd floor, Syuco Building 993 E de los Santos Ave. Araneta P.O. Box 136, Cubao RP – Quezon City	0063 2 371 3656 0063 2 371 3645 levinspi@skyinet.net
SA / Saudi Arabia	Saudi (Overseas) Marketing & Trading Company – Somatco Al-Asseel Centre, Dhabab Str. P.O. Box 1951 SA-Riyadh 11441	00966 1 402 5727 00966 1 405 5248 somatco@somatco.com www.somatco.com
SYR / Syria	Abboud Trade Co. P.O. Box 10971 SYR – Damascus	00963 11 231 4327 00963 11 231 2339
RC / Taiwan	SUNWAY SCIENTIFIC Corp. 2F/No. 169-15 Changan E. Road Sec. 2 RC-Taipei	00886 2 2771 8337 00886 2 2741 4646 hettich@mail.sun-way.com.tw www.sun-way.com.tw
VAE	Gulf Drug Establishment P.O. Box 3264 332/5 Al Wasl Road VAE – Dubai	00971 4 345 0163 00971 4 345 0917 gulfdrug@emirates.net.ae
T / Thailand	Becthai Bangkok Equipment & Chemical Co., Ltd. 308/1 Phaholyothin Road, Phayatai T – Bangkok 10400	0066 2 615 2130-44 0066 2 2714 533-34 becthai@ksc7.th.Com www.becthai.th.com
YE / Yemen	AL-Mudafar Med. & G.T. Corp. Zubairy Street P.O. Box 2595 ADN / Sana´a	00967 1 20 49 32 00967 1 30 49 33 Mudafar@y.net.ye

BD Onclarity™ HPV Assay

CE IVD REF 442946

8089899(11)

2019-05

English

Table of Contents

INTENDED USE 3
WARNING 3
SUMMARY AND EXPLANATION OF THE TEST 3
PRINCIPLES OF THE PROCEDURE 4
REAGENTS 4
WARNING AND PRECAUTIONS 8
Specimen 9
Assay/Reagent 9
STORAGE AND HANDLING REQUIREMENTS 10
Reagents and Materials Provided 10
Materials Required But Not Provided 10
Specimen Collection and Transport 11
Specimen Transfer to BD Onclarity HPV LBC Diluent Tubes 11
CERVICAL BRUSH SPECIMEN COLLECTION 11
QUALITY CONTROL 12
General QC Information for the BD Viper LT System 12
INSTRUCTIONS FOR USE 12
Quality Control Preparation 12
Processing Procedure For All Specimens 12
Pre-Warm Procedure 12
Test Procedure 13
INTERPRETATION OF TEST RESULTS 13
Interpretation of Quality Control Results 15
Monitoring for the Presence of DNA Contamination 15
PROCEDURAL LIMITATIONS 15
BD Onclarity Assay Clinical Study Design with SurePath Liquid Cytology Specimens 16
PERFORMANCE CHARACTERISTICS 17
Clinical Performance-SurePath 17
Baseline Phase 17
Follow-Up Phase 17
STUDY DESIGN TO DEMONSTRATE CLINICAL SENSITIVITY AND SPECIFICITY FOR SCREENING PATIENTS WITH ASC-US CYTOLOGY RESULTS TO DETERMINE THE NEED FOR REFERRAL TO COLPOSCOPY 17
STUDY DESIGN TO DEMONSTRATE CLINICAL PERFORMANCE OF THE BD ONCLARITY HPV ASSAY AS AN ADJUNCT TO CERVICAL CYTOLOGY IN WOMEN ≥ 30 YEARS 18
STUDY DESIGN TO DEMONSTRATE CLINICAL PERFORMANCE OF THE BD ONCLARITY HPV ASSAY AS A FIRST-LINE PRIMARY TEST FOR CERVICAL CANCER SCREENING 18
Performance Characteristics in the ASC-US Population (≥ 21 years) 18
NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY (NILM) 21
NILM (≥30 years) Population 21
NILM (≥30 years) Population-Performance Evaluation 21

PRIMARY SCREENING POPULATION (≥ 25 years) 23
Screening Algorithms 23
Baseline Risk of Disease for Women with NILM Cytology and Negative BD Onclarity HPV Test Results 24
Performance in Unvaccinated and Vaccinated Women 25
Comparison of Results from the BD Onclarity HPV Assay for PreQuot vs PostQuot BD SurePath Clinical Samples 26
Clinical Performance-PreservCyt and BD Onclarity HPV Cervical Brush specimens 27
Analytical Performance 29
Cross-Reactivity 30
Interfering Substances 31
Competitive Target Interference 32
Reproducibility 32
Cross Contamination 33
Neat (In-vial) Specimen Stability 33
Diluted Specimen Stability 33
Post Pre-warm Specimen Stability 34
REFERENCES 34

BD Onclarity™ HPV Assay

CE IVD REF 442946

8089899(11)
2019-05
English

#1.1, 1.2

1.1 **INTENDED USE**

The BD Onclarity™ HPV Assay is an amplified DNA test for the qualitative detection of high risk types of human papillomavirus (HPV). The assay detects all high risk HPV types (16,18,31,33,35,39,45,51,52,56,58,59,66 and 68) and provides the capability for individually genotyping six high risk types (HPV 16,18,31,45,51 and 52) and three genotype groups (33/58, 35/39/68 and 56/59/66). Cervical specimens that are tested with the BD Onclarity HPV Assay include the BD Onclarity HPV Cervical Brush Collection Kit, BD SurePath™ vial, and PreservCyt® Solution (using an aliquot that is removed prior to or after processing for either the BD SurePath or ThinPrep® Pap test). The BD Onclarity HPV Assay is performed with the BD Viper™ LT System.

The BD Onclarity HPV Assay is indicated with use of BD SurePath vial, and PreservCyt Solution:

a. In women with ASC-US (atypical squamous cells of undetermined significance) cervical cytology test results, the BD Onclarity HPV Assay can be used to detect high-risk HPV genotypes 16,18,31,33,35,39,45,51,52,56,58,59,66 and 68. This information together with physician's assessment of screening history, other risk factors, and professional guidelines, may be used to guide patient management. The results of this test are not intended to prevent women from proceeding to colposcopy.

b. The BD Onclarity HPV Assay can be used together with cervical cytology to adjunctively screen to detect high risk HPV types 16,18,31,33,35,39,45,51,52,56,58,59,66 and 68. This information, together with the physician's assessment of screening history, other factors, and professional guidelines, may be used to guide patient management.

1.1 c. The BD Onclarity HPV Assay can be used as a first-line primary cervical cancer screening test to detect high risk HPV types 16,18,31,33,35,39,45,51,52,56,58,59,66 and 68. Women who test negative for the high risk HPV types by the BD Onclarity HPV Assay should be followed up in accordance with the physician's assessment of screening and medical history, other risk factors, and professional guidelines. This information, together with the physician's assessment of screening history, other factors, and professional guidelines, may be used to guide patient management.

WARNING

The BD Onclarity HPV Assay is NOT intended:

- For use in determining the need for treatment (i.e. excisional or ablative treatment of the cervix) in the absence of high-grade cervical dysplasia.
- For women who have undergone hysterectomy.
- For use with samples other than those collected by a clinician using an endocervical brush/spatula combination or broom and placed in the BD SurePath vial or PreservCyt Solution or BD Onclarity HPV Cervical Brush Collection Kit.

HPV-negative cancers of the cervix do occur in rare circumstances.[1,2] Also, no cancer screening test is 100% sensitive. Use of this device for primary cervical cancer screening should be undertaken after carefully considering the performance characteristics put forth in this label, as well as recommendations of professional guidelines.

The use of this test has not been evaluated for the management of women with prior ablative or excisional therapy, or who are pregnant.

SUMMARY AND EXPLANATION OF THE TEST

There are more than 100 different genotypes of human papillomavirus (HPV), of which 14 are considered high-risk for cervical cancer and its precursor lesions. It is one of the most common sexually transmitted viruses in the world: nearly all sexually active men and women will get HPV at some point in their lives.[3] According to the World Health Organization (WHO), cervical cancer is the fourth largest contributor to female cancer mortality worldwide, claiming an estimated 270,000 lives annually.[4] It is estimated that in 2017 there were 12,820 cases of cervical cancer and 4,210 deaths in the United States, which correspond, respectively, to an age-adjusted rate of 7.4 and 2.3 per 100,000 women, annually.[5] In many cases, HPV infections are transient, and the body will clear the virus on its own.

HPV is a double-stranded DNA virus with a circular genome of approximately 8,000 base pairs and encodes 8 open reading frames (ORFs). Its ORFs are divided into early and late genes involved in replication (i.e. E1 and E2) and packaging (i.e. L1 and L2) with the remaining genes (E6, E7, E5, and E4) playing roles in driving cell cycle entry, immune evasion, and virus release.[6] A persistent infection of one of the fourteen sexually transmitted HPV genotypes considered high risk (genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) can lead to the development of cervical cancer and its precursor lesions.[7]

The identification of the HPV virus' relationship to cervical cancer disease has resulted in a rich volume of scientific activity in this field. These activities range from the development of therapeutic vaccines designed to prevent infection with HPV viruses to in vitro diagnostic tests for use as aids in cervical cancer screening and clinical patient management. Today, Pap tests can inform a clinician if there are changes to the cervical cells. If those cells are abnormal, an HPV test may be done to determine if those cervical changes are due to a high risk strain of HPV which can lead to cervical cancer. Not all molecular assays can distinguish among the different types of HPV. The BD Onclarity HPV Assay detects HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68 and allows simultaneous, discrete identification of the high-risk types 16, 18,31,45,51 and 52.

The clinical performance of the BD Onclarity HPV Assay when using PreservCyt Solution as a sample type in cervical disease screening paradigms has been investigated in multiple published studies.[8-15]

PRINCIPLES OF THE PROCEDURE

The BD Onclarity HPV Assay is based on two major processing steps: 1) automated specimen preparation to homogenize the matrix, lyse cells, and extract cellular DNA; and 2) PCR amplification of target DNA sequences using primers and fluorescently-labeled detector probes for both HPV and human beta globin. Human beta globin amplification and detection is included in the BD Onclarity HPV Assay to differentiate HPV negative specimens from those that do not exhibit HPV signal due to insufficient cell mass in the specimen. The human beta globin serves as an internal control of the entire test by concurrently assessing specimen processing, extraction, and amplification. The BD Onclarity HPV Assay uses HPV target regions for primers and probes (E6/E7 oncogenes) that provide robust detection of HPV genotypes reducing the potential risk for lack of detection due to nucleic acid deletions and/ or mutations.[16-18]

The automated specimen preparation for the BD Onclarity HPV Assay is completed by the BD Pre-Warm Heater and the BD Viper LT System. Cervical specimens are extracted using BD FOX™ Extraction to release cellular DNA. The purified cellular DNA solution from each extracted specimen is transferred into PCR tubes containing reagents which are then sealed to prevent contamination.

The BD Onclarity HPV Assay reagents are dried in three individual PCR tubes that are capable of detecting 14 high risk HPV genotypes and a specimen-derived internal control consisting of a fragment of DNA from the human beta globin gene. These genotypes are reported either individually (16, 18, 31,45, 51, 52) or as a genotype group (33/58, 59/56/66, and 35/39/68). Each of the three PCR tubes contains specific oligonucleotide sets to detect HPV genotype DNA and an oligonucleotide set to detect a region of the human beta globin gene.

The BD Onclarity HPV Assay uses real-time PCR technology.[19] The detection of the target DNA is accomplished using TaqMan DNA probes that include a fluorescent dye at the 5' end and a quenching molecule at the 3' end of the oligonucleotide. The BD Onclarity HPV Assay utilizes fifteen probes labeled with one of four fluorescent dyes. Each dye is paired with one of two Black Hole Quencher molecules (BHQ® Dye). Fluorescent detection of amplification occurs in four separate optical channels on the BD Viper LT System.

REAGENTS

BD Onclarity HPV Assay Reagent Pack (192 tests) Cat # 442946			
Components	**Quantity per kit**	**Ingredients**	**Safety and Warnings**
BD Onclarity G1 PCR tubes	2 x 96 tests	Tris Buffer Magnesium Acetate Glycerol Trehalose < 0.75% Upstream and downstream HPV primers < 0.06% Upstream and downstream beta-globin primers < 0.37% Fluorescent-labeled HPV probes < 0.12% Fluorescent-labeled beta-globin probes < 1.97% Hot Gold Star polymerase (microbial)	**N/A**

BD Onclarity HPV Assay Reagent Pack (192 tests) Cat # 442946			
Components	**Quantity per kit**	**Ingredients**	**Safety and Warnings**
BD Onclarity **G2 PCR tubes**	2 x 96 tests	Tris Buffer Magnesium Acetate Glycerol Trehalose < 1.00% Upstream and downstream HPV primers < 0.06% Upstream and downstream beta-globin primers < 0.62% Fluorescent-labeled HPV probes < 0.12% Fluorescent-labeled beta-globin probes < 1.97% Hot Gold Star polymerase (microbial)	**N/A**
BD Onclarity **G3 PCR tubes**	2 x 96 tests	Tris Buffer Magnesium Acetate Glycerol Trehalose < 1.00% Upstream and downstream HPV primers < 0.06% Upstream and downstream beta-globin primers < 0.50% Fluorescent-labeled HPV probes < 0.12% Fluorescent-labeled beta-globin probes < 1.97% Hot Gold Star polymerase (microbial)	**N/A**

Control Set for the BD Onclarity HPV Assay (24 sets) Cat #441993			
Components	**Quantity per kit**	**Ingredients**	**Safety and Warnings**
BD Onclarity HPV Positive Control	24 x 0.05 mL	< 1.178% Nonspecific DNA (biological) < 0.077% Non-infectious plasmid DNA (microbial) containing HPV-16, 18, 56 sequences < 0.013% Non-infectious plasmid DNA (microbial) containing human beta-globin sequence	**N/A**
BD Onclarity HPV Negative Control	24 x 0.05 mL	< 1.182% Nonspecific DNA (biological)	**N/A**

BD Onclarity HPV Cervical Brush Device (CBD) Diluent Cat # 441991			
Components	**Quantity per kit**	**Ingredients**	**Safety and Warnings**
Cervical Brush Device Specimen (CBD) Diluent	100 x 2.2 mL	< 0.9% Detergent < 0.05% Proclin < 4.0% Tris HCl < 5.0% Tris Base < 1.5% Sodium Chloride	 **WARNING** **H315** Causes skin irritation. **H320** Causes serious eye irritation. **H335** May cause respiratory irritation. **P261** Avoid breathing dust/fume/gas/mist/vapors/spray. **P280** Wear protective gloves/ protective clothing/ eye protection/ face protection. **P264** Wash thoroughly after handling. **P271** Use only outdoors or in a well-ventilated area. **P304+P340** IF INHALED: Remove person to fresh air and keep comfortable for breathing. **P332+P313** If skin irritation occurs: Get medical advice/attention. **P305+P351+P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **P302+P352** IF ON SKIN: Wash with plenty of soap and water. **P337+P313** If eye irritation persists: Get medical advice/attention. **P403+P233** Store in a well-ventilated place. Keep container tightly closed. **P501** Dispose of contents/ container in accordance with local/ regional/ national/ international regulations. The BD Onclarity HPV CBD Diluent Tube should be stored upright at 2–25 °C.

BD Onclarity HPV Liquid Based Cytology Specimen (LBC) Diluent (400 tubes) Cat # 442840			
Components	**Quantity per kit**	**Ingredients**	**Safety and Warnings**
Liquid Based Cytology Specimen (LBC) Diluent	400 x 1.7 mL	< 0.9% Detergent < 0.05% Proclin < 4.0% Tris HCl < 5.0% Tris Base < 1.5% Sodium Chloride	 **WARNING** **H315** Causes skin irritation. **H320** Causes serious eye irritation. **H335** May cause respiratory irritation. **P261** Avoid breathing dust/fume/gas/mist/vapors/spray. **P280** Wear protective gloves/ protective clothing/ eye protection/face protection. **P264** Wash thoroughly after handling. **P271** Use only outdoors or in a well-ventilated area. **P304+P340** IF INHALED: Remove person to fresh air and keep comfortable for breathing. **P332+P313** If skin irritation occurs: Get medical advice/attention. **P302+P352** IF ON SKIN: Wash with plenty of soap and water. **P305+P351+P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **P403+P233** Store in a well-ventilated place. Keep container tightly closed. **P337+P313** If eye irritation persists: Get medical advice/attention. **P501** Dispose of contents/ container in accordance with local/ regional/ national/ international regulations. The BD Onclarity HPV LBC Diluent Tube should be stored upright at 2–25 °C.

BD FOX PCR Extraction Tubes (384 tubes) Cat # 444187			
Components	**Quantity per kit**	**Ingredients**	**Safety and Warnings**
BD FOX PCR Extraction Tubes	48 x 8	Iron Oxide in dissolvable film	**N/A**

BD Viper PCR Extraction Reagent Trough with Piercing Tool (96 tests) Cat# 442841			
Components	**Quantity per kit**	**Ingredients**	**Safety and Warnings**
PCR Extraction Reagent Trough with Piercing Tool	96 tests	Sodium Phosphate, Monobasic Proclin 300 < 0.109% Detergent < 22.0% Sulfuric Acid < 38.0% Potassium Hydroxide < 0.3% Tris Base < 2.9% Tris HCl	 **DANGER** **H302** Harmful if swallowed. **H314** Causes severe skin burns and eye damage. **H318** Causes serious eye damage. **H350** May cause cancer. **P260** Do not breathe dusts or mists. **P270** Do not eat, drink or smoke when using this product. **P280** Wear protective gloves/ protective clothing/ eye protection/ face protection. **P264** Wash thoroughly after handling. **P201** Obtain special instructions before use. **P202** Do not handle until all safety precautions have been read and understood. **P301+P312** IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. **P305+P351+P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **P310** Immediately call a POISON CENTER or doctor/physician. **P303+P361+P353** IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. **P304+P340** IF INHALED: Remove person to fresh air and keep comfortable for breathing. **P308+P313** If exposed or concerned: Get medical advice/attention. **P301+P330+P331** IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. **P321** Specific treatment (see on this label). **P363** Wash contaminated clothing before reuse. **P405** Store locked up. **P501** Dispose of contents/ container in accordance with local/ regional/ national/ international regulations.

WARNING AND PRECAUTIONS

1. For *In Vitro* Diagnostic Use.
2. For warnings, precautions and cleaning procedures related to automated instrumentation, consult the BD Viper LT System User's Manual.
3. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions"[20-22] and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids. For additional specific warnings, cautions and notes specific to the BD Viper LT, consult the BD Viper LT System User's Manual.

#1.1, 1.2

1.1

Specimen

4. Cervical specimens that may be tested with the BD Onclarity HPV Assay include the BD Onclarity HPV Cervical Brush Collection Kit, BD SurePath vial (using an aliquot that is removed prior to or after processing with the BD SurePath Pap test) and PreservCyt Solution (using an aliquot that is removed prior to or after processing for the ThinPrep Pap test).
5. Optimal performance of the BD Onclarity HPV Assay requires proper specimen collection, handling and testing within the expiration dating of the BD Onclarity HPV LBC Diluent tube.
6. For liquid-based cytology specimens, use only the BD Onclarity HPV LBC Diluent tubes.
7. For cervical brush specimens, use only the BD Onclarity HPV Cervical Brush Collection Kit.
8. To reduce unnecessary bleeding, do not over-rotate the cervical brush during specimen collection.
9. When breaking the shaft of the cervical brush, take care to avoid splashing, spilling, or creating aerosols. Avoid contamination of the cervical brush head.
10. Do not test the BD Onclarity HPV Cervical Brush Diluent tube if received in the laboratory without the brush present. A false negative test result may occur.
11. Proper labeling should accompany each specimen to the laboratory.
12. Take care to avoid cross-contamination during the specimen handling steps. Ensure that specimen containers do not contact one another, and discard used materials without passing over open containers. If gloves come in contact with specimen, change gloves to avoid contamination.
13. Under- or over-dispensing of LBC specimen into the BD Onclarity HPV LBC Diluent tube may affect assay performance. Over filling the tubes may also result in liquid overflow on the BD Viper LT deck, and could cause contamination.
14. Use only polypropylene aerosol-resistant pipette tips to transfer specimens to the BD Onclarity HPV LBC Diluent tubes.
15. For automated transfer, only the BD Totalys™ MultiProcessor should be used to transfer BD SurePath LBC specimens to the BD Onclarity HPV LBC Diluent tubes.

Assay/Reagent

16. Use only sample and control tubes with pierceable caps on the BD Viper LT System. Do not remove pierceable caps prior to running the instrument. Be sure to replace any punctured pierceable caps with new pierceable caps prior to running the instrument.
17. Do not interchange or mix kit reagents from kits with different lot numbers.
18. Reagent pouches containing unused PCR tubes MUST be carefully resealed after opening. Verify that desiccant is present prior to resealing the reagent pouches.
19. Use only the BD Viper LT pipette tips as supplied by BD with the BD Viper LT System.
20. Use only the BD Viper LT Clear Plate Sealers on the PCR tubes with the BD Viper LT System.
21. The PCR tubes MUST be properly sealed with the BD Viper LT Clear Plate Sealers prior to removing the plate from the BD Viper LT System. Sealing ensures a closed reaction for amplification and detection and is necessary to avoid contamination of the instrument and work area with amplification products. Do not remove sealing material from PCR tubes at any time.
22. To prevent contamination of the work environment with amplification products, use the disposal bags provided in the BD Viper LT System PCR Accessory Kit to dispose of tested PCR tubes. Make sure the bags are properly closed before disposal.
23. Do not use reagents after their expiration dates.
24. The Positive and Negative Controls are intended to monitor for substantial system failure and ensures reagent functionality. Quality control requirements must be performed in conformance with applicable regulations or accreditation requirements and your laboratory's standard Quality Control procedures.
25. Although dedicated work areas are not required because the BD Viper LT design reduces the possibility of amplicon contamination in the testing environment, other precautions for controlling contamination, particularly to avoid contamination of specimens during manipulation, are necessary.
26. CHANGE GLOVES if they come in contact with specimen or appear to be wet, to avoid contaminating other specimens. Change gloves before leaving work area and upon entry into work area.
27. Safety Data Sheets (SDS) are available at www.bd.com or by contacting BD Technical Service and Support.
28. Contact BD Technical Service and Support in the event of an unusual situation, such as a spill into the BD Viper LT System or DNA contamination that cannot be removed by cleaning.

STORAGE AND HANDLING REQUIREMENTS

A. Do not freeze reagents.
B. The BD Onclarity HPV LBC Diluent Tube should be stored upright at 2–25 °C until the indicated expiration date.
C. All other reagents may be stored at 2–33 °C until the indicated expiration date.
D. Once a PCR tube pouch is opened, the PCR tubes are stable for 4 weeks at 2–33 °C, if properly sealed or until the expiration date, whichever comes first.

Reagents and Materials Provided

Contents	Quantity
BD Onclarity HPV Assay Reagent Pack- Cat# 442946	192 Tests
Control Set for the BD Onclarity HPV Assay Cat# 441993	24 Sets
BD Onclarity HPV Liquid Based Cytology Specimen (LBC) Diluent Cat# 442840	400 Tubes
BD FOX PCR Extraction Tubes Cat# 441992	384 Tubes
BD Viper PCR Extraction Reagent Trough with Piercing Tool Cat# 442841	96 Tests
BD Viper XTR Neutralization Pouch Cat# 441354	12 Pouches
BD Onclarity HPV Cervical Brush Collection Kit Cat# 441991	100 Tubes
BD Viper LT Pipette Tips Cat# 441996	3,840 Tips
BD Viper Waste Liners Cat# 442968	100 Liners
BD Viper LT PCR Accessory Kit Cat# 442967	80 Pieces
Pierceable Caps for the BD Viper XTR System (Black) Cat# 441359	400 Caps
BD Viper LT PCR Tube/Tray Kit Cat# 442957	20 Pieces
BD Viper LT System Cat# 442839	1 System
BD Key Card Cat# 443747 1,000 Cat# 443748 500 Cat# 443430 100	Each

Materials Required But Not Provided

- Vortex Mixer
- Nitrile gloves
- Displacement pipettes and polypropylene aerosol-resistant tips capable of delivering 0.5 ± 0.05 mL
- 0.5% or 1.0% (v/v) sodium hypochlorite
- 3% (v/v) hydrogen peroxide
- Isopropyl alcohol
- Molecular biology-grade nuclease free water
- BD Syringing Pipettes

#1.1, 1.2

Specimen Collection and Transport

PRECAUTION: Handle all specimens as if they are capable of transmitting infectious agents.

1.1

A. Specimen Collection

BD SurePath or PreservCyt specimens must be collected using either an endocervical broom or a brush/spatula combination as described in the BD SurePath or PreservCyt product insert. Once collected, BD SurePath or PreservCyt specimens can be stored and transported in their original vials for up to 30 days at 2–30 °C, 180 days at 2–8 °C, or 180 days if kept frozen at -20 °C prior to transfer to BD Onclarity HPV LBC Specimen Diluent tubes.

Specimen Transfer to BD Onclarity HPV LBC Diluent Tubes

NOTE: See the BD Onclarity HPV LBC Diluent tube Package Insert for additional information.

A 0.5 mL aliquot of the LBC specimen must be manually transferred from the original LBC vial to the BD Onclarity HPV LBC Diluent Tube. Wear gloves when handling the BD Onclarity HPV LBC Diluent Tube and the LBC specimen vial. If gloves come in contact with the specimen, immediately change them to prevent contamination of other specimens and handle one specimen at a time for processing.

Manual BD SurePath Specimen Transfer Prior to or After Processing for the BD SurePath test

NOTE: Refer to the BD PrepStain™ Slide Processor or BD Totalys SlidePrep product insert for instructions on removing an aliquot from the BD SurePath specimen vial prior to performing the BD SurePath liquid-based Pap test.

NOTE: Handle one specimen at a time for processing.

1. Label a BD Onclarity HPV LBC Diluent tube with patient identification information.
2. Remove the cap from the BD Onclarity HPV LBC Diluent tube.
3. In order to ensure a homogenous mixture, vortex the BD SurePath specimen vial for 10–20 s.
4. Quickly transfer 0.5 mL from the specimen vial using an aerosol-resistant tip to the BD Onclarity HPV LBC Diluent tube within one minute of vortexing.
5. Discard pipette tip.

NOTE: A separate pipette tip must be used for each specimen.

6. Tighten the cap on the BD Onclarity HPV LBC Diluent tube securely.
7. Invert the BD Onclarity HPV LBC Diluent tube 3 to 4 times to ensure that the specimen and diluent are well mixed.

Automated BD SurePath Specimen Transfer using BD Totalys MultiProcessor, Prior to or After Processing for the BD SurePath Test

1. Refer to the BD Totalys MultiProcessor User's Manual for instructions on removing an aliquot from the BD SurePath Collection Vial.
2. Refer to the BD Onclarity HPV LBC Diluent tube product insert for instructions on loading the BD Onclarity HPV LBC Diluent tube in the MultiProcessor for automated aliquot transfer.

Manual PreservCyt Specimen Transfer Prior to or After Processing for the ThinPrep Pap Test

NOTE: Refer to the ThinPrep 2000/5000 System Operator's Manual Addendum for instructions on removing an aliquot from the PreservCyt specimen vial prior to performing the ThinPrep test.

NOTE: Handle one specimen at a time for processing.

1. Label a BD Onclarity HPV LBC Diluent tube with patient identification information.
2. Remove the cap from the BD Onclarity HPV LBC Diluent tube.
3. In order to ensure a homogenous mixture, vortex the PreservCyt specimen vial at high speed for 8–12 s.
4. Immediately transfer 0.5 mL from the specimen vial using an aerosol-resistant tip to the BD Onclarity HPV LBC Diluent tube.
5. Discard pipette tip.

NOTE: A separate pipette tip must be used for each specimen.

6. Tighten the cap on the BD Onclarity HPV LBC Diluent tube securely.
7. Invert the BD Onclarity HPV LBC Diluent tube 3 to 4 times to ensure that the specimen and diluent are well mixed.

CERVICAL BRUSH SPECIMEN COLLECTION

1. Insert the BD Onclarity HPV Cervical Brush into the endocervix until only the bottom most bristles are exposed at the os. Slowly rotate 1/4 to 1/2 turn in one direction. To reduce unnecessary bleeding, do not over-rotate the brush.
2. Remove cap from the BD Onclarity HPV Cervical Brush Diluent tube and immediately place the brush into the bottom of the tube.
3. Carefully break the shaft at the score line. Avoid splashing of the contents.
4. Tightly recap the tube.

B. Specimen Transport

Once collected, cervical specimens can be transported in their original vials at 2–30 °C. Specimen transport should comply with applicable country, federal, state, and local regulations for the transport of etiological agents.

C. Specimen Storage

BD SurePath or PreservCyt specimens must be collected using either an endocervical broom or a brush/spatula combination as described in the BD SurePath or PreservCyt product insert. Once collected, BD SurePath or PreservCyt specimens can be stored and transported in their original vials for up to 30 days at 2–30 °C, 180 days at 2–8 °C, or 180 days if kept frozen at -20 °C prior to transfer to BD Onclarity HPV LBC Specimen Diluent tubes. After transfer to a BD Onclarity HPV LBC Diluent tube, the diluted specimen can be stored at 2–30 °C for up to 15 days, or up to 90 days when stored at -20 °C.

The cervical brush specimens in BD Onclarity HPV Cervical Brush Diluent tubes must be stored and transported to the laboratory and/or test site within 30 days after collection if kept at 2–30 °C within 180 days after collection if kept at 2–8 °C, or within 180 days after collection if kept frozen at -20 °C. Specimen storage and transport should not exceed the expiration date of the Cervical Brush Diluent tube.

QUALITY CONTROL

One BD Onclarity HPV Positive and one BD Onclarity HPV Negative Control must be included in each assay run and for each new reagent kit lot number. Controls must be positioned according to the BD Viper LT System User's Manual. The HPV Positive Control will monitor for substantial reagent failure. The BD Onclarity HPV Negative Control monitors for reagent and/or environmental contamination. Additional controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.

General QC Information for the BD Viper LT System

The location of the PCR tubes is shown in a color-coded plate layout screen on the LCD Monitor. The plus symbol (+) within the tube indicates the positive QC sample. The minus symbol (-) within the tube indicates the negative QC sample. A QC pair must be logged in for each reagent kit lot number. If QC pairs have not been properly logged in, a message box appears that prevents saving the rack and proceeding with the run until complete. Additional (optional) QC tubes for testing may be logged in if desired. These tubes are tested as regular samples and do not affect the Pass/Fail status of the run. Refer to the BD Viper LT System User's Manual HPV Addendum for instructions.

NOTE: BD Onclarity HPV Controls must be manually hydrated prior to loading them into the BD Viper LT Specimen Rack.

INSTRUCTIONS FOR USE

Quality Control Preparation

1. Uncap a BD Onclarity HPV Negative Control and a BD Onclarity HPV LBC Diluent tube.
2. Pour the entire contents of the BD Onclarity HPV LBC Diluent tube into the BD Onclarity HPV Negative Control.
3. Re-cap the rehydrated BD Onclarity HPV Negative Control. Re-cap and discard the empty BD Onclarity HPV LBC Diluent tube.
4. Uncap a BD Onclarity HPV Positive Control and a BD Onclarity HPV LBC Diluent tube.
5. Pour the entire contents of the BD Onclarity HPV LBC Diluent tube into the BD Onclarity HPV Positive Control.
6. Re-cap the rehydrated BD Onclarity HPV Positive Control. Re-cap and discard the empty BD Onclarity HPV LBC Diluent tube.
7. Using the Tube Layout Report, place the rehydrated BD Onclarity HPV Positive and Negative Controls into the appropriate positions in the BD Viper LT Specimen Rack.
8. Controls are ready to be pre-warmed with the specimens. Once hydrated, controls may be stored at 2–30 °C for up to 24 h prior to pre-warming.

Processing Procedure For All Speciments

NOTE: If previously prepared specimens are frozen, make sure they are thawed completely at room temperature and mixed by inversion prior to proceeding.

1. Using the Tube Layout Report, place the specimens in order in the BD Viper LT Specimen Rack and lock into place.
2. Specimens are ready to be pre-warmed.
3. Change gloves prior to proceeding to avoid contamination.

Pre-Warm Procedure

NOTE: The pre-warm procedure must be applied to all specimens to ensure that the specimen matrix is homogeneous prior to loading on the BD Viper LT System. Failure to pre-warm specimens may have an adverse impact on performance of the BD Onclarity HPV Assay and/or BD Viper LT System.

1. Insert the BD Viper LT Specimen Rack into the BD Pre-Warm Heater and select the BD Onclarity HPV Assay pre-warm protocol on the BD Viper LT Instrument.
2. The BD Pre-warm heater will automatically pre-warm the specimens and controls according to the BD Onclarity HPV Assay pre-warm protocol.
3. After the BD Onclarity HPV Assay pre-warm protocol is complete, remove the rack from the heater and load into the BD Viper LT instrument.
4. After pre-warming, specimens may be stored for up to 7 days at 2–30 °C without additional pre-warming prior to testing on the BD Viper LT System.
5. After pre-warming, controls may be stored for up to 24 hours at 2–30 °C without additional pre-warming prior to testing on the BD Viper LT System.

Test Procedure

NOTE: Refer to the BD Viper LT Instrument User's Manual for detailed instructions for operating and maintaining the components of the system.

1. The BD Onclarity HPV Assay may be used to run 1 to 30 specimens plus one Positive Control and one Negative Control.
2. Perform the system startup and maintenance procedures by following the instructions in the appropriate BD Viper LT User's Manual.
3. Access the Rack Login Display to log in the rack barcode and select the test type to be run.
4. Log in the Positive and Negative Control tubes in the first two positions (A1 and B1) as well as the HPV LBC Diluent tubes.
5. Log in specimen tubes by typing in or scanning each accession number/barcode in the Specimen Login window.
6. Log in Extraction tube QC information by tapping the "extraction lot" button and load extraction tubes where indicated on the Extraction Tube Lot Login display.
7. Tap the plate layout button to view the Plate Layout Display.
8. Load the PCR tubes into PCR Plate as shown on the display. PCR tubes are color-coded as follows:
   a. Blue=G1
   b. Green=G2
   c. Orange=G3

NOTE: Use empty PCR tubes to completely fill the PCR Plates if less than a full plate of tubes is required/logged in.

9. SurePath LBC samples and Positive and Negative Control tubes must be prewarmed prior to extraction on the BD Viper LT.
10. To prepare the BD Viper LT instrument for specimen processing and testing, follow the steps outlined in the BD Viper LT User's Manual.
11. After specimens have been logged in, pre-warmed, and the BD Viper LT instrument has been prepared, the run can be initiated by tapping the "start run" button on the Main status display.

INTERPRETATION OF TEST RESULTS

The BD Onclarity HPV Assay uses the real-time polymerase chain reaction to detect the presence of Human Papillomavirus (HPV) in clinical specimens. All calculations are performed automatically by the BD Viper LT software. The presence or absence of clinically relevant HPV DNA is determined by the PCR cycle (Ct) at which the signal crosses a pre-established threshold. The assay will extract, amplify and detect a fragment of the human beta globin gene as an internal control to assess specimen processing, extraction, amplification, and to indicate the presence of PCR inhibitors. If the HPV-specific signal is greater than a cycle threshold, the internal control is utilized by the algorithm in the interpretation of the result. If the HPV-specific signal is less than or equal to a cycle threshold, the internal control is ignored by the algorithm.

For HPV specimens, an "HR" result (the combination of all genotypes) appears on the Tube Results Report. A positive symbol in this column indicates that the HPV assay detected one or more genotypes.

Specific genotypes and combined genotypes appear in columns. If the results for a genotype have been unmasked, those results are reported as explained below. If any genotype results have not been configured for automatic unmasking, those results are masked by a "key" icon.

The instrument can be configured to unmask/report specific genotypes when the run is complete. See the BD Viper LT System User's Manual HPV Addendum for instructions on authorizing automatic genotype reporting.

If assay control results are not as expected, patient results are not reported. See the Quality Control section for expected control values. Reported results are determined as follows.

Table 1: Interpretation of High Risk HPV Genotype HPV Test Results for the BD Onclarity HPV Assay

High Risk HPV Result	Interpretation	Result	Report
HR ⊕←	Positive for High Risk HPV types	HPV HR Positive	HPV DNA detected by PCR.
HR ⊖	Negative for High Risk HPV types	HPV HR Negative	HPV DNA not detected by PCR.
~~IC~~	HPV DNA, if present, is not detectable	Internal Control Failure	Internal Control Failure. Repeat test from initial specimen tube or obtain another specimen for testing.
~~ET~~	HPV DNA, if present, is not detectable	Extraction Transfer Failure	Extraction Transfer Failure. Repeat test from initial specimen tube or obtain another specimen for testing.
~~▯~~	HPV DNA, if present, is not detectable.	Liquid Level Failure	Liquid Level Failure. Repeat test from initial specimen tube or obtain another specimen for testing.

Table 2: Interpretation of Specific HPV Genotype Test Results for the BD Onclarity HPV Assay

HPV Genotype Result	Interpretation	Result
16 ⊕←	Positive for HPV type 16	HPV type 16 Positive
16 ⊖	Negative for HPV type 16	HPV type 16 Negative
18 ⊕←	Positive for HPV type 18	HPV type 18 Positive
18 ⊖	Negative for HPV type 18	HPV type 18 Negative
45 ⊕←	Positive for HPV type 45	HPV type 45 Positive
45 ⊖	Negative for HPV type 45	HPV type 45 Negative
P1 ⊕←	Positive for HPV types 33 and/or 58	HPV type 33 and/or 58 Positive
P1 ⊖	Negative for HPV types 33 and/or 58	HPV type 33 and/or 58 Negative
31 ⊕←	Positive for HPV type 31	HPV type 31 Positive
31 ⊖	Negative for HPV type 31	HPV type 31 Negative
P2 ⊕←	Positive for HPV types 56, 59 and/or 66	HPV type 56, 59 and/or 66 Positive
P2 ⊖	Negative for HPV types 56, 59 and/or 66	HPV type 56, 59 and/or 66 Negative
51 ⊕←	Positive for HPV type 51	HPV type 51 Positive
51 ⊖	Negative for HPV type 51	HPV type 51 Negative
52 ⊕←	Positive for HPV type 52	HPV type 52 Positive
52 ⊖	Negative for HPV type 52	HPV type 52 Negative
P3 ⊕←	Positive for HPV types 35, 39 and/or 68	HPV type 35, 39 and/or 68 Positive
P3 ⊖	Negative for HPV types 35, 39 and/or 68	HPV type 35, 39 and/or 68 Negative
⊢	HPV genotype result is available for purchase	Genotype result is locked
- -	HPV genotype result is not available for purchase	HPV Negative result, Internal Control failure, Liquid Level failure or Extraction Transfer failure.

See the BD Viper LT System User's Manual HPV Addendum for additional information on results reporting.

Interpretation of Quality Control Results

If assay control results are not as expected, patient results are not reported. If either of the controls does not provide the expected result, repeat the entire run using a new set of controls. If either of the controls is consistently invalid, contact BD Technical Service and Support for technical assistance.

Table 3: Interpretation of Quality Control Results

Control Type	Tube Result Report Symbol	QC Disposition
BD Onclarity HPV Positive Control	OK	QC Pass
BD Onclarity HPV Positive Control		QC Failure
BD Onclarity HPV Positive Control		QC Failure
BD Onclarity HPV Positive Control		QC Failure
BD Onclarity HPV Negative Control	OK	QC Pass
BD Onclarity HPV Negative Control		QC Failure
BD Onclarity HPV Negative Control		QC Failure
BD Onclarity HPV Negative Control		QC Failure

Refer to the Interpretation of Test Results for a description of Tube Result Report symbols.

Monitoring for the Presence of DNA Contamination

At least monthly, the following test procedure should be performed to monitor the work area and equipment surfaces for the presence of DNA contamination. Environmental monitoring is essential to detect contamination prior to the development of a problem.

1. For each area to be tested, use a clean collection swab from the BD ProbeTec *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/GC) Amplified DNA Assay Endocervical Specimen Collection and DRY TRANSPORT Kit.
2. Pour off some molecular biology grade nuclease-free water into a small clean container.
3. Dip the swab into the molecular biology grade nuclease-free water and wipe the first area using a broad sweeping motion.
4. Remove the cap of a BD Onclarity HPV LBC Diluent tube and insert the swab into the Diluent. Mix by swirling the swab in the BD Onclarity HPV Diluent for 5–10 s.
5. Express the swab along the inside of the tube so that liquid runs back into the bottom of the tube.
6. Remove the swab carefully from the BD Onclarity HPV LBC Diluent tube to avoid splashing. Discard the swab.
7. Tightly recap the BD Onclarity HPV LBC Diluent tube with the black pierceable cap.
8. Repeat for each desired area.
9. After all swabs have been collected and expressed, process them according to the Pre-warming Procedure and then follow the Test Procedure.

Consult the BD Viper LT System User's Manual for more information on Environmental Monitoring and Cleaning Procedures. If a contamination event does not resolve, contact BD Technical Service and Support for additional information.

PROCEDURAL LIMITATIONS

1. The BD Onclarity HPV Assay detects DNA of the high-risk types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68. This test does not detect DNA of HPV low-risk types (e.g. 6, 11, 42, 43, 44) since there is no clinical utility for testing of low-risk HPV types for cervical cancer screening. [23]
2. The BD Onclarity HPV Assay is not recommended for evaluation of suspected sexual abuse.
3. Optimal performance of the test requires adequate specimen collection, transport, storage and processing. Follow the procedures in this Package insert and the BD Viper LT System User's Manual.
4. A negative test result does not exclude the possibility of infection because test results may be affected by improper specimen collection, technical error, specimen mix-up, or the number of organisms in the specimen which may be below the sensitivity of the test.
5. The BD Onclarity HPV Assay provides qualitative results.
6. Use of the BD Onclarity HPV Assay is limited to personnel who have been trained in the assay procedure and the BD Viper LT System.

7. The BD Onclarity HPV Assay has been validated for use with cervical specimens collected by a clinician using an endocervical brush/spatula combination or broom and placed in a BD SurePath vial or PreservCyt Solutions. In the clinical study, the Cytobrush® Plus GT Gentle Touch and Pap Perfect® Plastic Spatula (CooperSurgical, Inc.) and Rovers® Cervex-Brush® (Rovers Medical Devices B.V.) were used. BD SurePath cell pellets obtained after processing on the BD PrepStain Slide Processor have not been evaluated with the BD Onclarity HPV Assay. For cervical brush specimens, use only the BD Onclarity Cervical Brush Collection Kit
8. Cervical Specimens often show visibly detectable levels of blood as a pink or light brown coloration. If concentrations exceed 4% (v/v) in SurePath vial or 5% (v/v) in PreservCyt Solution prior to dilution in the BD Onclarity HPV Diluent tube, there is a likelihood of obtaining a false-negative HPV result. If concentrations exceed 3% (v/v) in the Cervical Brush collection kit there is also a likelihood of obtaining a false-negative HPV result.
9. False negatives may occur for specimens containing > 8% (v/v) mucin, >7% (w/v) Zovirax® (Acyclovir) Cream, and > 8% (w/v) clindamycin vaginal cream.
10. The effects of other potential variables such as vaginal discharge, use of tampons, douching, etc. and specimen collection variables have not been evaluated.
11. The BD Onclarity HPV Assay was not evaluated in women with acetic acid, iodine, spermicide, douche, or anti-fungal medications applied to the cervical area within 24 hours of specimen collection.
12. Detection of high-risk HPV is dependent on the number of copies present in the specimen and may be affected by specimen collection methods, patient factors, stage of infection and the presence of interfering substances.
13. Prevalence of HPV infection in a population may affect performance. Positive predictive values decrease when testing populations with low prevalence or individuals with no risk of infection.
14. A negative high-risk HPV result does not exclude the possibility of future cytologic high-grade squamous intraepithelial lesion (HSIL) or underlying CIN2-3 or cancer, but indicates a low likelihood of CIN2-3 or cancer.
15. Infection with HPV is not an indicator of cytologic HSIL or underlying high-grade CIN, nor does it imply that CIN2-3 or cancer will develop. Most women infected with one or more high-risk HPV types do not develop CIN2-3 or cancer.
16. An HPV negative specimen must have a valid beta globin signal within a pre-defined range to generate a negative result on the BD Viper LT System. The beta globin control does not differentiate between targeted (cervical) and non-targeted nucleated cell types.

BD Onclarity Assay Clinical Study Design with SurePath Liquid Cytology Specimens

A total of 33,858 women were enrolled in the study across 31 collection sites, and cervical samples were tested at 4 testing sites in the US. Of these, 33,634 (99.3%) women were eligible to participate in the study. Eligible women were ≥ 21 years, provided informed consent, satisfied study inclusion/exclusion criteria, had not enrolled in a cervical disease diagnostic trial since 2007, and had not withdrawn authorization before undergoing study procedures.

The median age of the eligible women was 37, with 28.0% of women in age group 21–29 years, 28.3% in age group 30–39, and 43.7% of women in age group ≥ 40 years. A total of 90.6% of women had NILM cytology, 5.8% of women had ASC-US cytology, 3.3% of women had >ASC-US cytology, and only 0.2% of women had unsatisfactory cytology.

The percent of final non-reportable BD Onclarity assay results was 0.24% (79/33,570). Not included in this calculation are specimens that did not yield a result (64/33,634) due to specimen labeling, processing and volume issues.

A total of 1,960 ASC-US women ≥ 21 years were enrolled in the study of which 1,953 were evaluable; evaluable women had an ASC-US cytology result and valid results from the BD Onclarity HPV Assay.

A total of 22,383 NILM women ≥ 30 years were enrolled in the study of which 22,284 were evaluable; evaluable women had a NILM cytology result and valid results from the BD Onclarity HPV Assay.

A total of 29,633 women ≥ 25 years were enrolled in the study of which 29,513 were evaluable; evaluable women had valid cytology and BD Onclarity HPV Assay results.

Table 4 shows HPV positivity of the BD Onclarity HPV Assay by testing site and study population. HPV prevalence was 39.1% in the ASC-US (≥ 21 years) population, 7.9% in the NILM (≥ 30 years) population and 12.7% in the Primary Screening (≥ 25 years) population.

Table 4: Summary of HPV Positivity of the BD Onclarity HPV Assay by Testing Sites and Study Population

	BD Onclarity HPV HR Positivity Rate		
Testing Site	**ASC-US (≥ 21 years)**	**NILM (≥ 30 years)**	**Primary Screening (≥ 25 years)**
1	39.5% (234/592)	9.3% (644/6,921)	14.2% (1,306/9,167)
2	36.7% (126/343)	7.4% (369/4,962)	12.0% (757/6,300)
3	33.3% (259/778)	7.1% (372/5,219)	12.7% (941/7,434)
4	60.0% (144/240)	7.3% (376/5,182)	11.3% (744/6,612)
Total	39.1% (763/1,953)	7.9% (1,761/22,284)	12.7% (3,748/29,513)

Table 5 shows HPV prevalence by the BD Onclarity HPV Assay by age and study population. HPV prevalence decreased with age in each study population.

Table 5: Summary of HPV Positivity of the BD Onclarity HPV Assay by Age and Study Population

BD Onclarity HPV HR Positivity Rate			
Age Group	**ASC-US (≥ 21 years)**	**NILM (≥ 30 years)**	**Screening (≥ 25 years)**
21–29	54.6% (398/729)	N/A	22.4% (1,216/5,432)
30–39	39.2% (204/521)	10.3% (889/8,663)	13.8% (1,310/9,477)
≥ 40	22.9% (161/703)	6.4% (872/13,621)	8.4% (1,222/14,604)
Total	39.1% (763/1,953)	7.4% (1,761/22,284)	12.7% (3,748/29,513)

PERFORMANCE CHARACTERISTICS

Clinical Performance-SurePath

Baseline Phase

A multicenter, prospective study was conducted to evaluate the performance of the BD Onclarity HPV Assay as a triage test to stratify women with ASC-US cytology results for referral to colposcopy, as an adjunctive test to cervical cytology to guide management decisions, and also as a primary cervical cancer screening test. The study consisted of a Baseline Phase and a 3 year Follow-up Phase. In the Baseline Phase, women ≥21 years old undergoing routine cervical cancer screening were invited to participate in the study. In total, 33,858 women were enrolled from August 2013 to June 2015 at 31 clinical sites in the Baseline Phase. Following written informed consent, demographic information and gynecologic histories were obtained. Two cervical specimens were collected from each woman and preserved in liquid based cytology (LBC) media. Cytology testing was performed on the first vial collected, at three different laboratories, and results were classified according to the 2001 Bethesda System criteria. HPV testing with the BD Onclarity HPV Assay was performed at one of four laboratories from a pre-cytology aliquot of the first vial collected and performance results are shown below. The second cervical specimen collected was tested with the BD Onclarity HPV assay and an FDA-approved HPV test, according to the manufacturer's instructions.

Those women ≥ 21 years old with ≥ ASC-US cytology and women ≥ 25 years old with unsatisfactory cytology were invited to undergo colposcopy. In addition, all women ≥ 25 years old with a positive high-risk HPV test result (positive by the BD Onclarity HPV Assay and/or the FDA-approved HPV test), as well as a randomly selected subset of women (approximately 5%) with NILM (negative for intraepithelial lesions or malignancy) cytology and negative high-risk HPV DNA (by both the BD Onclarity HPV assay and the FDA-approved HPV DNA test), were invited to proceed to colposcopy. In order to avoid observation bias, both study participants and colposcopists were blinded to all HPV tests and cytology results until after the colposcopy was completed. Colposcopy was conducted according to a standardized protocol in which biopsies were obtained on all visible lesions or acetowhite areas; endocervical curettage was performed in all patients, and a single random cervical biopsy at the squamocolumnar junction was obtained if no lesions or acetowhite areas were visible. All biopsies were examined by a Central Pathology Review Panel (CPR) consisting of three expert pathologists. Discordant results were adjudicated according to a pre-defined protocol. For all analyses, the clinical performance of the BD Onclarity HPV Assay was measured against CPR histopathology results using both conventional H&E staining and H&E with p-16 assisted immunohistochemical staining, in alignment with the consensus recommendations of The 2012 Lower Anogenital Squamous Terminology Standardization Project for HPV-Associated Lesions (LAST).[24] Clinical performance for the BD Onclarity HPV Assay is expressed using p-16-assisted H&E for purposes of consistency, especially in the histopathologic category of CIN2. Overall, there are no statistically significant differences in clinical performance of the BD Onclarity HPV Assay with both histology reference methods for each of the three intended use populations.

Follow-Up Phase

All women who were biopsied at baseline and not treated and approximately 10% of NILM women (≥ 25 years) with HPV HR negative results and no baseline biopsy or treatment were invited to participate in a 3 year longitudinal study. Approximately 8,900 women were eligible for the follow-up study. All women invited into this 3 year longitudinal study undergo annual visits for cervical sampling for cytology and HPV DNA testing with the BD Onclarity HPV Assay. All women with ≥ ASC-US are invited to proceed to colposcopy. Colposcopy and biopsies are performed in a standardized manner as described above. All cervical tissue is examined by the Central Pathology Review Panel. An exit colposcopy with biopsy and endocervical curettage (ECC) is collected from all women in Year 3. All women, regardless of histology result, will be followed through the duration of the study with the exception of those who receive treatment procedures; they will exit the study.

STUDY DESIGN TO DEMONSTRATE CLINICAL SENSITIVITY AND SPECIFICITY FOR SCREENING PATIENTS WITH ASC-US CYTOLOGY RESULTS TO DETERMINE THE NEED FOR REFERRAL TO COLPOSCOPY

Those women ≥ 21 years old with ASC-US cytology, regardless of HPV results, were invited to undergo colposcopy. Both study participants and colposcopists were blinded to all HPV tests and cytology results until after the colposcopy was completed. Colposcopy was conducted according to a standardized protocol and all biopsies were read by the CPR, as described above. The clinical performance of the BD Onclarity HPV Assay was measured against histology results of ≥ CIN2 and ≥ CIN3 by CPR.

#1.1, 1.2

STUDY DESIGN TO DEMONSTRATE CLINICAL PERFORMANCE OF THE BD ONCLARITY HPV ASSAY AS AN ADJUNCT TO CERVICAL CYTOLOGY IN WOMEN ≥ 30 YEARS

All women ≥ 30 years old with NILM cytology and a positive result for HR HPV DNA (BD Onclarity HPV Assay and/or the FDA approved HPV test), as well as a randomly selected subset of women (approximately 5%) with NILM cytology/negative HR HPV DNA (BD Onclarity HPV Assay and the FDA approved HPV test), were invited to proceed to colposcopy. The analyses were performed for histology results of ≥ CIN2 and ≥ CIN3 by CPR.

1.1 **STUDY DESIGN TO DEMONSTRATE CLINICAL PERFORMANCE OF THE BD ONCLARITY HPV ASSAY AS A FIRST-LINE PRIMARY TEST FOR CERVICAL CANCER SCREENING**

Women ≥25 years with ≥ ASC-US cytology and/or a positive result for HR HPV DNA (BD Onclarity HPV Assay and/or the FDA approved HPV test) were invited to proceed to colposcopy in the baseline phase. All women who were invited to colposcopy in the baseline phase and a portion (approximately 10%) of women ≥ 25 years with NILM cytology and HR HPV negative results, who did not have baseline biopsy and were not treated are eligible to participate in a 3 year longitudinal study for the BD Onclarity HPV assay. All women with follow-up cytology ≥ ASC-US are invited to proceed to colposcopy; colposcopy and biopsies are performed in a standardized manner as describe above. All cervical biopsies are examined by the CPR. Exit colposcopy with biopsy and ECC are performed on all women. The objectives of the follow-up phase of the study are to determine the 3-year risk (cumulative incidence rates, CIRs) of developing ≥ CIN2 and ≥CIN3 in different study sub-populations defined by baseline HPV status and cytology.

Baseline data were evaluated for all evaluable women 25 years and older. The clinical performance of the primary screening indication for the BD Onclarity HPV Assay was measured against histology results of ≥ CIN2 and ≥ CIN3 by CPR and compared to the performance of cytology alone.

Performance Characteristics in the ASC-US Population (≥ 21 years)

A total of 1,960 ASC-US women ≥ 21 years were enrolled in the study of which 1,953 were evaluable. Evaluable women had an ASC-US cytology result and valid results from the BD Onclarity HPV Assay. Of the 1,953 evaluable ASC-US women, 1,607 completed the colposcopy procedure with a valid CPR result. The results of the BD Onclarity HPV Assay reported as (HPV HR) Positive or (HPV HR) Negative together with the CPR diagnosis are presented in Table 6. Of the 1,607 ASC-US women with a valid CPR panel diagnosis and BD Onclarity HPV result, 105 women were ≥CIN2 (prevalence of 6.5%), and 35 women were ≥CIN3 (prevalence of 2.2%).

Table 6: Results of the BD Onclarity HPV Assay and Central Pathology Review Panel Diagnosis in the ASC-US Population

	Central Pathology Review Panel Diagnosis					
BD Onclarity HPV Assay Result	**NEG**	**CIN1**	**CIN2**	**≥ CIN3**	**Unknown Disease Status**	**Total**
Positive	423	116	58	32	134	763
Negative	888	75	12	3	212	1,190
Invalid/Missing*	6	0	0	0	1	7
Total	1,317	191	70	35	347**	1,960

NOTE:
* Invalid/Missing results include mislabeled specimens, instrument errors and non-reportable results
** 341 women did not return or were no longer eligible for a colposcopy procedure. Three women had unsatisfactory histology results and three women had biopsy specimen collection errors.

The performance of the BD Onclarity HPV Assay in detecting high-grade cervical disease (≥CIN2 and ≥CIN3) is presented in Table 7. The sensitivity and the specificity of the test for detecting ≥CIN2 histology were 85.7% (90/105) and 64.1% (963/1502), respectively. The positive likelihood ratio (PLR) was estimated as 2.4, which indicates a positive BD Onclarity HPV Assay result is 2.4 times more likely in women with ≥CIN2 than in women with < CIN2. The negative likelihood ratio (NLR) was estimated as 0.2, which indicates that a negative BD Onclarity HPV Assay result is 5 (1/0.2) times more likely in women with < CIN2 than in women with ≥CIN2.

The sensitivity and specificity of the BD Onclarity HPV Assay for detecting ≥CIN3 histology were 91.4% (32/35) and 62.0% (975/1,572), respectively.

Table 7: Performance of the BD Onclarity HPV Assay in the ASC-US Population (≥ 21 years)

Performance	**CIN2**	**CIN3**
	Central Pathology Review Panel Diagnosis	
Sensitivity (%) (95% CI)	85.7 90/105[a] (77.8, 91.1)	91.4 32/35[b] (77.6, 97.0)
Specificity (%) (95% CI)	64.1 963/1,502 (61.7, 66.5)	62.0 975/1,572 (59.6, 64.4)

Performance	CIN2	CIN3
	Central Pathology Review Panel Diagnosis	
PPV (%) (95% CI)	14.3 90/629 (13.0, 15.5)	5.1 32/629 (4.3, 5.6)
NPV (%) (95% CI)	98.5 963/978 (97.6, 99.0)	99.7 975/978 (99.2, 99.9)
PLR (95% CI)	2.39 (2.13, 2.63)	2.41 (2.03, 2.64)
NLR (95% CI)	0.22 (0.14, 0.35)	0.14 (0.05, 0.36)
Disease Prevalence (%)	6.5 105/1,607	2.2 35/1,607

[a]12 of the 15 BD Onclarity HPV Assay negative, ≥CIN2 subjects were also negative by the FDA approved HPV test. Three of the subjects were positive by the FDA approved HPV test and were identified as low risk HPV types 67 and/or 82 by a sequencing method.
[b]2 of the 3 BD Onclarity HPV Assay negative ≥CIN3 subjects were also negative by the FDA approved HPV test. One subject was positive by the FDA approved HPV test and was identified as low risk HPV type 67 by a sequencing method.

The performance of the BD Onclarity HPV Assay in detecting high-grade cervical disease (≥CIN2 and ≥CIN3) and the performance of the FDA approved HPV test is presented in Table 8. The sensitivity for detecting ≥CIN2 histology was 85.7% (90/105) for the BD Onclarity HPV Assay and 82.9% (87/105) for the FDA approved HPV test. The specificity for detecting ≥CIN2 histology was 64.1% (959/1,496) for the BD Onclarity HPV Assay and 61.4% (919/1,496) for the FDA approved HPV test.

The sensitivity for detecting ≥CIN3 histology was 91.4% (32/35) for the BD Onclarity HPV Assay and 85.7% (30/35) for the FDA approved HPV test. The specificity for detecting ≥CIN3 histology was 62.0% (971/1,566) for the BD Onclarity HPV Assay and 59.5% (932/1,566) for the FDA approved HPV test.

Table 8: Comparison of the Performance of the BD Onclarity HPV Assay and an FDA Approved HPV Test in the ASC-US Population (≥21 years)

Performance Metrics	BD Onclarity HPV Assay		FDA Approved HPV Test	
	Estimate	95% CI	Estimate	95% CI
≥CIN2; Prevalence 6.6% (105/1,601)				
Sensitivity (%)	85.7 (90/105)	(77.8, 91.1)	82.9 (87/105)	(74.5, 88.9)
Specificity (%)	64.1 (959/1,496)	(61.6, 66.5)	61.4 (919/1,496)	(58.9, 63.9)
PPV (%)	14.4 (90/627)	(13.0, 15.6)	13.1 (87/664)	(11.8, 14.3)
NPV (%)	98.5 (959/974)	(97.6, 99.0)	98.1 (919/937)	(97.2, 98.7)
PLR	2.39	(2.13, 2.63)	2.15	(1.90 2.37)
NLR	0.22	(0.14, 0.35)	0.28	(0.18, 0.42)
≥CIN3; Prevalence 2.2% (35/1,601)				
Sensitivity (%)	91.4 (32/35)	(77.6, 97.0)	85.7 (30/35)	(70.6, 93.7)
Specificity (%)	62.0 (971/1,566)	(59.6, 64.4)	59.5 (932/1,566)	(57.1, 61.9)
PPV (%)	5.1 (32/627)	(4.3, 5.6)	4.5 (30/664)	(3.7, 5.0)
NPV (%)	99.7 (971/974)	(99.2, 99.9)	99.5 (932/937)	(98.9, 99.8)
PLR	2.41	(2.03, 2.64)	2.12	(1.73, 2.37)
NLR	0.14	(0.05, 0.36)	0.24	(0.11, 0.49)

NOTE: This table is a paired analysis of specimens with a valid BD Onclarity HPV assay and FDA approved HPV test result. Six women (<CIN2) with a BD Onclarity result but no FDA approved HPV test result were excluded from this analysis.

The performance of the BD Onclarity HPV Assay and the FDA approved HPV test for detecting ≥CIN2 and ≥CIN3 evaluated by age group is presented in Table 9. The sensitivity of the BD Onclarity HPV Assay and the FDA approved HPV test ranged from 68.8–93.6% for ≥CIN2. The specificity of the BD Onclarity HPV Assay ranged from 49.5–78.2% and from 45.9–76.3% for the FDA approved HPV test.

The sensitivity of the BD Onclarity HPV Assay for detecting ≥CIN3 histology ranged from 85.7–92.9% and from 71.4–92.9% for the FDA approved HPV test. The specificity of the BD Onclarity HPV Assay ranged from 47.0–77.0% and from 43.7–75.6% for the FDA approved HPV test.

Table 9: Performance of the BD Onclarity HPV Assay and an FDA Approved HPV Test by Age Group in the ASC-US (≥21 years) Population

Performance Metrics	BD HPV	FDA Approved HPV Test	BD HPV	FDA Approved HPV Test	BD HPV	FDA Approved HPV Test
	21–29 Years		30–39 Years		≥40 Years	
≥CIN2						
Sensitivity (%) 95% CI	93.6 44/47 (82.8, 97.8)	91.5 43/47 (80.1, 96.6)	83.3 (35/42) (69.4, 91.7)	78.6 (33/42) (64.1, 88.3)	68.8 (11/16) (44.4, 85.8)	68.8 (11/16) (44.4, 85.8)
Specificity (%) 95% CI	49.5 260/525 (45.3, 53.8)	45.9 241/525 (41.7, 50.2)	63.2 (254/402) (58.4, 67.8)	60.7 (244/402) (55.8, 65.3)	78.2 (445/569) (74.6, 81.4)	76.3 (434/569) (72.6, 79.6)
PPV (%) 95% CI	14.2 44/309 (12.6, 15.6)	13.1 (43/327) (11.5, 14.4)	19.1 (35/183) (16.0, 21.9)	17.3 (33/191) (14.2, 20.0)	8.1 (11/135) (5.3, 10.6)	7.5 (11/146) (4.9, 9.7)
NPV (%) 95% CI	98.9 (260/263) (97.0, 99.6)	98.4 (241/245) (96.2, 99.4)	97.3 (254/261) (95.2, 98.6)	96.4 (244/253) (94.1, 98.0)	98.9 (445/450) (98.0, 99.5)	98.9 (434/439) (98.0, 99.5)
PLR 95% CI	1.85 (1.61, 2.06)	1.69 (1.46, 1.88)	2.26 (1.82, 2.69)	2.00 (1.59, 2.39)	3.15 (1.99, 4.20)	2.90 (1.83, 3.84)
NLR 95% CI	0.13 (0.04, 0.35)	0.19 (0.07, 0.44)	0.26 (0.13, 0.49)	0.35 (0.19, 0.60)	0.40 (0.18, 0.71)	0.41 (0.19, 0.73)
≥CIN3						
Sensitivity (%) 95% CI	92.9 (13/14) (68.5, 98.7)	92.9 (13/14) (68.5, 98.7)	92.9 (13/14) (68.5, 98.7)	85.7 (12/14) (60.1, 96.0)	85.7 (6/7) (48.7, 97.4)	71.4 (5/7) (35.9, 91.8)
Specificity (%) 95% CI	47.0 (262/558) (42.8, 51.1)	43.7 (244/558) (39.7, 47.9)	60.5 (260/430) (55.8, 65.0)	58.4 (251/430) (53.7, 62.9)	77.7 (449/578) (74.1, 80.9)	75.6 (437/578) (71.9, 78.9)
PPV (%) 95% CI	4.2 (13/309) (3.1, 4.7)	4.0 (13/327) (2.9, 4.4)	7.1 (13/183) (5.3, 8.1)	6.3 (12/191) (4.4, 7.4)	4.4 (6/135) (2.5, 5.5)	3.4 (5/146) (1.7, 4.6)
NPV (%) 95% CI	99.6 (262/263) (98.3, 99.9)	99.6 (244/245) (98.2, 99.9)	99.6 (260/261) (98.3, 99.9)	99.2 (251/253) (97.8, 99.8)	99.8 (449/450) (99.2, 100.0)	99.5 (437/439) (99.0, 99.9)
PLR 95% CI	1.75 (1.28, 1.96)	1.65 (1.21, 1.84)	2.35 (1.71, 2.72)	2.06 (1.42, 2.45)	3.84 (2.15, 4.80)	2.93 (1.45, 3.99)
NLR 95% CI	0.15 (0.03, 0.67)	0.16 (0.03, 0.72)	0.12 (0.02, 0.52)	0.24 (0.07, 0.69)	0.18 (0.03, 0.66)	0.38 (0.11, 0.85)

NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY (NILM)

NILM (≥30 years) Population

A total of 22,383 NILM women ≥ 30 years were enrolled in the study. Women with a NILM cytology result and an HPV positive result (1,991) and a random subset of women (1,228) with negative HPV results (from both the BD Onclarity HPV Assay and FDA-approved HPV test) were assigned to colposcopy for a histological diagnosis. Of the 3,219 women identified for colposcopy, 2,591 completed the procedure with a valid CPR and BD Onclarity HPV result. In order to account for the different rates of selection in the HPV positive and HPV negative groups, verification bias adjusted (VBA) performance estimates were calculated. Adjustment was made by calculating the likely number of diseased cases that would have been found if all women had colposcopy.

The results of the BD Onclarity HPV Assay in the NILM (≥30 years) population reported as HPV HR Positive or HPV HR Negative together with the CPR panel diagnosis are summarized in Table 10.

Table 10: BD Onclarity HPV Assay Result and CPR panel diagnosis in the NILM Population (≥30 years)

BD Onclarity HPV Assay Test Results	Central Pathology Review Panel Diagnosis				Unknown Disease Status	Total
	NEG	CIN1	CIN2	≥ CIN3		
Positive	1,198	93	27	43	400	1,761
Negative	1,184	36	7	3	19,293	20,523
Invalid/Missing[a]	5	1	0	0	93	99
Total	2,387	130	34	46	19,786[b]	22,383

[a] Invalid/Missing results include mislabeled specimens, instrument errors and non-reportable results

[b] 19,164 women were not identified for colposcopy. 609 women did not return or were no longer eligible for a colposcopy procedure. Six women had unsatisfactory histology results and seven women had biopsy specimen collection errors.

NILM (≥30 years) Population-Performance Evaluation

The performance of the BD Onclarity HPV Assay in detecting high grade cervical disease is presented in Table 11. The unadjusted estimates of sensitivity and specificity for detection of ≥CIN2 histology are 87.5% (78.5, 93.1) and 48.6% (46.6, 50.5), respectively. The positive likelihood ratio for the detection of ≥CIN2 was 5.86 (adjusted estimates), indicating a strong probability that a positive result is truly positive. The negative likelihood ratio for the detection of ≥CIN2 was 0.26 (crude estimates) and 0.60 (adjusted estimates), indicating a strong likelihood that a negative result was associated with the absence of disease.

Verification bias adjusted (VBA) sensitivity and specificity for ≥CIN2 are 44.4% (27.2, 76.2) and 92.4% (92.1, 92.8), respectively.

Unadjusted estimates of sensitivity and specificity for the detection of ≥CIN3 are 93.5% (82.5, 97.8) and 48.2% (46.3, 50.2), respectively. The positive likelihood ratio for the detection of ≥CIN3 was 9.02 (adjusted estimates) indicating that an HPV positive result is nearly 9 times more likely to occur in a subject with ≥CIN3 histology than in a subject with <CIN3. Negative likelihood ratio was 0.3 (adjusted estimates), indicating a strong likelihood that a negative result was associated with the absence of disease.

VBA sensitivity and specificity for the detection of ≥CIN3 are 69.3% (42.0, 100.0) and 92.3% (92.0, 92.7), respectively.

Table 11: Performance of the BD Onclarity HPV Assay in the NILM Population (≥30 years)

Performance	Central Pathology Review Panel Diagnosis			
	≥ CIN2		≥ CIN3	
	Unadjusted Estimate	Adjusted Estimate (%, 95% CI)	Unadjusted Estimate	Adjusted Estimate (%, 95% CI)
Sensitivity (%) (95% CI)	87.5 70/80 (78.5, 93.1)	44.4 (27.7, 76.2)	93.5 43/46 (82.5, 97.8)	69.3 (42.0, 100.0)
Specificity (%) (95% CI)	48.6 1,220/2,511 (46.6, 50.5)	92.4 (92.1, 92.8)	48.2 1,227/2,545 (46.3, 50.2)	92.3 (92.0, 92.7)
PPV (%) (95% CI)	5.1 70/1,361 (4.6, 5.5)	5.1 (3.9, 6.3)	3.2 43/1,361 (2.8, 3.4)	3.0 (2.1, 3.9)
NPV (%) (95% CI)	99.2 1,220/1,230 (98.6, 99.5)	99.5 (99.0, 99.9)	99.8 1,227/1,230 (99.3, 99.9)	99.9 (99.7, 100.0)
PLR (95% CI)	1.70 (1.52, 1.83)	5.86 (3.63, 10.11)	1.81 (1.59, 1.92)	9.02 (5.48, 13.21)

Performance	Central Pathology Review Panel Diagnosis			
	≥ CIN2		≥ CIN3	
	Unadjusted Estimate	Adjusted Estimate (%, 95% CI)	Unadjusted Estimate	Adjusted Estimate (%, 95% CI)
NLR (95% CI)	0.26 (0.14, 0.44)	0.60 (0.26, 0.78)	0.14 (0.05, 0.36)	0.33 (0, 0.63)
Disease Prevalence (%)	3.1 80/2,591	0.9 (0.5, 1.4)	1.8 46/2,591	0.3 (0.2, 0.6)

The performance of the BD Onclarity HPV Assay as well as the FDA approved HPV test for detecting ≥CIN2 and ≥CIN3 is presented in Table 12.

Table 12: Performance of the BD Onclarity HPV Assay and an FDA Approved HPV Assay in the NILM Population (≥30 years)

Performance	Central Pathology Review Panel Diagnosis			
	Unadjusted Estimates		Adjusted Estimates	
	BD HPV	FDA Approved HPV test	BD HPV	FDA Approved HPV test
≥CIN2; unadjusted prevalence 3.1%, adjusted prevalence 0.9%				
Sensitivity (%) (95% CI)	87.5 70/80 (78.5, 93.1)	82.5 66/80 (72.7, 89.3)	44.1 (27.7, 77.8)	40.3 (25.2, 69.0)
Specificity (%) (95% CI)	48.6 1,220/2,508 (46.7, 50.6)	52.3 1,312/2,508 (50.4, 54.3)	92.4 (92.1, 92.8)	93.4 (93.1, 93.8)
PPV (%) (95% CI)	5.2 70/1,358 (4.6, 5.5)	5.2 66/1,262 (4.6, 5.7)	5.0 (3.9, 6.1)	5.3 (4.1, 6.5)
NPV (%) (95% CI)	99.2 1,220/1,230 (98.6, 99.5)	98.9 1,312/1,326 (98.4, 99.4)	99.5 (98.9, 99.9)	99.4 (98.9, 99.8)
PLR (95% CI)	1.70 (1.52, 1.84)	1.73 (1.52, 1.90)	5.82 (3.65, 10.19)	6.14 (3.83, 10.59)
NLR (95% CI)	0.26 (0.14, 0.44)	0.33 (0.20, 0.52)	0.61 (0.24, 0.78)	0.64 (0.33, 0.80)
≥CIN3; unadjusted prevalence 1.8%, adjusted prevalence 0.3%				
Sensitivity (%) (95% CI)	93.5 43/6 (82.5, 97.8)	87.0 40/46 (74.3, 93.9)	69.5 (42.8, 100.0)	63.3 (38.7, 94.9)
Specificity (%) (95% CI)	48.3 1,227/2,542 (46.3, 50.2)	51.9 1,320/2,542 (50.0, 53.9)	92.3 (92.0, 92.7)	93.3 (93.0, 93.7)
PPV (%) (95% CI)	3.2 43/1,358 (2.8, 3.4)	3.2 40/1,262 (2.7, 3.5)	3.0 (2.2, 4.0)	3.2 (2.3, 4.2)
NPV (%) (95% CI)	99.8 1,227/1,230 (99.3, 99.9)	99.5 1,320/1,326 (99.1, 99.8)	99.9 (99.7, 100.0)	99.9 (99.7, 100.0)
PLR (95% CI)	1.81 (1.59, 1.92)	1.81 (1.54, 1.98)	9.05 (5.52, 13.19)	9.49 (5.82, 14.42)
NLR (95% CI)	0.14 (0.05, 0.36)	0.25 (0.12, 0.49)	0.33 (0, 0.62)	0.39 (0.06, 0.66)

Note: This table is a paired analysis of specimens with a valid BD Onclarity HPV assay and FDA approved HPV test result. Three women with BD Onclarity results but without FDA approved test results were not included in the analysis.

PRIMARY SCREENING POPULATION (≥ 25 years)

A total of 29,633 women ≥ 25 years were enrolled in the study of which 29,513 were evaluable. Evaluable women had valid cytology and BD Onclarity HPV Assay results.

The median age of enrolled women in the primary screening population was 39 years with 18% of women 25–29, 32% of women 30–39, and 50% of women ≥40 years old. Approximately 79% of women were white and 18% were Black or African American.

A total of 5,534 women ≥25 years completed the colposcopy procedure with a valid CPR and BD Onclarity HPV result.

Screening Algorithms

The use of the BD Onclarity HPV Assay as a first line screening method was evaluated by comparing the Primary Screening algorithm with the Cytology algorithm, shown in Figures 1 and 2.

Figure 1: Primary Screening Algorithm

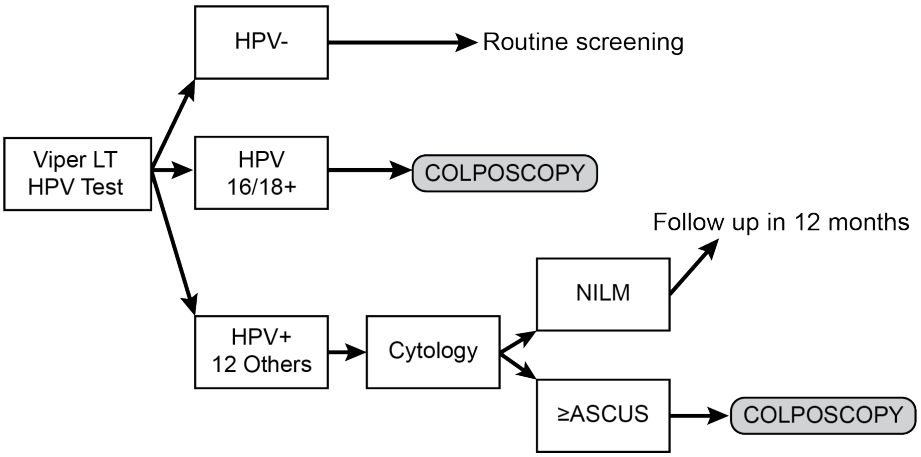
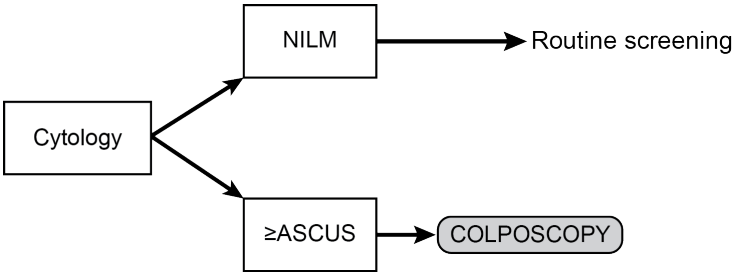


Figure 2: Cytology Algorithm



The performance of the Primary Screening algorithm with HPV 16 and 18 genotyping with reflex to cytology, and the Cytology algorithm (cytology alone) was evaluated and compared in the primary screening population by estimating the sensitivity, specificity, PPV, NPV, PLR, and NLR for the identification of ≥CIN2 and ≥CIN3. Results are presented in Table 13. As compared to cytology alone, the primary screening algorithm improves disease detection, while also reducing the number of colposcopies: 15.0% increase in ≥CIN3 sensitivity, 2.3% reduction in colposcopy rates (27.2% relative reduction).

Table 13: Performance Comparison of the Primary Screening Algorithm and Cytology Algorithm

Performance Metrics	≥CIN2; Prevalence (Adjusted) = 1.9%			≥CIN3; Prevalence (Adjusted) = 0.8%		
	Primary Screening Algorithm	Cytology Screening Algorithm	Difference	Primary Screening Algorithm	Cytology Screening Algorithm	Difference
Sensitivity (%) (95% CI)	53.72 (44.18, 65.52)	47.42 (39.31, 57.77)	6.30[a] (2.39, 10.51)	64.24 (50.59, 79.65)	49.20 (38.31, 62.64)	15.05[a] (9.12, 22.26)
Specificity (%) (95% CI)	94.80 (94.53, 95.06)	92.36 (92.03, 92.67)	2.45[a] (2.17, 2.74)	94.39 (94.11, 94.66)	91.96 (91.63, 92.27)	2.43[a] (2.15, 2.72)
PPV (%) (95% CI	16.48 (14.58, 18.48)	10.59 (9.34, 12.00)	5.89[a] (4.67, 7.16)	8.98 (7.70, 10.49)	5.00 (4.09, 5.98)	3.97[a] (3.14, 4.88)
NPV (%) (95% CI	99.08 (98.66, 99.41)	98.92 (98.53, 99.27)	0.15[a] (0.07, 0.24)	99.68 (99.44, 99.85)	99.53 (99.28, 99.71)	0.15[a] (0.09, 0.20)
PLR (95% CI)	10.34 (8.36, 12.76)	6.20 (5.06, 7.62)	4.13[a] (3.18, 5.50)	11.46 (8.99, 14.22)	6.12 (4.74, 7.82)	5.34[a] (4.00, 7.09)
NLR (95% CI)	0.49 (0.36, 0.59)	0.57 (0.46, 0.66)	-0.08[a] (-0.12, -0.04)	0.38 (0.22, 0.52)	0.55 (0.41, 0.67)	-0.17[a] (-0.25, -0.11)
Colposcopy Rate (95% CI)	6.11 (5.83, 6.38)	8.39 (8.08, 8.72)	-2.28[a] (-2.58, -2.00)	6.11 (5.83, 6.38)	8.39 (8.08, 8.72)	-2.28[a] (-2.58, -2.00)

[a]Indicates statistically significant difference at the 0.05 level

Baseline Risk of Disease for Women with NILM Cytology and Negative BD Onclarity HPV Test Results

The baseline risk of disease was compared in the primary screening population between women with a NILM cytology result and women with a negative BD Onclarity HPV result. Women with a negative BD Onclarity HPV result had a 0.20% baseline risk of ≥CIN3 compared to 0.47% for those with NILM cytology. The addition of a NILM cytology result to a negative BD Onclarity HPV result marginally decreased the ≥CIN3 risk (0.20 vs 0.19).

Table 14: Baseline Risk of Disease for Women with NILM Cytology and Negative BD Onclarity HPV Test Results in the Primary Screening (≥25 Years) Population

Subgroup	Percentage with result	≥CIN3 Risk (95% CI)	≥CIN2 Risk (95% CI)
NILM	91.61	0.47 (0.29, 0.72)	1.08 (0.73, 1.47)
HPV HR NEG	87.30	0.20 (0.03, 0.45)	0.63 (0.29, 1.07)
HPV HR NEG and NILM	82.95	0.19 (0.01, 0.46)	0.56 (0.20, 1.01)

Performance in Unvaccinated and Vaccinated Women

The clinical sites enrolled both HPV vaccinated and unvaccinated women, with a vaccinated enrollment limit of approximately 10%. The final vaccinated rate in the study was 9.1%, with an additional 1.4% unknown or missing vaccination status; vaccination status was self-reported.

The first HPV vaccine was introduced in 2006 and the clinical study occurred from 2013–2015, thus a majority of the vaccinated women in the study were under the age of 30 (3,064 vaccinated subjects overall, 2,625 under 30). The performance of the BD Onclarity HPV assay in vaccinated and unvaccinated women (excluding women with unknown or missing vaccination status) is shown below for women with ASCUS cytology (21–29 years old) and a subset of the primary screening population (25–29 years old).

Table 15: BD Onclarity HPV Assay Performance in Unvaccinated and Vaccinated Women with ASCUS Cytology (21–29 years old)

Performance Metrics	≥CIN2			
	Unvaccinated (prevalence 7.8%)		Vaccinated (prevalence 9.7%)	
	Estimate	95% CI	Estimate	95% CI
Sensitivity	100.0% (31/31)	(89.0%, 100.0%)	80.0% (12/15)	(54.8%, 93.0%)
Specificity	48.9% (180/368)	(43.8%, 54.0%)	52.1% (73/140)	(43.9%, 60.2%)
PPV	14.2% (31/219)	(13.3%, 15.5%)	15.2% (12/79)	(10.7%, 18.8%)
NPV	100.0% (180/180)	(98.1%, 100.0%)	96.1% (73/76)	(91.3%, 98.6%)
PLR	1.96	(1.82, 2.17)	1.67	(1.11, 2.16)
NLR	0	(0, 0.23)	0.38	(0.13, 0.89)
Performance Metrics	≥CIN3			
	Unvaccinated (prevalence 2.0%)		Vaccinated (prevalence 3.2%)	
	Estimate	95% CI	Estimate	95% CI
Sensitivity	100.0% (8/8)	(67.6%, 100.0%)	80.0% (4/5)	(37.6%, 96.4%)
Specificity	46.0% (180/391)	(41.2%, 51.0%)	50.0% (75/150)	(42.1%, 57.9%)
PPV	3.7% (8/219)	(3.6%, 4.0%)	5.1% (4/79)	(2.4%, 6.6%)
NPV	100.0% (180/180)	(98.6%, 100.0%)	98.7% (75/76)	(95.9%, 99.8%)
PLR	1.85	(1.82, 2.04)	1.60	(0.74, 2.12)
NLR	0	(0, 0.71)	0.40	(0.07, 1.28)

Table 16: BD Onclarity HPV Assay Performance in Unvaccinated and Vaccinated Women in the Primary Screening Population (25-29 years old)

Performance	Unadjusted Estimate		Adjusted Estimate	
	Unvaccinated	Vaccinated	Unvaccinated	Vaccinated
≥CIN2				
Sensitivity (%), (95% CI)	67.05 59/88 (56.69, 75.97)	60.00 15/25 (40.74, 76.60)	58.85 (41.92, 76.31)	59.26 (39.57, 76.83)
Specificity (%) (95% CI)	68.86 690/1,002 (65.93, 71.65)	79.64 223/280 (74.54, 83.94)	89.39 (88.39, 90.33)	93.78 (92.35, 95.43)
PPV (%) (95% CI)	15.90 59/371 (13.54, 18.15)	20.83 15/72 (14.46, 27.29)	15.97 (12.11, 19.79)	20.18 (10.83, 30.54)
NPV (%) (95% CI)	95.97 690/719 (94.75, 97.03)	95.71 223/233 (93.74, 97.45)	98.45 (97.00, 99.27)	98.86 (98.07, 99.44)
PLR (95% CI)	2.15 (1.78, 2.53)	2.95 (1.89, 4.20)	5.54 (3.80, 7.43)	9.53 (6.04, 14.24)
NLR (95% CI)	0.48 (0.35, 0.63)	0.50 (0.29, 0.75)	0.46 (0.26, 0.65)	0.43 (0.25, 0.65)

Performance	Unadjusted Estimate		Adjusted Estimate	
	Unvaccinated	Vaccinated	Unvaccinated	Vaccinated
Colpo Rate (95% CI)			12.21 (11.24, 13.23)	7.59 (5.84, 9.11)
Prevalence (95% CI)			3.31 (2.39, 4.67)	2.58 (1.65, 3.69)
≥CIN3				
Sensitivity (%) (95% CI)	81.58 31/38 (66.58, 90.78)	61.54 8/13 (35.52, 82.29)	58.48 (31.62, 92.66)	61.35 (34.93, 86.50)
Specificity (%) (95% CI)	67.68 712/1,052 (64.79, 70.44)	78.08 228/292 (72.99, 82.45)	88.59 (87.57, 89.54)	93.17 (91.77, 94.93)
PPV (%) (95% CI)	8.36 31/371 (6.83, 9.54)	11.11 8/72 (6.51, 15.54)	8.12 (5.43, 11.07)	11.20 (4.58, 19.77)
NPV (%) (95% CI)	99.03 712/719 (98.24, 99.51)	97.85 228/233 (96.44, 99.00)	99.20 (97.80, 99.90)	99.42 (98.87, 99.88)
PLR (95% CI)	2.52 (2.03, 2.92)	2.81 (1.57, 4.13)	5.12 (2.68, 8.28)	8.98 (4.86, 14.76)
NLR (95% CI)	0.27 (0.14, 0.49)	0.49 (0.23, 0.83)	0.47 (0.08, 0.77)	0.41 (0.14, 0.69)
Colpo Rate Performance (95% CI)			12.21 (11.24, 13.23)	7.59 (5.84, 9.11)
Prevalence (95% CI)			1.70 (0.92, 2.97)	1.39 (0.68, 2.25)

Comparison of Results from the BD Onclarity HPV Assay for PreQuot vs PostQuot BD SurePath Clinical Samples

An equivalence study design was employed to compare the performance of the BD Onclarity HPV Assay with a cervical specimen tested prior to (PreQuot) or after (PostQuot) normal cytology processing.

A total of 3,879 subjects were enrolled in the PreQuot vs. PostQuot study. During the Baseline Study, 0.5 mL of the cervical specimen stored in BD SurePath was manually transferred into a BD Onclarity HPV LBC Diluent tube (PreQuot). After normal processing per the BD PrepMate labeling, 0.5 mL of the residual specimen in BD SurePath was manually transferred into a BD Onclarity HPV LBC Diluent tube (PostQuot). The comparative performance of the PreQuot to the PostQuot sample when tested with the BD Onclarity HPV assay is shown in Tables 17 and 18.

Table 17: Agreement Results of the BD Onclarity HPV Assay PreQuot vs PostQuot

Population	Positive Percent Agreement (95%CI)	Negative Percent Agreement (95%CI)	Overall Percent Agreement (95%CI)
NILM ≥30 yrs (%)	86.0	99.3	98.3
	(80.3, 90.3)	(98.8, 99.5)	(97.8, 98.8)
ASC-US ≥21 yrs (%)	100.0	97.7	98.5
	(95.0, 100.0)	(93.5, 99.2)	(95.8, 99.5)
>ASC-US ≥21 yrs (%)	97.6	100.0	98.1
	(91.8, 99.4)	(83.2, 100.0)	(93.3, 99.5)
Screening Population ≥25 yrs (%)	91.0	99.0	98.1
	(87.7, 93.4)	(98.6, 99.3)	(97.6, 98.5)

Table 18: BD Onclarity HPV Assay PreQuot vs PostQuot Results

BD Onclarity HPV Assay PostQuot Result	BD Onclarity HPV Assay PreQuot Result							
	ASC-US ≥21		>ASC-US ≥21		NILM ≥30		All Subjects ≥25	
	POS	NEG	POS	NEG	POS	NEG	POS	NEG
Positive	73	3	83	0	160	18	353	30
Negative	0	129	2	19	26	2,431	35	3,052
Total	73	132	85	19	186	2,449	388	3,082

Clinical Performance-PreservCyt and BD Onclarity HPV Cervical Brush specimens

BD Onclarity HPV Cervical Brush specimens and PreservCyt specimens, were collected from 836 protocol compliant women who were referred for follow-up due to abnormal Pap test or HPV infection, or women attending a clinic for a routine visit at two geographically diverse clinical sites in Europe. Two specimens were collected from each enrolled subject in the following order: PreservCyt specimen and a BD Onclarity HPV Cervical Brush specimen (transported in a BD Onclarity HPV Cervical Brush Diluent tube). For each cytology vial collected, 0.5 mL was aliquoted into a BD Onclarity HPV LBC Diluent tube. Cytology, HPV DNA results (digene® Hybrid Capture 2 (hc2) High-Risk HPV DNA Test), and Roche LINEAR ARRAY® HPV Genotyping Test (RLA) results were available for most of the specimens. Histology results were available for most of the subjects attending a high-risk clinic. Each site also enrolled residual specimens (PreservCyt) with associated cytology results, HPV DNA results (digene Hybrid Capture 2 High-Risk HPV DNA Test), Roche LINEAR ARRAY HPV Genotyping Test results, and where applicable, histology results. For each specimen enrolled, 0.5 mL was aliquoted into a BD Onclarity HPV LBC Diluent tube. There were 510 compliant retrospective specimens enrolled, with histology results available for 234 women.

All specimens were tested on the BD Viper LT System in accordance with the assay package insert and user's manual. For each media type, the clinical sensitivity and specificity for detection of disease, which is defined as (1) Cervical Intraepithelial Neoplasia (CIN2) or greater histology result or (2) Cervical Intraepithelial Neoplasia (CIN3) or greater histology result, was calculated. Final data analysis includes BD Onclarity HPV assay results 361 PreservCyt specimens and a total of 515 BD Onclarity HPV Cervical Brush specimens. The performance estimates for the detection of high grade cervical disease for the BD Onclarity HPV assay and the hc2 assay are presented in Tables 19 and 20 for PreservCyt media, and Tables 22 and 23 for the BD Onclarity HPV Cervical Brush specimens.

BD Onclarity HPV assay results were also compared to HPV DNA results from the *digene* Hybrid Capture 2 High-Risk HPV DNA Test and Roche LINEAR ARRAY HPV Genotyping Test (composite comparator). A positive result from both the hc2 and RLA (high risk) assays is defined as composite comparator positive, a negative result from both the hc2 and RLA (high risk) assays is defined as composite comparator negative, and when the two assays disagree (or results were not available; for both tests), the composite comparator result is defined as unresolved. Positive, negative, and overall percent agreement was calculated for each media type versus the composite comparator. Final data analysis includes BD Onclarity HPV Assay and composite comparator results (regardless of histology status) from 674 PreservCyt specimens (Table 21).

Table 19: Performance of the BD Onclarity HPV Assay with PreservCyt Media Compared to Histology Results (CIN2+)

	BD Onclarity HPV Assay		hc2 HPV DNA Test	
	Estimate	95% Confidence Interval	Estimate	95% Confidence Interval
Sensitivity	96.4% (163/169)	(92.5, 98.4)	97.0% (160/165)	(93.1, 98.7)
Specificity	49.0% (94/192)	(42.0, 56.0)	40.8% (75/184)	(33.9, 48.0)

Table 20: Performance of the BD Onclarity HPV Assay with PreservCyt Media Compared to Histology Results (CIN3+)

	BD Onclarity HPV Assay		hc2 HPV DNA Test	
	Estimate	95% Confidence Interval	Estimate	95% Confidence Interval
Sensitivity	95.6% (86/90)	(89.1, 98.3)	97.7% (85/87)	(92.0, 99.4)
Specificity	35.4% (96/271)	(30.0, 41.3)	29.8% (78/262)	(24.6, 35.6)

Table 21: Performance of the BD Onclarity HPV Assay with PreservCyt Media Compared to Composite Comparator

BD Onclarity HPV Assay	Composite Comparator Result						
	Positive	Negative	Unresolved*	Total	Positive Percent Agreement (95% Confidence Interval)	Negative Percent Agreement (95% Confidence Interval)	Overall Percent Agreement (95% Confidence Interval)
Positive	249	10	20	279	97.3% (94.5%, 98.7%)	97.3% (95.1%, 98.5%)	97.3% (95.7%, 98.3%)
Negative	7	361	27	395			
Total	256	371	47	674			

* hc2 and RLA results do not agree or results were not available for both tests.

Table 22: Performance of the BD Onclarity HPV Assay with the BD Onclarity HPV Cervical Brush Compared to Histology Results (CIN2+)

Site		BD Onclarity HPV Assay		hc2 HPV DNA Test	
		Estimate	95% Confidence Interval	Estimate	95% Confidence Interval
A	Sensitivity	97.2% (104/107)	(92.1%, 99.0%)	99.1% (106/107)	(94.9%, 99.8%)
	Specificity	17.9% (25/140)	(12.4%, 25.0%)	21.4% (30/140)	(15.4%, 28.9%)
B	Sensitivity	100.0% (121/121)	(96.9%, 100.0%)	97.5% (116/119)	(92.8%, 99.1%)
	Specificity	37.4% (55/147)	(30.0%, 45.5%)	43.0% (61/142)	(35.1%, 51.2%)

Table 23: Performance of the BD Onclarity HPV Assay with the BD Onclarity HPV Cervical Brush Compared to Histology Results (CIN3+)

Site		BD Onclarity HPV Assay		hc2 HPV DNA Test	
		Estimate	95% Confidence Interval	Estimate	95% Confidence Interval
A	Sensitivity	97.3% (72/74)	(90.7%, 99.3%)	98.6% (73/74)	(92.7%, 99.8%)
	Specificity	15.0% (26/173)	(10.5%, 21.1%)	17.3% (30/173)	(12.4%, 23.7%)
B	Sensitivity	100.0% (60/60)	(94.0%, 100.0%)	98.3% (57/58)	(90.9%, 99.7%)
	Specificity	26.4% (55/208)	(20.9%, 32.8%)	31.0% (63/203)	(25.1%, 37.7%)

.

Analytical Performance

Analytical Sensitivity at the Clinical Cutoff

The limit of detection (LOD) at the HPV clinical cutoff was determined for the BD Onclarity HPV Assay using HPV positive cell lines: SiHa (HPV 16), HeLa (HPV 18) and MS751 (HPV 45) and cloned plasmid DNA containing the sequences for the following HPV genotypes: HPV 31, 33, 35, 39, 51, 52, 56, 58, 59, 66, and 68 in BD SurePath Preservative Fluid, PreservCyt Solution and BD Onclarity HPV Cervical Brush Diluent containing a HPV-negative cell line (C33A). The HPV cell lines were tested individually whereas the HPV plasmids were tested collectively in three groups: 1) HPV 31, 33, 51, 52, and 59; 2) HPV 56, 58, 68; and 3) HPV 35 and 66. A minimum of forty-five replicates of each of six target levels for the HPV cell lines and twenty replicates of each of six target levels for the HPV plasmids were tested across a minimum of three lots of reagents and a minimum of three BD Viper LT Systems. The LOD is the level of HPV DNA in the undiluted specimen that has positive results above the clinical cutoff at least 95% of the time. The maximum LOD value for each of the HPV genotypes and media is described in Table 24. The cells/mL nomenclature refers to the target concentration in the LBC diluent tube.

Table 24: Analytical Sensitivity

Target	BD SurePath Media (95% Confidence Interval)	PreservCyt Media (95% Confidence Interval)	BD Onclarity HPV Cervical Brush Diluent (95% Confidence Interval)
SiHa (HPV 16) cells/mL	50 (37–67)	163 (117–228)	137 (131–144)
HeLa (HPV 18) cells/mL	208 (168–257)	406 (267–617)	51 (46–56)
MS751 (HPV 45) cells/mL	862 (669–1,111)	1233 (947–1,606)	305 (284–343)
HPV 31 copies/mL	830 (718–879)	936 (886–961)	692 (650–817)
HPV 33 copies/mL	1,665 (1,495-2,030)	1,880 (1,806–1,987)	1,376 (1,272–1,451)
HPV 35 copies/mL	1,550 (1,472–1,655)	1,655 (1,567–1,744)	1,552 (1,317–1,780)
HPV 39 copies/mL	1,794 (1,617–1,862)	1,880 (1,775–2,136)	1,531 (1,419–1,685)
HPV 51 copies/mL	1,522 (1,317-1,613)	1,343 (1,262–1,551)	1,229 (1,155–1,353)
HPV 52 copies/mL	814 (776–951)	951 (850–1082)	833 (744–934)
HPV 56 copies/mL	1,131 (941–1,295)	1,085 (1,018–1,363)	836 (737–911)
HPV 58 copies/mL	2,294 (2,137–2,541)	2,611 (2,043–2,809)	2,990 (2,656–7,819)
HPV 59 copies/mL	1,000 (942–1,152)	994 (933–1,246)	772 (722–899)
HPV 66 copies/mL	862 (823–916)	1,014 (911–1,101)	701 (646–767)
HPV 68 copies/mL	2,367 (2,227–2,646)	2,382 (2,231 –2,746)	2,079 (1,995–2,125)

Cross-Reactivity

A panel of bacteria, yeast and cultured viruses along with cloned plasmid DNA containing high-risk and low-risk HPV target sequences was used to evaluate the analytical specificity of the BD Onclarity HPV Assay on the BD Viper LT System. Each potential cross-reactant was tested individually in BD SurePath Preservative Fluid and PreservCyt Solution containing a HPV- negative cell line (C33A). The microorganisms are described in Tables 25 and 26. The BD Onclarity HPV Assay did not cross-react with any of the microorganisms tested.

Table 25: Microorganisms Tested for Analytical Specificity

Bacteria*	**Bacteria***	**Viruses****
Actinomyces israelii	*Mycoplasma genitalium*	Adenovirus, type 5
Atopobium vaginae	*Neisseria gonorrhoeae*	EBV-1, B95-8 Strain
Bacteroides fragilis	*Peptostreptococcus anaerobius*	HCMV, AD169 Strain
Bacteroides ureolyticus ureolyticus	*Prevotella bivia*	HIV-1
Bifidobacterium adolescentis	*Prevotella disiens*	HSV1
Bifidobacterium breve	*Proteus mirabilis*	HSV2
Bifidobacterium longum ssp. *longum*	*Proteus vulgaris*	**High risk HPV*****
Chlamydia trachomatis	*Providencia stuartii*	HPV 16
Clostridium perfringens	*Pseudomonas aeruginosa*	HPV 18
Corynebacterium genitalium	*Staphylococcus aureus*	HPV 31
Enterobacter cloacae ssp. *cloacae*	*Staphylococcus epidermidis*	HPV 33
Enterococcus faecalis	*Streptococcus agalactiae*	HPV 35
Enterococcus faecium	*Streptococcus pyogenes*	HPV 39
Escherichia coli	*Ureaplasma urealyticum*	HPV 45
Fusobacterium nucleatum ssp. *nucleatum*	**Yeast/Protozoa********	HPV 51
Gardnerella vaginalis	Candida albicans	HPV 52
Klebsiella pneumonia ssp. *ozaenae*	*Trichomonas vaginalis*	HPV 56
Lactobacillus acidophilus		HPV 58
Mycobacterium smegmatis		HPV 59
		HPV 66
		HPV 68

*Bacteria tested at approximately 1.0 x 10^7 CFU/mL except for the following: *Chlamydia trachomatis* (1.0 x 10^7 EB/mL), Mycobacterium smegmatis (2.5 x 10^6 CFU/mL), and Ureaplasma urealyticum (8.0 x 10^6 CFU/mL).

**Viruses tested at 1.0 x 10^6 VP/mL.

***High risk HPV plasmid DNA tested at 1.0 x 10^6 copies/mL.

**** Yeast (Candida albicans) tested at approximately 1.0 x 10^7 CFU/mL; Protozoa (*Trichomonas vaginalis*) tested at 1.4 x 10^6 CFU/mL.

Table 26: Low Risk HPV Plasmids Tested for Analytical Specificity

HPV 6	HPV 69
HPV 11	HPV 70
HPV 26	HPV 73
HPV 30	HPV 82
HPV 34	HPV 97
HPV 53	HPV c85
HPV 67	

* Low-risk HPV plasmid DNA tested at 1.0 x 10^6 copies/mL

Interfering Substances

The potential for interference in the BD Onclarity HPV Assay on the BD Viper LT System was determined with exogenous and endogenous substances that may be present in clinical cervical specimens. Contrived HPV negative specimens and HPV positive specimens (co-spiked with SiHa, HeLa and MS751 cells at 3 x LOD) were tested in the presence or absence of each potential interfering substance. Substances used in these studies are described in Table 27. The concentrations represent the highest level of substance that did not result in any interference in the BD Onclarity HPV Assay.

Table 27: Potential Interfering Substances

	BD Onclarity HPV Cervical Brush Diluent	BD SurePath Media	PreservCyt Media
Potential Interfering Substance	**Concentration tested**	**Concentration tested**	**Concentration tested**
KY® Vaginal Lubricant	10% (w/v)	6% (w/v)	10% (w/v)
VCF® Vaginal Contraceptive Film	3% (w/v)	10% (w/v)	10% (w/v)
VCF® Vaginal Contraceptive Foam	10% (w/v)	10% (w/v)	10% (w/v)
Conceptrol ® Contraceptive Gel	1% (w/v)	10% (w/v)	10% (w/v)
Monistat® 3*	2% (w/v)	2% (w/v)	1.4% (w/v)
Clotrimazole 7	10% (w/v)	10% (w/v)	10% (w/v)
Vagistat®-1 Tioconazole	2% (w/v)	2% (w/v)	2% (w/v)
Clindamycin Vaginal Cream	9% (w/v)	8% (w/v)	10% (w/v)
Summer's Eve® Douche	10% (v/v)	10% (v/v)	10% (v/v)
Replens	10% (w/v)	10% (w/v)	
Zovirax® (Acyclovir) Cream	10% (w/v)	7% (w/v)	7% (w/v)
Vandazole™ Gel (Metronidazole Vaginal Gel, 0.75%)	10% (w/v)	10% (w/v)	10% (w/v)
Summer's Eve Deodorant	2% (w/v)	3% (w/v)	2% (w/v)
Bovine Mucin	10% (v/v)	8% (v/v)	8% (v/v)
Progesterone	20 ng/mL	20 ng/mL	20 ng/mL
Estradiol	1.2 ng/mL	1.2 ng/mL	1.2 ng/mL
Whole Blood	4% (v/v)	5% (v/v)	5% (v/v)
Leukocytes	$1x10^6$ cells/mL	$1x10^6$ cells/mL	$1x10^6$ cells/mL
Semen	10% (v/v)	10% (v/v)	10% (v/v)
Acetic Acid Wash**			5% (v/v)
Blood + Acetic Acid Wash			5% Blood (v/v), 2.5% Acetic Acid Wash (v/v)

*Concentrations higher than those listed resulted in liquid level failures during extraction on the BD Viper LT System.

**Acetic Acid Wash consists of 1 part Glacial Acetic Acid: 9 parts CytoLyt® solution.

Competitive Target Interference

The potential for the inhibition of HPV detection due to one target present at a high level and another target present at low levels during a mixed infection was evaluated in the BD Onclarity HPV Assay. SiHa, HeLa and MS751 cells were tested individually or collectively at 3 x LOD in the presence or absence of competitive HPV target(s) at 1.0 x 10^6 copies/mL in BD SurePath Preservative Fluid, PreservCyt Solution and BD Onclarity HPV Cervical Brush Diluent containing a HPV negative cell line (C33A) (Table 28)

Table 28: Competitive Target Interference

HPV Assay Tube Type	Individual HPV Cellular Targets at 3 x	HPV Plasmids at 1 x 10^6 copies/mL	HPV Cellular Target Detection in the Presence or Absence of Competing Genotypes (HPV Plasmids)
G1 Genotypes with G1 co-amplified targets	SiHa (HPV 16)	HPV 18 + HPV 45	Yes
	HeLa (HPV 18)	HPV 16 + HPV 45	Yes
	HPV 45 (MS751)	HPV 16 + HPV 18	Yes
G1 Genotypes with G2 co-amplified targets	SiHa + HeLa + MS751	HPV 31 + HPV 33 + HPV 56 + HPV 58 + HPV 59 + HPV 66	Yes
G1 Genotypes with G3 co-amplified targets	SiHa + HeLa + MS751	HPV 35 + HPV 39 + HPV 51+ HPV 52 + HPV 68	Yes

Reproducibility

The reproducibility of the BD Onclarity HPV Assay was evaluated on the BD Viper LT instrument using a four-member panel consisting of negative, high negative, low positive, and moderate positive specimens. The positive panel members were composed of SiHa, HeLa and MS751 cells spiked collectively into pools of HPV negative clinical BD SurePath specimens and BD Onclarity HPV Cervical Brush Diluent containing a HPV negative cell line (C33A). The panel was tested across an equal distribution of three lots of reagents and three instruments over 12 days. The data are summarized in Table 29.

Table 29: Summary of Reproducibility Data for the BD Onclarity HPV Assay on the BD Viper LT System

							Inter-Run		Intra-Run		Total	
Media	**Cell Line (Genotype)**	**Panel Level**	**Concentration (cells/mL)**	**% Correct**	**95% Confidence Interval**	**Mean Ct**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
SurePath	SiHa (HPV16)	Neg	0	100% (216/216)	(98.25–100%)	NA	NA	NA	NA	NA	NA	NA
		High Neg	8.8	95.79% (205/214)	(92.20–97.77%)	38.42	0.23	0.59	0.40	1.04	0.54	1.41
		Low Pos	220	95.83% (207/216)	(92.27–97.79%)	36.59	0.00	0.00	0.65	1.78	0.67	1.84
		Mod Pos	660	99.07% (213/215)	(96.67–99.74%)	34.98	0.17	0.50	0.55	1.56	0.59	1.68
	HeLa (HPV18)	Neg	0	100% (216/216)	(98.25–100%)	NA	NA	NA	NA	NA	NA	NA
		High Neg	102	98.61% (213/216)	(96– 99.53%)	35.89	0.24	0.68	0.75	2.09	0.85	2.37
		Low Pos	914	99.54% (215/216)	(97.42–99.92%)	32.7	0.16	0.5	0.3	0.92	0.37	1.14
		Mod Pos	2,742	100% (216/216)	(100–98.25%)	30.68	0.13	0.43	0.22	0.72	0.3	0.98
	MS-751 (HPV 45)	Neg	0	100% (216/216)	(98.25–100%)	NA	NA	NA	NA	NA	NA	NA
		High Neg	395	100% (216/216)	(98.25–100%)	35.77	0	0	0.52	1.45	0.55	1.53
		Low Pos	3,793	100% (216/216)	(100–98.25%)	32.71	0.2	0.6	0.26	0.8	0.36	1.1
		Mod Pos	11,378	99.54% (215/216)	(97.42–99.92%)	31.33	0.18	0.57	0.35	1.1	0.41	1.31

							Inter-Run		Intra-Run		Total	
Media	**Cell Line (Genotype)**	**Panel Level**	**Concentration (cells/mL)**	**% Correct**	**95% Confidence Interval**	**Mean Ct**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Cervical Brush Diluent	SiHa (HPV16)	Neg	0	100% (214/214)	(98.24–100%)	NA	NA	NA	NA	NA	NA	NA
		High Neg	32	100% (218/218)	(98.27–100%)	36.29	0.09	0.25	0.59	1.63	0.62	1.71
		Low Pos	205	94.91% (205/216)	(91.11–97.13%)	33.63	0.26	0.78	0.33	0.97	0.43	1.27
		Mod Pos	615	100% (216/216)	(98.25–100%)	31.8	0.16	0.51	0.18	0.56	0.25	0.79
	HeLa (HPV18)	Neg	0	100% (214/214)	(98.24–100%)	NA	NA	NA	NA	NA	NA	NA
		High Neg	13	99.07% (214/216)	(96.69–99.75%)	35.69	0.1	0.29	0.78	2.18	0.8	2.23
		Low Pos	76	99.08% (216/218)	(96.72–99.75%)	33.34	0.15	0.44	0.25	0.76	0.3	0.91
		Mod Pos	228	99.54% (215/216)	(97.42–99.92%)	32.07	0.24	0.73	0.25	0.78	0.37	1.16
	MS-751 (HPV45)	Neg	0	100% (214/214)	(98.24–100%)	NA	NA	NA	NA	NA	NA	NA
		High Neg	59	100% (216/216)	(98.25–100%)	36.54	0.22	0.61	0.62	1.68	0.66	1.81
		Low Pos	457	99.54% (215/216)	(97.42–99.92%)	33.22	0.16	0.48	0.25	0.75	0.32	0.95
		Mod Pos	1,371	100% (218/218)	(98.27–100%)	31.74	0.14	0.43	0.21	0.67	0.27	0.84

Cross Contamination

A study was performed to evaluate the risk of producing a false positive result in either the same run (within run cross- contamination) or in a subsequent run (between run carry-over contamination) on the BD Viper LT System. One run was performed per day over five days on each of three instruments comprising a total of 675 test replicates. Each run consisted of BD SurePath Preservative Fluid or PreservCyt Solution specimens containing a HPV negative cell line (C33A) with and without SiHa cells spiked at 1.0×10^5 cells/mL arranged in an alternating checkerboard pattern. The overall contamination rate with both BD SurePath Preservative Fluid and PreservCyt Solution was 0.00%.

Neat (In-vial) Specimen Stability

Analytical studies were performed to support the storage claims for the stability of neat cervical specimens. BD SurePath Preservative Fluid, PreservCyt Solution and BD Onclarity HPV Cervical Brush Diluent specimens containing a HPV negative cell line (C33A), were spiked with SiHa cells at 3 x LOD and stored at 2–8 °C, 30 °C and -20 °C for multiple time points. At each time point, the specimens were removed from storage and tested with the BD Onclarity HPV Assay on the BD Viper LT System. Twenty-four assay replicates were generated for each condition (specimen type/temperature/duration). Stability was achieved for 180 days at 2–8 °C, and 180 days at 20 °C.

Diluted Specimen Stability

Analytical studies were performed to support the storage claims for the stability of diluted cervical specimens. BD SurePath Preservative Fluid and PreservCyt Solution specimens containing a HPV negative cell line (C33A) were spiked with SiHa cells at 3 X LOD, diluted with BD HPV LBC Diluent and then stored at 2–8 °C, 30 °C and -20 °C for multiple time points. At each time point, the specimens were removed from storage and tested with the BD Onclarity HPV Assay on the BD Viper LT System. Twenty-four assay replicates were generated for each condition (specimen type/temperature/duration). Stability was achieved for 15 days 2–30 °C and for 90 days at -20 °C.

Post Pre-warm Specimen Stability

Analytical studies were performed to support the storage claims for the stability of post pre-warm cervical specimens. BD SurePath Preservative Fluid, PreservCyt Solution and BD Onclarity HPV Cervical Brush Diluent specimens containing a HPV negative cell line (C33A), were spiked with SiHa cells at 3 x LOD, diluted with BD Onclarity HPV LBC Diluent and then pre-warmed with the BD Viper LT Pre-warm Heater. The processed specimens were stored at 2–8 °C, 30 °C and -20 °C for multiple time points. At each time point, the specimens were removed from storage and tested with the BD Onclarity HPV Assay on the BD Viper LT System. Twenty-four assay replicates were generated for each condition (specimen type/ temperature/duration). Stability was achieved for 7 days at 2–30 °C and for 180 days at -20 °C.

REFERENCES

1. Pirog EC, Kleter B, Olgac S, Bobkiewicz P, Lindeman J, Quint WG, et al. (2000). Prevalence of human papillomavirus DNA in different histological subtypes of cervical adenocarcinoma. The *American Journal of Pathology*, 157(4): 1055–1062.
2. Rodríguez-Carunchio L, Soveral I, Steenbergen RDM, Torné A, Martinez S, Fusté P, et al. (2015). HPV-negative carcinoma of the uterine cervix: a distinct type of cervical cancer with poor prognosis. BJOG, 122(1): 119–127.
3. CDC. (2016). Genital HPV Infection - Fact Sheet. http://www.cdc.gov/std/hpv/stdfact-hpv.htm.
4. WHO. (2015). Human papillomavirus (HPV) and cervical cancer. Fact sheet N°380 http://www.who.int/mediacentre/factsheets/fs380/en/.
5. National Cancer Institute. (2018). Surveillance, Epidemiology, and End Results Program-Cervical Cancer. https://seer.cancer.gov/statfacts/html/cervix.html.
6. Doorbar J, Egawa N, Griffin H, Kranjec C & Murakami I. (2015). Human papillomavirus molecular biology and disease association. *Reviews in Medical Virology*, 25 Suppl 1, 2–23.
7. Kjær SK, Frederiksen K, Munk C, Iftner T. (2010). Long-term absolute risk of cervical intraepithelial neoplasia grade 3 or worse following human papillomavirus infection: role of persistence. J Natl Cancer Inst.;102(19):1478–88.
8. Ejegod DM, Serrano I, Cuschieri KS, Nussbaumer WA, Vaughan LM, et al. 2013. Clinical Validation of the BD Onclarity™ HPV Assay Using a Non-Inferiority Test. *J Med Microb Diagn* S3: 003. doi:10.4172/2161-0703.S3-003
9. Cuzick J, Ahmad AS, Austin J, Cadman L, Ho L, et al. 2016. A comparison of different human papillomavirus tests in PreservCyt versus SurePath in a referral population-PREDICTORS 4. *J. Clin. Virol.* 82:145–51
10. Szarewski A, Mesher D, Cadman L, Austin J, Ashdown-Barr L, Ho L, Terry G, Liddle S, Young M, Stoler M, McCarthy J, Wright C, Bergeron C, Soutter WP, Lyons D, Cuzick, J. Comparison of seven tests for high-grade cervical intraepithelial neoplasia in women with abnormal smears: the Predictors 2 study. *J. Clin. Microbiol.* 2012;50:1867–73
11. Cuzick, J, Cadman, L, Mesher, D, Austin, J, Ashdown-Barr, L, Ho, L, Terry, G, Liddle, S, Wright, C, Lyons, D, Szarewski, A. Comparing the performance of six human papillomavirus tests in a screening population. *Br. J. Cancer* 2013;108:908–13
12. Bottari F, Sideri M, Gulmini C, Igidbashian S, Tricca A, Casadio C, Carinelli S, Boveri S, Ejegod D, Bonde J, Sandri MT. Comparison of Onclarity Human Papillomavirus (HPV) Assay with Hybrid Capture II HPV DNA Assay for Detection of Cervical Intraepithelial Neoplasia Grade 2 and 3 Lesions. *J. Clin. Microbiol.* 2015;53: 2109–14
13. Cuschieri K, Geraets DT, Moore C, Quint W, Duvall E, Arbyn M. Clinical and Analytical Performance of the Onclarity HPV Assay Using the VALGENT Framework. *J. Clin. Microbiol.* 2015;53:3272–9
14. Bhatia R, Kavanagh K, Cubie HA, Serrano I, Wennington H, Hopkins M, Pan J, Pollock KG, Palmer TJ, Cuschieri K. Use of HPV testing for cervical screening in vaccinated women Insights from the SHEVa (Scottish HPV Prevalence in Vaccinated Women) study. *Int. J. Cancer* 2016;138, 2922–31.
15. Cuzick J, Ahmad AS, Austin J, Cadman L, Ho L, et al. A comparison of different human papillomavirus tests in PreservCyt versus SurePath in a referral population-PREDICTORS 4. *J. Clin. Virol.* 2016;82:145–51
16. Tjalma WA & Depuydt CE. (2013). Cervical cancer screening: which HPV test should be used-L1 or E6/E7? *European Journal of Obstetrics & Gynecology and Reproductive Biology*, 170(1): 45–46.
17. Tjalma WA & Depuydt CE. (2014). Cervical atypical glandular cells and false negative HPV testing: a dramatic reality of the wrong test at the right place. *European Journal of Gynaecological Oncology*, 35(2): 117–20.
18. Higuchi R, Fockler C, Dollinger G & Watson R. (1993). Kinetic PCR analysis: real-time monitoring of DNA amplification reactions. *Biotechnology (N Y)*, 11(9): 1026–30.
19. Clinical and Laboratory Standards Institute. 2005. Approved Guideline M29-A3. Protection of laboratory workers from occupationally acquired infections, 3rd ed., CLSI, Wayne, PA.
20. Garner JS. (1996). Hospital Infection Control Practices Advisory Committee, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Guideline for isolation precautions in hospitals. *Infect. Control Hosp. Epidemiol.* 17: 53–80.
21. US Department of Health and Human Services. (2007). "Biosafety in microbiological and biomedical laboratories." HHS Publication (CDC), 5th ed. US Government Printing Office, Washington, DC.

22. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC). Official Journal L262, 17/10/2000, p. 0021–0045.

23. Wright TC, Massad LS, Dunton CJ, Spitzer M, Wilkinson EJ, et al. (2007). 2006 consensus guidelines for the management of women with abnormal cervical cancer screening tests. *American Journal of Obstetrics and Gynecology*, 197 (4);

24. Darragh TM, Colgan TJ, Cox JT, Heller DS, Henry MR, Luff RD, McCalmont T, Nayar R, Palefsky JM, Stoler MH, Wilkinson EJ, Zaino RJ, Wilbur DC, for members of the LAST Project Work Groups. The Lower Anogenital Squamous Terminology Standardization Project for HPV-Associated Lesions: Background and Consensus Recommendations from the College of American Pathologists and the American Society for Colposcopy and Cervical Pathology. Arch Pathol Lab Med 2012; 136:1266–1297 Available at http://www.archivesofpathology.org/doi/pdf/10.5858/arpa.LGT200570?code=coap-site (Accessed 12/28/16)

Technical Information: In the United States contact BD Technical Service and Support at 1.800.638.8663 or www.bd.com.

Change History

Revision	Date	Change Summary
11	2019-05	Updated Intended Use Statement to include ASCUS, Co-test and Primary Screening for BD SurePath and PreservCyt. New content for Summary and Explanation of Test, and Principles of the Procedure. Added GHS/CLP Warning and Precautions. Added procedural steps to Test Procedure. Added additional Procedural Limitations. Converted the Reagent and Material Provided section into a table format. Updated Clinical study design and data section by removing previous BD SurePath trial data and replacing with US PMA clinical Trial design and related data. Updated PreservCyt clinical trial data with new clinical cutoff. Updated analytical performance for both BD SurePath and PreservCyt with new clinical cutoff.

US Customers only: For symbol glossary, refer to www.bd.com/symbols-glossary

Manufacturer / Производител / Výrobce / Fabrikant / Hersteller / Κατασκευαστής / Fabricante / Tootja / Fabricant / Proizvođač / Gyártó / Fabbricante / Атқарушы / 제조업체 /Gamintojas / Ražotājs / Tilvirker / Producent / Producător / Производитель / Výrobca / Proizvođač / Tillverkare / Üretici / Виробник / 生产厂商

Use by / Използвайте до / Spotřebujte do / Brug før / Verwendbar bis / Χρήση έως / Usar antes de / Kasutada enne / Date de péremption / 사용 기한 / Upotrijebiti do / Felhasználhatóság dátuma / Usare entro / Дейін пайдалануға / Naudokite iki / Izlietot līdz / Houdbaar tot / Brukes for / Stosować do / Prazo de validade / A se utiliza până la / Использовать до / Použite do / Upotrebiti do / Använd före / Son kullanma tarihi / Використати до\line / 使用截止日期
YYYY-MM-DD / YYYY-MM (MM = end of month)
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = края на месеца)
RRRR-MM-DD / RRRR-MM (MM = konec měsíce)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutning af måned)
JJJJ-MM-TT / JJJJ-MM (MM = Monatsende)
EEEE-MM-HH / EEEE-MM (MM = τέλος του μήνα)
AAAA-MM-DD / AAAA-MM (MM = fin del mes)
AAAA-KK-PP / AAAA-KK (KK = kuu lõpp)
AAAA-MM-JJ / AAAA-MM (MM = fin du mois)
GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)
ÉÉÉÉ-HH-NN / ÉÉÉÉ-HH (HH = hónap utolsó napja)
AAAA-MM-GG / AAAA-MM (MM = fine mese)
ЖЖЖЖ-АА-КК / ЖЖЖЖ-АА / (АА = айдың соңы)
YYYY-MM-DD/YYYY-MM(MM = 월 말)
MMMM-MM-DD / MMMM-MM (MM = mėnesio pabaiga)
GGGG-MM-DD/GGGG-MM (MM = mēneša beigas)
JJJJ-MM-DD / JJJJ-MM (MM = einde maand)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutten av måneden)
RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
AAAA-MM-DD / AAAA-MM (MM = fim do mês)
AAAA-LL-ZZ / AAAA-LL (LL = sfârşitul lunii)
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = конец месяца)
RRRR-MM-DD / RRRR-MM (MM = koniec mesiaca)
GGGG-MM-DD / GGGG-MM (MM = kraj meseca)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutet av månaden)
YYYY-AA-GG / YYYY-AA (AA = ayın sonu)
PPPP-MM-ДД / PPPP-MM (ММ = кінець місяця)
YYYY-MM-DD / YYYY-MM (MM = 月末)

Catalog number / Каталожен номер / Katalogové číslo / Katalognummer / Αριθμός καταλόγου / Número de catálogo / Kataloginumber / Numéro catalogue / Kataloški broj / Katalógusszám / Numero di catalogo / Каталог нөмірі / 카탈로그 번호 / Katalogo / numeris / Kataloga numurs / Catalogus nummer / Numer katalogowy / Număr de catalog / Номер по каталогу / Katalógové číslo / Kataloški broj / Katalog numarası / Номер за каталогом / 目录号

Authorized Representative in the European Community / Оторизиран представител в Европейската общност / Autorizovaný zástupce pro Evropském společenství / Autoriseret repræsentant i De Europæiske Fællesskaber / Autorisierter Vertreter in der Europäischen Gemeinschaft / Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα / Representante autorizado en la Comunidad Europea / Volitatud esindaja Euroopa Nõukogus / Représentant autorisé pour la Communauté européenne / Autorizuirani predstavnik u Europskoj uniji / Meghatalmazott képviselő az Európai Közösségben / Rappresentante autorizzato nella Comunità Europea / Европа қауымдастығындағы уәкілетті өкіл /유럽 공동체의 위임 대표 / Įgaliotasis atstovas Europos Bendrijoje / Pilnvarotais pārstāvis Eiropas Kopienā / Bevoegde vertegenwoordiger in de Europese Gemeenschap / Autorisert representant i EU / Autoryzowane przedstawicielstwo we Wspólnocie Europejskiej / Representante autorizado na Comunidade Europeia / Reprezentantul autorizat pentru Comunitatea Europeană / Уполномоченный представитель в Европейском сообществе / Autorizovaný zástupca v Európskom spoločenstve / Autorizovano predstavništvo u Evropskoj uniji / Auktoriserad representant i Europeiska gemenskapen / Avrupa Topluluğu Yetkili Temsilcisi / Уповноважений представник у країнах ЄС / 欧洲共同体授权代表

In Vitro Diagnostic Medical Device / Медицински уред за диагностика ин витро / Lékařské zařízení určené pro diagnostiku in vitro / In vitro diagnostisk medicinsk anordning / Medizinisches In-vitro-Diagnostikum / In vitro διαγνωστική ιατρική συσκευή / Dispositivo médico para diagnóstico in vitro / In vitro diagnostika meditsiiniaparatuur / Dispositif médical de diagnostic in vitro / Medicinska pomagala za In Vitro Dijagnostiku / In vitro diagnosztikai orvosi eszköz / Dispositivo medicale per diagnostica in vitro / Жасанды жағдайда жүргізетін медициналық диагностика аспабы / In Vitro Diagnostic 의료 기기 / In vitro diagnostikos prietaisas / Medicīnas ierīces, ko lieto in vitro diagnostikā / Medisch hulpmiddel voor in-vitro diagnostiek / In vitro diagnostisk medisinsk utstyr / Urządzenie medyczne do diagnostyki in vitro / Dispositivo médico para diagnóstico in vitro / Dispozitiv medical pentru diagnostic in vitro / Медицинский прибор для диагностики in vitro / Medicínska pomôcka na diagnostiku in vitro / Medicinski uređaj za in vitro dijagnostiku / Medicinteknisk produkt för in vitro-diagnostik / İn Vitro Diyagnostik Tıbbi Cihaz / Медичний пристрій для діагностики in vitro / 体外诊断医疗设备

Temperature limitation / Температурни ограничения / Teplotní omezení / Temperaturbegrænsning / Temperaturbegrenzung / Περιορισμοί θερμοκρασίας / Limitación de temperatura / Temperatuuri piirang / Limites de température / Dozvoljena temperatura / Hőmérsékleti határ / Limiti di temperatura / Температураны шектеу /온도 제한 / Laikymo temperatūra / Temperatūras ierobežojumi / Temperatuurlimiet / Temperaturbegrensning / Ograniczenie temperatury / Limites de temperatura / Limite de temperatură / Ограничение температуры / Ohraničenie teploty / Ograničenje temperature / Temperaturgräns / Sıcaklık sınırlaması / Обмеження температури / 温度限制

Batch Code (Lot) / Код на партидата / Kód (číslo) šarže / Batch-kode (lot) / Batch-Code (Charge) / Κωδικός παρτίδας (παρτίδα) / Código de lote (lote) / Partii kood / Numéro de lot / Lot (kod) / Tétel száma (Lot) / Codice batch (lotto) / Топтама коды / 배치 코드(로트) / Partijos numeris (LOT) / Partijas kods (laidiens) / Lot nummer / Batch-kode (parti) / Kod partii (seria) / Código do lote / Cod de serie (Lot) / Код партии (лот) / Kód série (šarža) / Kod serije / Partinummer (Lot) / Parti Kodu (Lot) / Код партії / 批号(亚批)

Contains sufficient for <n> tests / Съдържанието е достатъчно за <n> теста / Dostatečné množství pro <n> testů / Indeholder tilstrækkeligt til <n> tests / Ausreichend für <n> Tests / Περιέχει επαρκή ποσότητα για <n> εξετάσεις / Contenido suficiente para <n> pruebas / Külladane <n> testide jaoks / Contenu suffisant pour <n> tests / Sadržaj za <n> testova / <n> teszthez elegendő / Contenuto sufficiente per <n> test / <n> тесттері үшін жеткілікті / <n> 테스트가 충분히 포함됨 / Pakankamas kiekis atlikti <n> testų / Satur pietiekami <n> pārbaudēm / Inhoud voldoende voor “n” testen / Innholder tilstrekkelig til <n> tester / Zawiera ilość wystarczającą do <n> testów / Conteúdo suficiente para <n> testes / Conţinut suficient pentru <n> teste / Достаточно для <n> тестов(а) / Obsah vystačí na <n> testov / Sadržaj dovoljan za <n> testova / Innehåller tillräckligt för <n> analyser/ <n> test için yeterli malzeme içerir / Вистачить для аналізів: <n> / 足够进行 <n> 次检测

Consult Instructions for Use / Направете справка в инструкциите за употреба / Prostudujte pokyny k použití / Se brugsanvisningen / Gebrauchsanweisung beachten / Συμβουλευτείτε τις οδηγίες χρήσης / Consultar las instrucciones de uso / Lugeda kasutusjuhendit / Consulter la notice d’emploi / Koristi upute za upotrebu / Olvassa el a használati utasítást / Consultare le istruzioni per l’uso / Пайдалану нұсқаулығымен танысып алыңыз / 사용 지침 참조 / Skaitykite naudojimo instrukcijas / Skatīt lietošanas pamācību/ Raadpleeg de gebruiksaanwijzing / Se i bruksanvisningen / Zobacz instrukcja użytkowania / Consultar as instruções de utilização / Consultaţi instrucţiunile de utilizare / См. руководство по эксплуатации / Pozri Pokyny na používanie / Pogledajte uputstvo za upotrebu / Se bruksanvisningen / Kullanım Talimatları’na başvurun / Див. інструкції з використання / 请参阅使用说明

Do not reuse / Не използвайте отново / Nepoužívejte opakovaně / Ikke til genbrug / Nicht wiederverwenden / Μην επαναχρησιμοποιείτε / No reutilizar / Mitte kasutada korduvalt/ Ne pas réutiliser / Ne koristiti ponovo / Egyszer használatos / Non riutilizzare / Пайдаланбаңыз / 재사용 금지 / Tik vienkartiniam naudojimui / Nelietot atkārtoti / Niet opnieuw gebruiken / Kun til engangsbruk / Nie stosować powtórnie / Não reutilize / Nu refolosiţi / Не использовать повторно / Nepoužívajte opakovane / Ne upotrebljavajte ponovo / Får ej återanvändas / Tekrar kullanmayın / Не використовувати повторно / 请勿重复使用

Serial number / Сериен номер / Sériové číslo / Serienummer / Seriennummer / Σειριακός αριθμός / N° de serie / Seerianumber / Numéro de série / Serijski broj / Sorozatszám / Numero di serie / Топтамалық нөмірі / 일련 번호 / Serijos numeris / Sērijas numurs / Serie nummer / Numer seryjny /Número de série / Număr de serie / Серийный номер / Seri numarası / Номер серії / 序列号

For IVD Performance evaluation only / Само за оценка качеството на работа на IVD / Pouze pro vyhodnocení výkonu IVD / Kun til evaluering af IVD ydelse / Nur für IVD- Leistungsbewertungszwecke / Μόνο για αξιολόγηση απόδοσης IVD / Sólo para la evaluación del rendimiento en diagnóstico in vitro / Ainult IVD seadme hindamiseks / Réservé à l'évaluation des performances IVD / Samo u znanstvene svrhe za In Vitro Dijagnostiku / Kizárólag in vitro diagnosztikához / Solo per valutazione delle prestazioni IVD / Жасанды жағдайда «пробирка ішінде»,диагностикада тек жұмысты бағалау үшін / IVD 성능 평가에 대해서만 사용 / Tik IVD prietaisų veikimo charakteristikoms tikrinti / Vienīgi IVD darbības novērtēšanai /Uitsluitend voor doeltreffendheidsonderzoek / Kun for evaluering av IVD-ytelse / Tylko do oceny wydajności IVD / Uso exclusivo para avaliação de IVD / Numai pentru evaluarea performanţei IVD / Только для оценки качества диагностики in vitro / Určené iba na diagnostiku in vitro / Samo za procenu učinka u in vitro dijagnostici / Endast för utvärdering av diagnostisk användning in vitro / Yalnızca IVD Performans değerlendirmesi için / Тільки для оцінювання якості діагностики in vitro / 仅限 IVD 性能评估
For US: "For Investigational Use Only"

Lower limit of temperature / Долен лимит на температурата / Dolní hranice teploty / Nedre temperaturgrænse / Temperaturuntergrenze / Κατώτερο όριο θερμοκρασίας / Límite inferior de temperatura / Alumine temperatuuripiir / Limite inférieure de température / Najniža dozvoljena temperatura / Alsó hőmérsékleti határ / Limite inferiore di temperatura / Температураның төменгі руқсат шегі / 하한 온도 / Žemiausia laikymo temperatūra / Temperatūras zemākā robeža /Laagste temperatuurlimiet / Nedre temperaturgrense / Dolna granica temperatury / Limite mínimo de temperatura / Limită minimă de temperatură / Нижний предел температуры / Spodná hranica teploty / Donja granica temperature / Nedre temperaturgräns / Sıcaklık alt sınırı / Мінімальна температура / 温度下限

CONTROL

Control / Контролно / Kontrola / Kontrol / Kontrolle / Μάρτυρας / Kontroll / Contrôle / Controllo / Бақылау / 컨트롤 / Kontrolė / Kontrole / Controle / Controlo / Контроль / kontroll / Контроль / 对照

CONTROL +

Positive control / Положителен контрол / Pozitivní kontrola / Positiv kontrol / Positive Kontrolle / Θετικός μάρτυρας / Control positivo / Positiivne kontroll / Contrôle positif / Pozitivna kontrola / Pozitív kontroll / Controllo positivo / Оң бақылау / 양성 컨트롤 / Teigiama kontrolė / Pozitīvā kontrole / Positieve controle / Kontrola dodatnia / Controlo positivo/ Control pozitiv / Положительный контроль / Pozitif kontrol / Позитивний контроль / 阳性对照试剂

CONTROL −

Negative control / Отрицателен контрол / Negativní kontrola / Negativ kontrol / Negative Kontrolle / Αρνητικός μάρτυρας / Control negativo / Negatiivne kontroll / Contrôle négatif/ Negativna kontrola / Negatív kontroll / Controllo negativo / Негативтік бақылау / 음성 컨트롤 / Neigiama kontrolė / Negatīvā kontrole / Negatieve controle / Kontrola ujemna / Controlo negativo / Control negativ / Отрицательный контроль / Negatif kontrol / Негативний контроль / 阴性对照试剂

STERILE EO

Method of sterilization: ethylene oxide / Метод на стерилизация: етиленов оксид / Způsob sterilizace: etylenoxid / Steriliseringsmetode: ethylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / Método de esterilización: óxido de etileno / Steriliseerimismeetod: etüleenoksiid / Méthode de stérilisation : oxyde d'éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszere: etilén-oxid / Metodo di sterilizzazione: ossido di etilene / Стерилизация әдісі – этилен тотығы / 소독 방법: 에틸렌옥사이드 / Sterilizavimo būdas: etileno oksidas / Sterilizēšanas metode: etilēnoksīds / Gesteriliseerd met behulp van ethyleenoxide / Steriliseringsmetode: etylenoksid/ Metoda sterylizacji: tlenek etylu / Método de esterilização: óxido de etileno / Metodă de sterilizare: oxid de etilenă / Метод стерилизации: этиленоксид / Metóda sterilizácie: etylénoxid / Metoda sterilizacije: etilen oksid / Steriliseringsmetod: etenoxid / Sterilizasyon yöntemi: etilen oksit / Метод стерилізації: етиленоксидом / 灭菌方法：环氧乙烷

STERILE R

Method of sterilization: irradiation / Метод на стерилизация: ирадиация / Způsob sterilizace: záření / Steriliseringsmetode: bestråling / Sterilisationsmethode: Bestrahlung / Μέθοδος αποστείρωσης: ακτινοβολία / Método de esterilización: irradiación / Steriliseerimismeetod: kiirgus / Méthode de stérilisation : irradiation / Metoda sterilizacije: zračenje / Sterilizálás módszere: besugárzás / Metodo di sterilizzazione: irradiazione / Стерилизация әдісі – сәуле түсіру / 소독 방법: 방사 / Sterilizavimo būdas: radiacija / Sterilizēšanas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Steriliseringsmetode: bestråling / Metoda sterylizacji: napromienianie / Método de esterilização: irradiação / Metodă de sterilizare: iradiere / Метод стерилизации: облучение / Metóda sterilizácie: ožiarenie / Metoda sterilizacije: ozračavanje / Steriliseringsmetod: strålning / Sterilizasyon yöntemi: irradyasyon / Метод стерилізації: опроміненням / 灭菌方法：辐射

Biological Risks / Биологични рискове / Biologická rizika / Biologisk fare / Biogefährdung / Βιολογικοί κίνδυνοι / Riesgos biológicos / Bioloogilised riskid / Risques biologiques / Biološki rizik / Biológiailag veszélyes / Rischio biologico / Биологиялық тәуекелдер / 생물학적 위험 / Biologinis pavojus / Bioloģiskie riski / Biologisch risico / Biologisk risiko / Zagrożenia biologiczne / Perigo biológico / Riscuri biologice / Биологическая опасность / Biologické riziko / Biološki rizici / Biologisk risk / Biyolojik Riskler / Біологічна небезпека/ 生物学风险

Caution, consult accompanying documents / Внимание, направете справка в придружаващите документи / Pozor! Prostudujte si přiloženou dokumentaci! / Forsigtig, se ledsagende dokumenter / Achtung, Begleitdokumente beachten / Προσοχή, συμβουλευτείτε τα συνοδευτικά έγγραφα / Precaución, consultar la documentación adjunta / Ettevaatust! Lugeda kaasnevat dokumentatsiooni / Attention, consulter les documents joints / Upozorenje, koristi prateću dokumentaciju / Figyelem! Olvassa el a mellékelttájékoztatót / Attenzione: consultare la documentazione allegata / Абайлаңыз, тиісті құжаттармен танысыңыз / 주의, 동봉된 설명서 참조 / Dėmesio, žiūrėkite pridedamus dokumentus / Piesardzība, skatīt pavaddokumentus / Voorzichtig, raadpleeg bijgevoegde documenten / Forsiktig, se vedlagt dokumentasjon / Należy zapoznać się z dołączonymi dokumentami / Cuidado, consulte a documentação fornecida / Atenţie, consultaţi documentele însoţitoare / Внимание: см. прилагаемую документацию / Výstraha, pozri sprievodné dokumenty / Pažnja! Pogledajte priloženа dokumenta / Obs! Se medföljande dokumentation / Dikkat, birlikte verilen belgelere başvurun / Увага: див. супутню документацію / 小心，请参阅附带文档。

Upper limit of temperature / Горен лимит на температурата / Horní hranice teploty / Øvre temperaturgrænse / Temperaturobergrenze / Ανώτερο όριο θερμοκρασίας / Límite superior de temperatura / Ülemine temperatuuripiir / Limite supérieure de température / Gornja dozvoljena temperatura / Felső hőmérsékleti határ / Limite superiore di temperatura / Температураның руқсат етілген жоғарғы шегі / 상한 온도 / Aukščiausia laikymo temperatūra / Augšējā temperatūras robeža / Hoogste temperatuurlimiet / Øvre temperaturgrense / Górna granica temperatury / Limite máximo de temperatura / Limită maximă de temperatură / Верхний предел температуры / Horná hranica teploty / Gornja granica temperature / Övre temperaturgräns / Sıcaklık üst sınırı / Максимальна температура / 温度上限

Keep dry / Пазете сухо / Skladujte v suchém prostředí / Opbevares tørt / Trocklagern / Φυλάξτε το στεγνό / Mantener seco / Hoida kuivas / Conserver au sec / Držati na suhom/ Száraz helyen tartandó / Tenere all'asciutto / Құрғақ күйінде ұста / 건조 상태 유지 / Laikykite sausai / Uzglabāt sausu / Droog houden / Holdes tørt / Przechowywać w stanie suchym / Manter seco / A se feri de umezeală / Не допускать попадания влаги / Uchovávajte v suchu / Držite na suvom mestu / Förvaras torrt / Kuru bir şekilde muhafaza edin / Берегти від вологи / 请保持干燥

Collection time / Време на събиране / Čas odběru / Opsamlingstidspunkt / Entnahmeuhrzeit / Ώρα συλλογής / Hora de recogida / Kogumisaeg / Heure de prélèvement / Sati prikupljanja / Mintavétel időpontja / Ora di raccolta / Жинау уақыты / 수집 시간 / Paėmimo laikas / Savākšanas laiks / Verzameltijd / Tid prøvetaking / Godzina pobrania / Hora de colheita / Ora colectării / Время сбора / Doba odberu / Vreme prikupljanja / Uppsamlingstid / Toplama zamanı / Час забору / 采集时间

Peel / Обелете / Otevřete zde / Åbn / Abziehen / Αποκολλήστε / Desprender / Koorida / Décoller / Otvoriti skini / Húzza le / Staccare / Ұстіңгі қабатын алып таста / 벗기기 / Plėšti čia / Atlīmēt / Schillen / Trekk av / Oderwać / Destacar / Se dezlipeşte / Отклеить / Odtrhnite / Oljuštiti / Dra isär / Ayırma / Відклеїти / 撕下

Perforation / Перфорация / Perforace / Perforering / Διάτρηση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Тесік тесу / 절취선 / Perforacija / Perforācija / Perforatie / Perforacja / Perfuração / Perforare / Перфорация / Perforácia / Perforasyon / Перфорація / 穿孔

Do not use if package damaged / Не използвайте, ако опаковката е повредена / Nepoužívejte, je-li obal poškozený / Må ikke anvendes hvis emballagen er beskadiget / Inhal beschädigter Packungnicht verwenden / Μη χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά. / No usar si el paquete está dañado / Mitte kasutada, kui pakend on kahjustatud/ Ne pas l'utiliser si l'emballage est endommagé / Ne koristiti ako je oštećeno pakiranje / Ne használja, ha a csomagolás sérült / Non usare se la confezione è danneggiata/ Егер пакет бұзылған болса, пайдаланба / 패키지가 손상된 경우 사용 금지 / Jei pakuotė pažeista, nenaudoti / Nelietot, ja iepakojums bojāts / Niet gebruiken indien de verpakking beschadigd is / Må ikke brukes hvis pakke er skadet / Nie używać, jeśli opakowanie jest uszkodzone / Não usar se a embalagem estiver danificada / A nu se folosi dacă pachetul este deteriorat / Не использовать при повреждении упаковки / Nepoužívajte, ak je obal poškodený / Ne koristite ako je pakovanje oštećeno / Använd ej om förpackningen är skadad / Ambalaj hasar görmüşse kullanmayın / Не використовувати за пошкодженої упаковки / 如果包装破损，请勿使用

Keep away from heat / Пазете от топлина / Nevystavujte přílišnému teplu / Må ikke udsættes for varme / Vor Wärme schützen / Κρατήστε το μακριά από τη θερμότητα / Mantener alejado de fuentes de calor / Hoida eemal valgusest / Protéger de la chaleur / Držati dalje od izvora topline / Óvja a melegtől / Tenere lontano dal calore / Салқын жерде сақта/ 열을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt no karstuma / Beschermen tegen warmte / Må ikke utsettes for varme / Przechowywać z dala od źródeł ciepła / Manter ao abrigo do calor / A se feri de căldură / Не нагревать / Uchovávajte mimo zdroja tepla / Držite dalje od toplote / Får ej utsättas för värme / Isıdan uzak tutun / Берегти від дії тепла / 请远离热源

Cut / Срежете / Odstřihněte / Klip / Schneiden / Κόψτε / Cortar / Lõigata / Découper / Reži / Vágja ki / Tagliare / Кесіңіз / 잘라내기 / Kirpti / Nogriezt / Knippen / Kutt / Odciąć / Cortar / Decupaţi / Отрезать / Odstrihnite / Iseći / Klipp / Kesme / Розрізати / 剪下

Collection date / Дата на събиране / Datum odběru / Opsamlingsdato / Entnahmedatum / Ημερομηνία συλλογής / Fecha de recogida / Kogumiskuupäev / Date de prélèvement / Dani prikupljanja / Mintavétel dátuma / Data di raccolta / Жинаған тізбекүні / 수집 날짜 / Paėmimo data / Savākšanas datums / Verzameldatum / Dato prøvetaking / Data pobrania/ Data de colheita / Data colectării / Дата сбора / Dátum odberu / Datum prikupljanja / Uppsamlingsdatum / Toplama tarihi / Дата забору / 采集日期

µL/test / µL/тест / µL/Test / µL/εξέταση / µL/prueba / µL/teszt / µL/테스트 / мкл/тест / µL/tyrimas / µL/pārbaude / µL/teste / мкл/аналіз / µL/检测

Keep away from light / Пазете от светлина / Nevystavujte světlu / Må ikke udsættes for lys / Vor Licht schützen / Κρατήστε το μακριά από το φως / Mantener alejado de la luz / Hoida eemal valgusest / Conserver à l'abri de la lumière / Držati dalje od svjetla / Fény nem érheti / Tenere al riparo dalla luce / Қараңғыланған жерде ұста / 빛을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt no gaismas / Niet blootstellen aan zonlicht / Må ikke utsettes for lys / Przechowywać z dala od źródeł światła / Manter ao abrigo da luz / Feriţi de lumină / Хранить в темноте / Uchovávajte mimo dosahu svetla / Držite dalje od svetlosti / Får ej utsättas för ljus / Işıktan uzak tutun / Берегти від дії світла / 请远离光线

Hydrogen gas generated / Образуван е водород газ / Možnost úniku plynného vodíku / Frembringer hydrogengas / Wasserstoffgas erzeugt / Δημιουργία αερίου υδρογόνου / Producción de gas de hidrógeno / Vesinikgaasi tekitatud / Produit de l'hydrogène gazeux / Sadrži hydrogen vodik / Hidrogén gázt fejleszt / Produzione di gas idrogeno / Газтектес сутеri пайда болды / 수소 가스 생성됨 / Išskiria vandenilio dujas / Rodas ūdeņradis / Waterstofgas gegenereerd / Hydrogengass generert / Powoduje powstawanie wodoru / Produção de gás de hidrogénio / Generare gaz de hidrogen / Выделение водорода / Vyrobené použitím vodíka / Oslobađa se vodonik / Genererad vätgas / Açığa çıkan hidrojen gazı / Реакція з виділенням водню / 会产生氢气

Patient ID number / ИД номер на пациента / ID pacienta / Patientens ID-nummer / Patienten-ID / Αριθμός αναγνώρισης ασθενούς / Número de ID del paciente / Patsiendi ID/ No d'identification du patient / Identifikacijski broj pacijenta / Beteg azonosító száma / Numero ID paziente / Пациенттің идентификациялық нөмірі / 환자 ID 번호 / Paciento identifikavimo numeris / Pacienta ID numurs / Identificatienummer van de patiënt / Pasientens ID-nummer / Numer ID pacjenta / Número da ID do doente / Număr ID pacient / Идентификационный номер пациента / Identifikačné číslo pacienta / ID broj pacijenta / Patientnummer / Hasta kimlik numarası / Ідентифікатор пацієнта / 患者标识号

Fragile, Handle with Care / Чупливо, Работете с необходимото внимание. / Křehké. Při manipulaci postupujte opatrně. / Forsigtig, kan gå i stykker. / Zerbrechlich, vorsichtighandhaben. / Εύθραυστο. Χειριστείτε το με προσοχή. / Frágil. Manipular con cuidado. / Õrn, käsitsege ettevaatlikult. / Fragile. Manipuler avec précaution. / Lomljivo, rukujte pažljivo. / Törékeny! Óvatosan kezelendő. / Fragile, maneggiare con cura. / Сынғыш, абайлап пайдаланыңыз. / 조심 깨지기 쉬운 처리 / Trapu, elkitės atsargiai. / Trausls; rīkoties uzmanīgi / Breekbaar, voorzichtig behandelen. / Ømtålig, håndter forsiktig. / Krucha zawartość, przenosić ostrożnie. / Frágil, Manuseie com Cuidado. / Fragil, manipulaţi cu atenţie. / Хрупкое! Обращаться с осторожностью. / Krehké, vyžaduje sa opatrná manipulácia. / Lomljivo - rukujte pažljivo. / Bräckligt. Hantera försiktigt. / Kolay Kırılır, Dikkatli Taşıyın. / Тендітна, звертатися з обережністю / 易碎，小心轻放

bd.com/e-labeling
KEYCODE: 442946

bd.com/e-labeling

Europe, CH, GB, NO:	+800 135 79 135		
International:	+31 20 794 7071		
AR	+800 135 79 135	LT	8800 30728
AU	+800 135 79 135	MT	+31 20 796 5693
BR	0800 591 1055	NZ	+800 135 79 135
CA	+1 855 805 8539	RO	0800 895 084
CO	+800 135 79 135	RU	+800 135 79 135
EE	0800 0100567	SG	800 101 3366
GR	00800 161 22015 7799	SK	0800 606 287
HR	0800 804 804	TR	00800 142 064 866
IL	+800 135 79 135	US	+1 855 236 0910
IS	800 8996	UY	+800 135 79 135
LI	+31 20 796 5692	VN	122 80297

BD

This product is sold under license, and purchase of this product does not include rights to use for certain blood and tissue screening applications, nor for certain industrial applications.

Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

EC REP Benex Limited
Pottery Road, Dun Laoghaire
Co. Dublin, Ireland

Australian Sponsor:
Becton, Dickinson Pty Ltd.
4 Research Park Drive
Macquarie University Research Park
North Ryde, NSW 2113
Australia

Offering accuracy from collection to result

Reduce unsatisfactory results

Increase abnormal cell detection

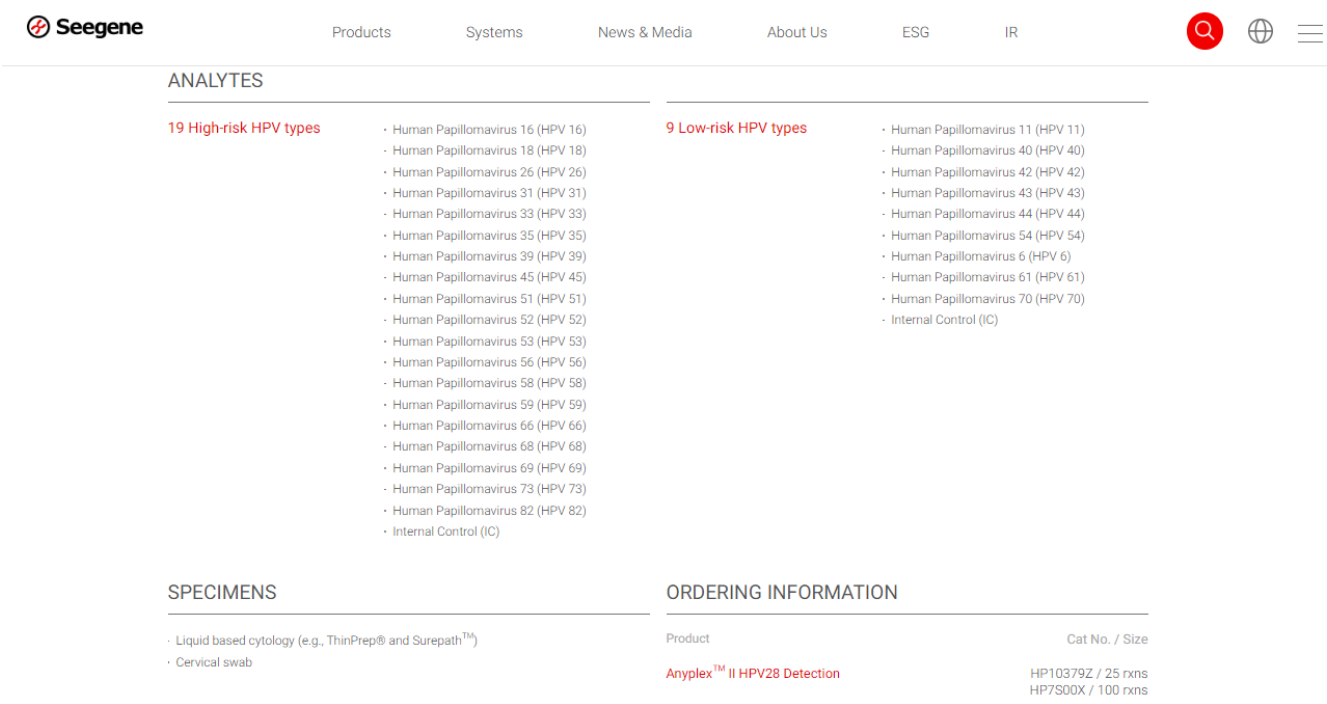
Improve the continuum of care

The BD SurePath™ Liquid-based Pap Test is your trusted partner for reliable sample collection and accurate result reporting

- The BD SurePath™ collection vial is designed to improve patient care while providing physicians with the convenience of a single-source collection for Pap screening and molecular diagnostic testing
- The BD SurePath™ Liquid-based Pap Test and the BD Onclarity™ HPV Assay provide HPV primary screening, co-testing and cytology primary with ASCUS reflex
- When used with the BD Totalys™ MultiProcessor, the BD SurePath™ collection vial 2D barcodes allow Positive Sample Identification from collection through cytological and molecular testing, providing confidence in the results
- The BD SurePath™ Liquid-based Pap Test can be processed according to the throughput and the automation levels needed. BD Totalys™ MultiProcessor or BD PrepMate™ (sample preparation, including cell enrichment), BD Totalys™ SlidePrep (slide preparation and staining) and BD FocalPoint™ GS Imaging System (slide analysis)

1.1
1.1

Standardized sample collection **Accurate result reporting**



1.1. Pateikta informacija SeeGene puslapyje, jog jų ŽPV testai taip pat yra suderinami su SurePath terpėmis.

BD PrepMate™ Vartotojo vadovas

Automated Accessory (automatizuoto priedo)

Operatoriaus vadovas

780-08157-00(05) 2015-02
REF 491103, 491424

CE

TriPath Imaging, Inc.
7780 Plantation Drive
Burlington, NC 27215 JAV

EC REP Benex Limited
Pottery Road, Dun Laoghaire
Co. Dublin, Airija

Atstovas Australijoje:
Becton Dickinson Pty Ltd.
4 Research Park Drive
Macquarie University Research Park,
North Ryde, NSW 2113 Australija

Pakeitimų istorija

Peržiūra	Puslapiai	Priežastis
1	Visi	Atnaujinti grafiniai elementai. Naujos programinės įrangos naujiniai. Bendrieji atnaujinimai. Šią peržiūrą tikrina FDA, šiuo metu ja neprekiaujama.
02	Visi	Naujo išspausdinamo ir įrišamo specifikacijų lapo atnaujinimas.
03	Visi	Atstovo Australijoje adreso pridėjimas; Įgaliotojo atstovo (atstovo Europos Bendrijoje) adreso atnaujinimas. LCD ekrano trikčių šalinimo skyriaus pridėjimas.
04	Visi	Pakeitimai: Įgaliotojo atstovo (atstovo Europos Bendrijoje) adreso pakeitimas atgal į esamą Shannon, County Clare adresą. Peržiūros formato pakeitimas. BD PrepStain tankio reagento pakeitimas į BD tankio reagentą. BD PrepStain švirkštų pakeitimas į BD švirkštimo pipetes.
05	Visi	Atstovo Europos Bendrijoje adreso pakeitimas; atnaujintas mėginio stovo įkrovimo ir iškrovimo skyrius; pridėtos vartotojo įdiegimo instrukcijos.

Turinys

Įžanga 1
Apie šį vadovą 1
Dokumente vartojami sutartiniai ženklai 1
Simbolių žodynas 2
Rekomenduojamojo pobūdžio informacija 3
Įvadas 5
Reikalavimai 5
Medžiagos 7
Tiekiamos medžiagos 7
Būtinos, bet netiekiamos medžiagos 7
Būtina įranga 7
BD PrepMate Automated Accessory naudojimo seka 7
Naudojimo sekos apžvalga 7
Išsami informacija apie naudojimo seką 7
Operatoriaus valdikliai 9
Valdymo mygtukų aprašymai 9
BD PrepMate Automated Accessory naudojimas 11
Reikmenų sudėjimas į mėginių stovą ir išėmimas iš jo 11
BD PrepMate naudojimo instrukcijos 13
Prietaiso išjungimas 14
Sistemos priežiūra 14
Pranešimai 15
Būsenos pranešimai 15
Klaidų pranešimai 16
Gedimų pranešimai 18
Profilaktinė priežiūra 18
Kasmetė priežiūra 18
Trikčių nustatymas ir šalinimas 18
Prietaiso generuoti gedimų pranešimai 18
Remontas ir utilizavimas 22
Atitikties deklaracija 23
Informacija apie garantiją 23
Naudojimo techniniai duomenys 24
Elektros srovės reikalavimai 24
Naudojimo sąlygos 24
Laikymo sąlygos 24
Bendroji informacija 24
Saugikliai 24
Priedas: BD Prepmate Automated Accessory įdiegimo instrukcijos 25

Paveikslų sąrašas

1 pav. Įspėjimo dėl įtampos etiketė 4
2 pav. BD PrepMate Automated Accessory vaizdas iš priekio 6
3 pav. BD PrepMate Automated Accessory vaizdas iš galo 6
4 pav. BD PrepMate Automated Accessory operatoriaus valdikliai 9
5 pav. Reikmenų sudėjimas į mėginių stovą 11
6 pav. Centrifugos mėgintuvėliai, sudėti į mėginių stovą 11
7 pav. BD PrepMate mėginių stovo ir objektinių stiklelių dėklo eilių bei stulpelių atitikimas 12
8 pav. Visiškai sustumti švirkštų stūmokliai 12

Įžanga

Apie šį vadovą

Šiame vadove aprašomos BD PrepMate™ Automated Accessory (automatizuoto priedo) funkcijos, naudojimas ir priežiūra. BD PrepMate Automated Accessory yra didesnės BD SurePath™ Liquid-based Pap Test ir BD PrepStain™ sistemos dalis, taigi pats prietaisas nėra atskira sistema. Šis dokumentas taip pat nėra atskiras dokumentas; jis yra BD SurePath Liquid-based Pap Test ir BD PrepStain sistemos dokumentacijos dalis ir turi būti segamas į trižiedį segtuvą, skirtą BD SurePath Liquid-based Pap Test ir BD PrepStain sistemos operatoriaus vadovui.

Visus klausimus apie BD PrepMate Automated Accessory reikėtų pateikti BD Diagnostics techninės pagalbos tarnybai. Kontaktinį adresą ir telefono numerį galima rasti **Informacijos apie garantiją** skyriuje.

Dokumente vartojami sutartiniai ženklai

Šiame dokumente svarbi informacija žymima tokiais sutartiniais ženklais.

- Toks šriftas (**ŠIS MYGTUKAS**) nurodo spaustiną mygtuką.
- Toks šriftas (žr. ***Įvadą***) yra nuoroda į tekstą, esantį kitoje šio vadovo dalyje.

Šiame vadove pateikiami penkių tipų pranešimai: Trijų tipų perspėjimai, įspėjimas ir pastaba. Kiekvieno tipo pranešimo išvaizda ir vartosena yra aprašyti toliau.

Perspėjimas
Nurodo sunkaus arba mirtino asmens sužalojimo galimybę, jeigu nebus laikomasi nurodymų.

Perspėjimas
Nurodo elektros šoko ir gaisro galimybę, jeigu nebus laikomasi nurodymų.

Perspėjimas
Nurodo sąlyčio su krauju arba kitais galimai užkrečiamais kūno skysčiais galimybę, jeigu nebus laikomasi nurodymų.

Įspėjimas
Nurodo rimto įrangos sugadinimo arba netinkamų rezultatų galimybę, jeigu nebus laikomasi nurodymų.

Pastaba: Pateikia naudingos informacijos apie BD PrepMate Automated Accessory.

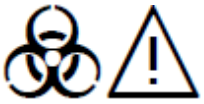
Simbolių žodynas

Ant prietaiso pateikiama kelėtas simbolių. Šie simboliai ir jų reikšmės nurodomi toliau.

	Katalogo numeris		Gamintojas
	Įgaliotas atstovas Europos Bendrijoje		*In vitro* diagnostinis medicinos prietaisas
	Žr. naudojimo instrukcijas		Temperatūros ribos
	Biologinis pavojus		Perspėjimas: elektros šoko pavojus
	Įspėjimas, pavojaus rizika. Žr. pridedamus dokumentus.		Atskirai surenkami elektriniai ir elektroniniai prietaisai pagal 2002/96/EB direktyvą (WEEE). Taikoma Europos Sąjungos šalyse bei Norvegijoje ir Švedijoje.
	Kintanti srovė		Apsauginio įžeminimo gnybtas

Rekomenduojamojo pobūdžio informacija

Biologiniai ir cheminiai pavojai



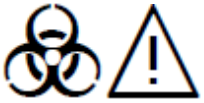
Perspėjimas
BD PrepMate Automated Accessory apdorojamuose skysčiuose gali būti infekuotų klinikinių mėginių ir (arba) toksinių arba ėsdinančių cheminių medžiagų. Šios medžiagos gali išsipilti, todėl yra pavojingo sąlyčio tikimybė. Visuomet reikia dėvėti rankų, akių apsaugos priemones ir apsauginius drabužius.

Bendrosios atsargumo priemonės

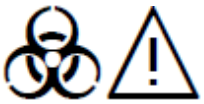
Dirbant su BD PrepMate Automated Accessory būtina laikytis geros laboratorinės praktikos ir griežtai vykdyti visas naudojimo procedūras. Jei nebus laikomasi šiame vadove nurodytų rekomenduojamų procedūrų, gali pablogėti prietaiso veikimas.

Ruošti mėginius naudojantis BD PrepMate Automated Accessory turi tik tie asmenys, kurie buvo tinkamai apmokyti, kaip naudoti BD PrepMate Automated Accessory.

Mėginio paėmimas ir apdorojimas



Perspėjimas
Mėginiuose gali būti infekcinių ligų sukėlėjų. Reikia imtis universalių atsargumo priemonių, kad mėginiai nesiliestų su oda arba kūno skysčiais.



Perspėjimas
Jeigu mėginių medžiagos išsilieja, išsiliejusį turinį reikia nedelsiant išvalytas, o valant naudotos medžiagos tinkamai pašalinti.

Mechaniniai pavojai

BD PrepMate Automated Accessory yra kompiuterio valdomas prietaisas. Kai prietaisas veikia, judančios mechaninės detalės gali sužeisti arba sužaloti. Siekiant apsaugoti nuo atsitiktinio sąlyčio su judančiomis detalėmis, pridedamas apsauginis dangtis.

Perspėjimas
BD PrepMate Automated Accessory yra kompiuterio valdomas prietaisas. Šis prietaisas skirtas automatiniam darbui. Niekuomet nelieskite gaubto, kai prietaisas veikia. Kaip ir dirbant su visais judančiais įrenginiais, galima susižaloti. Niekuomet nekiškite rankų į prietaiso darbo sritį, kai jis veikia.

Įspėjimas
Pagal federalinius įstatymus šis prietaisas gali būti naudojamas tik gydytojo ar kito praktikuojančio specialisto, turinčio valstijos leidimą užsakyti su šiuo prietaisu susijusį tyrimą, užsakymu. Visi šio prietaiso ir jo plonasluoksnių objektinių stiklelių gaminių naudotojai turi būti tinkamai apmokyti ir turėti naudojimo bei konkrečių susijusių užduočių atlikimo patirties.

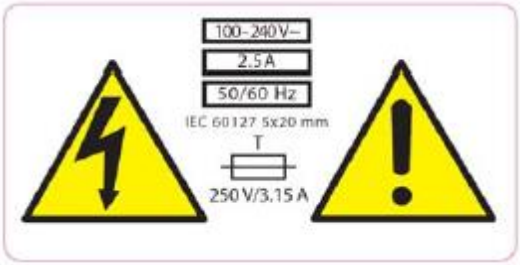
Įspėjimas
Patikrinus šį prietaisą buvo nustatyta, kad jis atitinka ISM įrangos ribas pagal FCC 15 dalies J paragrafo A klasės ir EN 5011 B klasės reikalavimus, skirtus apsaugoti nuo tokių trikdžių gyvenamosiose patalpose. Jeigu šis įrenginys naudojamas nesilaikant gamintojo nurodymų, jis gali trukdyti priimti radijo ir TV signalus arba trikdyti kitų elektros prietaisų veikimą.

Pastaba: Jeigu reikia pertraukti prietaiso veikimą, paspauskite mygtuką **STOP** (STABDYTI), esantį BD PrepMate Automated Accessory naudotojo sąsajoje.

Elektros pavojai

Naudojant šį prietaisą reikia laikytis tų pačių atsargumo priemonių, kaip ir naudojant bet kurią kitą elektros įrangą.

Kitoje prietaiso pusėje yra šis perspėjamasis teiginys:



1 pav. *Įspėjimo dėl įtampos etiketė*

Galiniame skyde esantis maitinimo laido lizdas (žr. *3 pav.*) laikomas pagrindiniu prietaiso išjungikliu.

Pastaba: Jeigu prietaisas naudojamas ne taip, kaip nurodė BD Diagnostics, šio prietaiso apsaugos priemonės gali būti pažeistos, o garantija netekti galios.

Įvadas

BD PrepMate Automated Accessory yra priedas, papildantis BD SurePath Liquid-based Pap Test ir BD PrepStain sistemą. BD PrepMate Automated Accessory automatizuoja pradinį praturtinimo procesą, per kurį mėginys maišomas ir paskirstomas ant BD Density Reagent (tankio reagento).

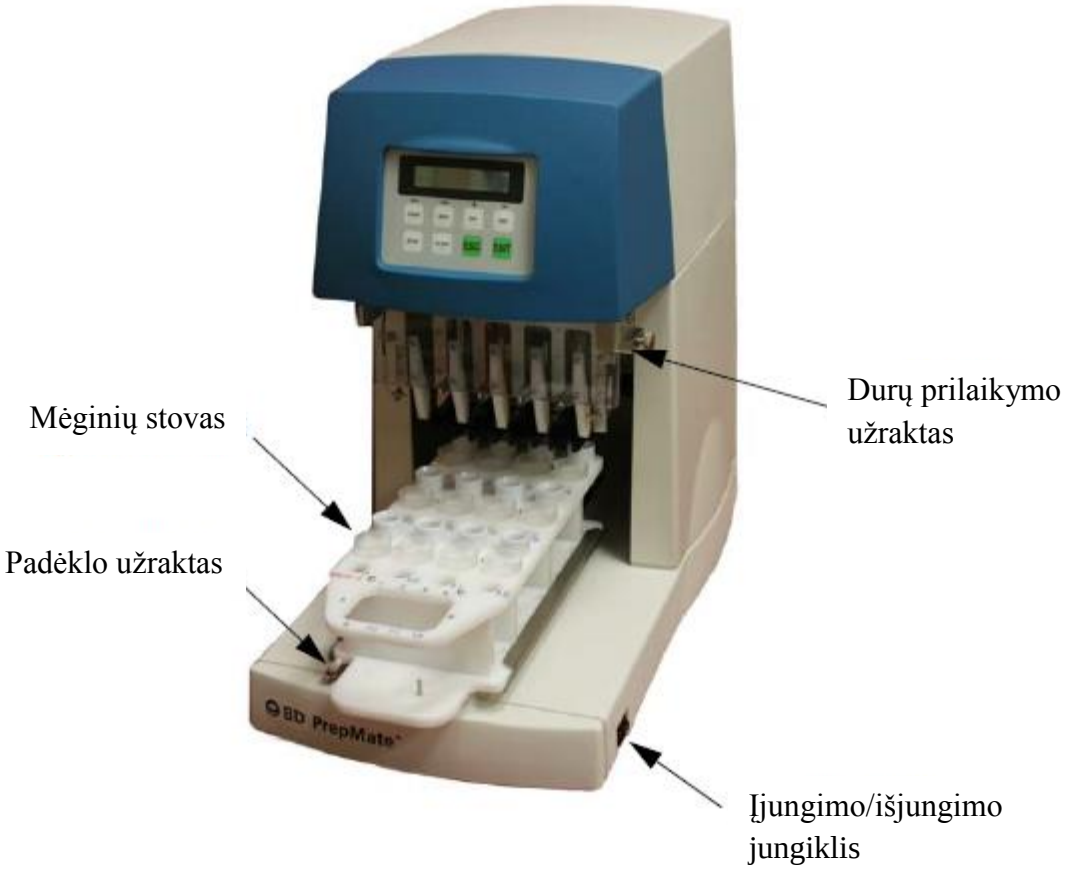
BD PrepMate Automated Accessory sumaišo ir ištraukia mėginį iš BD PrepStain konservanto buteliuko. Tuomet prietaisas užpila mėginio sluoksnį ant tankio reagento, esančio centrifugos mėgintuvėlyje. Per vieną šio automatinio proceso ciklą gali būti apdorojama nuo vieno iki dvylikos mėginių.

Siekiant sumažinti mėginių užteršimo galimybę, buteliukų dangteliai per procesą nenuimami. BD PrepMate Automated Accessory veikia unikaliu būdu – sumaišo ir paskirsto mėginius praduriant buteliukų dangtelius. Buteliukai, švirkštai ir mėgintuvėliai yra vienkartiniai. Siekiant užkirsti kelią galimam mėginio užteršimui, jų negalima naudoti pakartotinai.

Reikalavimai

- Ginekologiniai mėginiai, paruošiami naudoti su BD PrepMate Automated Accessory, turi būti paimami naudojant patvirtintą mėginių ėmimo prietaisą, laikantis standartinės gamintojo pateikiamos mėginių ėmimo procedūros.
- Ruošti BD SurePath objektinius stiklelius gali tik išmokytas įgaliotasis personalas.
- Privaloma naudoti BD PrepStain reikmenis. Žr. skyrių ***Būtinos, bet netiekiamos medžiagos***, esantį toliau šiame vadove.

Įspėjimas
Šį prietaisą reikia kelti ir nešti paėmus už pagrindo apačios. Keldami neimkite už mėlynų priekinių skydų. Niekada nekelkite ir neneškite prietaiso, laikydami už priekinio skydo.



2 pav. *BD PrepMate Automated Accessory vaizdas iš priekio*

3 pav. *BD PrepMate Automated Accessory vaizdas iš galo*

Medžiagos

Tiekiamos medžiagos

- BD PrepMate Automated Accessory ir maitinimo laidas (-ai)
- BD PrepMate mėginių stovai

Būtinos, bet netiekiamos medžiagos

BD Diagnostics parduoda toliau nurodytas vienkartinio naudojimo medžiagas:
- BD PrepMate vartojimo reikmenų rinkinys
- BD Syringing Pipettes (švirkštimo pipetės)
- BD centrifugos mėgintuvėliai
- 12 vietų centrifugos mėgintuvėlių laikikliai
- BD SurePath surinkimo buteliukai
- BD Density Reagent (tankio reagentas)

Būtina įranga

- Centrifuga (galimi įvairūs modeliai – pasirinkite savo darbo apimčiai tinkamiausią modelį).

BD PrepMate Automated Accessory naudojimo seka

Naudojimo sekos apžvalga

Toliau išvardinti BD PrepMate Automated Accessory pagrindiniai naudojimo sekos veiksmai:
1. Naudotojas į BD PrepMate mėginių stovą sudeda ne daugiau kaip 12 mėginių ir apdorojimo komponentų.
2. Naudotojas įdeda mėginių stovą į BD PrepMate Automated Accessory ir paspaudžia **START** (PRADĖTI).
3. BD PrepMate Automated Accessory sumaišo, perkelia ir susluoksniuoja visus mėginius. Žr. skyrių ***Išsami informacija apie naudojimo seką***. Pasigirsta signalas, nurodantis, kad ši ląstelių praturtinimo proceso dalis baigta.
4. Naudotojas išima mėginių stovą ir perduoda susluoksniuotus mėginius centrifuguoti.

Išsami informacija apie naudojimo seką

Toliau pateikiama išsami BD PrepMate Automated Accessory naudojimo seka.
1. Naudotojas įjungia ir paruošia prietaisą. Žr. skyrių ***BD PrepMate naudojimo instrukcijos***.
2. Pirma švirkštų eilė pozicionuojama paėmimui ir iškeliama iš mėginių stovo.

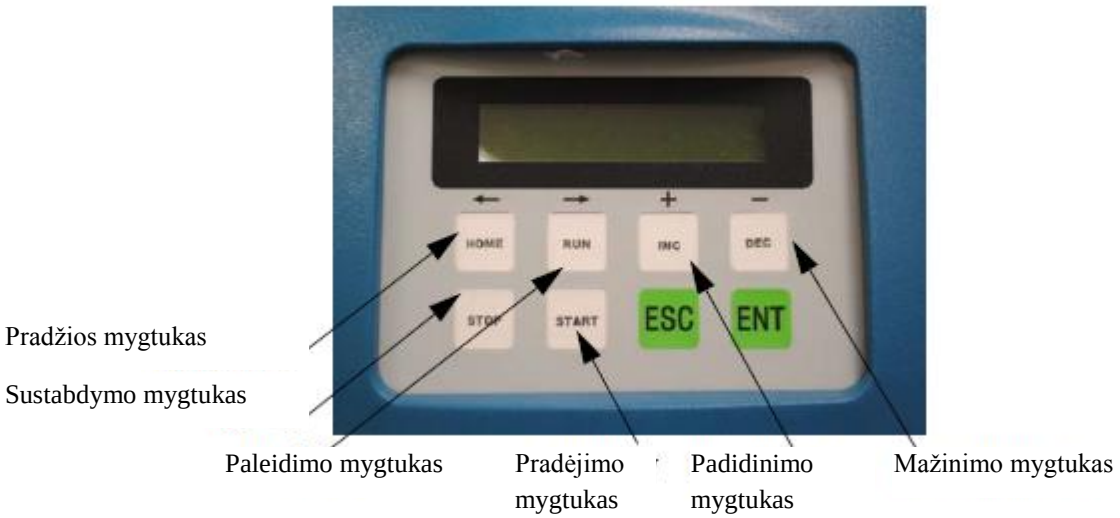
3. Švirkštų stūmokliai pakeliami iki įtraukimo lygio ir vieną kartą nustumiami žemyn, kol švirkštai keliami. Šis veiksmas prieš maišant pagerina stūmoklio slydimą švirkšto vidiniu paviršiumi per švirkštimo ciklą.
4. Mėginių stovas pozicionuojamas taip, kad BD SurePath Liquid-based Pap Test konservantų buteliukai būtų tiesiai po švirkštais.
5. Švirkštai nuleidžiami taip, kad jų smaigaliai pradurtų sandarius BD SurePath Liquid-based Pap Test konservantų buteliukų dangtelius ir sustotų prie pat kiekvieno buteliuko dugno.
6. Švirkštų stūmokliai aštuonis ciklus juda aukštyn ir žemyn, kad sumaišytų mėginį.
7. Stūmokliai pakeliami, kad įtrauktų mėginius į švirkštus.
8. Švirkštai pakeliami, o mėginių stovas pastumiamas taip, kad smaigaliai atsidurtų tiesiai virš centrifugos mėgintuvėlių.
9. Švirkštai nuleidžiami taip, kad jų smaigaliai atsidurtų ties mėgintuvėlių, kuriuose yra BD Density Reagent (tankio reagentas), vidinėmis sienelėmis.
10. Mėginys lėtai paskirstomas į mėgintuvėlius trimis pamažu didėjančiais greičiais, kad mėgintuvėliuose nesusimaišytų su BD Density Reagent (tankio reagentu).

Pastaba: Atlikdamas šį veiksmą prietaisas gali neskleisti jokio garso ir atrodyti nustojęs veikti.

11. Tuomet švirkštai pakeliami ir mėginių stovas sugrįžta į pradinę švirkštų pripildymo padėtį.
12. Švirkštai vėl nuleidžiami į mėginių stovą ir dėklas pasitraukia atgal, kad jie atsilaisvintų.
13. Švirkštų laikiklis pakeliamas į viršutinę padėtį, taip baigiamas pirmos keturių mėginių grupės perkėlimas.
14. 1–12 veiksmai kartojami su likusiomis eilėmis, kol užbaigiamas apdorojimo ciklas.

Operatoriaus valdikliai

Operatoriaus valdikliai yra įrengti priekinėje instrumento panelėje. *4 paveiksle* pateikiami šie valdikliai.



4 pav. *BD PrepMate Automated Accessory operatoriaus valdikliai*

Operatoriaus sąsają sudaro skystųjų kristalų ekrano (LCD) skydelis ir aštuoni valdymo mygtukai. LCD skydelyje pateikiami pranešimai, nurodantys veikimo būseną ir įspėjantys, kada reikia atlikti veiksmą. Paspaudus mygtuką esamas pranešimas trumpam pertraukiamas, kad būtų nurodytas paspaustasis mygtukas. Laikykitės LCD skydelyje pateikiamų nurodymų. Kai prietaisas veikia normaliai, operatoriui tiesiog nurodoma įdėti stovą, jį pakeisti arba paspausti **START** (PRADĖTI).

Išsamesnės informacijos apie tai, kas rodoma šiame skydelyje, rasite tolesniame šio vadovo skyriuje ***Pranešimai***.

Valdymo mygtukų aprašymai

Valdymo mygtukai yra prietaiso priekiniame skyde (žr. *4 pav*.). Šiais mygtukais valdomas BD PrepMate Automated Accessory.

HOME (PRADŽIA)
Šiuo mygtuku sugrąžinkite visus BD PrepMate Automated Accessory komponentus į jų pradinę padėtį. Jeigu apdorojama kuri nors eilė, paspaudus **HOME** (PRADŽIA) komponentai į savo pradinę padėtį nesugrįžta, kol eilė nebaigiama apdoroti. Šis mygtukas taip pat naudojamas įjungiant prietaisą, kad varikliukai užimtų pradines padėtis.

RUN (PALEISTI)
Paspaudę šį mygtuką tęskite apdorojimą po pertraukimo. Paspaudus mygtuką **RUN** (PALEISTI), tęsiama įprasta apdorojimo seka.

INC (DIDINTI)
Šiuo mygtuku didinkite apdorojimo ciklo eilių skaičių. Šis mygtukas reikalingas tik tuomet, jeigu buvo pasirinkta per mažai eilių. Kiekvieną kartą pasibaigus apdorojimo ciklui, ši nuostata grįžta prie numatytosios vertės (3).
Nekeiskite šio nustatymo, kai vykdomas apdorojimo ciklas. Palaukite, kol bus įdėtas naujas stovas.

DEC (MAŽINTI)
Šiuo mygtuku mažinkite apdorojimo ciklo eilių skaičių. Kai reikia apdoroti mažiau nei 12 buteliukų, eilių skaičių pakeiskite į 2 (8 buteliukai) arba 1 (4 buteliukai). Kiekvieną kartą pasibaigus apdorojimo ciklui, šis nustatymas grįžta prie numatytosios vertės (3).
Nekeiskite šių nustatymų, kai vykdomas apdorojimo ciklas. Palaukite, kol bus įdėtas naujas stovas.

STOP (STABDYTI)
Šiuo mygtuku pertraukite apdorojimą. Mygtuką **STOP** (STABDYTI) galima paspausti bet kuriuo ciklo momentu.

START (PRADĖTI)
Šiuo mygtuku pradėkite apdorojimo ciklą. Kai įdedate, išimate arba pakeičiate mėginių stovą, paspauskite šį mygtuką, kad ciklas būtų pradėtas. Stovo įdėjimas arba pakeitimas suaktyvina dėklo užraktą. Prietaisas nepradės veikti, kol dėklas bus tinkamai užfiksuotas.

ESC (GRĮŽTI) ir ENT (ĮVESTI)
Šie mygtukai naudojami tik gamybos vietoje. Jais programuojama operatoriaus sąsaja. Jie nereikalingi kasdieniam gaminio naudojimui. Nespauskite šių mygtukų.

BD PrepMate Automated Accessory naudojimas

Prieš pradėdami naudoti, atidžiai perskaitykite šią procedūrą.

Įspėjimas
Rankiniu būdu judindami dėklą sugadinsite instrumentą. Susisiekite su BD dėl pagalbos judinant metalinį dėklą rankomis.

Reikmenų sudėjimas į mėginių stovą ir išėmimas iš jo

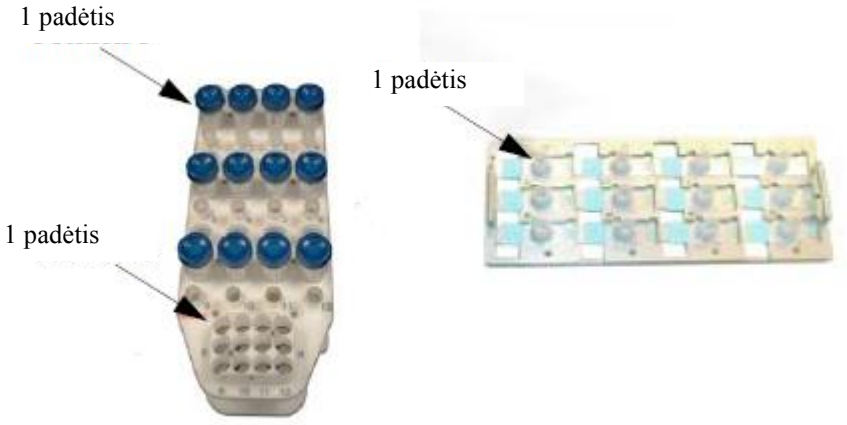
1. Įsitikinkite, kad mėginių buteliukai ir centrifugos mėgintuvėliai yra tinkamai paženklinti. Pasūkuriuokite buteliukus.
2. Įdėkite norimus apdoroti mėginių buteliukus į mėginių stovą pradėdami nuo 1 buteliukų eilės (žr. *5 pav.*). Iš eilės užpildykite visas eiles po 4 buteliukus, kol stovas bus pilnas (12 buteliukų) arba, kol bus sudėti visi norimi apdoroti buteliukai. Įsitikinkite, kad buteliukai gerai įstatyti į jiems skirtus apvalius šulinėlius. Jeigu apdorojate mažiau nei tris buteliukų eiles, pradėkite dėti buteliukus nuo 1 eilės.

5 pav. *Reikmenų sudėjimas į mėginių stovą*

3. Sudėkite centrifugos mėgintuvėlius į mėginių stovą. Kiekvieną mėgintuvėlį dėkite greta jo mėginio buteliuko ir tuomet pipete į kiekvieną mėgintuvėlį įlašinkite 4 mL BD Density Reagent (tankio reagento).

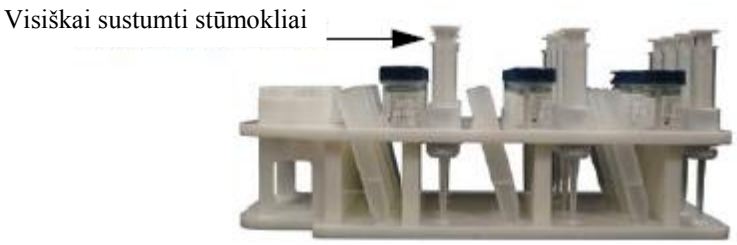
6 pav. *Centrifugos mėgintuvėliai, sudėti į mėginių stovą*

4. Įsitikinkite, kad visi mėgintuvėliai paženklinti taip pat, kaip atitinkamas mėginio buteliukas (t. y. buteliukas, įdėtas į tą pačią eilę ir stulpelį). Mėginių stovo ir BD PrepStain objektinio stiklelio dėklo eilių ir stulpelių atitikimas yra parodytas *7 pav.* Iliustracijoje parodyta 1 padėties (1 eilės 1 stulpelio) vieta trijose vietose: švirkštų, buteliukų ir mėgintuvėlių eilės BD PrepMate mėginių stove; centrifugos stovo eilės; ir objektinių stiklelių dėklo eilės.



7 pav. *BD PrepMate mėginių stovo ir objektinių stiklelių dėklo eilių bei stulpelių atitikimas*

5. Įdėkite švirkštą į stovą greta kiekvieno buteliuko. Įsitikinkite, kad kiekvieno švirkšto stūmoklis yra visiškai sustumtas. BD PrepMate Automated Accessory neveiks, jeigu stūmoklis bus per aukštai.



8 pav. *Visiškai sustumti švirkštų stūmokliai*

6. Apdoroję mėginių stovą (žr. toliau esančias ***BD PrepMate naudojimo instrukcijas***), atsargiai viską iš jo išimkite. Sudėkite mėgintuvėlius su ląstelių suspensija ir tankio reagentu į centrifugos stovus ta pačia tvarka, kaip jie buvo sudėti į BD PrepMate Automated Accessory. Kaip centrifugos stovai ir BD PrepMate mėginių stovas atitinka vienas kitą, yra parodyta *5* ir *7 pav*.

7. Kiekvienam likusio mėginio buteliukui, kurį norite išsaugoti, pakeiskite esamą dangtelį. (Atsarginius dangtelius galite užsakyti iš BD). Atsargiai tvarkykite pradurtus dangtelius ir atvirus mėginių buteliukus, kad išvengtumėte kryžminio užteršimo. Tinkamai utilizuokite pradurtus dangtelius biologiškai pavojingų medžiagų talpyklose.
8. Išimkite ir išmeskite švirkščiančias pipetes. Švirkštus tinkamai pašalinkite biologiškai pavojingų medžiagų talpyklose. Švirkštų smaigaliai neturi liestis su mėginių stovu.
9. Išvalykite mėginių stovą po kiekvieno naudojimo, kad neįvyktų kryžminis užteršimas. Kaip išvalyti mėginių stovą žr. skyriuje ***Sistemos priežiūra***.

Įspėjimas
Kai mėginiai mėgintuvėliuose susluoksniuojami ant tankio reagento, juos per 30 minučių reikia centrifuguoti, kad būtų gauti optimalūs apdorojimo rezultatai.

Įspėjimas
Siekdami išlaikyti saugojimo grandinę, tinkamai nukreipkite paženklintus centrifugos mėgintuvėlius ir mėginių buteliukus, kai dedate juos į BD PrepMate mėginių stovą ir perkeliate centrifugos mėgintuvėlius į centrifugos stovus.

BD PrepMate naudojimo instrukcijos

1. Įsitikinkite, kad prietaisas yra prijungtas prie kintamosios srovės maitinimo šaltinio, o ant šoninio skydo esantis maitinimo jungiklis yra nustatytas į padėtį **On** (įjungta). Kai tik įjungiamas maitinimas, LCD skydelyje parodomas pranešimas **INITIALIZING** (INICIJUOJAMA). Maždaug po 15 sekundžių parodomas pranešimas **READY TO HOME vX.X PRESS HOME** (PARUOŠTA PRADŽIAI, X.X v., PASPAUSKITE „PRADŽIA“). Paspauskite mygtuką **HOME** (PRADŽIA), kad inicijavimas būtų užbaigtas ir visi varikliukai būtų nustatyti į pradinę padėtį.

Pastaba: Šis veiksmas atliekamas tik įjungus prietaiso maitinimą ir, jeigu panaudojus anksčiau prietaisas nebuvo išjungtas, šis veiksmas nekartojamas.

Baigus inicijavimo seką prietaiso skydelyje rodomas pranešimas **PREPMATE READY, (v X.X) LOAD SPECIMEN RACK** („PREPMATE“ PARUOŠTAS, (X.X v.) ĮDĖKITE MĖGINIŲ STOVĄ) (X.X nurodo esamą programinės įrangos versiją).
2. Įsitikinkite, kad buteliukų prilaikymo durelės yra vertikalioje padėtyje ir užrakintos.
3. Įdėkite paruoštą mėginių stovą į prietaiso dėklą. Nurodymus, kaip reikmenis sudėti į mėginių stovą, rasite skyriuje ***Reikmenų sudėjimas į mėginių stovą ir išėmimas iš jo***. Stumkite mėginių stovą iš priekio, kol dėklo užraktas priekiniame kairiajame kampe užsifiksuos (žr. *2 pav.*).

4. Jeigu apdorojate mažiau nei tris eiles, spauskite **DEC** (MAŽINTI), kad būtų sumažinta mėginių eilių iki tinkamo nustatymo, ir tik tada paspauskite **START** (PRADĖTI). Apdorotinų eilių skaičius bus rodomas skliausteliuose kaip pranešimo **PRESS START** (SPAUSKITE „PRADĖTI“) dalis. Kai paspaudžiama **DEC** (MAŽINTI) arba **INC** (DIDINTI), atitinkamai atnaujinamas ekranas. Jeigu kiltų problemų, laikykitės ekrane pateikiamų nurodymų.
5. Kai mėginių stovo apdorojimo ciklas baigiamas, pasigirsta garsinis signalas. Pakeiskite užbaigtą apdoroti stovą kitu norimu apdoroti stovu, jeigu reikia nustatykite eilių skaičių ir spauskite **START** (PRADĖTI).
6. **Patikrinkite, ar į centrifugos mėgintuvėlius perkeltas tinkamas kiekis mėginio.** Paskirstomo mėginio kiekis nustatomas automatiškai, bet jo lygį reikia patikrinti ir vizualiai, jeigu švirkšto smaigalys užsikištų arba sistema sugestų. Tinkamas mėginio kiekis mėgintuvėlyje: 12 mL ± 1 mL (4 mL tankio reagento ir 8 mL mėginio).

Prietaiso išjungimas

Darbo dienos pabaigoje, kai visi reikmenys iš prietaiso išimti, paspauskite dviejų padėčių jungiklį (dešinėje prietaiso pusėje) į padėtį **OFF** (IŠJUNGTA), ir prietaisas išsijungs.

Sistemos priežiūra

Kai reikia, atlikite šias sistemos priežiūros užduotis.

Įspėjimas
- Prieš atlikdami priežiūrą ar valydami atjunkite maitinimą.
- Nenuimkite gaubto.
- Viduje nėra prižiūrimų dalių.
- Dėl priežiūros kreipkitės tik į kvalifikuotą personalą.
- Neapipurkškite jokiais skysčiais; pernelyg didelė drėgmė gali kelti elektros pavojų.
- Neleiskite skysčiui patekti į apatiniame gaubte esančias horizontalias judėjimo angas, ir į kitoje prietaiso pusėje esančias ventiliacijos angas.

Išvalykite mėginių stovus po kiekvieno naudojimo, kad neįvyktų kryžminis užteršimas.
1. Sudrėkinkite šluostę antiseptiniu tirpalu, pvz., 5–10 % baliklio tirpalu. Skysčio perteklių išgręžkite.

2. Nušluostykite mėginių stovą drėgna antiseptine šluoste, kad niekur neliktų skysčio.
Nepurkškite antiseptinio tirpalo tiesiai ant mėginių stovų.
Nedėkite mėginių stovų į indaplovę.
Pakartokite 1 ir 2 veiksmus valydami visus mėginių stovus.
3. Visas šluostes išmeskite į biologiškai pavojingų medžiagų konteinerį.

Jeigu reikia pašalinti iš mėginių stovų likučius ar susikaupusius nešvarumus, nuplaukite juos šiltu vandeniu su muilu. Taip valyti po kiekvieno naudojimo nėra būtina.

Kasdien valykite prietaiso dėklą ir plotą po dėklu.
1. Sudrėkinkite šluostę antiseptiniu tirpalu, pvz., 5–10 % baliklio tirpalu. Skysčio perteklių išgręžkite.
2. Nušluostykite dėklą drėgna antiseptine šluoste, kad niekur neliktų skysčio.
3. Šluostę išmeskite į biologiškai pavojingų medžiagų konteinerį.

Prireikus nuvalykite prietaiso išorinius paviršius.
1. Prietaiso išorinius paviršius valykite švelniu muilo ir vandens tirpalu. Jeigu reikia dezinfekuoti, naudokite izopropilo alkoholį.
Plastikinėse vienkartinėse priemonėse gali būti infekuotų medžiagų, todėl jas reikia šalinti kaip biologiškai pavojingas atliekas.

Pranešimai

LCD skydelyje rodomi įvairūs būsenos, klaidų ir gedimų pranešimai.
Pranešimų tipai apibrėžti toliau.

- Būsenos pranešimai apibūdina apdorojimo ciklo eigą.
- Klaidų pranešimai apibūdina problemą ir nurodo, kaip ją išspręsti.
- Gedimų pranešimai apibūdina remonto reikalaujančią problemą ir nurodo kviestis techninę pagalbą.

Būsenos pranešimai

Šie būsenos pranešimai rodomi įprasto apdorojimo ciklo eigoje. Pranešimai pateikiami abėcėline, o ne chronologine tvarka.

CHANGE SPECIMEN RACK (BAIGTA, PAKEISKITE MĖGINIŲ STOVĄ)
PRESS RUN (PAKEISKITE MĖGINIŲ STOVĄ, SPAUSKITE „PALEISTI“)
Šis pranešimas rodomas, jeigu paspaudžiate **RUN** (PALEISTI) pasibaigus apdorojimo ciklui, bet dar nepakeitus mėginių stovo.
Išimkite mėginių stovą, įdėkite kitą ir tuomet spauskite **RUN** (PALEISTI), kad apdorojimas būtų tęsiamas.

DEC TO # OF SPECIMEN
ROWS (-) PRESS START
(SUMAŽINTI IKI # MĖGINIŲ EILIŲ (-), SPAUSKITE „PRADĖTI“)
Šis pranešimas rodomas, kai užbaigiama įprasta paleidimo seka, o mėginių stovas su visais reikmenimis yra savo vietoje. Jeigu eilių skaičius (nurodytas skliausteliuose) yra netikslus, mygtukais **DEC** (MAŽINTI) ir **INC** (DIDINTI) nustatykite tikslų skaičių. Kai skaičius bus tikslus, paspauskite **START** (PRADĖTI), kad būtų pradėta apdorojimo seka.

FINISHED
CHANGE SPECIMEN RACK
(BAIGTA, PAKEISKITE MĖGINIŲ STOVĄ)
Šis pranešimas rodomas, kai užbaigiamas apdorojimo ciklas. Išimkite mėginių stovą, įdėkite kitą ir tuomet spauskite **RUN** (PALEISTI), kad apdorojimas būtų tęsiamas.

BD PREPMATE READY v x.x
LOAD SPECIMEN RACK
(BD PREPMATE PARUOŠTAS, x.x v., SUDĖKITE REIKMENIS Į MĖGINIŲ STOVĄ)
Šiame pranešime „x.x“ nurodo esamą programinės įrangos versiją. Kai užbaigiama įprasta paleidimo seka, Šis pranešimas bus rodomas, kol įdėsite mėginių stovą su reikmenimis į prietaisą.

PROCESSING...STAY
CLEAR WHILE RUNNING
(APDOROJAMA... LAIKYKITĖS ATOKIAU, KOL PRIETAISAS VEIKIA)
Šis pranešimas rodomas esant įprastai veikimo sekai. Nereikia nieko daryti, kol parodomas apdorojimo pabaigos pranešimas ir pasigirsta signalas.

Klaidų pranešimai

Toliau pateikti klaidų pranešimai apibūdina problemą ir nurodo, kaip ją išspręsti. Pranešimai pateikiami abėcėline tvarka.

CLOSE VIAL HOLD-DOWN
DOOR, PRESS RUN
(UŽDARYKITE BUTELIUKŲ PRILAIKYMO DURELES, SPAUSKITE „PALEISTI“)
Šis pranešimas rodomas, jeigu buteliukų prilaikymo durelės yra neužrakintos. Jis bus rodomas, kol uždarysite užraktą ir paspausite mygtuką **RUN** (PALEISTI).

Buteliukų prilaikymo durelės prilaiko mėginių buteliukus ir neleidžia švirkštams pajudinti jų iš vietos. Durelės yra su vyriais, kad prireikus būtų galima pasiekti švirkštų griebtuvus. Jutiklis nustato durelių padėtį ir neleidžia prietaisui veikti, jeigu durelės neužrakintos. Prietaisas veiks tik, kai durelės bus uždarytos.

PIPETTE PLUNGER UP
FIX & PRESS RUN
(PIPETĖS STŪMOKLIS PAKELTAS, PATAISYKITE IR SPAUSKITE „PALEISTI“)
Šis pranešimas rodomas, jei nors vieno švirkšto (pipetės) stūmoklis nėra visiškai sustumtas, kai paleidžiate prietaisą. Skersinio spindulio optinių skaidulų jutiklis, esantis buteliukų prilaikymo durelių apačioje, nustatytas taip, kad nukreiptų šviesos spindulį tiesiai virš švirkštų stūmoklių. Jeigu bent vienas iš keturių stūmoklių eilėje yra nevisiškai sustumtas prieš švirkštui patenkant į švirkštų griebtuvus, jutiklis tai nustato ir sustabdo horizontalųjį judėjimą, kad švirkštas nepatektų į griebtuvą. Kad būtų galima tęsti, stūmoklį reikia įstumti ranka.

SEAT RACK IN TRAY
PRESS RUN
(ĮSTATYKITE STOVĄ Į DĖKLĄ, SPAUSKITE „PALEISTI“)
Stovų dėklo priekiniame kairiajame kampe yra sukamasis užraktas. Šis užraktas išlaiko stovą dėkle, bet leidžia stovą išimti. Po dėklu esantis atstumo jutiklis nustato, ar užraktas atidarytas, ar uždarytas. Prietaiso negalima paleisti, jeigu užraktas neuždarytas. Užraktą reikia atidaryti ir vėl uždaryti, kad būtų galima pradėti darbą. Atrakinamas ir užrakinamas užraktas nurodo, kad mėginių stovas buvo įdėtas arba pakeistas.

Šis pranešimas rodomas, jeigu užraktas nėra tinkamai užsifiksavęs, kai paspaudžiama **START** (PRADĖTI), arba jeigu užraktas atsilaisvina apdorojant. Užraktą reikia uždaryti prieš pradedant arba tęsiant apdorojimą.

TRAY ALIGNED, PRESS
RUN TO CONTINUE
(DĖKLAS SULYGIUOTAS, NORĖDAMI TĘSTI SPAUSKITE „PALEISTI“)
Šis pranešimas rodomas, kai dėklas pakartotinai pozicionuojamas į tinkamą padėtį. Kai dėklas jau savo vietoje ir parodomas šis pranešimas, vizualiai patikrinkite, ar švirkštų eilė sulygiuota su vertikaliuoju įrenginiu, kuris paima švirkštus, tuomet spauskite **RUN** (PALEISTI), kad būtų tęsiama. Šis pranešimas rodomas tik tada, kai parodžius pranešimą **TRAY MOVEMENT DETECT RE-ALIGN TRAY** (NUSTATYTAS DĖKLO JUDĖJIMAS, SULYGIUOKITE DĖKLĄ) dėklo padėtis tinkamai pakoreguojama.

TRAY MOVEMENT DETECT
RE-ALIGN TRAY
(NUSTATYTAS DĖKLO JUDĖJIMAS, SULYGIUOKITE DĖKLĄ)
Šis pranešimas nurodo, kad dėklas nesulygiuotas. Taip gali atsitikti, jeigu dėklas yra išstumiamas iš savo vietos. Pamažu stumkite dėklą pirmyn arba atgal, kol bus parodytas pranešimas **TRAY ALIGNED, PRESS RUN TO CONTINUE** (DĖKLAS SULYGIUOTAS, NORĖDAMI TĘSTI SPAUSKITE „PALEISTI“). Kai dėklas jau savo vietoje, vizualiai patikrinkite, ar švirkštų eilė yra sulygiuota su vertikaliuoju įrenginiu, kuris paima švirkštus, tuomet spauskite **RUN** (PALEISTI), kad būtų tęsiama. Jeigu pranešimas vėl parodomas, įvyko horizontaliojo jutiklio gedimas. Kreipkitės į BD Diagnostics techninės pagalbos tarnybą arba įgaliotąjį platintoją.

WRONG DRAW VOLUME
PRESS RUN TO RETRY
(KLAIDINGAS ĮTRAUKIMO KIEKIS, NORĖDAMI BANDYTI DAR KARTĄ SPAUSKITE „PALEISTI“)
Mechaninis skysčio traukimas į švirkštus yra tikrinamas per kiekvieną įtraukimą. Jeigu traukiama nepakankamai, rodomas šis pranešimas.

Paskutinis ***BD PrepMate naudojimo instrukcijų*** veiksmas yra vizualioji įtraukto kiekio patikra. Jeigu šis klaidos pranešimas nerodomas, reiškia, kad įtraukimo veiksmas mechaniniu požiūriu vyko sklandžiai. Vis dėlto reikia atlikti ir vizualiąją apžiūrą.

Ši problema gali atsirasti užsikimšus vienam iš švirkštų antgalių. Pabandykite paleisti įtraukimo ciklą iš naujo paspausdami **RUN** (PALEISTI) (tai galima kartoti tiek kartų, kiek reikia). Jeigu po kelių bandymų šis pranešimas vis tiek rodomas, kreipkitės į BD Diagnostics techninės pagalbos tarnybą arba įgaliotąjį platintoją.

Gedimų pranešimai

Gedimų pranešimai yra rodomi, kai prietaisas nustato, kad yra problema, kurią būtina taisyti. Apie visus tokius gedimus perspėjama pranešimu **CALL MAINTENANCE** (KREIPKITĖS Į TECHNINĘ PAGALBĄ), kuriame taip pat būna nurodyta gedimo rūšis.

Jeigu rodomas vienas iš tokių pranešimų, kreipkitės į BD Diagnostics techninės pagalbos tarnybą arba į įgaliotąjį platintoją.

Profilaktinė priežiūra

Įspėjimas
- Prieš atlikdami priežiūrą ar valydami atjunkite maitinimą.
- Nenuimkite gaubto.
- Viduje nėra prižiūrimų dalių.
- Dėl priežiūros kreipkitės tik į kvalifikuotą personalą.

Kasmetė priežiūra

- BD PrepMate Automated Accessory yra sukurtas būti eksploatuojamas be nuolatinės techninės priežiūros, išskyrus valymą. Daugiau žr. skyriuje ***Sistemos priežiūra*.**
- Kasmetę priežiūrą turi atlikti įgaliotasis personalas.

Trikčių nustatymas ir šalinimas

Prietaiso generuoti gedimų pranešimai

Šiame skyriuje aprašyti pranešimai, nurodantys aptiktą gedimą. Laikantis trikčių nustatymo ir šalinimo nurodymų, problema turėtų būti išspręsta.

VAIZDAS SKYSTŲJŲ KRISTALŲ (LCD) EKRANE TAMPA IŠKRAIPYTAS ARBA NEĮSKAITOMAS
Jei įvykus trikčiai prietaisas toliau apdoroja dėklą, prieš pradėdami nustatyti ir šalinti triktis leiskite jam baigti apdoroti dėklą. Jei įvykus trikčiai įrenginys nustoja veikti, išimkite apdorojamą dėklą ir švirkštus, pašalinkite strigtį ir pareikite prie trikčių nustatymo ir šalinimo.

Trikčių nustatymas ir šalinimas
- Perjunkite jungiklį į **OFF** (IŠJUNGIMO) poziciją, palaukite 30 sekundžių ir vėl įjunkite maitinimą. Jei iš naujo įjungus maitinimą skystųjų kristalų ekranas ir prietaisas veikia tinkamai, tęskite darbą kaip įprasta.
- Jei išjungus ir vėl įjungus maitinimą triktis nepašalinama, pakartokite veiksmus dar kartą. Jei iš naujo įjungus maitinimą skystųjų kristalų ekranas ir prietaisas veikia tinkamai, tęskite darbą kaip įprasta.
- Jei išjungus ir vėl įjungus maitinimą triktis nepašalinama arba problema išlieka, paskambinkite į BD Diagnostics techninės pagalbos tarnybą.

SEAT RACK IN TRAY
PRESS RUN (ĮSTATYKITE STOVĄ Į DĖKLĄ, SPAUSKITE „PALEISTI“)
Šis gedimo pranešimas rodomas tada, kai mėginių stovą dėkle įtvirtinantis užraktas nėra užsifiksavęs savo vietoje. Stovo dėklo priekiniame kairiajame kampe yra sukamasis užraktas, kuris laiko stovą dėkle, bet leidžia stovą išimti. Po dėklu esantis atstumo jutiklis nustato, ar užraktas yra uždarytas, ar atidarytas. *Prietaisas neveiks, jei užraktas neuždarytas. Be to, užraktą reikia atidaryti ir vėl uždaryti prieš pradedant naują apdorojimo ciklą.*

Užraktą reikia atidaryti ir uždaryti, kad būtų galima pradėti darbą. Tai nurodo, kad buvo įdėtas arba pakeistas mėginių stovas. Šis pranešimas rodomas, jeigu užraktas nėra visiškai uždarytas, kai paspaudžiamas **START** (PRADĖTI), arba jei užraktas atsidaro apdorojant. *Užraktą reikia uždaryti prieš pradedant arba tęsiant apdorojimą.*

Trikčių nustatymas ir šalinimas
- Ar užraktas buvo atidarytas ir uždarytas?
- Ar mėginių stovas buvo išimtas ir (arba) įdėtas į dėklą?
- Ar užraktas laisvai sukasi iš atidarymo į uždarymo padėtį, kai stovas įdėtas ir kai neįdėtas?
- Jeigu į visus šiuos klausimus atsakymas yra teigiamas, o problema vis tiek neišsprendžiama, kreipkitės į BD Diagnostics techninės pagalbos tarnybą.

Trikties pašalinimas: vadovaukitės pranešimu ekrane, užtikrinkite, kad užraktas būtų uždarytas ir gerai užfiksuotas ir paspauskite mygtuką **START** (PRADĖTI) arba **RUN** (PALEISTI), kad apdorojimas būtų tęsiamas.

CLOSE VIAL HOLD-DOWN
DOOR, PRESS RUN
(UŽDARYKITE BUTELIUKŲ PRILAIKYMO DURELES, SPAUSKITE „PALEISTI“)
Buteliukų prilaikymo dureles reikia užrakinti apačioje, kad būtų galima paleisti BD PrepMate Automated Accessory. Prie šių durelių yra pritvirtinti mechaniniai pirštai, kurie užsikabina už mėginių buteliuko viršaus, kad traukiant iš buteliuko švirkšto smaigalį, buteliukas nebūtų iškeltas iš stovo.

Dureles galima pasukti į viršų, kad būtų įmanoma pasiekti švirkštų griebtuvus / pipetes. Yra atstumo jutiklis, kuris nustato durelių padėtį ir neleidžia BD PrepMate Automated Accessory veikti, jeigu durelės yra pakeltos arba neužrakintos. Šis pranešimas rodomas bet kuriuo metu, kai durelės pakeltos.

Jeigu apdorojimo ciklas nevyksta, negalima jo pradėti, kol durelės neuždarytos. Jeigu apdorojimo ciklas vyksta, pakėlus dureles jis bus sustabdytas. Jeigu norite vėl pradėti ciklą, uždarykite dureles ir tuomet spauskite **RUN** (PALEISTI).

Trikčių nustatymas ir šalinimas
- Ar buteliukų prilaikymo durelės yra gerai užrakintos?
- Ar BD PrepMate Automated Accessory buvo judinamas?
- Patikrinkite, kaip prietaiso gaubtas ir prilaikymo durelės pritvirtinti.
- Jeigu problema neišnyksta, kreipkitės į BD Diagnostics techninės pagalbos tarnybą.

PIPETTE PLUNGER UP,
PRESS RUN
(PIPETĖS STŪMOKLIS PAKELTAS, SPAUSKITE „PALEISTI“)
Priešais buteliukų prilaikymo dureles yra skersinio spindulio optinių skaidulų jutiklis. Jis yra tokioje padėtyje, kad šviesos spindulys būtų nukreiptas tiesiai virš švirkštų stūmoklių. Jeigu bent vienas iš keturių stūmoklių eilėje yra ne visiškai įstumtas prieš pat švirkštui patenkant į švirkštų griebtuvus, jutiklis tai nustato ir sustabdo horizontalųjį judėjimą, kad švirkštas nepatektų į griebtuvą. Bus rodomas šis pranešimas ir *prieš tęsiant darbą stūmoklį reikės sustumti.*

Trikčių nustatymas ir šalinimas
- Ar optiniai jutikliai yra sulygiuoti vienas su kitu ant durelių?
- Ar jutiklis siunčia šviesos spindulį į kitą jutiklį?
- Ar visi švirkštų stūmokliai sustumti?
- Ar mėginių stovas buvo pakartotinai įdėtas į dėklą?
- Ar ant stūmoklio viršaus nestyro koks nors plastiko gabaliukas (tai išduotų šviesos žybsėjimas)?
- Jeigu problema neišnyksta, kreipkitės į BD Diagnostics techninės pagalbos tarnybą.

Trikties pašalinimas: vadovaukitės pranešimu ekrane ir paspauskite mygtuką **RUN** (PALEISTI), kad apdorojimas būtų tęsiamas.

TRAY MOVEMENT DETECT,
RE-ALIGN TRAY
(NUSTATYTAS DĖKLO JUDĖJIMAS, SULYGIUOKITE DĖKLĄ)
Šis pranešimas nurodo, kad dėklas nesulygiuotas. Taip gali atsitikti, jeigu dėklas yra išstumiamas iš savo vietos. Jeigu sulygiavus dėklą iš naujo šis pranešimas vis tiek rodomas, tai reiškia horizontaliojo jutiklio gedimą.

Trikčių nustatymas ir šalinimas
- Pamažu stumkite dėklą pirmyn arba atgal, kol bus parodytas pranešimas **TRAY ALIGNED, PRESS RUN TO CONTINUE** (DĖKLAS SULYGIUOTAS, NORĖDAMI TĘSTI SPAUSKITE „PALEISTI“).
- Patikrinkite, ar švirkštų eilė yra tinkamai sulygiuota su esama švirkštų griebtuvų eile.
- Spauskite mygtuką **RUN** (PALEISTI).
- Jeigu stovas buvo stuktelėtas, kol buvo įdedamas, patraukite stovą iki pat priekinės ribos ir paspauskite **RUN** (PALEISTI). Jeigu problema neišnyksta, gali būti sugedęs horizontalusis jutiklis. Kelioms sekundėms išjunkite BD PrepMate Automated Accessory ir paskui vėl įjunkite, kad nusistatytų pradinė padėtis.
- Jeigu problema neišnyksta, kreipkitės į BD Diagnostics techninės pagalbos tarnybą.

WRONG DRAW VOLUME,
PRESS RUN TO RETRY
(KLAIDINGAS ĮTRAUKIMO KIEKIS, NORĖDAMI BANDYTI DAR KARTĄ SPAUSKITE „PALEISTI“)
Mechaninis skysčio traukimas į švirkštus yra tikrinamas per kiekvieną įtraukimą. Jeigu traukiama nepakankamai (dažniausiai taip būna užsikimšus), rodomas šis pranešimas.

Paskutinis ***BD PrepMate naudojimo instrukcijų*** veiksmas yra vizualioji įtraukto kiekio patikra. Jeigu ši klaida nenurodoma, vadinasi, įtraukimas mechaniniu požiūriu vyko sklandžiai. Vis dėlto reikia atlikti ir vizualiąją apžiūrą.

Trikčių nustatymas ir šalinimas
- Trikties pašalinimas: operatorius paraginamas pabandyti dar kartą paspausti **RUN** (PALEISTI). Bandyti įtraukti galite tiek kartų, kiek norite. Kartojant įtraukimo ciklą, maišymo ciklas nebus kartojamas.
- Paleiskite esamos eilės įtraukimo ciklą keletą kartų, ir kamštis galbūt pasišalins. Jeigu gedimo pašalinti nepavyksta, paspauskite **RUN** (PALEISTI) ir, kai švirkšto stūmoklis pasieks savo eigos apatinį tašką, paspauskite **STOP** (STABDYTI). Tai padarius turėtų pavykti pakelti buteliukų prilaikymo dureles, kad švirkštus būtų galima išimti apžiūrai. Vienu metu tvarkykite tik vieną švirkštą. Stenkitės nestuktelėti stovo, kad neišsiderintų jo padėtis švirkštų atžvilgiu. Atlikdami šią procedūrą laikykitės geros laboratorinės praktikos.

- Vizualiai patikrinkite išimtą švirkštą, ar nesimato susidariusio kamščio.
    - Ar pipetės kakliukui niekas netrukdo?
    - Ar mėginyje nėra nuosėdų, kurios užkemša pipečių antgalius?
- Jeigu švirkštas užsikimšęs, pakeiskite jį; tą pačią procedūrą atlikite su kitu švirkštu. Patikrinę visus švirkštus eilėje, uždarykite buteliukų prilaikymo dureles ir paspauskite **RUN** (PALEISTI).
- Ar pipečių smaigaliai remiasi į buteliukų dugnus dėl netinkamos vertikaliojo sustabdymo padėties?
- Jeigu problema neišnyksta, kreipkitės į BD Diagnostics techninės pagalbos tarnybą.

HORIZONTAL IN FAULT (HORIZONTALIOJO ĮSTŪMIMO GEDIMAS)
Trikčių nustatymas ir šalinimas
- Išjunkite prietaisą. Ištraukite dėklą; vėl įjunkite prietaisą.

HORIZONTAL OUT FAULT (HORIZONTALIOJO IŠSTŪMIMO GEDIMAS)
Trikčių nustatymas ir šalinimas
- Išjunkite prietaisą. Įstumkite dėklą; vėl įjunkite prietaisą.

KITI GEDIMAI
Jei įvyktų kuris nors iš toliau išvardytų gedimų ar ekrane būtų rodomas atitinkamas pranešimas, kreipkitės į BD Diagnostics techninės pagalbos tarnybą.
- Horizontaliosios padėties gedimas
- Vertikaliojo viršaus gedimas
- Vertikaliojo vidurio gedimas
- Vertikaliosios apačios gedimas
- Stūmoklio variklio gedimas
- Galinė judėjimo riba
- Ištraukimo jutiklio gedimas
    - Ištraukimo jutiklio arba ryšio gedimas
- Stūmoklio jutiklio gedimas
- Dėklas netyčia nusistumia į galinę judėjimo padėtį
- Nesulygiuotos optinių skaidulų jutiklių galvutės
- Atsilaisvino buteliukų prilaikymo durelių vyrių varžtai

Pastaba: Jeigu dirbant su BD PrepMate Automated Accessory dingsta elektra, procesorius savo atmintyje darbo eigos neišsaugo. Operatorius turės nustatyti, kurį etapą procesas buvo pasiekęs ir atnaujinti darbą nuo atitinkamo etapo.

Remontas ir utilizavimas

Jeigu BD PrepMate Automated Accessory reikia remontuoti ar išmesti, dėl nurodymų kreipkitės į BD Diagnostics techninės pagalbos tarnybą. Šios tarnybos darbuotojai suteiks nukenksminimo sertifikatą, kuris yra grąžinamų medžiagų aprobavimo formos dalis.

Prieš grąžindami prietaisą remontuoti ar pakeitimui, atlikite toliau nurodytą nukenksminimo procedūrą.
1. Nušluostykite visus išorinius paviršius 5–10 % baliklio tirpalu.
2. Pridėkite pasirašytą nukenksminimo sertifikatą.

Šalinant prietaisą būtina laikytis atitinkamų teisinių nuostatų. Pagal direktyvą 2002/96/EB (WEEE), jokių prietaisų, pristatytų po 2005 m. rugpjūčio 13 d., negalima išmesti kartu su buitinėmis atliekomis.
Perbraukto šiukšlių konteinerio piktograma rodo, kad prietaiso negalima išmesti kartu su buitinėmis atliekomis. Atskirose EB šalyse nurodymai dėl atliekų šalinimo gali skirtis. Prireikus kreipkitės į tiekėją.

Atitikties deklaracija

BD Diagnostics patvirtina, kad BD PrepMate Automated Accessory yra pagamintas pagal visus galiojančius standartus ir reglamentus.
Visą atitikties deklaraciją galima gauti paprašius. Kreipkitės į BD Diagnostics techninės pagalbos tarnybą.

Informacija apie garantiją

BD PrepMate Automated Accessory nuo pristatymo datos suteikiama vienerių metų garantija. Dėl remonto arba informacijos apie techninę pagalbą kreipkitės į įgaliotąjį platintoją arba BD Diagnostics techninės pagalbos tarnybą.

Techninės pagalbos tarnyba
USA
Technical Service and Support
BD Diagnostics – Diagnostic Systems
www.bd.com/ds
technical_services@bd.com
1-800-638-8663

Dėl priežiūros darbų, kuriuos atliko ne BD Diagnostics arba jos įgaliotieji atstovai, BD Diagnostics savo nuožiūra gali panaikinti šią garantiją. Nė viena kita šalis nėra įgaliota suteikti garantiją arba prisiimti atsakomybę už BD Diagnostics gaminius. Nė viena kita numanoma arba raštiška garantija nebus pripažįstama.

Naudojimo techniniai duomenys

Elektros srovės reikalavimai

Nominalioji įtampa: 100 – 240 V kintamoji srovė, 50 – 60 Hz
Didžiausias srovės stipris: 2,5 A

Naudojimo sąlygos

Aplinkos temperatūra: 0 – 36 °C, 32 – 97 ^{0}F
Aplinkos drėgmė: 30 – 85 % santykinis drėgnis (be kondensacijos)

Laikymo sąlygos

Temperatūra: 0 – 50 °C, 32 – 122 ^{0}F

Bendroji informacija

Svoris: 36,3 kg, 80 svarų
Aukštis: 55,9 cm, 22 coliai
Plotis: 35,5 cm, 14 colių
Gylis: 58,4 cm, 23 coliai

Saugikliai

Visi saugikliai yra 5 x 20 mm, nominaliosios jų vertės yra 3,15 A esant 250 V kintamosios srovės, yra lėtai suveikiantys, atitinka IEC 60127 reikalavimus. Gaminio techninių duomenų plokštelė yra ant galinio skydo su maitinimo lizdu, joje nurodyti saugiklių duomenys. Pakeičiamieji saugikliai turi būti to paties galingumo ir tipo (T), kaip nurodyta. Tipas T reiškia lėtai suveikiantį saugiklį.

Priedas: BD Prepmate Automated Accessory įdiegimo instrukcijos

Apie šias instrukcijas

Šiose instrukcijose aprašomos BD PrepMate™ Automated Accessory įdiegimo instrukcijos.
Tikimasi, kad įdiegimą atliekantis asmuo yra BD PrepMate Automated Accessory naudotojas arba įgaliotas BD Diagnostics atstovas. Taip pat tikimasi, kad įdiegimą atliekantis asmuo perskaitė ir supranta instrukcijas, pateiktas BD PrepMate™ Automated Accessory operatoriaus vadove.

Dokumente vartojami sutartiniai ženklai

Šiame dokumente svarbi informacija žymima tokiais sutartiniais ženklais.

- Toks šriftas (**ŠIS MYGTUKAS**) nurodo spaustiną mygtuką.
- Toks šriftas (žr. ***Įvadą***) yra nuoroda į tekstą, esantį kitoje šio vadovo dalyje.

Šiame vadove pateikiami dviejų tipų pranešimai: Įspėjimas ir pastaba. Kiekvieno tipo pranešimo išvaizda ir vartosena yra aprašyti toliau.

Įspėjimas
Nurodo rimto įrangos sugadinimo arba netinkamų rezultatų galimybę, jeigu nebus laikomasi nurodymų.

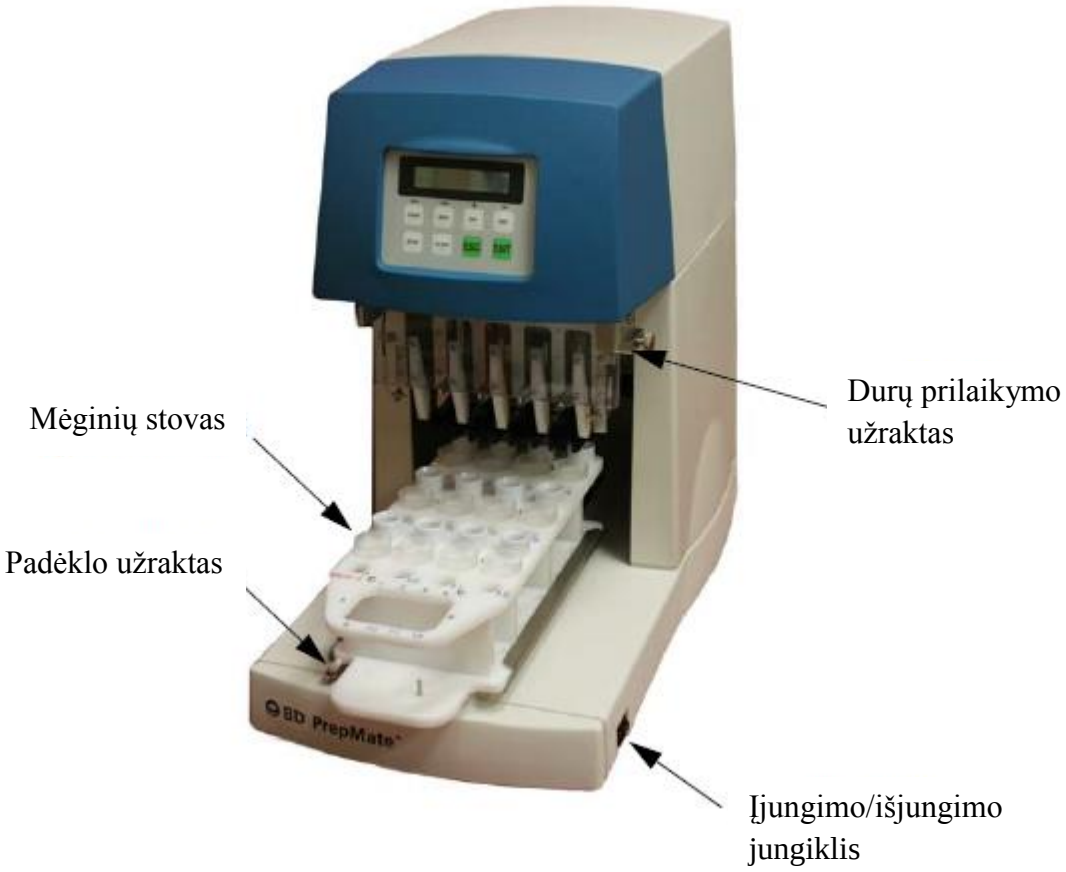
Pastaba: Pateikia naudingos informacijos apie BD PrepMate Automated Accessory.

Rekomenduojamojo pobūdžio informacija

Bendrosios atsargumo priemonės

Įspėjimas

- Šį prietaisą reikia kelti ir nešti paėmus už pagrindo apačios. Keldami neimkite už mėlynų priekinių skydų. Niekada nekelkite ir neneškite prietaiso, laikydami už priekinio skydo.
- Įdiegimo rinkinyje esantys vartojimo reikmenys nėra skirti klinikiniam naudojimui. Kai baigsite patvirtinimo procesą, utilizuokite bet kokius nepanaudotus vartojimo reikmenis.
- Naudojant prietaisą netinkamoje įtampoje galite sugadinti prietaisą.
- Nenaudokite sistemos, kuri prijungta prie tokio AC galios lizdo, kuris neturi tinkamos įžeminimo jungties.
- Įdiegiant galios laidą su netinkamus poliškumu galite sukurti elektros šoko pavojų arba sugadinti prietaisą.



1 pav. *BD PrepMate Automated Accessory vaizdas iš priekio*

2 pav. *BD PrepMate Automated Accessory vaizdas iš galo*

BD PrepMate Automated Accessory išpakavimas

Pastaba: Prieš pradėdami perskaitykite visas instrukcijas.

1. Išpakuokite visus elementus iš transportavimo dėžės.
2. Patvirtinkite, kad toliau nurodyti komponentai yra įdėti į transportavimo dėžę:
   - BD PrepMate Automated Accessory (1)
   - Galios laidas (1)
   - Mėginio stovai (4) sunumeruoti nuo 1 iki 4
   - Vienkartinis įdiegimo rinkinys (1), sudarytas iš:
     - Švirkščiamos pipetės (12)
     - Tušti mėginio surinkimo buteliukai (12)
     - Buteliuko dangtelis (12)
     - Centrifugos mėgintuvėliai (12)
3. Atidarykite prilaikymo dureles ir išimkite porolono pakavimo medžiagą, kuri palaiko griebtuvo korpusą, o tada atlikite kitas procedūras.

Pirminis nustatymas ir tikrinamasis paleidimas

Prieš naudojant prietaisą, nustatykite ir atlikite tikrinamąjį ciklą, kad patvirtintumėte tinkamą veikimą.

Pirminis nustatymas

1. Atidžiai patikrinkite instrumentą ir priedus dėl bet kokių fizinių sugadinimų, kurie galėjo atsirasti transportavimo metu. Jeigu instrumentas sugadintas, tolimesnių veiksmų neatlikite. Kreipkitės į klientų aptarnavimą.
2. Padėkite BD PrepMate Automated Accessory ant tvirto stalviršio. Pozicionuokite instrumentą taip, kad priekinis apatinis kraštas būtų nutolęs mažiausiai šešis colius atgal nuo priekinio stalviršio krašto. Tai leis pilnai ištrauktam dėklui neišsikišti už stalviršio ribų. Prietaiso nedėkite tokioje vietoje, kur jis būtų paveiktas tiesioginių saulės spindulių arba šalia karščio šaltinio.
3. Prieš prijungdami galios laidą patvirtinkite, kad įtampa, nurodyta galinėje panelėje esančioje specifikacijų plokštelėje, suderinama su AC įtampa prietaiso naudojimo vietoje. Jeigu prieinama įtampa nėra suderinama, įspėkite BD Diagnostics techninę pagalbą.
4. Prijunkite AC galios laidą tarp instrumento galios įvesties modulio (parodyto 2 paveiksle) ir elektros lizdo arba nepertraukiamo elektros šaltinio (UPS).

> **Pastaba:** UPS (rekomenduojamo, tačiau netiekiamo) naudojimas tarp elektros šaltinio ir BD PrepMate Automated Accessory yra rekomenduojamas, kad būtų išvengta proceso nutraukimo galios tiekimo sutrikimo metu. UPS nominali galio turėtų būti mažiausiai 150 VA 5 minutėms.

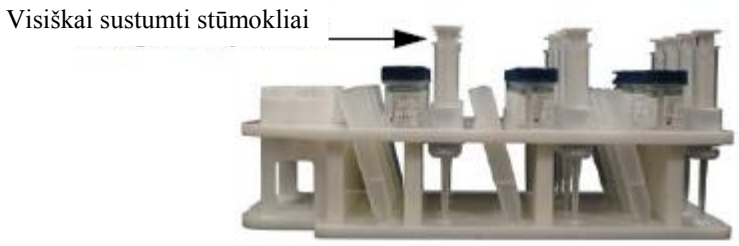
BD PrepMate Automated Accessory įkrovimas tikrinamajam veikimui

1. Įjunkite BD PrepMate Automated Accessory pasukdami šoninės panelės jungiklį į poziciją **On** (įjungta). On pozicija nurodoma vertikalia linija (|).
LCD panelė įsižiebs ir parodys identifikacinius pranešimus. Jeigu instrumentas neįsižiebia, patikrinkite saugiklius ir/arba galios šaltinį. Švirkštą suimantys pirštai judės aukštyn, o dėklas į priekinę poziciją.
2. Kai tik įjungiamas maitinimas, LCD skydelyje parodomas pranešimas **INITIALIZING** (INICIJUOJAMA). Maždaug po 15 sekundžių parodomas pranešimas **READY TO HOME vX.X PRESS HOME** (PARUOŠTA PRADŽIAI, X.X v., PASPAUSKITE „PRADŽIA“). Paspauskite mygtuką **HOME** (PRADŽIA), kad inicijavimas būtų užbaigtas ir visi varikliukai būtų nustatyti į pradinę padėtį.

> **Pastaba:** Šis veiksmas atliekamas tik įjungus prietaiso maitinimą ir, jeigu panaudojus anksčiau prietaisas nebuvo išjungtas, šis veiksmas nekartojamas.

Baigus inicijavimo seką prietaiso skydelyje rodomas pranešimas **PREPMATE READY, (v X.X) LOAD SPECIMEN RACK** („PREPMATE“ PARUOŠTAS, (X.X v.) ĮDĖKITE MĖGINIŲ STOVĄ) (X.X nurodo esamą programinės įrangos versiją).
3. Naudokite vartojimo reikmenis, pridėtus prie įdiegimo rinkinio, kad įkrautumėte mėginio stovą su 12 uždarytų buteliukų, švirkščiančių pipečių (švirkštų) ir centrifugos mėgintuvėlių. Įsitikinkite, kad buteliukai gerai įstatyti į jiems skirtus apvalius šulinėlius, ir sudėkite švirkštus į stovą šalia kiekvieno buteliuko. Įsitikinkite, kad kiekvieno švirkšto stūmoklis pilnai sustumtas.

> **Pastaba:** BD PrepMate Automated Accessory neveiks, jeigu stūmoklis bus pernelyg aukštai.



3 pav. *Visiškai sustumti švirkštų stūmokliai*

> **Pastaba:** Šio įdiegimo tikslais nenaudojami jokie gyvo paciento mėginiai. Žr. BD PrepMate™ Automated Accessory operatoriaus vadovą instrukcijoms dėl gyvų pacientų mėginių apdorojimo.

4. Įkraukite mėginių stovą į instrumento dėklą. Stumkite mėginio stovą nuo priekinės dalies tol, kol dėklo užraktas priekiniame kairiajame kampe užsirakins (žr. *1 paveikslą* dėklo užrakto iliustracijai).

Pastaba: Jeigu dėklas nėra tinkamai užrakintas, LCD ekranas neatsinaujins.

Tikrinamojo ciklo apdorojimas

1. Kai mėginio stovas yra įkrautas į dėklą, bus parodytas pranešimas **DEC TO # OF SPECIMEN ROWS (-) PRESS START**.
2. Įsitikinkite, kad prilaikymo durelės yra vertikalioje, užrakintoje pozicijoje. Jeigu durys nėra tinkamai užrakintos, pasirodys pranešimas **CLOSE VIAL HOLD-DOWN DOOR, PRESS RUN**. Šis pranešimas bus rodomas tol, kol Jūs uždarysite užraktą ir paspausite **RUN.**
3. Paspauskite **START**. Apdorojamų eilių skaičius bus rodomas lenktiniuose skliaustuose, kaip **PRESS START** pranešimo dalis. Jeigu įvyksta bet kokia problema, sekite instrukcijas, kurios pasirodo ekrane.
4. Laikykitės darbinės sekos ir patvirtinkite, kad:
   - Švirkšto sugriebimo pirštai suima ir pakelia švirkštus.
   - Švirkštai susilygiuoja ir praduria tuščių mėginio surinkimo buteliukų dangtelių tarpines ir sustoja netoli kiekvieno buteliuko dugno.
   - Švirkštų stūmokliai yra pakeliami ir nuleidžiami per aštuonis maišymo ciklus.
   - Švirkštų stūmokliai yra pakeliami lyg ištraukiant konservanto skystį į švirkštus.
   - Palaikymo pirštai išlaiko buteliukus, kai švirkštai yra ištraukiami.
   - Švirkštai centruojasi į centrifugos mėgintuvėlius ir jų antgaliai yra nuleidžiami palei centrifugos mėgintuvėlio vidinę sienelę prieš paskirstymo atlikimą.
   - Stūmokliai juda lėtai į švirkščiančias pipetes lyg paskirstytų skystį į centrifugos mėgintuvėlį.
   - Švirkštai yra pakeliami ir nuleidžiami atgal į mėginio stovą.
5. Kai mėginio stovo apdorojimo ciklas yra baigiamas, girdimas garsinis tonas.
6. Jeigu funkcijos 4 žingsnyje nėra atliekamos kaip aprašyta, išjunkite BD PrepMate Automated Accessory ir kreipkitės į klientų aptarnavimą.

Tai užbaigia BD PrepMate Automated Accessory įdiegimą. Instrumentas paruoštas naudoti.

BD PrepStain™ stiklelių paruošimo sistema

Vartotojo vadovas

Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152 JAV

EC REP Benex Limited
Pottery Road, Dun Laoghaire
Co. Dublin, Airija

Atstovas Australijoje:
Becton Dickinson Pty Ltd.
4 Research Park Drive
Macquarie University Research Park
North Ryde, NSW 2113 Australija

500005572 (2015-06)(03)

CE

Pakeitimų istorija

Peržiūra/Data	Puslapiai	Priežastis
(01)(2014-11)	Visi	Vadovas atnaujintas dėl vietos perkėlimo iš Burlington, NC į Sparks, MD.
(02)(2014-12)	Visi	Ištaisyts BD SurePath iš anksto padengtų stiklelių katalogo numeris.
(03)(2015-06)	Visi	Pabrėžta svarba nedaužyti/nepurtyti roboto. Pabrėžta svarba tinkamai nustatyti agregatą (kad išvengti roboto susidūrimo). Pridėto instrukcijos klaviatūros inicializacijai, kai įvyksta robotizuotos atšakos klaida.

Šis naudotojo vadovas apibūdina BD PrepStain™ stiklelių paruošimo sistemos funkciją, naudojimą ir aptarnavimą, kai sistema naudojama ruošiant BD SurePath™ skysčio pagrindo PAP testo stiklelius. Prieš sistemos naudojimą būtina gauti mokymus iš įgalioto BD personalo. Prieš naudodami BD PrepStain™ stiklelių paruošimo sistemą su BD SurePath™ reagentais, pirmiausia perskaitykite šį vadovą. BD SurePath, BD FocalPoint, BD PrepStain, BD logotipas ir visi kiti prekės ženklai yra Becton, Dickinson and Company nuosavybė.

UNIX yra registruotas UNIX System Laboratories, Inc. prekės ženklas.

Hewlett Packard yra registruotas Hewlett Packard Company prekės ženklas.

Turinys

Turinys iii
Įvadas vii
Apie šį vartotojo vadovą vii
Skyrių sandara vii
Trumpinių formos viii

1: Sistemos bendra informacija
Įdiegimas 1-1
Įvadas 1-1
PrepStain komponentai 1-1
Maišyklės apibūdinimai 1-1
PrepMate apibūdinimas 1-2
PrepMate mėginio stovas 1-3
BD švirkščiančios pipetės 1-3
Centrifugos indai 1-4
Stikleliai 1-4
Mėginių buteliukai 1-4
Centrifugos mėgintuvėliai 1-4
Centrifuga 1-4
Skysčių apsiravimo sistema 1-5
PrepStain instrumentas 1-7

2: Sistemos specifikacijos
BD PrepStain™ stiklelių apdorojimo sistemos komponentai 2-1
Kelių buteliukų maišyklė (opcija) 2-1
Vieno buteliuko maišyklė 2-1
PrepMate specifikacijos 2-2
Centrifuga 2-3
BD PrepStain™ instrumento specifikacijos 2-3
PREP sistemos komponentų schema 2-5
Reikalingos medžiagos (įsigyjamos iš BD) 2-6
Reikalingos, tačiau netiekiamos medžiagos 2-7
Medžiagos (opcija) 2-7
Įdiegimas 2-7

3: Veikimo principai

Bendra proceso informacija 3-1
Mėginio surinkimas 3-1
Surinkimo buteliukas ir prietaisai 3-2
Mėginio tvarkymas ir ląstelių praturtinimas 3-4
Mėginio maišymas 3-4
BD tankio reagentas 3-4
Maišymas ir sluoksniavimas 3-5
Centrifugavimas 3-7
Mėginio apdorojimas BD PrepStain™ sistema 3-7
BD nusėdimo kamera 3-7
Kompiuterinė darbo vieta 3-7
PrepStain instrumentas 3-8
Stiklelio paruošimas ir dažymas 3-11
BD SurePath plono sluoksnio ruošinių tyrimas 3-15

4: Išankstinio apdorojimo žingsniai

Buferizuoto vandens paruošimas 4-1
Reikalingos medžiagos 4-1
Sandėlio buferio gamybos procedūra 4-1
Buferizuoto vandens darbinio tirpalo gamybos procedūra 4-2
Mėginio perkėlimo nustatymas 4-2
Gamybos grandinė 4-2
Stiklelių paruošimas ant stiklelių stovo 4-3
PrepStain proceso procedūra 4-4
BD SurePath ląstelių gumulėlių pakartotinis apdorojimas 4-10

5: Ginekologinių (GYN) stiklelių apdorojimas

PrepStain GYN programa 5-1
Programos bendra informacija 5-1
Pagrindinio meniu ekranas 5-2
Ekrano Step in Progress detali informacija 5-3
Ginekologinių (GYN) mėginių apdorojimas 5-4
Tik Prep 5-11
Stiklelių dažymas 5-12
Mėginio/dažymo parametrų keitimas 5-15
Brūkšninių kodų skanavimas (laisvai pasirenkama funkcija) 5-19

6: Priežiūros procedūros
Reikalingos medžiagos 6-1
Kasdieninė prevencinė priežiūra 6-1
Sistemos valymo atlikimas 6-2
Kas savaitinė prevencinė priežiūra 6-3
5 proc. valymo tirpalo paruošimas 6-3
Dažymo ir vakuumo linijų skalavimas 6-3
Z strypo valymas 6-5
Gravitacijos ir atliekų talpyklų ištuštinimas 6-5
Prevencinė priežiūra 6-5
Kas mėnesinė prevencinė priežiūra 6-6
Schuco vakuuminio siurblio juntamo slopintuvo keitimas 6-6
Visų vandens butelių ir vamzdelių valymas 6-6

7: Trikčių šalinimas
Klaidų kodai ir pranešimai 7-1
Bendrų klaidų pranešimų kodai 7-2
Švirkšto pompos klaidų atvejai 7-2
Robotizuotos atšakos klaidų kodai 7-3
Problemos ir sprendimai 7-4

8: Terminų žodynėlis

9: Nustatymas ir diagnostikos
Sistemos nustatymas 9-1
Įrenginio nustatymas 9-2
Priemonių stovai 9-3
Kompiuterio nustatymas 9-3
Slaptažodžio nustatymas 9-3
Diagnostikos 9-4
Klaviatūros veikimas 9-5
Atsitiktinis XYZ testas 9-5
DiTi testai 9-7

10: Ne GYN stiklelių apdorojimas
PrepStain ne GYN programa 10-1
Programos bendra informacija 10-1
Ne GYN pagrindinis meniu 10-2
Ne ginekologinių (ne GYN) mėginių apdorojimas 10-3
Stiklelių sutvarkymas daugialypiams stikleliams 10-7

Priedas: Pagalbiniai tyrimai iš BD SurePath surinkimo buteliuko
Procedūra 11-1
Procedūros apribojimai 11-2
Bendros atsargumo priemonės pagalbiniams tyrimams iš BD SurePath surinkimo buteliuko 11-2

Naudojami simboliai 12-1

Užsakymų informacija 13-1

Įvadas

Apie šį vartotojo vadovą

Šis vartotojo vadovas yra skirtas būti pagrindiniu šaltiniu, nurodančiu kaip naudoti BD PrepStain™ stiklelių paruošimo sistemą (PrepStain) gaminant BD SurePath™ skysčio pagrindo PAP testų stiklelius (SurePath stikleliai). Šio vartotojo vadovo naudotojai turi gauti BD įgalioto personalo mokymus bei turėti patirties apdorojant mėginius.

Skyrių sandara

Skyriai padalinti pagal pagrindines užduotis, susijusias su mėginių apdorojimu naudojant PrepStain sistemą.

- ***1 skyrius, bendra sistemos informacija*** pristato PrepStain stiklelių paruošimo sistemą ir BD PrepStain sistemos komponentus.
- ***2 skyrius, sistemos specifikacijos*** detaliai pateikia kiekvieno PrepStain sistemos komponento specifikacijas.
- ***3 skyrius, veikimo principai*** apibūdina PrepStain stiklelių paruošimo darbo eigos veiksmų seką.
- ***4 skyrius, išankstinio apdorojimo žingsniai*** apibūdina procedūras, naudojamas ruošiant ginekologinius mėginius apdorojimui PrepStain instrumente.
- ***5 skyrius, ginekologinių (GYN) stiklelių apdorojimas*** apibūdina, kaip naudoti GYN taikymą apdorojant ginekologinių mėginių stiklelius.
- ***6 skyrius, priežiūros procedūros*** pateikia detalią informaciją apie procedūras, kurios reikalingos PrepStain sistemos priežiūrai.
- ***7 skyrius, trikčių šalinimas*** suteikia informaciją apie procedūras, kurias galite naudoti izoliuojant ir sprendžiant PrepStain sistemos problemas.
- ***8 skyrius, terminų žodynėlis*** pateikia mechaninių komponentų apibrėžimus, kurie sudaro PrepStain stiklelių paruošimo sistemą ir terminus, naudojamus procese.
- ***9 skyrius, nustatymas ir diagnostikos*** apibūdina, kaip atidaryti ir atlikti PrepStain instrumento nustatymus ir diagnostinius testus.
- ***10 skyrius, ne GYN stiklelių apdorojimas*** apibūdina, kaip naudoti ne GYN pritaikymą, kad apdoroti ne GYN mėginių stiklelius.

Įspėjimas:

- Federalinis įstatymas riboja šio prietaiso pardavimą tik gydytojui arba gydytojo užsakymu, arba bet kokio kito praktikos, kuris licencijuotas pagal valstijos, kurioje praktikas dirba, įstatymus, naudoti arba užsakyti naudoti prietaisą, ir yra apmokytas ir turintis patirtį naudojant BD PrepStian™ stiklelių paruošimo sistemą.
- Ši įranga generuoja ir naudoja radijo dažnio energiją. Jos tipas buvo ištirtas ir nustatytas kaip atitinkantis ribas ISM įrangai pagal FCC 15 dalies J skirsnio, A klasės ir EN 55011, B klasės reikalavimus, kurie sukurti suteikti apsaugą nuo tokių trikdžių gyvenamajame įdiegime. Jeigu įranga nėra naudojama pagal gamintojo instrukcijas, ji gali sukurti trikdžius radijo arba TV imtuvams arba kitų elektrinių prietaisų funkcionalumui.

Trumpinių formos

Toliau pateikti formatavimo tipai naudojami šiame dokumente tam, kad identifikuoti svarbią informaciją.

- Šis tipas (**Šis mygtukas**) nurodo mygtuką, kurį reikia paspausti.
- Šis tipas (Į v e s k i t e t a i) nurodo klavišus, kuriuos Jūs spaudžiate.
- Šis tipas (**EKRANO TEKSTAS**) nurodo tekstą, kuris pasirodo ekrane.
- Šis tipas (žr. ***Įvadą***) nurodo kitą, šiame vartotojo vadove esančią, informaciją.

Šiame vadove pateikiami penkių tipų pranešimai: Trijų tipų perspėjimai, įspėjimas ir pastaba. Tai pažymi svarbią informaciją arba įspėja vartotoją apie potencialiai pavojingas situacijas. Kiekvieno tipo pranešimo išvaizda ir vartosena yra aprašyti toliau.

Perspėjimas
Nurodo sunkaus arba mirtino asmens sužalojimo galimybę, jeigu nebus laikomasi nurodymų.

Perspėjimas
Nurodo elektros šoko ir gaisro galimybę, jeigu nebus laikomasi nurodymų.

Perspėjimas
Nurodo sąlyčio su krauju arba kitais galimai užkrečiamais kūno skysčiais galimybę, jeigu nebus laikomasi nurodymų.

Įspėjimas
Nurodo rimto įrangos sugadinimo arba netinkamų rezultatų galimybę, jeigu nebus laikomasi nurodymų.

Pastaba: Pateikia naudingos informacijos apie PrepStain sistemą.

1 skyrius
Bendra sistemos informacija

Įdiegimas

Įdiegimą ir našumo patvirtinimą gali atlikti tik BD įgaliotas serviso personalas.
BD PrepStain™ sistema pristatoma vienoje arba keliose transportavimo dėžėse. Likusios šio skyriaus dalys detaliai paaiškina apie šių dėžių turinį.

Įvadas

Šiame skyriuje pristatoma BD PrepStain™ stiklelių paruošimo sistema ir sistemos komponentai. Apibūdinami sistemos komponentai ir jų funkcijos bei įvairūs vartojimo reikmenų elementai, naudojami apdorojant BD SurePath PAP testus.
Kiekvieno PrepStain proceso komponentų iliustracijos pateikiamos tokia tvarka, su kokia susidursite kasdieniniuose laboratoriniuose procesuose.

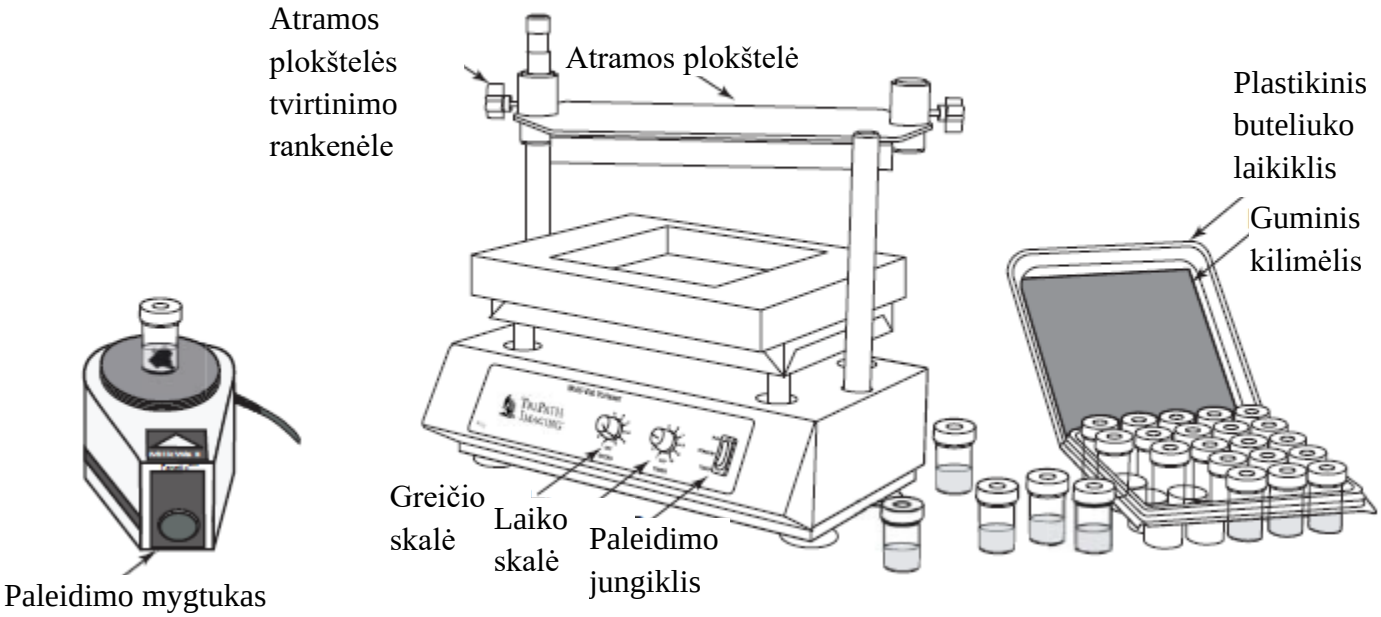
PrepStain komponentai

Toliau esančios iliustracijos ir apibūdinimai nurodo pagrindinius komponentus, kurie sudaro PrepStain sistemą.

Maišyklės apibūdinimai

1-1 paveikslas: iliustruoja vieno ir kelių buteliukų maišykles, kurios yra naudojamos mėginių maišymui, kad ląstelės būtų homogeniškai pasiskirsčiusios apdorojimui BD PrepStain™ stiklelių paruošimo instrumente.

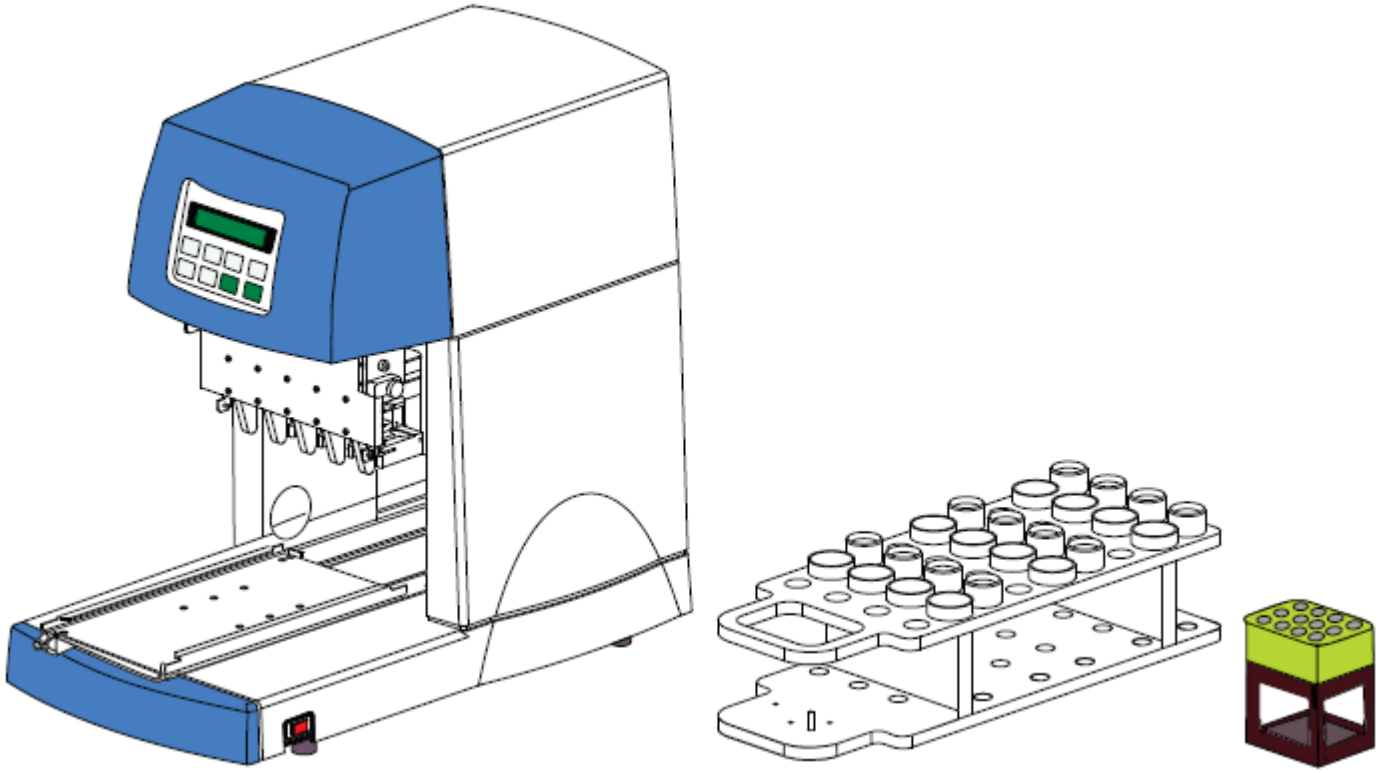
- Vieno buteliuko maišyklė vienu metu apdoroja vieno mėginio buteliuką. Ji taip pat naudojama maišyti centrifugos talpyklą po antrojo centrifugavimo ciklo (šis elementas nėra tiekiamas BD).
- Kelių buteliukų maišyklė vienu metu leidžia apdoroti iki 25 mėginių buteliukų (šį elementą tiekia BD).



1-1 iliustracija: *vieno ir kelių buteliukų maišyklės*

PrepMate apibūdinimas

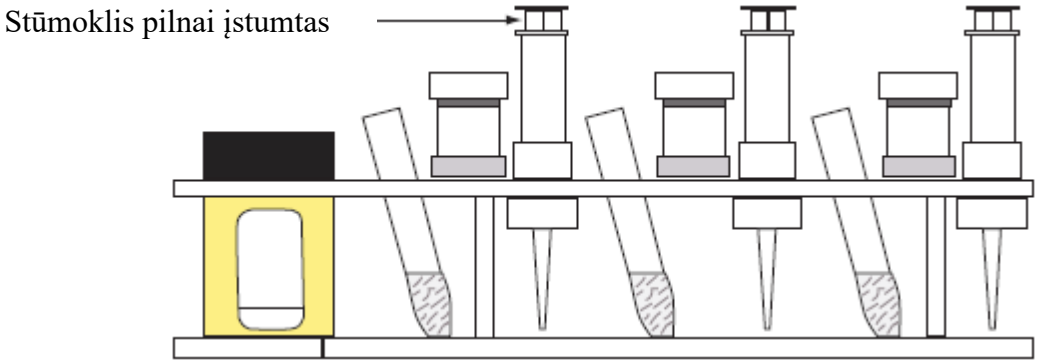
1-2 iliustracija: iliustruoja BD PrepMate automatizuotą priedą (PrepMate), mėginio apdorojimo stovą ir centrifugos talpyklą. PrepMate sukurtas perkelti ląstelių tirpalą iš BD SurePath Collection Vial (surinkimo buteliuko) į BD centrifugos mėgintuvėlį, kuriame yra BD Density Reagent (tankio reagentas).
Mėginio stove įstatoma centrifugos talpykla ir iki 12 mėginio buteliukų rinkinių, BD centrifugos mėgintuvėliais ir BD Syringing Pipettes (švirkščiančios pipetės). Mėginio buteliukuose yra atjungtos mėginio paėmimo prietaiso galvutės BD SurePath konservanto skystyje. Centrifugavimo mėgintuvėliuose yra 4 ml BD tankio reagento (vartotojo padalinto alikvotinėmis dalimis į kiekvieną mėgintuvėlį). Švirkščiančios pipetės yra naudojamas mėginio tirpalo maišymui ir perkėlimui iš surinkimo buteliukų į centrifugavimo mėgintuvėlius. Po perkėlimo centrifugavimo mėgintuvėliai yra sudedami į centrifugavimo stovą.



1-2 iliustracija: *PrepMate, plastikinis mėginio stovas ir centrifugavimo talpykla*

PrepMate mėginio stovas

1-3 iliustracija: iliustruoja Prepmate mėginio stovą pilnai įkrautą su centrifugos talpykla, BD centrifugavimo mėgintuvėliais, mėginio buteliukais ir BD švirkščiančiomis pipetėmis.



1-3 iliustracija: *įkrautas mėginio stovas*

BD švirkščiančios pipetės

BD švirkščiančios pipetės (iliustruotos *1-3 iliustracijoje*) yra plastikiniai švirkštai, kurie perkelia mėginį iš mėginio buteliuko į centrifugavimo mėgintuvėlį.

Centrifugos indai

1-4 iliustracija: iliustruoja centrifugos ind1. Kaip nurodyta *1-3, 1-5* ir *1-13* iliustracijose, šis komponentas įsistato į PrepMate padėklą, centrifugą ir PrepStain atliekų stotelę. Į indą sudedami BD centrifugos mėgintuvėliai, kuriuose yra ląstelių tirpalas ir tankio reagentas. Inde vienu metu telpa iki dvylikos centrifugos mėgintuvėlių, kai atliekami abu centrifugavimo ciklai ir apdorojimas BD PrepStain™ instrumente.

Stikleliai

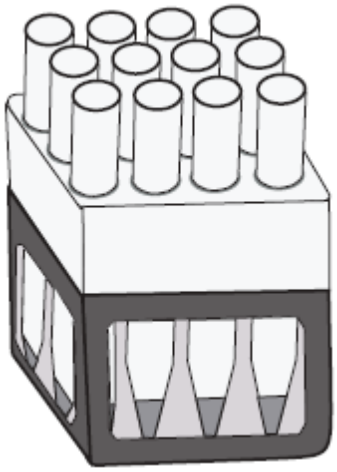
BD SurePath PreCoat Slides (BD SurePath iš anksto padengti stikleliai) yra standartiniai 25 ant 75 mm mikroskopo objektiniai stikleliai, kurie gamintojo buvo padengti ir paruošti naudoti BD PrepStain™ sistemoje.

Mėginių buteliukai

BD SurePath Collection Vial (BD SurePath surinkimo buteliukas) (iliustruotas *1-1* ir *1-3* iliustracijose) yra naudojamas paciento mėginio transportavimui.

Centrifugos mėgintuvėliai

BD Centrifuge Tubes (BD centrifugos mėgintuvėliai) (iliustruoti *1-4* ir *3-11* iliustracijose) yra 12 ml plastikiniai tyrimų mėgintuvėliai, kuriuose patalpinami mėginiai ląstelių praturtinimo procese.



1-4 iliustracija: *centrifugos indas*

Centrifuga

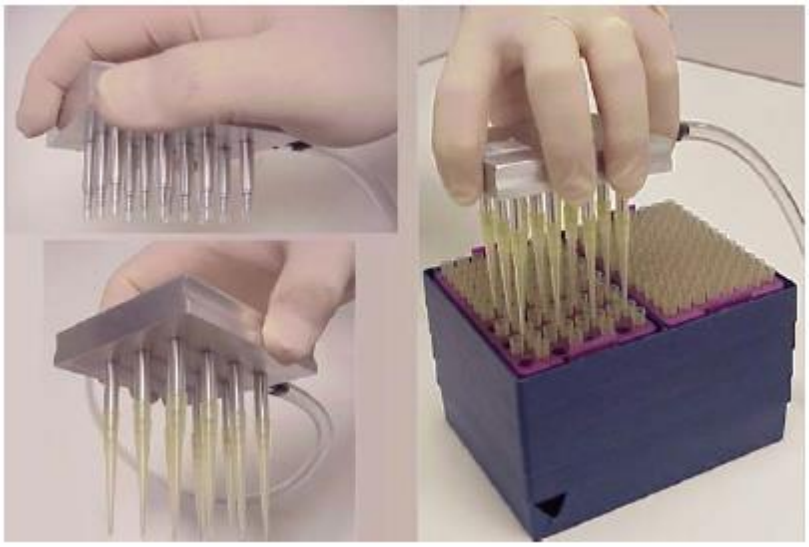
Centrifuga naudojama paruošti koncentruotą ląstelių gumulėlį, kuris yra apdorojamas BD PrepStain™ instrumente. Centrifuga, tiekiama su PrepStain sistema, yra programuojama ir sudaryta iš įvairių saugos ypatybių. Visos programos, reikalingos mėginių apdorojimui PrepStain instrumente, Jūsų patogumui gamintojo buvo iš anksto suprogramuotos. Šios programos centrifugoje užima vietas, pažymėtas nuo 1 iki 4.
1-5 iliustracija: iliustruoja centrifugos stovus, įkraunamus į centrifugą. Centrifugos modelis gali skirtis.

1-5 iliustracija: *ląstelių mėginių centrifugavimas*

Įspėjimas
Centrifugos vartotojo vadovas yra atskiras vadovas. Prašome atidžiai perskaityti centrifugos vartotojo vadovą ir tik tada naudoti centrifugą.

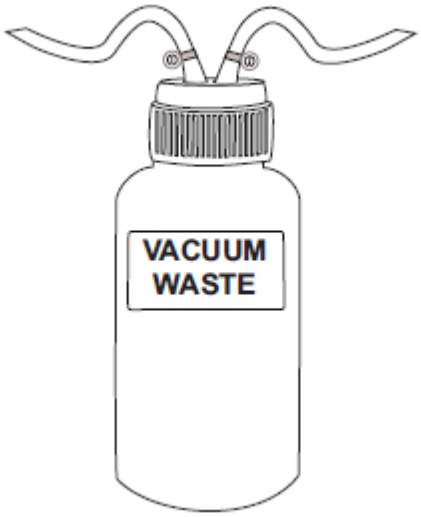
Skysčių apsiravimo sistema

1-6 iliustracija: iliustruoja Easy Aspirator (aspiratoriaus) bloką su įdiegtais antgaliais. Aspiratoriaus blokas prijungiamas prie vakuuminio siurblio per atliekų butelį, kuris surenka aspiruojamus skysčius.



1-6 iliustracija: *aspiratorius su antgaliais*

1-7 iliustracija: iliustruoja vakuuminį atliekų butelį su tinkamai fiksuotu dangčiu ir vamzdelių jungtimis.



1-7 iliustracija: *atliekų butelis aspiruotiems skysčiams*

Vakuuminis siurblys, parodytas *1-8 iliustracijoje* ir *1-9 iliustracijoje* yra naudojamas skysčių pertekliaus aspiracijai. Įprastame BD PrepStain™ sistemos įdiegime yra įmontuoti du tokie siurbliai. (Gali būti bet kuris modelis.)

- Vienas siurblys prijungtas prie aspiratoriaus bloko. Antgaliai įterpiami į BD centrifugos mėgintuvėlius ir naudojami skysčių, kurie buvo izoliuoti ląstelių mėginyje per pirmą centrifugavimo ciklą, pertekliui pašalinti.
- Antrasis siurblys prijungiamas prie PrepStain instrumento keturkampės atšakos. Jis skirtas aspiruoti skysčius iš BD Settling Chambers (BD nusėdimo kamerų).

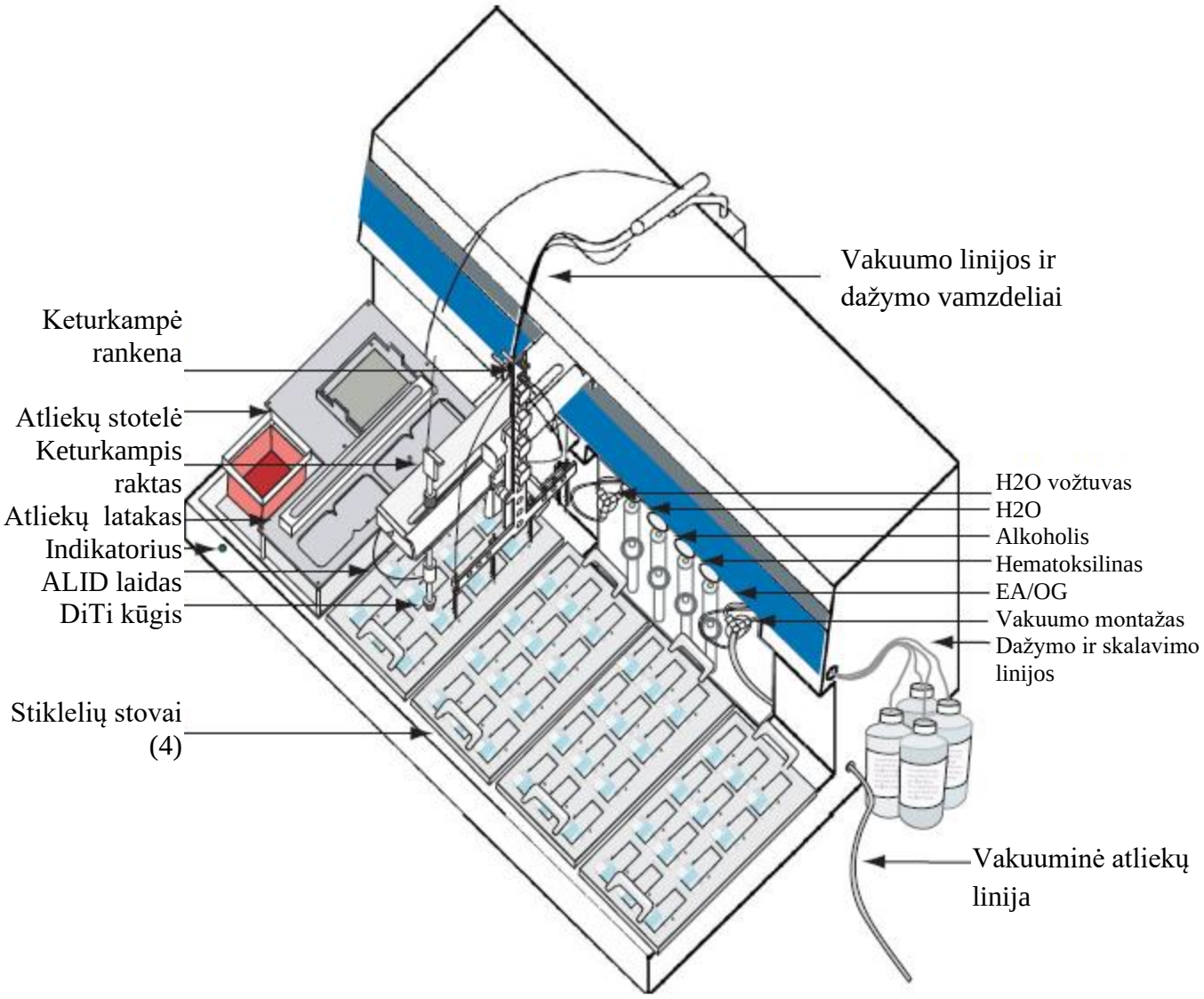
1-8 iliustracija: *vakuuminis siurblys (tarptautiniai modeliai gali skirtis)*

1-9 iliustracija: *KNF siurblys*

Perspėjimas
Buvo identifikuotas potencialus saugumo pavojus dėl alkoholio garų, kurie yra išmetami iš BD PrepStain vakuuminio siurblio (visi Schuco ir KNF-Neuberger modeliai). Įprastai veikdamas vakuuminis siurblys į aplinką išmeta alkoholio garus, kurie gali sukurti lengvai užsidegančią atmosferą, jeigu siurblys naudojamas uždaroje vietoje, pvz. spintoje. Pašalinkite vakuuminį siurblį iš bet kokių uždarų erdvių, kurios nėra tinkamai ventiliuojamos. Vakuuminis siurblys turi būti naudojamas gerai ventiliuojamoje vietoje, kurioje arti išmetimo angos nėra uždegimo šaltinių.

PrepStain instrumentas

1-10 iliustracija: iliustruoja BD PrepStain™ Slide Processor (BD PrepStain™ stiklelių apdorojimo sistemą). PrepStain instrumentas perkelia ląstelių mėginius iš BD centrifugos mėgintuvėlio į nusėdimo kamerą, sumontuotą ant mikroskopo objektinio stiklelio. PrepStain instrumentas automatiškai nudažo ir skalauja kiekvieną stiklelį.



1-10 iliustracija: *PrepStain instrumento vaizdas iš priekio*

Perspėjimas

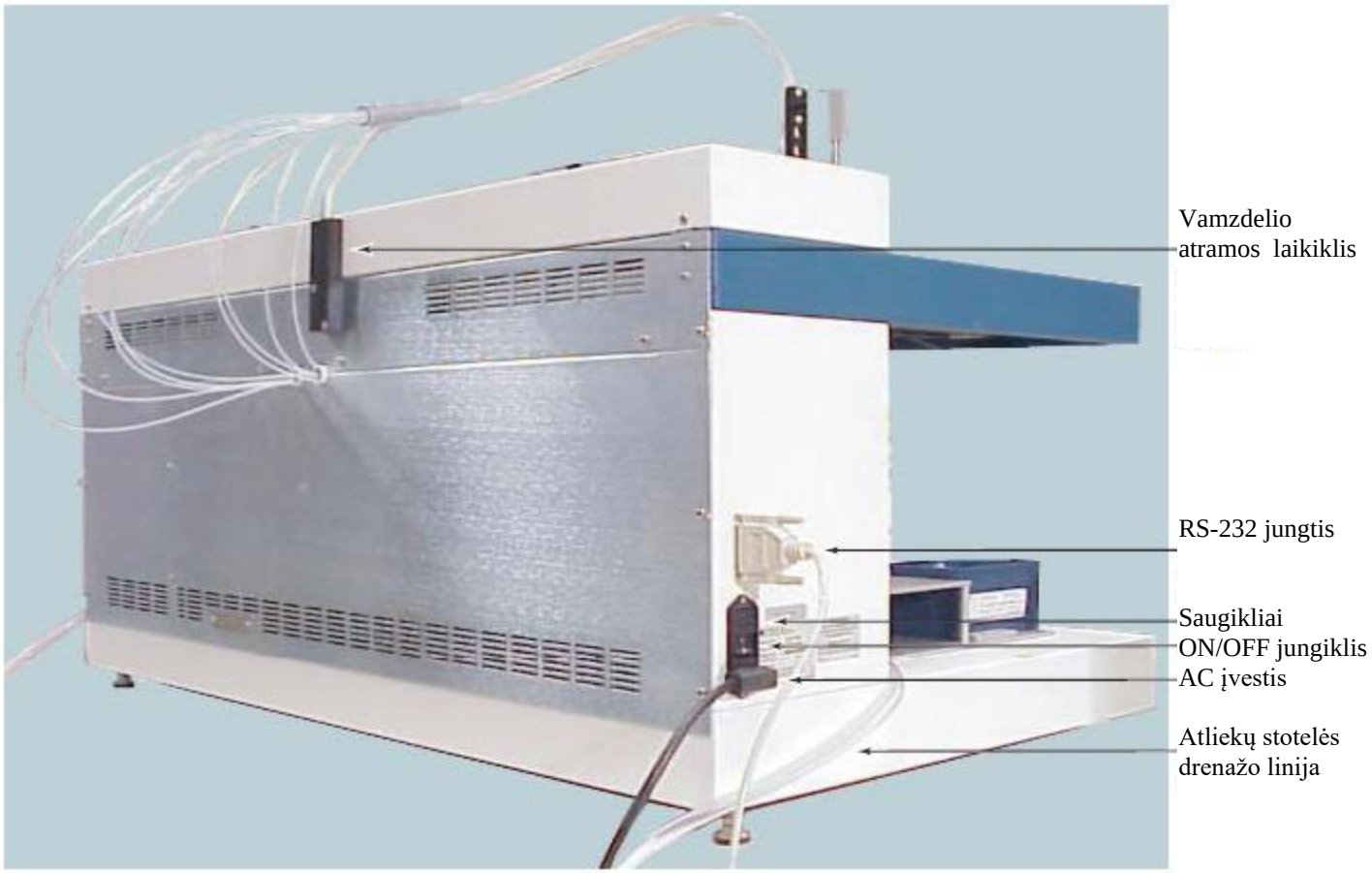
- Lašinimo pipete instrumentas yra robotizuotas prietaisas, kuris veikia valdomas kompiuterio. Kaip ir su dauguma robotizuotų prietaisų, veikiant instrumentui egzistuoja sužeidimo ir kūno sužalojimo rizika dėl judančių mechaninių komponentų. Instrumentas sukurtas tik automatiniam veikimui be vartotojo įsikišimo. Niekada nesiekite instrumento darbinės erdvės, kai instrumentas veikia. Siekiant išvengti netyčinio kontakto su bet kokiomis judančiomis dalimis, prietaisas aprūpintas apsauginiu įtaisu.
- Sutrenkdami robotizuotą prietaisą (keturkampę atšaką arba DiTi montažą) galite sugadinti instrumentą.
- Jeigu reikia nutraukti prietaiso veikimą, ekrane ieškokite komandos „User Break“ (<F-10> mygtukas kompiuterio klaviatūroje). Sistema sustos tada, kai pabaigs esamą komandą, ir ekrane pasirodys opcijų meniu.

Perspėjimas
Ši įranga generuoja, naudoja ir gali spinduliuoti radijo dažnio energiją ir, jeigu įdiegta ir naudojama ne pagal instrukcijas, esančias šiame vartotojo vadove, gali sukelti trikdžius radijo komunikacinei įrangai.

Toliau pateikiami pagrindiniai BD PrepStain™ instrumento komponentai:

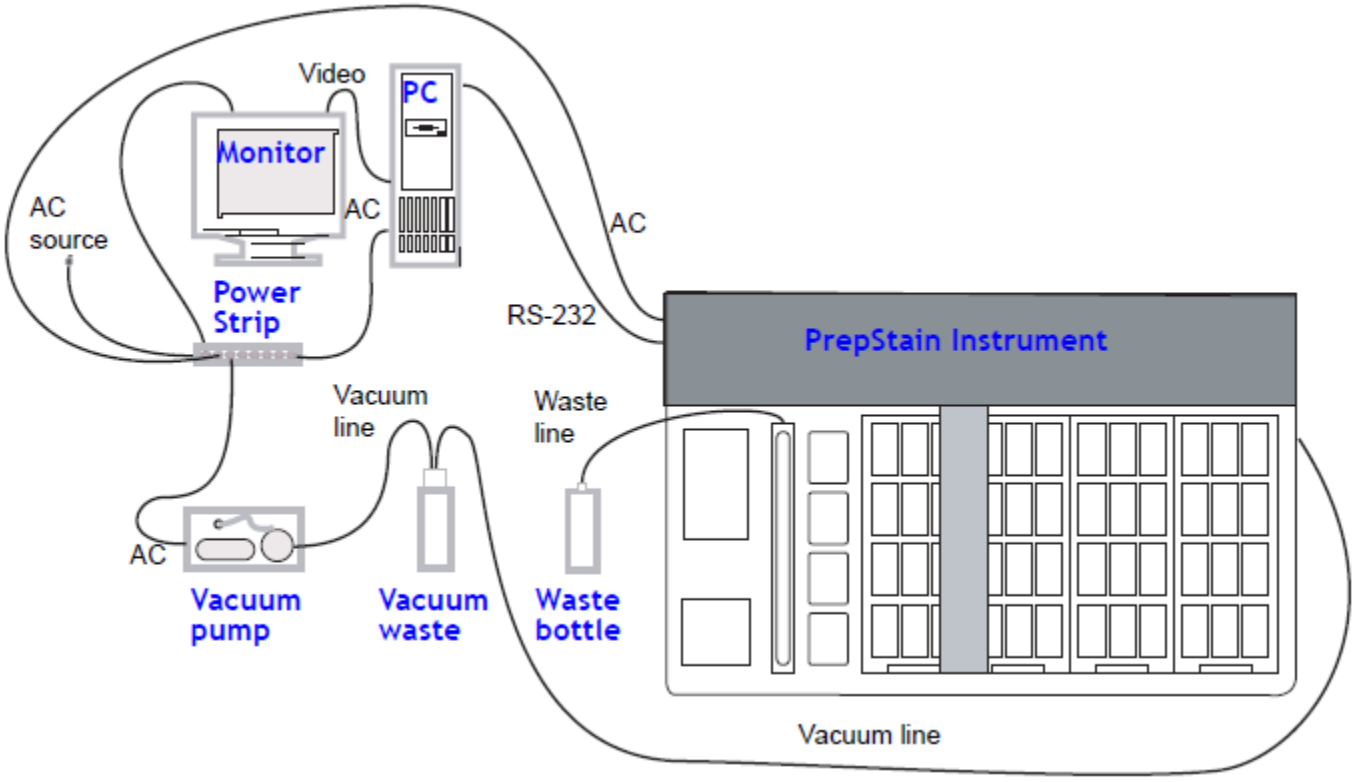
- Robotizuotas procesorius,
- Atliekų stotelė,
- Keturkampė atšaka,
- Vienkartinių antgalių (DiTi) montažas,
- Skalavimo ir dažymo švirkštai,
- Stiklelių stovai.

1-11 iliustracija: iliustruoja tipinės PrepStain instrumento galinės panelės išdėstymą. Remkitės šia iliustracija dėl jungčių, jungiklių ar saugiklių vietos nustatymo.



1-11 iliustracija: *PrepStain instrumento galinė panelė*

1-12 iliustracija: iliustruoja įvesčių ir išvesčių į BD PrepStain™ instrumentą, AK darbo vietą ir vaizduoklį, vakuuminį siurblį, vakuuminį atliekų butelių ir atliekų butelį jungčių planą. Remkitės šia iliustracija, kai nustatote, ar visos jungtys yra atliktos tinkamai.



*

*Iliustracijos teksto vertimas: AC source – KS šaltinis, Monitor – vaizduoklis, PC – asmeninis kompiuteris, AC – kintamoji srovė (KS), Power strip – ilgintuvas, Vacuum line – vakuumo linija, Vacuum pump – vakuumo siurblys, Vaccum waste – vakuuminės atliekos, Waste bottle – atliekų butelis, Vacuum line – vakuuminė linija.

1-12 iliustracija: *PrepStain sistemos jungtys*

PrepStain instrumento jungtys

Egzistuoja dvi elektros įvestys: KS galia, ateinanti iš ilgintuvo, ir RS-232 jungtis, suteikianti komunikaciją į AK darbo vietą.

AK darbo vietos jungtys

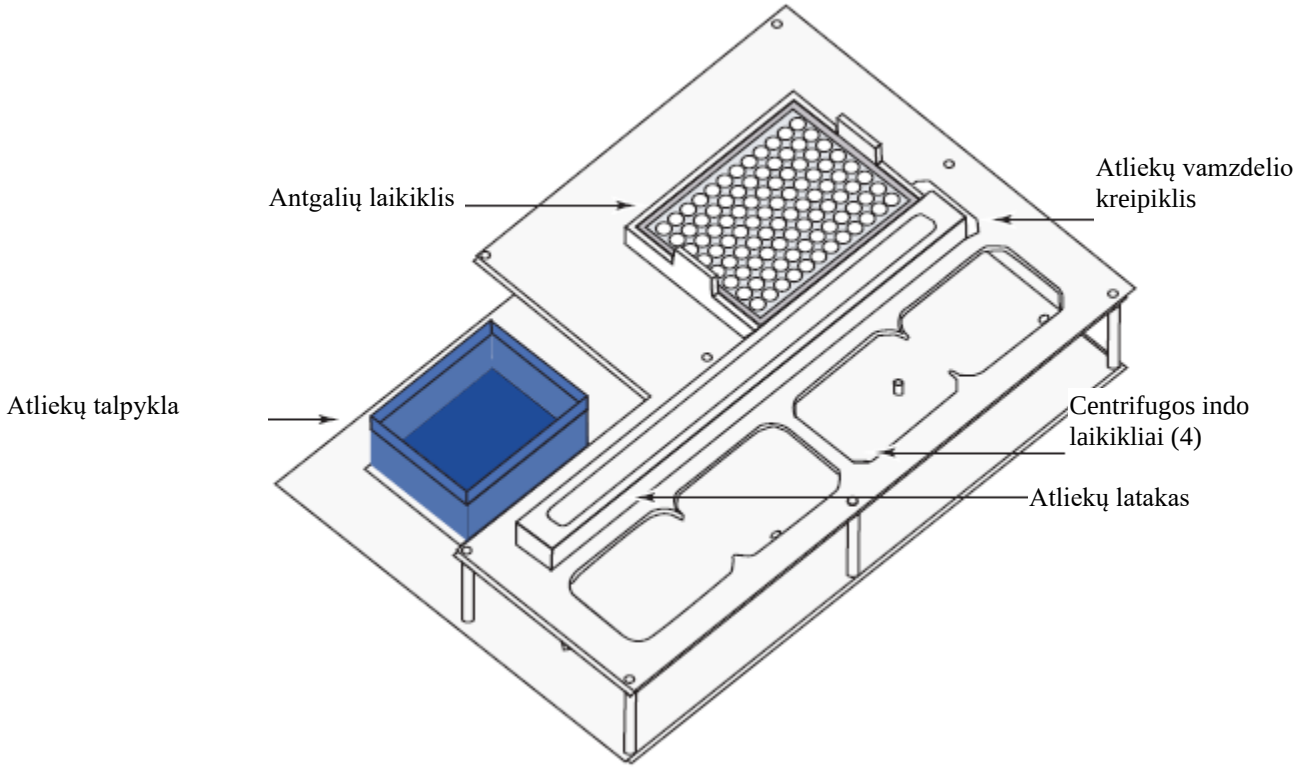
Darbo vieta ir vaizduoklis KS galią gauna iš ilgintuvo. Darbo vieta prisijungia PrepStain instrumentą RS-232 laidu. Vaizduoklis ir darbo vieta susijungia su standartiniu VGA laidu.

Vakuuminio siurblio ir atliekų butelio jungtys

Vakuuminiam siurbliui AC galia tiekiama iš ilgintuvo. Vakuuminė linija prijungia siurblį prie vakuuminio atliekų butelio. Kita linija iš vakuuminio atliekų butelio prijungiama prie vakuumo montažo galinėje PrepStain instrumento dalyje (žr. *1-11 iliustraciją*). Atliekų butelis prijungiamas prie atliekų per atliekų linijos vamzdelį.

1-13 iliustracija: iliustruoja pagrindinius atliekų stotelės elementus. Šis komponentas uždedamas ant stiklelių paruošimo sistemos, kaip parodyta *1-10 iliustracijoje*.

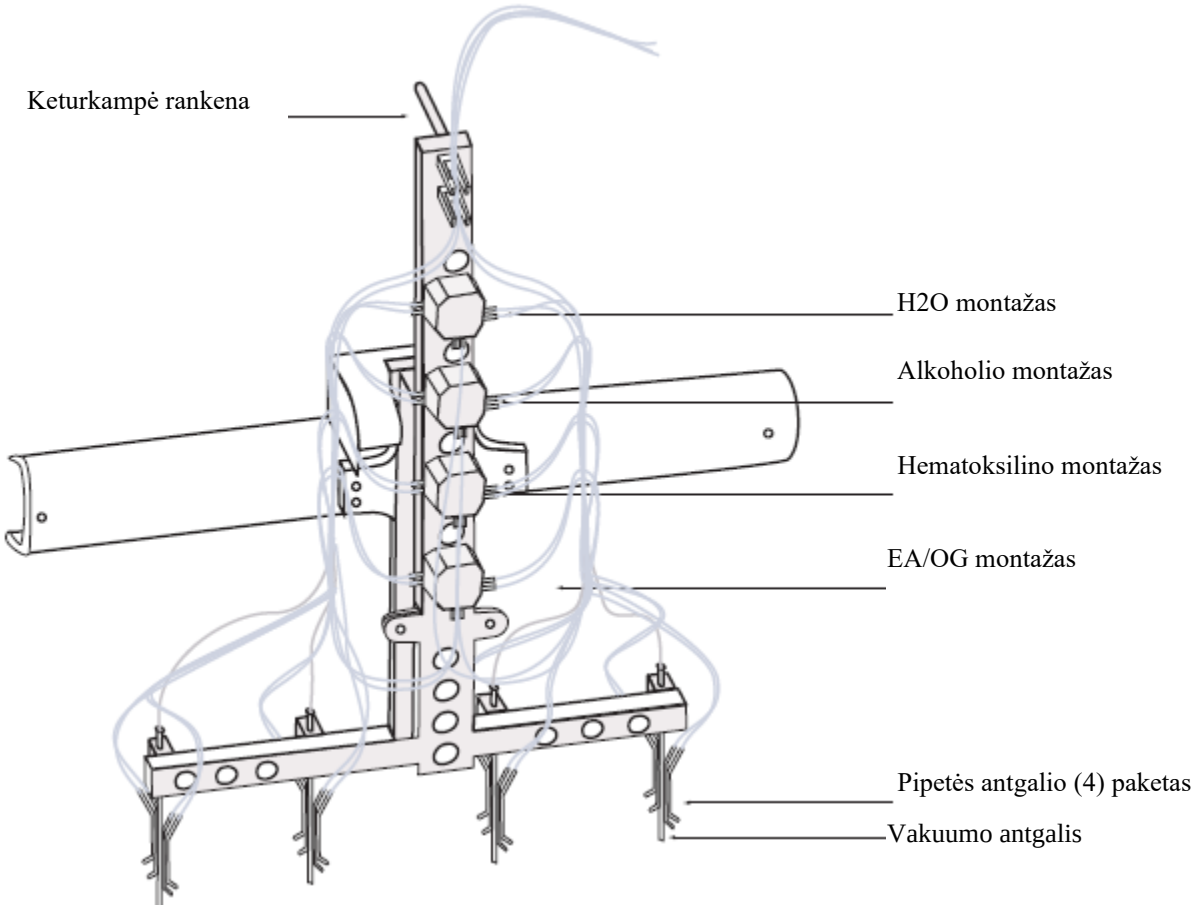
- Atliekų talpykloje sudedami išmetami antgaliai.
- Antgalių laikiklyje laikomi nepanaudoti antgaliai tokioje pozicijoje, kad DiTi atšaka galėtų juos paimti.
- Keturi centrifugos indų laikikliai pozicionuoja BD centrifugos mėgintuvėlius, kad ląstelių mėginių gumulėliai būtų perkelti į BD nusėdimo kameras.
- Atliekų latakas naudojamas perteklinio tirpalo, kuris užpildomas per DiTi surinkimą ir reagento pipetės paketą, pašalinimui.
- Atliekų vamzdelis ištuština atliekų lataką.



1-13 iliustracija: *atliekų stotelė*

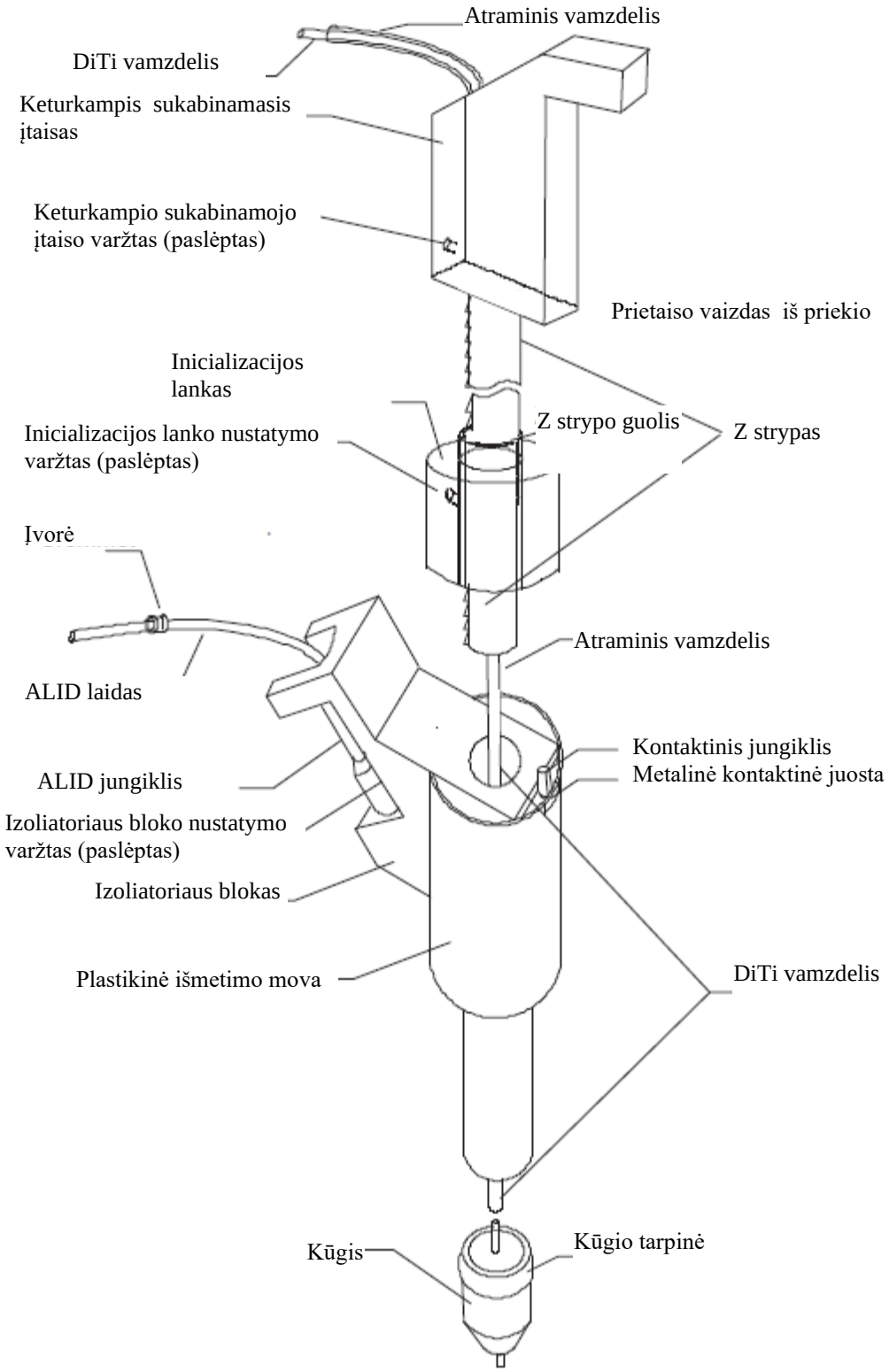
1-14 iliustracija: iliustruoja keturkampės atšakos surinkimą. Šis surinkimas sumontuojamas ant ašies po dengiamąja plokšte.
Atšaka yra pozicionuojama statmenai darbinei platformai ir sulygiuojama su stiklelių stovais paraleliai Y ašiai. Atšakos judėjimas yra paralelus X ašiai.

Pastaba: Keturi montažai atitinka keturis naudojamus reagentus, o ne keturis pipetės antgalių ir aspiratorių antgalių rinkinių paketus. Vamzdelis iš kiekvieno montažo yra pravedamas į kiekvieną paketą.



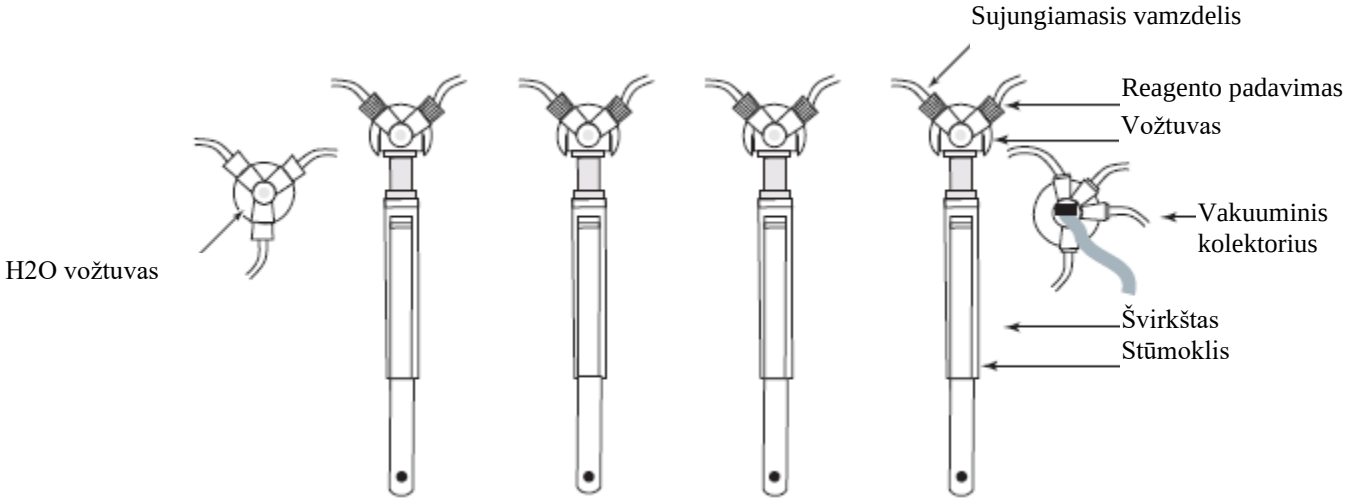
1-14 iliustracija: *keturkampė atšaka su pipetės paketais, dažymo ir vakuumo linijomis*

1-15 iliustracija: iliustruoja esminius komponentus, kurie sudaro vienkartinių antgalių (DiTi) surinkimą.



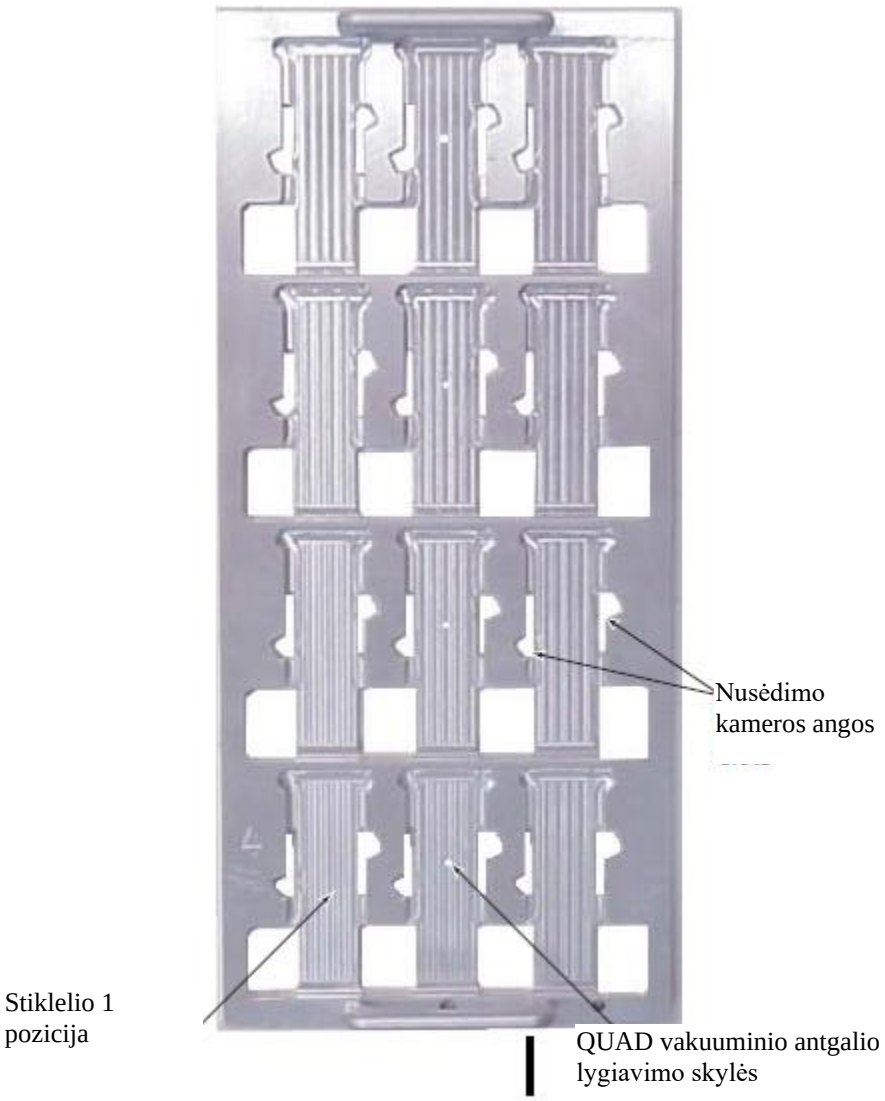
1-15 iliustracija: *vienkartinių antgalių (DiTi) surinkimo detali informacija*

1-16 iliustracija: iliustruoja 5 ml švirkštus, kurie naudojami skalavimo ir dažymo skysčių pumpavimui į keturkampės atšakos pipetės paketus.



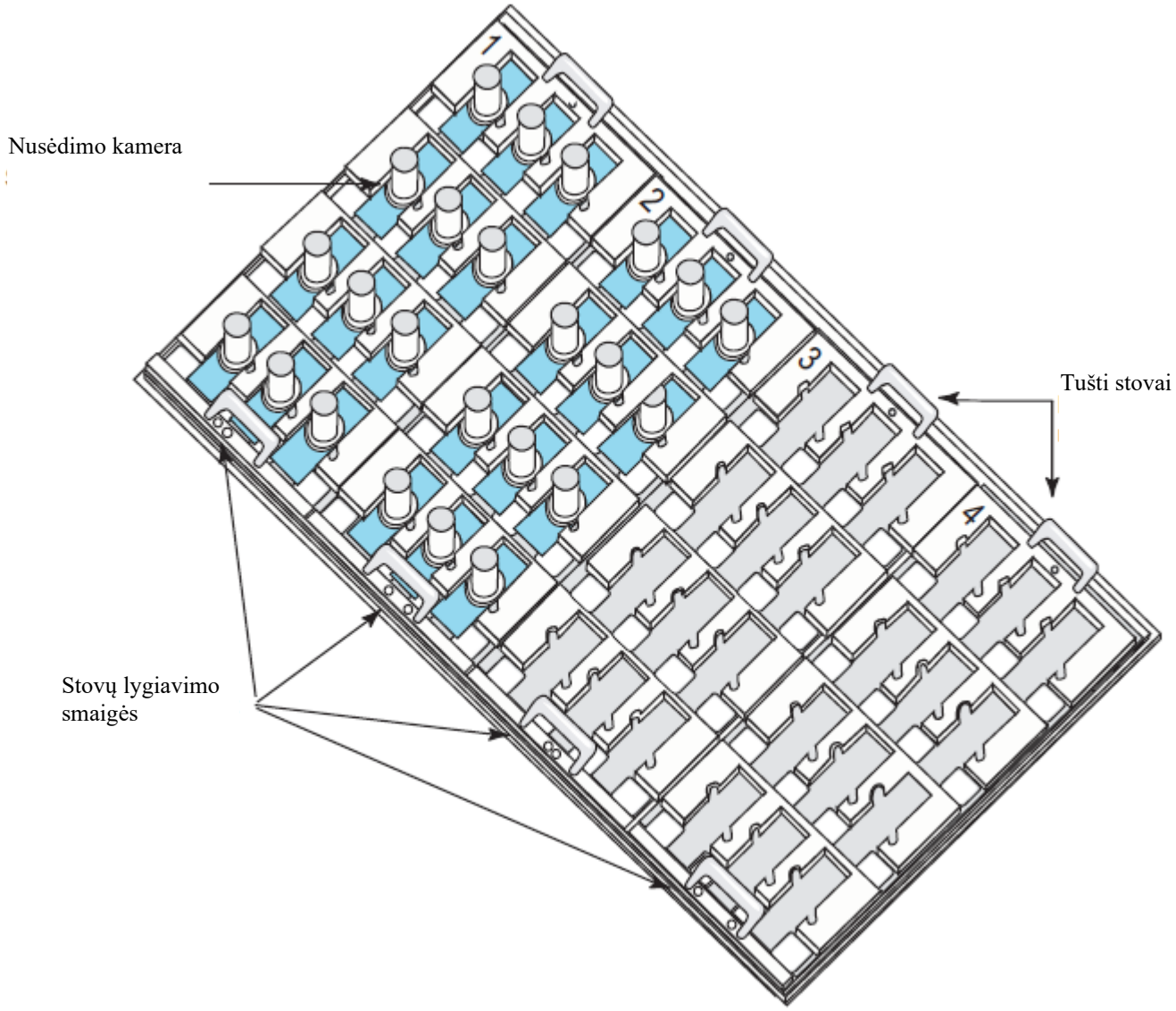
1-16 iliustracija: *skalavimo ir dažymo švirkštai*

1-17 iliustracija: iliustruoja vieną iš keturių stiklelių stovų. BD nusėdimo kameros įstatomos į angas, o tada fiksuojamos pasukant pagal laikrodžio rodyklę. Kiekviena kamera turi nusėdimo kameros tarpiklį. Šis tarpiklis apdorojimo metu neleidžia ląstelių tirpalo skysčiui prasiskverbti iš nusėdimo kameros.



1-17 iliustracija: *stiklelių stovas su nusėdimo kameros angomis*

Stiklelio stovai sudedami ant darbinės platformos, kaip pateikta *1-18 iliustracijoje*. Darbinė platforma sumontuota dešinėje atliekų stotelės pusėje.



1-18 iliustracija: *PrepStain stiklelių stovai*

2 skyrius
Sistemos specifikacijos

BD PrepStain™ stiklelių apdorojimo sistemos komponentai

Kelių buteliukų maišyklė (opcija)

Kelių buteliukų maišyklės, kurią gausite, modelis priklauso nuo Jūsų vietos įtampos reikalavimų. Žemiau pateikiamos abiejų modelių specifikacijos:

	490406	**490125**
Įtampa	Nuo 100 iki 120 Voltų	Nuo 220 iki 240 voltų
Dažnis	Nuo 50 iki 60 Hz	Nuo 50 iki 60 Hz
Galia	100 Vatų	100 Vatų
Saugiklis	5 amperų spartus veikimas (F) 5mmx20mm	1 ampero spartus veikimas (F) 5mmx20mm

Sandėliavimas ne darbo sąlygomis

Aplinkos temperatūra:	Nuo -20 iki 65 ^{0}C, nuo -4 iki 149 ^{0}F
Aplinkos drėgmė:	Nuo 20 iki 80 % RH, be kondensacijos

Darbo sąlygos

Naudoti tik uždarose patalpose

Aplinkos temperatūra:	Nuo 18 iki 33 ^{0}C, nuo 64 iki 91 ^{0}F
Aplinkos drėgmė:	Nuo 20 iki 80 % RH, be kondensacijos
Aukštis virš jūros lygio:	Nuo 0 iki 6,562 pėdų (2000m) virš jūros lygio

2 įdiegimo kategorija ir 2 taršos laipsnis pagal IEC 664.
Bendras svoris: 36 svarai, 16.3 kg
Plotis: 15 colių
Gylis: 12 colių

Vieno buteliuko maišyklė

Reikalinga, tačiau netiekiama, vieno buteliuko maišyklė, kurios našumas 3000 RPM.
100 iki 12 voltų, 50 iki 60 Hz, 40 vatų.

PrepMate specifikacijos

		PrepMate 490410, 490104	**PrepMate 491103**
Darbinės sąlygos	Nominali įtampa	115 arba 230 V~	100-240 V~
	Dažnis	50/60 Hz	50/60 Hz
	Nominali srovė	2 Amps	2.5 Amps
	Nominali galia	140 VA	150 VA
	Aplinkos temperatūra	0-36^{0}C (32-97^{0}F)	0-36^{0}C (32-97^{0}F)
Bendros sąlygos	Svoris	80 svarų, 36.3 kg	80 svarų, 36.3 kg
	Aukštis	21 colis	21 colis
	Plotis	12 ½ colis	12 ½ colis
	Gylis	23 coliai	23 coliai

Saugikliai	**PrepMate 490410, 490104** • Visi saugikliai yra 5x20mm ir 250 V. Produkto pavadinimo plokštelė yra ant galinio skydelio su galios įvadu ir pateikia informaciją apie saugiklius. Keičiamieji saugikliai privalo turėti tokias pat savybes bei (F) tipą. F tipas nurodo greito veikimo saugiklį. • PrepMate turi 2 saugiklius, įrengtus galios įvesties modulyje. Jie veikia kaip pagrindinės elektros energijos saugikliai. • Pagrindinis AC saugiklis yra 2 Amp: • 115 V~ PrepMate modeliui naudokite CSA 2 amp saugiklį galios įvesties modulyje. • 230 V~ PrepMate modeliui naudokite IEC 60127 standarto saugiklį galios įvesties modulyje.	**PrepMate 491103** • Visi saugikliai yra 5x20mm ir 3.15 A prie 250 V~ laiko atidėjimo ir IEC 60127 savybėmis. Produkto pavadinimo plokštelė yra ant galinio skydelio su galios įvadu ir pateikia informaciją apie saugiklius. Keičiamieji saugikliai privalo turėti tokias pat savybes bei (T) tipą. T tipas nurodo atidėto veikimo saugiklį. • PrepMate turi 2 saugiklius, įrengtus galios įvesties modulyje.

Centrifuga

Centrifugos specifikacijos gali skirtis priklausomai nuo modelio, pristatyto su Jūsų sistema. Žemiau pateikiamos tipinės vertės:

Įtampa:	120 voltų
Galia:	400 vatų
Aukštis:	17 colių
Užimama vieta:	38 coliai (pilnai atidarius)
Plotis:	24 coliai

BD PrepStain™ instrumento specifikacijos

Svoris:	147 svarai (67 kg)
Aukštis:	34 coliai (86 cm)
Plotis:	40 colių (102 cm)
Užimama vieta:	44 coliai (112 cm)
Gylis:	25 coliai (64 cm)
Atliekos:	408 ml/48 mėginiai – perkėlimas ir dažymas

Darbinės sąlygos

Temperatūra:	15 iki 40 ^{0}C, nuo 59 iki 104 ^{0}F
Santykinė drėgmė:	30-85 proc. prie 40^{0}C arba žemiau nekondensuojanti
Aukštis virš jūros lygio:	iki 4000 m (13,000 pėdų)

Sandėliavimo sąlygos

Temperatūra:	0 iki 50 ^{0}C, nuo 32 iki 122 ^{0}F
Santykinė drėgmė:	30-85 proc. prie 40^{0}C arba žemiau nekondensuojanti
Aukštis virš jūros lygio:	iki 10,000 m (32,000 pėdų)

Galios reikalavimai

Įtampa:	100-240 VAC
Dažnis:	50/60 Hz

Kompiuteris

AK 386 arba naujesnis, arba bet kuris, kuris visiškai suderinamas
Mažiausiai 4 MB RAM
RS 232
Kietasis diskas su mažiausiai 10 MB laisvos vietos
3.5 colių diskelis
VGA (640x480) arba SVGA ekrano adapteris arba vaizduoklis
MS DOS 6.0 arba naujesnis
Įtampa: 120V/50-60 Hz
Galia: 350 W

Vaizduoklis

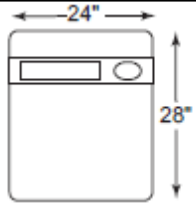
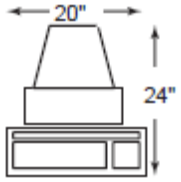
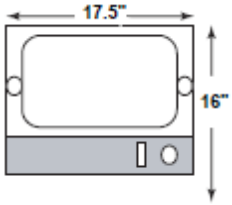
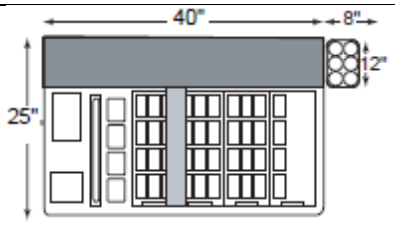
Įtampa: 100-240V~/6A 50-60 Hz
Galia: 25 vatai
Apytikslis aukštis: 24 coliai

Perspėjimas

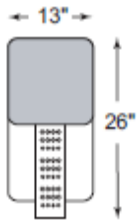
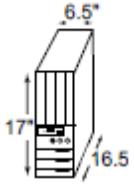
- Lašinimo pipete instrumentas yra robotizuotas prietaisas, kuris veikia valdomas kompiuterio. Kaip ir su dauguma robotizuotų prietaisų, veikiant instrumentui egzistuoja sužeidimo ir kūno sužalojimo rizika dėl judančių mechaninių komponentų. Instrumentas sukurtas tik automatiniam veikimui be vartotojo įsikišimo. Niekada nesiekite instrumento darbinės erdvės, kai instrumentas veikia. Siekiant išvengti netyčinio kontakto su bet kokiomis judančiomis dalimis, prietaisas aprūpintas apsauginiu įtaisu.
- Sutrenkdami robotizuotą prietaisą (keturkampę atšaką arba DiTi montažą) galite sugadinti instrumentą.
- Jeigu reikia nutraukti prietaiso veikimą, ekrane ieškokite komandos „User Break“ (<F-10> mygtukas kompiuterio klaviatūroje). Sistema sustos tada, kai pabaigs esamą komandą, ir ekrane pasirodys opcijų meniu.

PREP sistemos komponentų schema

Toliau esanti lentelė apibūdina fizinį BD PrepStain™ sistemos planą. Kiekvieno komponento išdėstymas šalia kitų priklauso nuo Jūsų turimos erdvės ir darbo eigos.

Komponento pavadinimas	Komponento iliustracija	Užimama vieta
Centrifuga		Užimama vieta virš prietaiso: 38 coliai dangčiui pilnai atsidaryti. Tačiau dangčio stabilizatoriai leidžia tik dalinį atidarymą siaurose vietose.
Vaizduoklis ir klaviatūra		Užimama vieta virš prietaiso: 24 coliai. Nors vaizduoklis ir klaviatūra neturi būti ant stalo, jie turi būti šalia instrumento (modelis gali skirtis).
Kelių buteliukų maišyklė		**Pastaba:** siekiant sumažinti vibracijos poveikį, automatizuotus komponentus naudokite ant tokio stalo, kuris yra atskirtas nuo kitų, ant kurių padėtas PrepStain instrumentas.
PrepStain instrumentas ir dažymo stovas		Užimama vieta galinėje dalyje: 4 coliai. Užimama vieta virš prietaiso: 34 coliai. **Pastaba:** siekiant sumažinti vibracijos poveikį, automatizuotus komponentus naudokite ant tokio stalo, kuris yra atskirtas nuo kitų, ant kurių padėtas PrepStain instrumentas.

2-1 lentelė. PrepStain stiklelių paruošimo sistemos užimama vieta ant stalo

Komponento pavadinimas	Komponento iliustracija	Užimama vieta
PrepMate		**Pastaba:** siekiant sumažinti vibracijos poveikį, automatizuotus komponentus naudokite ant tokio stalo, kuris yra atskirtas nuo kitų, ant kurių padėtas PrepStain instrumentas.
Darbo vietos AK		Nors kompiuteris gali būti ir nededamas ant stalo, jis turi būti įrengtas šalia instrumento.

2-1 lentelė. PrepStain stiklelių paruošimo sistemos užimama vieta ant stalo (tęsinys)

Nors žemiau pateiktiems komponentams nėra vietos specifikacijų, įsitikinkite, kad prietaisas sumontuojamas gerai ventiliuojamoje vietoje ir virš jo arba žemiau jo yra pakankamai erdvės orui cirkuliuoti.

Komponentas	Ilgis x gylis
PrepStain instrumento vakuuminis siurblys	12 x 18 colių
PrepStain instrumento atliekų butelis	7 x 10 colių

2-2 lentelė. BD PrepStain™ stiklelių paruošimo sistemos plotas ant grindų arba po stalu

Taip pat, laisva vieta už prietaiso galinės dalies svarbi galios laidams, vakuuminiams siurbliams ir CPU oro paėmimo angoms.

Įspėjimas
Nesandėliuokite uždarose, ne ventiliuojamose vietose, nes vakuuminiai siurbliai išmeta alkoholio garus, kurie gali sukurti lengvai užsidegančią atmosferą, jeigu siurbliai veikia uždaroje vietoje, pvz. spinta.

Reikalingos medžiagos (įsigyjamos iš BD)

- BD PrepStain™ stiklelių paruošimo sistema ir priedai.
- BD SurePath surinkimo buteliukai (su BD SurePath™ konservanto skysčiu).
- Gimdos kaklelio mėginio paėmimo prietaisas (-ai) su nuimamomis galvutėmis.
- BD tankio reagentas.
- BD švirkščiančios pipetės.
- BD nusėdimo kameros.
- BD citologinis dažymo rinkinys.
- BD SurePath PreCoat stikleliai.
- BD PrepStain perkėlimo antgaliai.
- BD centrifugos mėgintuvėliai.
- BD PrepMate automatizuotas priedas.
- BD aspiratoriaus antgaliai.
- Centrifuga ir priedai.

Reikalingos, tačiau netiekiamos medžiagos

- Easy Aspirator rinkinys.
- Sūkurinė maišyklė.
- Dejonizuotas vanduo.
- BD alkoholio mišinys skalavimui arba izopropanolis ir reagento klasės alkoholis.
- BD SurePath konservantų skystis.
- Išvalymo medžiaga, montavimo terpė ir stiklinė dengiamoji plokštelė.
- Tris buferizuoto druskos tirpalo paketas.
- Contrad 70, Decon 90 arba baliklis.

Medžiagos (opcija)

- Kelių buteliukų maišyklė.
- 4 mL tankio reagento išdavimo įtaisas.

Įdiegimas

BD PrepStain™ stiklelių paruošimo sistemos įdiegimą turi atlikti tik BD įgaliotas asmuo. Serviso atstovas bendradarbiaus su naudotojais ir suteiks tinkamo sistemos įdiegimo patvirtinimo dokumentaciją.

3 skyrius
Veikimo principai

Šis skyrius apibūdina BD PrepStain™ sistemos procesus ruošiant BD SurePath stiklelius. Čia taip pat aprašomas užduočių ir veikimo principų, naudojamų kiekvieno komponento procese, eiliškumas.

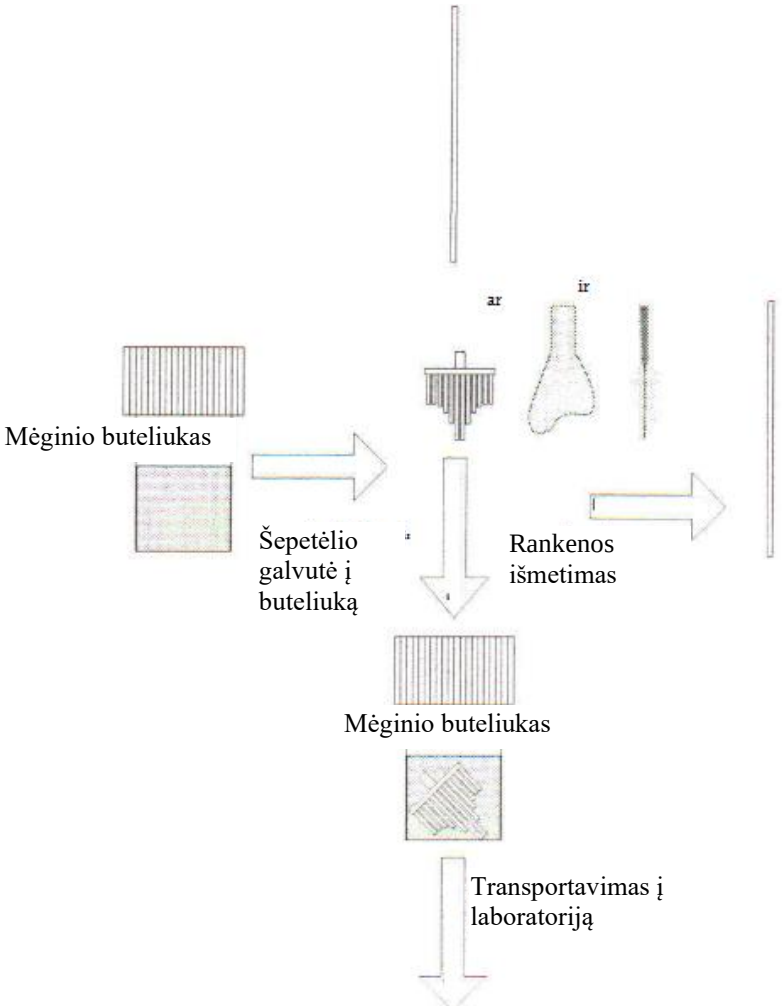
Bendra proceso informacija

PrepStain sistema paremta pusiau automatizuota procedūra, skirta paruošti skysčio pagrindo gimdos kaklelio ląstelių mėginius.
BD SurePath stiklelių ruošimo procese yra trys pagrindinės fazės. Pastarosios nurodomos toliau:

- Mėginio paėmimas,
- Ląstelių praturtinimas,
- Stiklelio paruošimas ir dažymas.

Mėginių surinkimas

Naudodami paėmimo prietaisą, surinkite mėginį gydytojo kabinete. Prietaiso galvutė su gimdos kaklelio mėginiu yra padedama į BD SurePath konservanto skysčio buteliuką ir siunčiama į laboratoriją.



3-1 iliustracija: *Mėginio surinkimo prietaisas ir surinkimo buteliukas*

Surinkimo buteliukas ir prietaisai

BD SurePath surinkimo buteliukas turi buferizuoto 24% etanolio tirpalą, kuris panašus į kitus citologinius konservantų skysčius. Konservantų skystis fiksuoja diagnostines ląsteles ir yra baktericidinis gram neigiamoms žarnyno, gram teigiamos kokų bakterijoms ir grybams.

Nuimamos paėmimo prietaisų galvutės
Šepetėlio tipo prietaisas ir šepetėlio/plastikinės mentelės kombinacija yra du rekomenduojami mėginio paėmimo prietaisai, su kuriais reikia paimti gimdos kaklelio mėginius BD SurePath PAP testui. Šie prietaisai pateikit *3-2 iliustracijoje*.

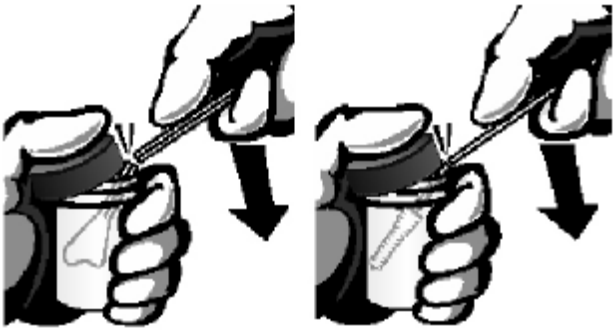
3-2 iliustracija: *Nuimamos paėmimo prietaiso galvutės*

Šepetėlio tipo prietaisas
Šepetėlio tipo prietaisas (pvz. Rovers® Cervex-Brush, Rovers Medical Devices B.V., Oss – Nyderlandai) yra vienas iš dviejų rekomenduojamų gimdos kaklelio mėginio paėmimo prietaisų BD SurePath sistemai. Centriniai prietaiso šereliai įterpiami pakankamai giliai į gimdos kaklelį, kad būtų paimtos ląstelės iš antmakštinės gimdos kaklelio dalies. Šoniniai šereliai paima ląsteles nuo gimdos kaklelio makšties dalies ir transformacijos zonos.

Šepetėlio/plastikinės mentelės kombinacijos tipo prietaisas
Pap Perfect® (CooperSurgical Inc., Trumbull, CT) mentelė ir Cytobrush® Plus GT prietaisai kombinuojami, kad sudarytų kitą rekomenduojamą mėginio paėmimo metodą gimdos kaklelio mėginių surinkimui BD SurePath PAP testui.
Pirmiausia, kontūrinis plastikinės mentelės galas yra įterpiamas į gimdos kaklelį ir tada pasukamas 360^0 apie visą eksocervikalinę dalį. Toliau šepetėlis yra įterpiamas į endocervikalinę dalį. Lėtai pasukite ¼ iki ½ sūkio viena kryptimi.

3-3 iliustracija: *BD SurePath surinkimo buteliukas ir paėmimo prietaisai*

Kai mėginys yra paimtas, paciento mėginys patalpinamas į konservanto skysčio buteliuką. Prietaiso rankena nuimama, surinkimo buteliuke paliekant tik prietaiso galvutę. Buteliukas sandariai uždaromas ir transportuojamas į klinikinę laboratoriją tyrimams atlikti.



3-4 iliustracija: *BD SurePath surinkimo buteliukas ir prietaisų kombinacija*

Numeskite arba nulaužkite prietaiso galvutę nuo rankenos ir įmeskite nuimamą prietaiso galvutę į BD SurePath buteliuką. Šių galvučių nuėmimui patvirtinti keli metodai. Metodas su dangtelio pagalba pavaizduotas iliustracijoje. Instrukcijos pateikiamos produkto įdėtiniame lape.

Mėginio tvarkymas ir ląstelių praturtinimas

Šios BD SurePath stiklelių paruošimo proceso fazės metu gimdos kaklelio makšties mėginiai yra maišomi ir klinikinė mėginio sudėtis yra praturtinama. Procese mėginys paruošiamas serija rankinių žingsnių, kuriuos sudaro sūkuriavimas mėginiui sumaišyti ir išskaidyti, maišymas, sluoksniavimas ant BD tankio reagento ir centrifugavimas.

Mėginio maišymas

Norint pradėti ląstelių praturtinimo procesą, BD SurePath surinkimo buteliukai sūkuriuojami 15 ± 5 sekundes prie 3000 rpm. Paskirstant maišyklės jėgas ląstelės ir jų grupės atlaisvinamos nuo mėginio surinkimo prietaiso ir dalinai išskaido ląstelių grupes.

Rankinė maišyklė Kelių buteliukų maišyklė

3-5 iliustracija: *mėginio buteliukų paruošimas perkėlimui*

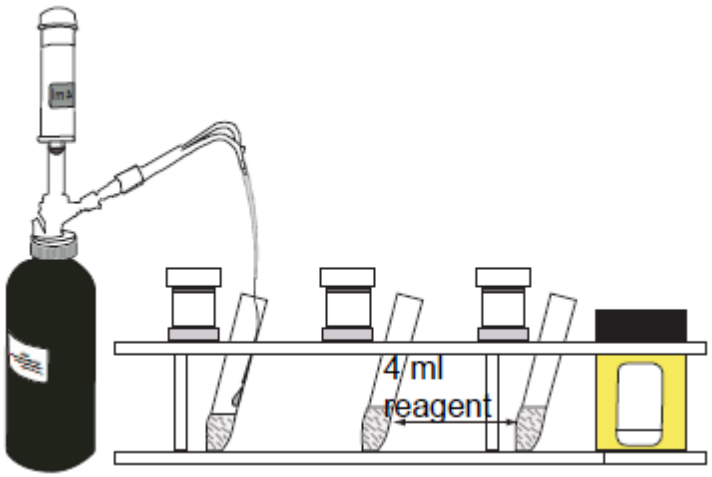
Pastaba: iliustracijose *3-5* ir *3-6* pateikiami kai kurie komponentai, naudojami šių tam tikrų užduočių atlikimui.

Pastaba: mėginio alikvotinės dalys (iki 0.5 mL) gali būti pašalinamos iš buteliuko išoriniams tyrimams prieš BD SurePath PAP testo procesą. Daugiau informacijos rasite prieduose.

BD tankio reagentas

BD tankio reagentas yra polisacharidinis tirpalas su natrio azidu, kaip konservantu. Ląstelių suspensija 2 minutes ± 15 sekundžių centrifuguojama per tankio reagentą esant 200 rcf ± 25. Mažos dalelės ir nuosėdos, kurios yra sulaikomos virš sąsajos tarp paviršiuje plūduriuojančio konservanto skysčio ir tankio reagento, yra pašalinamos, praturtinant klinikines medžiagas mėginyje.

Antrasis 10 ± 1 minutės centrifugavimas prie 800 rcf ± 50 koncentruoja diagnostines ląstelines medžiagas mėgintuvėlio apačioje. Likęs tankio reagentas yra dekantuojamas, BD centrifugos mėgintuvėlyje paliekant tik praturtintą ląstelinės medžiagos gumulėlį, kuris yra sūkuriuojamas ir patalpinamas ant PrepStain instrumento tolimesniam apdorojimui.



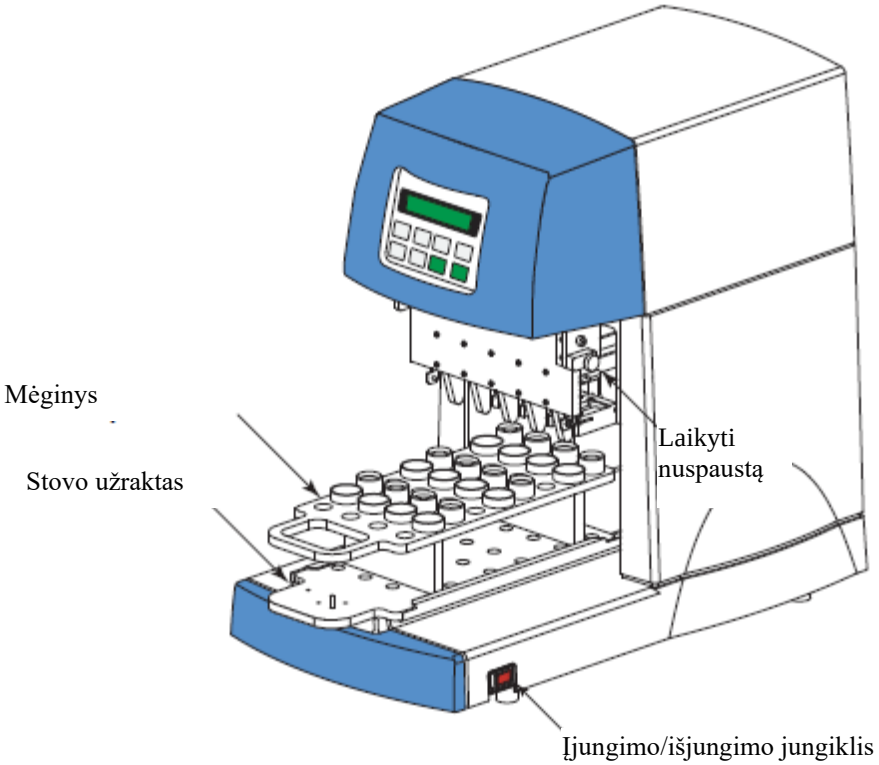
*

*Iliustracijos teksto vertimas: 4 ml reagent – 4 ml reagento.

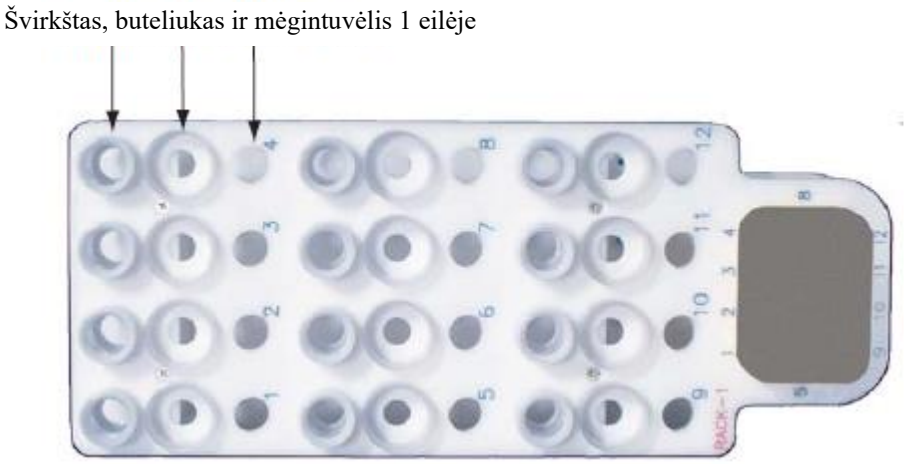
3-6 iliustracija: *centrifugos mėgintuvėlio paruošimas perkėlimui*

Maišymas ir sluoksniavimas

Mėginiai yra maišomi ir tada palaipsniui perkeliami į BD centrifugos mėgintuvėlį, kuriame yra BD tankio reagentas. Šis perkėlimas įvardijamas kaip sluoksniavimas. Ši proceso dalis atliekama automatiškai, naudojant BD Prepmate automatizuotą priedą. Šio metodo santrauka pateikiama žemiau.
PrepMate yra automatizuotas priedas prie PrepStain sistemos. PrepMate automatizuoja pirminį mėginio praturtinimo maišymo ir paskirstymo procesą ant tankio reagento.



3-7 iliustracija: *PrepMate vaizdas iš priekio*



3-8 iliustracija: *PrepMate apdorojimo stovas*

BD PrepMate automatizuotas priedas maišo ir pašalina mėginį iš konservanto buteliuko. Tada prietaisas sluoksniuoja mėginį ant tankio reagento BD centrifugos mėgintuvėlyje. PrepMate automatizuotas procesas per ciklą tvarko nuo vieno iki dvylikos mėginių.

Siekiant sumažinti mėginio užteršimo galimybę, buteliukų dangteliai proceso metu nėra nuimami. PrepMate suteikia unikalų, praduriamo viršaus procesą, kuris maišo ir paskirsto su uždėtais dangteliais. Buteliukai, švirkštai ir mėgintuvėliai yra vienkartinio naudojimo. Siekiant pašalinti mėginio užteršimo galimybę, pastarieji produktai nėra naudojami pakartotinai.

Centrifugavimas

Centrifugavimą sudaro trys etapai:

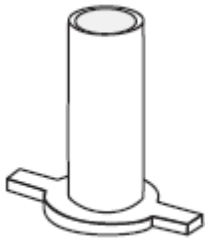
- „Švelnus sukimas“ traukia ląstelių tirpalą per tankio reagenta,
- Easy Aspirator pašalinta supernatantą,
- „smarkus sukimas“ koncentruoja diagnostines ląstelines medžiagas mėgintuvėlio apačioje.

Mėginio apdorojimas BD PrepStain™ sistema

PrepStain sistema atlieka automatizuotą stiklelių paruošimo ir dažymo etapus plono sluoksnio citologinių medžiagų paruošimui ant BD SurePath PreCoat Slide.
BD SurePath PreCoat Slide buvo padengtas didelio molekulinio svorio katijoniniu tirpalu. Gauta teigiama įkrova leidžia neigiamai įkrautų diagnostinių citologinių medžiagų prilipimą ant stiklelio per stiklelio paruošimo procesą.

BD nusėdimo kamera

BD Settling Chamber naudojamas kaip indas sumaišyti ląstelines medžiagas, kol jos sėda ant padengto mikroskopo objektinio stiklelio. Gautas plono sluoksnio ruošinys yra diskretiškai dažomas toje pačioje nusėdimo kameroje.



3-9 iliustracija: *BD nusėdimo kamera*

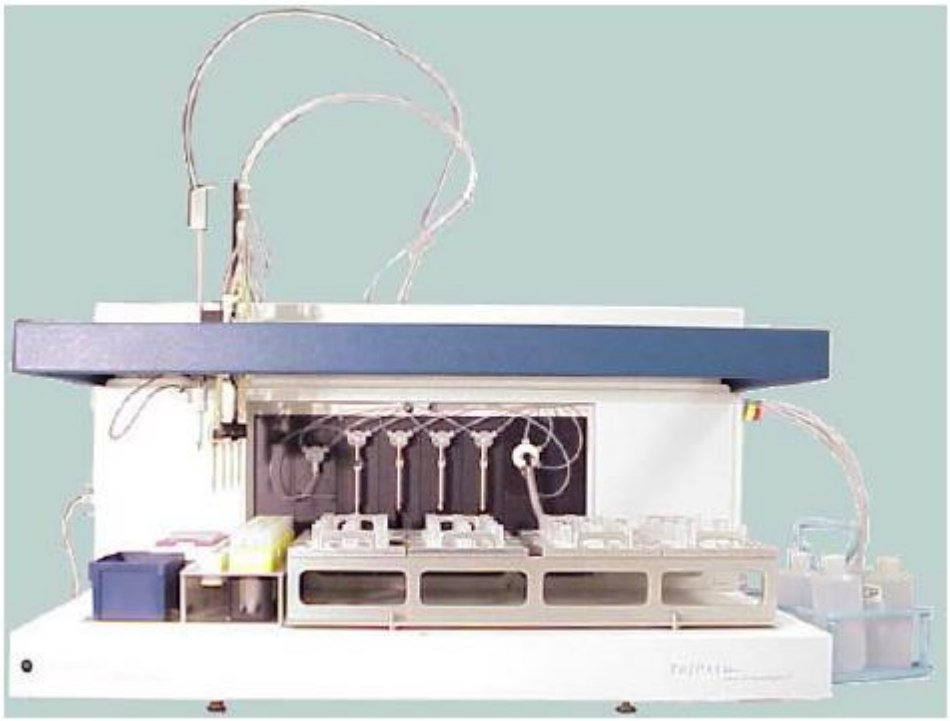
Kompiuterinė darbo vieta

BD PrepStain™ instrumentas yra susietas su DOS paremtu kompiuteriu. Programinė įranga, kuri valdo mėginio apdorojimo įrenginį, yra paleidžiama DOS paklausime įvedant tam tikrą komandą, o tada valdoma naudojant pateiktus meniu.

Pastaba: PrepStain instrumento naudojimo ne GYN procedūroms informacija pateikiama *10 skyriuje **Ne GYN stiklelių apdorojimas***.

PrepStain instrumentas

BD PrepStain™ instrumentas atlieka automatinį mėginio perkėlimą ir dažymą, tada sukuria ploną citologinės medžiagos ruošinį ant padengto mikroskopo objektinio stiklelio.



3-10 iliustracija: *PrepStain instrumentas*

Robotizuotas mėginio apdorojimo prietaisas
Tecan robotizuotas mėginio apdorojimo prietaisas, iliustruotas *3-10 iliustracijoje*, yra pilnai automatizuotas mėginio procesorius. Jis yra pagrindinis PrepStain sistemos prietaisas. PrepStain instrumentas yra mikroprocesoriumi valdoma skysčių tvarkymo komponentų sistema, kuri veikia su sistemos programine įranga, įdiegta kietajame kompiuterio diske. Naudotojas valdo mechaninius komponentus naudodamas kompiuterio klaviatūrą. Specialūs ruošimo metodai, tiekiami BD, naudojami kiekvienam apdorojimui.
PrepStain instrumentas sumaišo ląstelių mėginių gumulėlį buferizuotame dejonizuotame (DI) vandenyje ir perkelia alikvotines ląstelių suspensijos dalis į BD nusėdimo kamerą, kur sumontuoti BD SurePath PreCoat stikleliai. Inkubacijos periodas leidžia ląstelėms nusėsti ant mikroskopo stiklelio paviršiaus, o tada procesorius atlieka eilę plovimo ir dažymo etapų, kad nudažytų stiklelius naudojant Papanicolaou metodą. Eiliškumą, tūrius, kartus ir perkėlimo bei dažymo etapų orientacijas valdo kompiuterinė darbo vieta.

PrepStain instrumento techninė įranga paremta modulio dizaino koncepcija, kurioje kiekviena pagrindinė procesoriaus funkcijos yra atliekamos nepriklausomi instrumento komponentu. Procesorius komponentų principas pateikiamas žemiau:

- Švirkšto siurblys,
- X/Y/Z judėjimo mechanizmas (atšaka),
- Vienkartinių antgalių (DiTi) montažas,
- Keturkampė atšaka,
- Išorinis vandens vožtuvas,
- Atliekų stotelė,
- Stiklelių stovai ir darbinė platforma.

Švirkšto pompa

Švirkšto pompa yra mikroprocesoriumi valdomas švirkštas su pompa ir dviejų krypčių vožtuvu, kuris per vamzdelius yra prijungtas prie keturių vamzdelių ir reagento talpos. Visos dalys, kurios sąveikauja su skysčiu, yra pagamintos iš inertinių medžiagų, tokių kaip stiklas, teflonas, fluoroetilpropileno (FEP). Žingsninis variklis valdo švirkšto stūmoklį. Ir vožtuvas, ir motoras yra valdomi įmontuoto mikroprocesoriaus. BD PrepStain™ prietaisas turi 4 švirkšto siurblius, kurie yra skirti valdyti užprogramuotų reagentų tūrių bei mėginių, esant aukštam tikslumas bei esant skirtingai spartai, išsiurbimui (aspiracijai) bei pašalinimui.

X/Y/Z judėjimo mechanizmas (atšaka)

Robotizuota atšaka juda X (iš kairės į dešinę), Y (pirmyn-atgal) ir Z (aukštyn-žemyn) kryptimis. Turi Z-strypą, kuris juda aukštyn ir žemyn. DiTi (vienkartinis antgalis) yra užmaunamas ant Z-strypo, kuri galima paaukštinti arba pažeminti (Z-kryptis) naudojantis Z žingsniniu motoru. Keturkampė atšaka yra užmaunama ant robotizuotos atšakos ir pritvirtinama prie apsauginės juostelės. Atšaka juda į kairę ir į dešinę (X kryptis) ir yra valdoma X motoro. X, Y ir Z motorai yra aprūpinami energija ir valdomi elektronikos, kuri yra įmontuota prietaiso vidinėje dalyje.

Vienkartinių antgalių (DiTi) montažas

PrepStain instrumentas naudoja vienkartinių antgalių montažą mėginių aspiravimui ir lašinimui pipete. *1-15 iliustracija:* iliustruoja komponentus, kurie sudaro šį montažą.

Instrumentas naudoja naują BD PrepStain perkėlimo antgalį kiekvieno mėginio maišymui, aspiravimui ir perkėlimui. Tai užtikrina, kad perkėlimai yra neužteršti. Antgaliai yra paimami DiTi kūgio, kai jis nuleidžiamas į antgalį pakankama jėga, kad būtų suformuota sandari jungtis apie antgalio kraštinę. Tai fiksuoja antgalį prie kūgio paėmimu ir išstumia kontaktinę spyruoklę. PrepStain instrumentas naudoja šį išstūmimą, kad aptiktų tinkamą antgalio paėmimą. Mėginys tada perkeliamas (iš mėgintuvėlio ant stiklelio), antgalis išmetamas ir naujas antgalis paimamas kitam perkėlimui atlikti.

Keturkampė atšaka
Ši atšaka, pavaizduota *1-14 iliustracijoje:* yra BD švirkščiančių pipečių, vamzdelių ir montažų sistema, kuri sumontuota ant BD PrepStain™ instrumento atšakos. Prietaisas yra savaime atsitraukiantis ir išlieka nuošaliai DiTi procedūrų, kai jis nėra naudojamas. Z strypas ir DiTi montažo keturkampė atšaka sujungia keturkampę rankeną taip, kad atšaka judėtų paraleliai su DiTi, kai ji yra nuleidžiama. Tai nukreipia keturis pipečių rinkinius į keturias BD nusėdimo kameras.
Kiekvienas pipečių rinkinys turi keturis vienkartinius antgalius, ant kurių yra uždėti didesni vakuuminiai antgaliai. Kai jie yra nuleidžiami šiek tiek žemiau nei objektinio stiklelio paviršius, tuomet vakuuminis antgalis ištuština kamerą. Paskirstymo antgaliai gali kameras aprūpinti vienu iš keturių reagentų. Tokiu būdu pritaikant nuimamus ir vakuuminius antgalius, suteikia galimybę atlikti atitinkamas dažymo procedūras keturiems mėginiams.

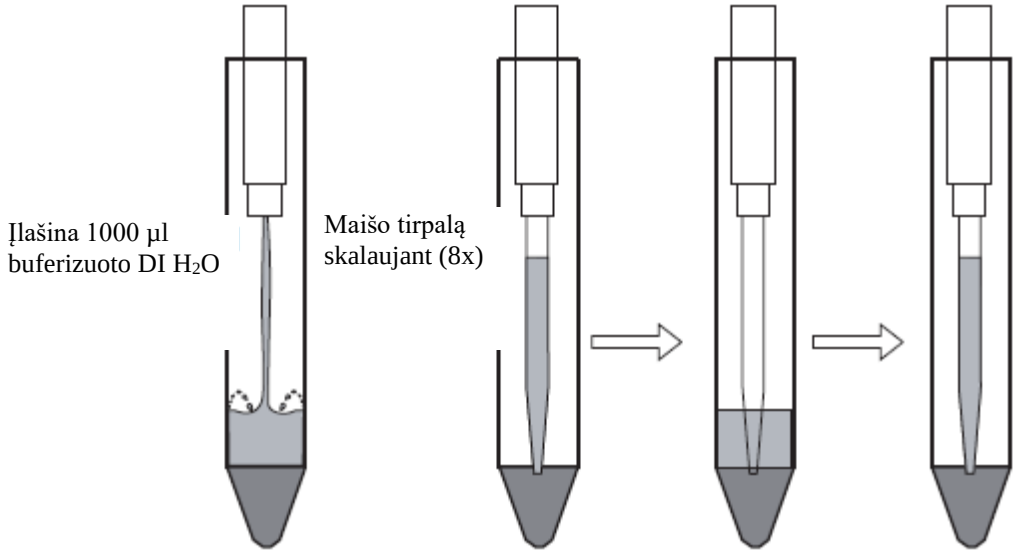
Atliekų stotelė
Atliekų stotelė, kuri yra įrengta kairėje instrumento pusėje, iliustruota *1-13 iliustracijoje*.
Sistemos vamzdelių užpildymo ar valymo metu, skysčiau pertekliai yra išleidžiami į atliekų lataką, kuris išleidžiamas į didesnę atliekų talpyklą saugiam ir lengvam utilizavimui. Po naudojimo BD PrepStain perkėlimo antgaliai taip pat išmetami į atliekų talpyklą.
Atliekų stotelę taip pat sudaro BD PrepStain perkėlimo antgalio laikiklis, kuris pozicionuoja 96 vienkartinius antgalius DiTi kūgio paėmimui. Palei dešinę atliekų stotelės pusę, keturiose angose laikomi centrifugos indeliai. Siekiant išlaikyti gamybos grandinę, indelių laikikliai sunumeruoti nuo 1 iki 4 ir yra unikaliai fiksuoti prie pagrindo, kad kiekvienas centrifugos indelis tiktų tik į vieną pozicija ir viena orientacija.
Pavyzdžiui: mėgintuvėlio indelis numeris 1 tiks tik mėgintuvėlio laikiklio 1 pozicijoje ir turi būti nukreiptas į stotelės priekį.

Stiklelio stovai ir darbinė platforma
Darbinė platforma iliustruota *1-18 iliustracijoje*: laiko stiklelių stovus ir montuojama dešinėje atliekų stotelės pusėje.
Kiekvienas stiklelio stovas turi 4 eiles ir 3 stulpelius stiklinių stiklelių pozicijoms. Darbinė platforma ir stiklelių stovai sunumeruoti nuo 1 iki 4 ir unikaliai fiksuojami, kad kiekvienas stiklelio stovas tiktų tik į atitinkamai pažymėtą poziciją.

Kiekvienas stiklelis sumontuotas ant stovo po nusėdimo kamera ir fiksuojamas pasukant pagal laikrodžio rodyklę. Nusėdimo kameros tarpiklis ir stiklelis suformuoja barjerą, kuris apsaugo nuo pratekėjimo, kai kamera užpildoma skysčiu. Ląstelių nusėdimas ant stiklelio paviršiaus ir toliau atliekamas dažymas vyksta nusėdimo kameroje. Po dažymo, nusėdimo kamera yra pašalinama ir išmetama. Stiklelis yra nuvalomas ir uždengiamas, kad būtų paruoštas tyrimui.

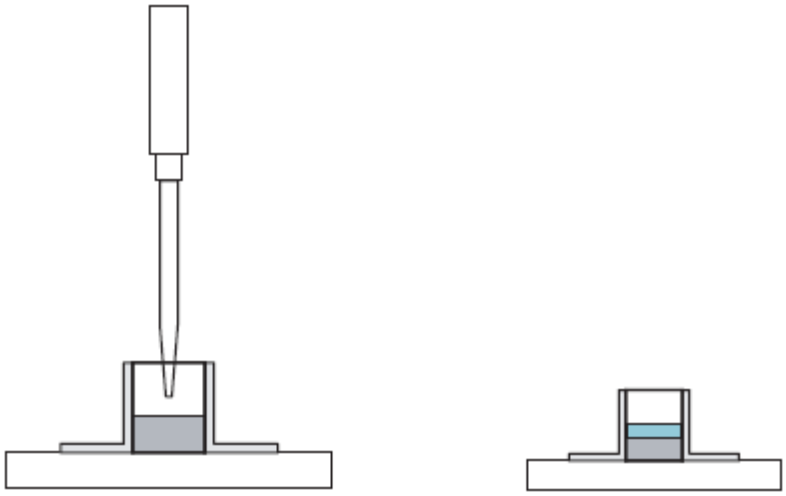
Stiklelio paruošimas ir dažymas

Stiklelio paruošimas, dažymas ir skalavimo procesas atliekami BD PrepStain™ instrumento. Šio proceso žingsniai pateikiami žemiau:



3-11 iliustracija: *Pasiruošimas perkelti ląstelių gumulėlį*

- Pirmiausia instrumentas prideda buferizuoto DI vandens į nusėdimo kamerą per keturkampės atšakos pipetės paketą.
- Toliau, instrumentas įlašina 1000 µl buferizuoto DI vandens į ląstelių gumulėlį per DiTi.
- Tada sistema paima BD PrepStain perkėlimo antgalį ir 8 kartus maišo gautą tirpalą skalaujant jį įtraukimu ir išleidimu vienkartinės pipetės antgalyje.

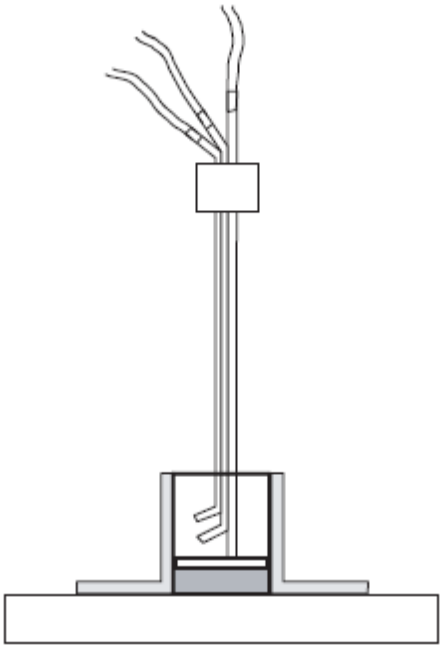


3-12 iliustracija: *mėginio perkėlimas į nusėdimo kamerą*

- Toliau, PrepStain instrumentas aspiruoja 200 µl mėginio iš BD centrifugos mėgintuvėlio ir įlašina 200 µl mėginio į nusėdimo kamerą. Mėgintuvėlis ir likęs mėginys gali būti išmetamas arba išsaugomas papildomiems tyrimams.

  Pastaba: Jeigu mėgintuvėlis su mėginiu išsaugomas, pridėkite 2 ml BD SurePath konservanto skysčio į mėgintuvėlį, kad konservuotumėte ląstelių gumulėlį.

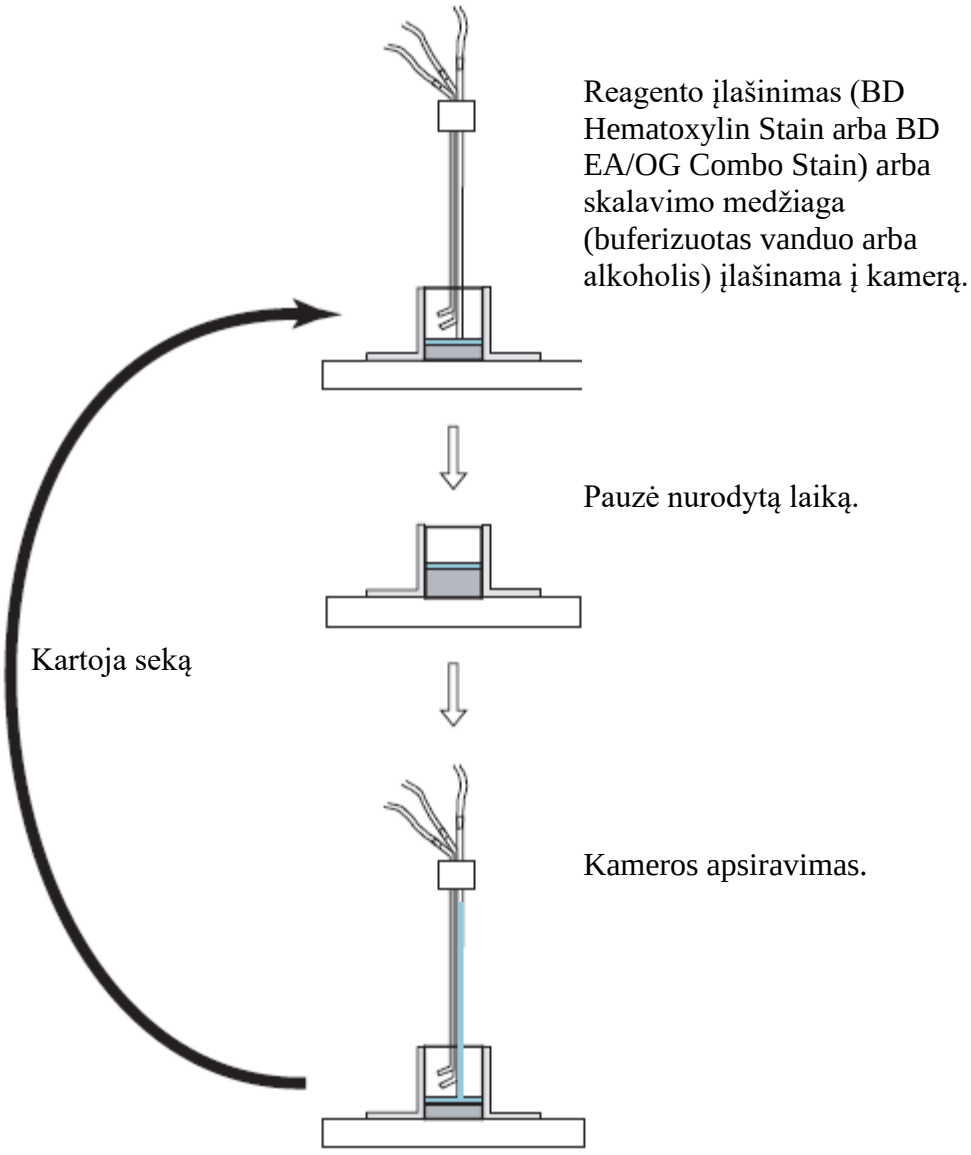
- Mėginiui suteikiama mažiausiai 10 minučių nusėsti ant stiklelio. Šiuo metu ląstelės susiriša su BD SurePath PreCoat stiklelio padengimu ir suformuoja ploną ląstelių sluoksnį.



3-13 iliustracija: *ląstelių mėginio plovimas*

- BD PrepStain™ instrumentas įlašina 600 µl alkoholio ploviklio į mėginį ir ištraukia likusius skysčius.
- Mėginys 60 sekundžių džiūsta.
- Paskutinė automatizuoto proceso dalis yra dažymo ir skalavimo ciklų seka. Dažymo ir skalavimo ciklai iš esmės yra tie patys: viskas, kas skiriasi cikluose, yra naudojami reagentai ir pauzės trukmė.

3-14 iliustracijoje iliustruojama įprasta dažymo ir skalavimo seka.



3-14 iliustracija: *tipinis dažymo arba skalavimo ciklas*

BD SurePath plono sluoksnio ruošinių tyrimas

BD PrepStain™ sistema sukuria tolygų nudažytų ląstelių sluoksnį 13 mm diametro apskritime. Mėginio sluoksnis turi atskiras ląsteles arba mažas ląstelių grupes. Yra labai mažai gleivių bei mažai susipynusių ląstelių didelių grupių.
Visas stiklelio ruošinis tiriamas naudojant 10x objektyvą ir skanuojant per stiklelį serpentino metodu. Rekomenduojame kiekvieną stiklelį tirti du kartus, judant horizontaliai ir judant vertikaliai per ruošinio plotą (kaip nurodyta iliustracijoje).

3-15 iliustracija: *serpentino, dvigubo tyrimo metodas*

Visi diagnostiniai kriterijai esamoje citologinėje laboratorijoje ir naudojami įprastiems PAP tepinėliams, yra taikomi BD SurePath plono sluoksnio ruošiniams. Rezultatų pateikimui laikykitės standartinių laboratorinių procedūrų.

4 skyrius
Išankstinio apdorojimo žingsniai

Šiame skyriuje pateikiamos procedūros, kurios naudojamos gimdos kaklelio makšties mėginių paruošimui apdorojant su BD PrepStain™ instrumentu. Šios procedūros pateikiamos žemiau.

Buferizuoto vandens paruošimas

Reikalingos medžiagos

- Vieno (1) litro tūrinis flakonas.
- Dejonizuotas (DI) arba distiliuotas vanduo.
- Tris buferizuoto druskos tirpalo paketas, pH 8.0.
- Matavimo prietaisas, 200 ml.
- Vienas (1) 4L butelis.

Įspėjimas
Atidžiai perskaitykite šią procedūrą. Sandėlio buferio tirpalas turi būti paruoštas prieš gaminant darbinį tirpalą.

Sandėlio buferio gamybos procedūra

1.Dejonizuotu (DI) arba distiliuotu vandeniu užpildykite 1 litro flakoną maždaug iki pusės.
2.Ištuštinkite 1 pakuotę tris buferizuoto druskos tirpalo paketą, pH 8.0 į flakoną ir sūkuriuokite, kol pilnai ištirps.
3.Užpildykite flakoną iki 1 litro žymės ir užsandarinkite flakoną su parafilmu.
4.Kelis kartus pavartykite flakoną ir įsitikinkite, kad skystis pilnai susimaišęs.
5.Perkelkite sandėlio tirpalą į 1 L butelį, gautą įdiegimo metu.
6.Paženklinkite butelį su paruošimo data ir galiojimo laiku.
7.Sandėlio tirpalas stabilus keturias (4) savaites laikant jį šaldytuve (2-10^{0}C). Po keturių savaičių išmeskite. Išvalykite arba pakeiskite talpyklą ir tik tada pagaminkite naują sandėlio tirpalo partiją. (žr. toliau esančias pastabas).

Buferizuoto vandens darbinio tirpalo gamybos procedūra

1.Išmatuokite 200 ml sandėlio buferio ir įpilkite į 4 L butelį, pažymėtą BD tris buferizuotu vandens darbiniu tirpalu.
2.Pridėkite 3400 ml dejonizuoto (DI) arba distiliuoto vandens.
3.Uždėkite dangtelį ir vartydami gerai išmaišykite.

- Pažymėkite talpyklą su paruošimo data ir galiojimo laiku.

Darbinis tirpalas stabilus dvi (2) savaites laikant kambario temperatūroje (15-30^{0}C). Išvalykite arba pakeiskite talpyklą ir tik tada pagaminkite naują darbinio tirpalo partiją. (žr. toliau esančias pastabas).

Pastaba: talpyklas plaukite naudodami atitinkamą laboratorinį valiklį (nenaudokite baliklio). Po valymo arba prieš naudodami naują talpyklą, skalaukite talpyklą dejonizuotu (DI) arba distiliuotu vandeniu.

Mėginio perkėlimo nustatymas

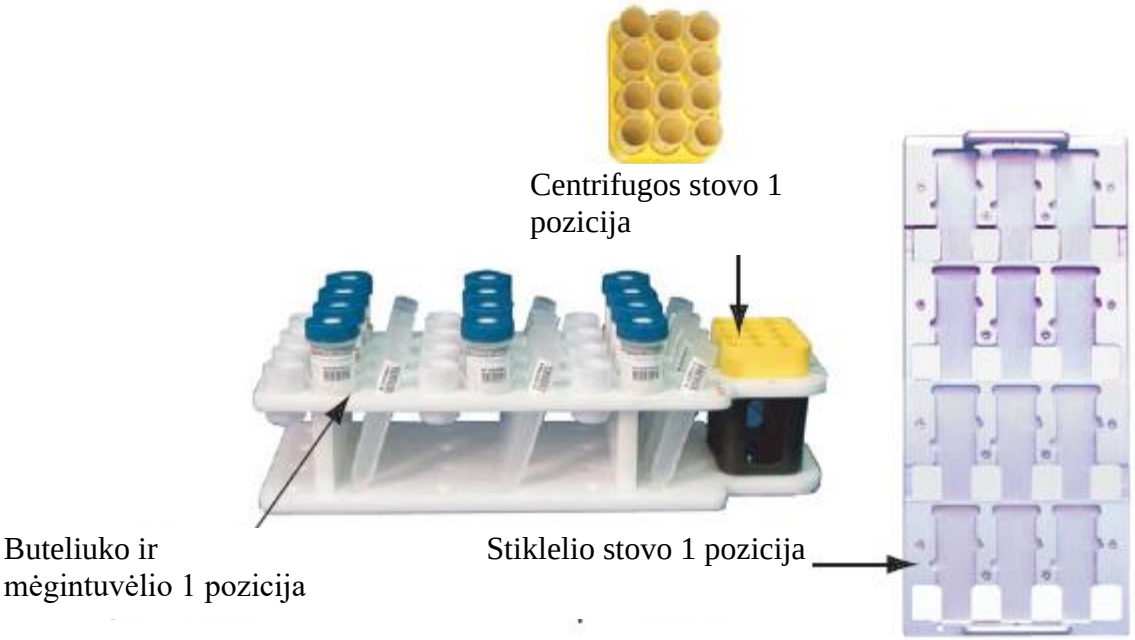
Įspėjimas
Citologiniai mėginiai gali turėti infekcinių medžiagų. Tvarkydami mėginių indus mūvėkite pirštines ir laikykitės atitinkamų biologinio pavojaus atsargumo priemonių.

Šiame skyriuje aptariamas PrepMate automatizuotas perkėlimo metodas.

Gamybos grandinė

Norėdami palaikyti tiriamų mėginių gamybos grandinę, visi mėginių buteliukai, BD centrifugų mėgintuvėliai ir stikliniai stikleliai yra įkraunami į jų atitinkamus stovus **iš priekio į galą** ir **iš kairės į dešinę**. Atitikimas tarp eilių ir stulpelių PrepMate stove, centrifugos mėgintuvėlių stove ir stiklelių stove yra iliustruotas *4-1 iliustracijoje*. Iliustracija identifikuoja 1 pozicijos vietą (1 eilutė, 1 stulpelis) trijose vietose: ant PrepMate stovo, centrifugos mėgintuvėlio stovo ir stiklelio stovo.

Perspėjimas
Mėgintuvėliai centrifugos stovuose turi būti atidžiai orientuojami su atitinkamais stiklelių stovais. Tinkamas paženklintų mėgintuvėlių padėjimas su atitinkamai pažymėtais stikleliais yra esminis veiksnys ir turi būti patvirtinamas vartotojo, kad būtų išvengta mėginių susimaišymo.



4-1 iliustracija: *PrepMate stovo, centrifugos mėgintuvėlio stovo ir stiklelio stovo eilutės ir stulpelio atitikimas*

Pastaba: pozicionavimo smaigės ant PrepMate stovo ir PrepStain instrumento padeda užtikrinti tinkamą sulygiavimą. Tai užtikrina, kad mėginys iš 1 PrepMate stovo pozicijos yra paskirstomas ant 1 pozicijos stiklelio stiklelių stove.

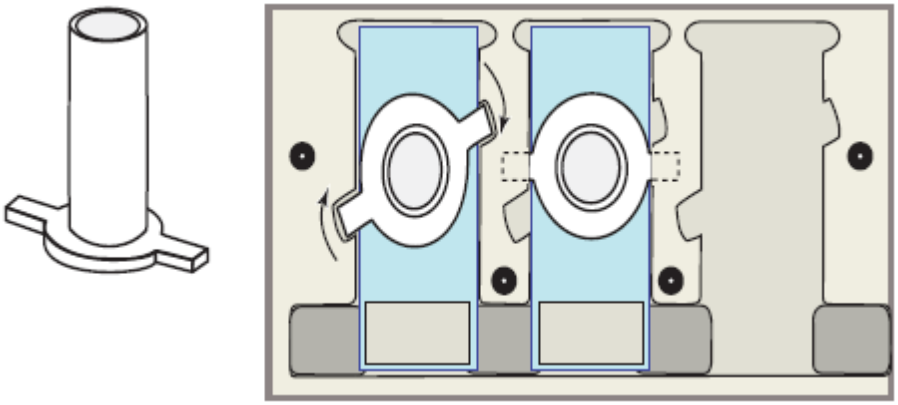
Stiklelių paruošimas ant stiklelių stovo

Stiklelių stovas

1.Padėkite BD SurePath PreCoat stiklelius ant stiklelių stovo toje pačioje pozicijoje kaip ir mėgintuvėliai centrifugos mėgintuvėlių stove. *Būkite atsargūs ir nelieskite objektinio stiklelio paviršiaus*.

Įspėjimas
Stiklelio padengimas gali būti pašalinamas nuo stiklelio paviršiaus, jeigu paviršius yra subraižomas arba paliečiamas dedant juos į nusėdimo kamerą. Tai gali paveikti stiklelio paruošimo kokybę.

2.Fiksuokite kamerą ant kiekvieno stiklelio stove, kaip parodyta *4-2 iliustracijoje*.
3.Jeigu stulpelyje yra mažiau nei keturi mėginiais, sudėkite tuščius stiklelius ir BD nusėdimo kameras į atitinkamas vietas.



Pasukite nusėdimo kamerą, kad fiksuotumėte ant stiklelių stovo.
4-2 iliustracija: *BD nusėdimo kamerų fiksavimas ant kiekvieno stiklelio*

PrepStain proceso procedūra

1.Kiekvienam tiriamam mėginiui pažymėkite testo pareikalavimą, mėginio buteliuką, BD centrifugos mėgintuvėlį ir BD SurePath PreCoat Slide su unikaliu identifikaciniu lipduku. Naudokite tirpikliams atsparius žymeklius, kad rašytumėte ant matinio stiklinio stiklelio galo arba užklijuokite atspausdintą lipduką su mėginio identifikacija.

Įspėjimas
Patikrinkite etiketes ant surinkimo buteliukų, BD SurePath PreCoat stiklelių ir centrifugos mėgintuvėlių specifinėse ruošinio stovo pozicijose, kad užtikrintumėte, jog kiekvienas mėginio rinkinys atitinka tinkamą mėginį.

Maišyklė

2.Maišykite mėginio buteliukus mažiausiai 15 ± 5 sekundes. Maišyklės greitis turi būti pakankamas, kad sukurtų sūkurį surinkimo buteliuke (maždaug 3000 rpm). Jeigu naudojate kelių buteliukų maišyklę, ant buteliukų viršaus uždėkite guminį paklotą, kad apsaugotumėte buteliukus ir neleistumėte buteliukams suktis, kas sumažintų maišymo efektyvumą.

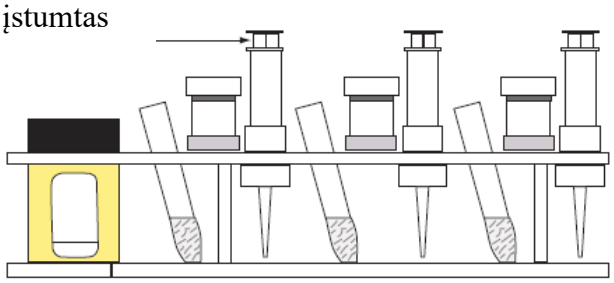
PrepMate stovas

3.Sudėkite pažymėtus mėginio buteliukus ir centrifugos mėgintuvėlius į Prepmate stovą didėjančia tvarka (tinkama PrepMate stovo orientacija yra tada, kai centrifugos mėgintuvėlio stovas nukreiptas į dešinę). Patvirtinkite, kad kiekvienas centrifugos mėgintuvėlis yra paženklintas taip pat, kaip ir atitinkamas mėginio buteliukas.

Tankio reagentas

4.Įlašinkite 4 ± 0.1 ml BD tankio reagento į kiekvieną BD centrifugos mėgintuvėlį.
5.Įstatykite švirkščiančią pipetę į stovą šalia kiekvieno mėginio buteliuko. Įsitikinkite, kad kiekvieno švirkšto stūmoklis pilnai įstumtas. BD PrepMate automatizuotas priedas neveiks, jeigu stūmoklis bus pernelyg aukštai. Šį faktą iliustruoja *4-3 iliustracija*.

Stūmoklis pilnai įstumtas



4-3 iliustracija: *centrifugos mėgintuvėliai pilnai įstatyti*

PrepMate

6.Paleiskite PrepMate. (Detalias instrukcijas rasite BD PrepMate vartotojo vadove).

a. Įsitikinkite, kad PrepMate yra prijungtas prie AK galios šaltinio, o šoninės panelės jungiklis yra pozicijoje ON. Sekite ekrane pateikiamas užklausas prieš įkraudami mėginio stovą. Neįkraukite mėginio stovo tol, kol ekrane nepamatysite užrašo **PREPMATE READY, (v x.x) LOAD SPECIMEN RACK**.
b. Įsitikinkite, kad buteliuką prilaikančios durys yra vertikalioje, fiksuotoje pozicijoje.
c. Padėkite įkrautą mėginio stovą į instrumento padėklą. Stumkite stovą į vidų, kol padėklas fiksuosis priekiniame kairiajame padėklo kampe. Rankiniu būdu nejudinkite metalinio padėklo, nes tokiu būdu sugadinsite prietaisą.
d. Jeigu apdorojate mažiau nei tris eiles, paspauskite **Dec**, kad sumažintumėte mėginių eilių skaičių iki tinkamo nustatymo ir tik tada paspauskite **Start**. Apdorojamų eilių skaičius pasirodo skliausteliuose kaip paleidimo pranešimo dalis. Kai paspaudžiate **Dec** arba **Inc**, ekrane rodoma informacija atitinkamai atnaujinama. Jeigu susiduriate su problemomis, sekite ekrane pateikiamas instrukcijas.
e. Kai mėginio stovo apdorojimo ciklas baigiasi, girdimas garsinis tonas. Pakeiskite užbaigtą stovą nauju stovu, skirtu apdoroti. Jeigu reikia, nustatykite eilių skaičių, ir paspauskite **Start**.

f. Patikrinkite centrifugos mėgintuvėlius, kad patvirtintumėte, kad buvo perkeltas tinkamas mėginio kiekis. Tinkamas mėginio kiekis mėgintuvėlyje yra 12 ± 1 ml (4 ml tankio reagento ir 8 ml mėginio).

7.Kai mėginio stovas apdorojamas, atsargiai iškraukite stovą iš BD PrepMate automatizuoto priedo.

Pastaba: PrepMate mėginio stovai turi būti valomi tarp panaudojimų, kad būtų išvengta kryžminio užteršimo. Daugiau informacijos rasite PrepMate vartotojo vadove.

8.Sudėkite mėgintuvėlius su ląstelių suspensija ir tankio reagentu į centrifugos mėgintuvėlių stovus ta pačia tvarka, kokia jie buvo PrepMate stove.

9.Išimkite švirkštus ir išmeskite.

Patarimas: leiskite mėginių buteliukams likti PrepMate stove (tai gali būti naudojama kaip ženklinimo šablonas stiklelių stovui).

Pastaba: Kiekvienam likusiam mėginio buteliukui, kurie busi išsaugomi, turi būti pakeisti dangteliai. (Atsarginius dangtelius galite užsisakyti iš BD.) Atsargiai tvarkykite pradurtus dangtelius ir atvirus mėginių buteliukus, kad išvengtumėte kryžminio užteršimo. Utilizuokite pradurtus dangtelius į biologiškai pavojingų medžiagų talpyklas.

Įspėjimas

- Norėdami gauti optimalius rezultatus, susluoksniavus mėginį ant tankio reagento, mėginiai turi būti centrifuguojami ir paviršiuje plūduriuojančios medžiagos nusiurbiamos per 30 minučių.
- Norėdami išlaikyti gamybos grandinę, būkite atidūs pozicionuodami BD centrifugos mėgintuvėlius ir mėginio buteliukus, kai įkraunate PrepMate stovą ir perkeliant centrifugos mėgintuvėlius į mėgintuvėlių stovą.

1 centrifugos programa

10.Įsitikinkite, kad centrifugos mėgintuvėlių stovai tinkamai subalansuoti.

a. Jeigu mėgintuvėlių kiekis tarp dviejų stovų neatitinka, sudėkite tuščius mėgintuvėlius ir atsvarą su DI vandeniu.
b. Pakartotinai nepozicionuokite mėgintuvėlių, kad subalansuotumėte mėgintuvėlių stovus, nes tai paveiks gamybos grandinę.

11.2 minutes ± 15 sekundžių centrifuguokite mėgintuvėlius prie 200 rcf ± 25 naudodami 1 programą.

Tube Vac

12.Pašalinkite paviršiuje plūduriuojančias medžiagas naudodami Tube Vac ir Easy Aspirator.

a. Įjunkite Tube Vac vakuuminį siurblį, sureguliuokite vakuumo slėgį ties 8-10 in. Hg (Shuco) arba 5-6 in. Hg / 180-220 mBAR (KNF). Visada leiskite siurbliui sukalibruoti vakuuminį slėgį ir tik tada pradėkite aspiraciją.
b. Prijunkite antgalių rinkinį prie Easy Aspirator galvutės. Tik su labai vidutiniu slėgiu spauskite galvutę statmenai ir tolygiai žemyn, kad prijungtumėte antgalius.

> **Pastaba:** Nestumkite sandariklio taip giliai į antgalio įvorę, kad įvorė būtų lygi su metaliniu poliumi.

c. Patikrinkite, ar dvylika BD Aspirator Tips (aspiratoriaus antgalių) yra saugiai fiksuoti prie polių ant Easy Aspirator galvutės.
d. Lėtai leiskite aspiratoriaus antgalius į paviršiuje plūduriuojantį skystį šiek tiek žemiau lašinamo skysčio lygio, kol apisratoriaus galvutė tolygiai užsidės ant BD centrifugos mėgintuvėlių viršaus. Šiuo metu Jūs turite girdėti, kaip antgaliai traukia orą.

> **Pastaba:** Šioje pozicijoje sąsajos frakcijos lygis ties tankio reagentu turi būti įsiskverbęs, o didžioji paviršiuje plūduriuojančios frakcijos ir sąsajos frakcijos dalis pašalinta.

e. Atsargiai ištraukite aspiratoriaus galvutę su įkrautais antgaliais iš mėgintuvėlių rinkinio.

> **Pastaba:** Jeigu antgaliai naudojami papildomai aspiracijai, skalaukite antgalius dejonizuotu vandeniu po kiekvieno mėgintuvėlių stovo. Pakeiskite antgalius, kai atliksite keturių centrifugos stovų (iki 48 mėginių) aspiraciją. Alternatyviai, vienkartiniam antgalio naudojimui, išmeskite ir pakeiskite antgalį kaip nurodyta toliau.

f. Laikykite aspiratoriaus antgalio išmetimo įtaiso galvutę priekyje ir toje pačioje plokštumoje kaip ir Delrin pleištas antgalių išmetimo įtaiso viršuje. Stumkite aspiratoriaus galvutę palei pleišto viršų, kad poliai susilygiuotu į angas.

> **Pastaba:** Antgalio išmetimo įtaiso angos pirmiausia gali atrodyti kiek per sandarios. Šis sandarumas per laiką sumažės, kadangi naudojant balto Delrin pleišto medžiaga dėvisi ir koreguojasi.

g. Aspiratoriaus galvutės stūmimas turi išmesti visus antgalius į išmetimo padėklą (žr. pastabą žemiau). Ištraukite galvutę traukdami aukštyn ir lauk. Jeigu kiti mėginiai neturi būti aspiruojami, išjunkite vakuuminį siurblį.

Pastaba: Siekiant išvengti užkišimo, prieš išjungiant vakuuminį siurblį labai svarbu skalauti vandeniu. Atlikite šį skalavimą po paskutinio mėgintuvėlio indo apsiravimo, kai antgaliai vis dar yra aspiratoriaus poliuose.

h. Panaudotus antgalius išmeskite pagal vietos procedūras, skirtas pavojingų atliekų utilizavimui.
i. Po to, kai paviršiuje plūduriuojantis skystis yra aspiruojamas, pakartotinai subalansuokite mėgintuvėlių stovus pagal 10 žingsnio instrukcijas.

Centrifugos 2 programa

13.10 minučių ± 1 minutė centrifuguokite likusį skystį prie 800 rcf ± 50 naudodami 2 programą. Šis centrifugavimas koncentruoja diagnostinius komponentus į ląstelių gumulėlį.

Mėgintuvėlių išleidimas

14.Išimkite mėgintuvėlių stovus iš centrifugų. Vienu greitu judesiu išleiskite paviršiuje plūduriuojančias medžiagas paversdami kiekvieną mėginio stovą 180 laipsnių taip, kad nebūtų paveiktas ląstelių gumulėlis. Pavertus atsargiai nusausinkite visus stovo mėgintuvėlius sugeriamuoju popieriui. Po 3-5 sekundžių apverskite stovą į statmeną poziciją.

Rankinė sūkuriavimas

15.Laikydami ranką su pirštine ant mėgintuvėlių viršaus, sūkuriuokite mėgintuvėlių stovą 15 ± 5 sekundes. Absorbuojanti medžiaga rankinio sūkuriavimo metu gali būti laikoma šalia nusausinimui po išleidimo.

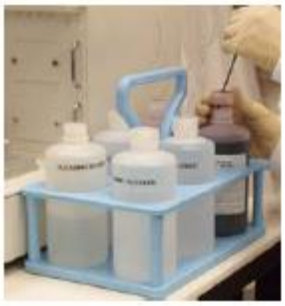
PrepStain

16.Paleiskite BD PrepStain™ stiklelių paruošimo sistemą:

a. Sudėkite mėgintuvėlių stovus ir stiklelių stovus ant PrepStain instrumento. Patvirtinkite, kad visos kiekvienos paženklintos pusės ant stiklelių stovo pozicijos atitinka mėgintuvėlio stove paženklintus mėgintuvėlius. Įsitikinkite, kad visi mėgintuvėlio stovai ir stiklelių stovai tinkamai įstatyti į prietaisą.

b. Padėkite kiekvieną pažymėtą paėmimo mėgintuvėlį į atitinkamą reagento talpyklą (paėmimo mėgintuvėlis turi būti pilnai įstatytas iki reagento butelio dugno). Patvirtinkite, kad kiekviename butelyje yra pakankamas reagento kiekis.

Reagento talpyklos



c. Padėkite 96 iš anksto įkrautus BD PrepStain Transfer Tips ant DiTi stotelės. Tvirtai įstatykite plastikinį antgalio laikiklį, kad priekinė ir galinė auselės fiksuotųsi į stotelę.

Įspėjimas
Lašinimo pipete instrumentas yra robotizuotas prietaisas, kuris veikia valdomas kompiuterio. Kaip ir su dauguma robotizuotų prietaisų, veikiant instrumentui egzistuoja sužeidimo ir kūno sužalojimo rizika dėl judančių mechaninių komponentų. Instrumentas sukurtas tik automatiniam veikimui be vartotojo įsikišimo. Jeigu robitizuotas judėjimas yra paveikiamas, tai sugeneruos klaidą. Siekiant atlikimo nutraukimo išvengimo, nekliudykite robotizuotos atšakos veikimo.

d. Įjunkite PrepStain sistemą. Kompiuteris automatiškai paleis GYN programinės įrangos taikomąją programą.
e. Norėdami apdoroti ir nudažyti stiklelius, pagrindiniame meniu pasirinkite **SLIDE PREPARATION AND STAINING** ir sekite instrumento raginimus. Žr. ***5 skyrių*** šiame vartotojo vadove, kur pateikiamos programinės įrangos naudojimo instrukcijos.
f. Kiekvieną kartą atlikus stiklelio stovo dažymo procesą girdimas aliarmo signalas.

17.Kai kiekvienas stiklelio stovas yra užbaigiamas, išimkite jį iš BD PrepStain™ instrumento.

18.Apverskite stiklelio stovą, kad išleistumėte alkoholio likučius. Prieš grąžindami į normalią poziciją, absorbuokite alkoholį iš BD nusėdimo kamerų su sugeriamuoju popieriumi. Apverskite stiklelių stovą statmenai.

19.Vienu metu išimdami vieną stiklelį išimkite ir išmeskite nusėdimo kamerą, o tada uždenkite stiklelį dengiamąja plokštele.

a. Nukreipkite reagento alkoholio arba 2-propanolio srautą virš paruošimo vietos ant stiklelio.
b. Valykite kiekvieną stiklelį nukreipdami ksileno arba ksileno pakaitalo srautą virš paruošimo vietos ant stiklelio.
c. Naudodami 24 mm x 30 mm dengiamąją stiklinę plokštelę, uždenkite stiklelį kaip įprasta naudodami polimero pagrindo montavimo terpę.

Įspėjimas

- Išimdami nusėdimo kamerą, venkite ląstelių apskritimo išmetimo nuo stiklelio.
- Neleiskite stikleliams išdžiūti iki uždengimo dengiamąja plokštele. Kiekvienas stiklelis turi būti uždengiamas po vieną.
- Ilgą laiką paliekant mėginius alkoholyje galite išblukinti ląsteles.

20.Išimkite mėgintuvėlio stovus iš PrepStain instrumento. Įlašinkite 2 ml BD SurePath konservanto skysčio į kiekvieną mėgintuvėlį. Uždenkite kiekvieną mėgintuvėlį dangteliu arba parafilmu. Nuo surinkimo dienos ląstelių gumulėliai su konservantu gali būti sandėliuojami iki 4 savaičių kambario temperatūroje (15-30^{0}C) arba 5 mėnesių šaldytuve (2-10^{0}C).
21.Sistemos valymas ir išjungimas:

a. Pasirinkite **CLEAN UP SYSTEM** ir sekite nurodymus, pateikiamus vaizduoklyje.
b. Po valymo procedūros ekranas grįš į pagrindinį meniu.
c. Pasirinkite **QUIT**.
d. Išjunkite elektros tiekimą.

BD SurePath ląstelių gumulėlių pakartotinis apdorojimas

Pakartotinio apdorojimo procedūra pradedama su ląstelių gumulėliu, likusiu po pirminio **SLIDE PREPARATION AND STAINING** atlikimo.
1.Jeigu mėginys buvo šaldomas, leiskite mėginiui pasiekti kambario temperatūrą.
2.Atlikite 13-19 PrepStain proceso procedūros žingsnius.

5 skyrius
Ginekologinių (GYN) stiklelių apdorojimas

Šiame skyriuje pateikiamos ginekologinių mėginių stiklelių apdorojimo BD PrepStain™ instrumente instrukcijos ir bendra informacija. Norint pereiti tiesiai prie mėginio stiklelių apdorojimo procedūros, atsiverskite 5-4 puslapį. Norėdami susipažinti su ekranais ir valdikliais, kurie naudojami šioje procedūroje, žr. toliau pateikiamą informaciją.

PrepStain GYN programa

Programos bendra informacija

GYN programos veikimo principai ir įvykių seka yra aptariami ***3 skyriuje: veikimo principai***. Trumpai aptariant šią seką, stiklelių paruošimo sistema perkelia mėginiu ir tada atlieka seriją dažymo ir skalavimo ciklų, kurie sukuria ploną citologinių medžiagų ruošinio sluoksnį ant BD SurePath PreCoat stiklelio.
Kiekvienas dažymo ir skalavimo ciklas atliekamas tuo pačiu šablonu: skiriasi tik naudojami reagentai ir pauzės trukmė.
BD PrepStain™ instrumento funkcijos yra valdomos naudojant kompiuterinę darbo vietą. Trys DOS pagrindo meniu taikomosios programos suteikia prieigą prie programų, kurios valdo PrepStain instrumentas.
Naudodami darbo vietos meniu Jūs komunikuojate su instrumentu ir stebite stiklelio paruošimo progresą.
Norint pasiekit ginekologinių (GYN) stiklelių apdorojimo funkcijas, Jums reikia įjungti darbo vietą. Jeigu darbo vieta jau veikia, Jūs galite pasiekti šias ir kitas funkcijas įvesdami atitinkamas komandas į DOS ir paspausdami mygtuką **Enter**. *5-1 lentelėje* pateikiamos komandos ir jų atitinkamos funkcijos.

5-1 lentelė. PrepStain darbo vietos komandos

Komanda	**Funkcija**
GYN	Suteikia prieigą prie stiklelių paruošimo ir dažymo, stiklelių paruošimo ir stiklelių dažymo procedūrų ginekologiniams mėginiams.
NONGYN	Suteikia prieigą prie stiklelių paruošimo ir dažymo, stiklelių dažymo procedūrų ne ginekologiniams mėginiams.
UTIL	Dažymo ir DiTi linijų skalavimas.

5-1 iliustracija: iliustruoja pasisveikinimo ir versijos tikrinimo ekraną, kuris rodomas Jums atidarius GYN programą.

5-1 iliustracija: *GYN versijos tikrinimo meniu*

Ekranai GYN taikomojoje programoje yra padalinti į tris dalis, kaip nurodyta *5-1 iliustracijoje*.

a. Viršutinė (reklaminės juostos) dalis rodo tekstinį pranešimą keliose linijose. Šie pranešimai nurodo Jums, kokį veiksmą atlieka sistema, ar kokį ruošiasi atlikti.
b. Vidurinė (meniu) dalis rodo meniu raginimus, kuriuos naudojate sistemos valdymui.
c. Apatinė (raginimo) dalis rodo tekstinius pranešimus vienoje linijoje. Šie pranešimai nurodo Jums, kas vyksta ir ką reikia daryti toliau.

Pastaba: vadove esančių ekranų iliustracijos skirtos tik iliustraciniais tikslais. Esamas ekranas gali skirtis savo išvaizda.

Pagrindinio meniu ekranas

Kai patvirtinsite versiją, pasirodys GYN pagrindinis meniu. *5-2 iliustracija* pateikia šio ekrano pavyzdį.

5-2 iliustracija: *GYN pagrindinis meniu*

Šiame skyriuje aptariamos **SLIDE PREPARATION AND STAINING, SLIDE PREPARATION** ir **SLIDE STAINING** opcijos. **CLEAN UP SYSTEM** opcija aptariama ***6 skyriuje***. **SYSTEM SETUP** ir **DIAGNOSTICS** opcijos aptariamos ***9 skyriuje***. Šios dvi paskutinės opcijos pasiekiamos tik (arba su pagalba) BD įgalioto techniko, nebent tai nurodoma kaip dalis kasdieninės priežiūros.

Ekrano Step in Progress detali informacija

Kai apdorojimas yra atliekamas, vaizduoklis rodo esamą proceso būseną naudodamas Step in Progress ekraną. *5-3 iliustracijoje* iliustruojamas šis ekranas.

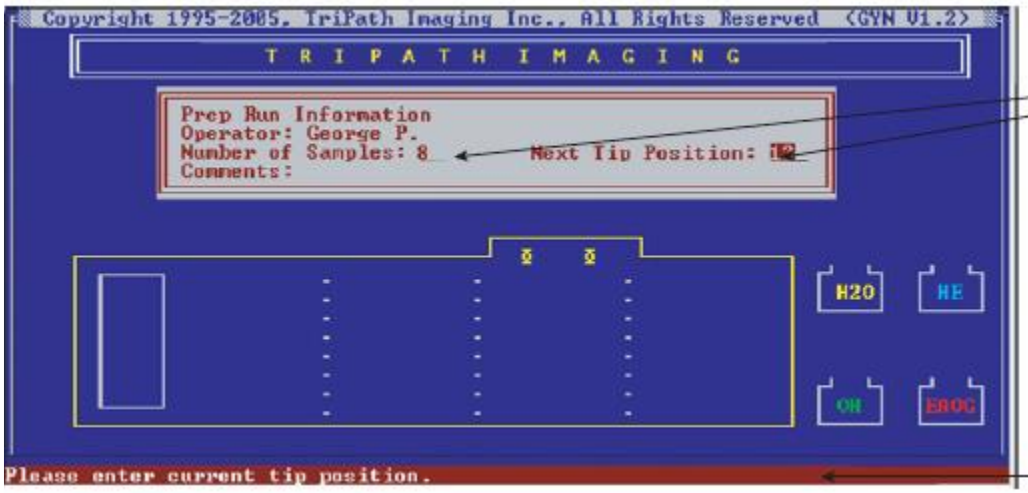
5-3 iliustracija: *ekranas Step in Progress*

Kaip pateikiama *5-3 iliustracijoje*, mėginio ir dažymo proceso žingsniai yra pateikiami ekrano viršuje. Žingsnis, kurį BD PrepStain™ instrumentas atlieka, yra pažymėtas ir mirksi.
Apatinė ekrano dalis rodo nusėdimo kameros piktogramą kiekvienam apdorojamam mėginiui (šiame pavyzdyje 8). Esamai apdorojamas mėginys mirksi.
Apatinis dešinysis kampas rodo piktogramas reagento švirkšto siurbliams. Mirksinti rodyklė nurodo naudojamą reagentą.
Kiekvieno žingsnio apibrėžimas pateikiamas žemiau:
Resuspended Sample (Sumaišomas mėginys): buferizuotas vanduo pridedamas, kad sumaišyti ląstelių gumulėlį BD centrifugos mėgintuvėlyje.
Mix Sample (Mėginio maišymas): ląstelių gumulėlis yra pakartotinai aspiruojamas ir paskirstomas, kad būtų sumaišyta ląstelės medžiaga.
Transfer Sample (Mėginio perkėlimas): maišoma ląstelės suspensija yra aspiruojama ir paskirstoma į atitinkamo stiklelio nusėdimo kameros poziciją.
Preparation Pause (Paruošimo pauzė): PrepStain sistema nutraukia ląstelių nusėdimą, džiovinimą, dehidratavimą, rehidraciją ir dažymų inkubaciją.
Wash with Water (plovimas vandeniu): nusėdimo kamera ištuštinama, o tada skalaujama dejonizuotu vandeniu.
Wash with Alcohol (plovimas alkoholiu): nusėdimo kamera ištuštinama, o tada skalaujama BD Alchohol Blend Rinse.
Stain with Hematoxylin (dažymas hematoksilinu): BD Hematoxylin Stain (hematokslinias) yra panaudojamas, aspiruojamas ir vėl pakartotinai taikomas dažymui atlikti. BD Hematoxylin yra pirmasis dažas, naudojamas dažymo procese.
Stain with EA/OG (dažymas su EA/OG): BD EA/OG Combo Stain (EA/OG) yra panaudojamas, aspiruojamas ir vėl pakartotinai taikomas dažymui atlikti. EA/OG yra antrasis dažas, naudojamas dažymo procese.

Ginekologinių (GYN) mėginių apdorojimas

Prieš atliekant šią procedūrą, pirmiausia turite užbaigti paruošimo procedūras, pateiktas ***4 skyriuje Išankstinio apdorojimo žingsniai***.
1.GYN taikomoji programa paleidžiama automatiškai, kai įjungiama BD PrepStain™ instrumento darbo vieta. Jeigu darbo vieta jau veikia, tačiau GYN taikomoji programa ne:
DOS raginime įveskite **Gyn**, o tada paspauskite **Enter**. Pasirodys GYN versijos tikrinimo ekranas.
2.Meniu pasirinkite **Run Version 1.3.0.3**. Tada paspauskite **Enter**. Tokiu būdu atidarysite GYN pagrindinį meniu. Pagrindinis meniu (*5-2 iliustracija*) suteikia prieigą prie visų programos funkcijų.

3.Pasirinkite **Slide Preparation and Staining**, o tada paspauskite **Enter**. Pasirodys PrepStain Run Information ekranas (*5-4 iliustracija*).



5-4 iliustracija: *PrepStain Run Information ekranas*

> **Pastaba:** Jūs galite naudoti **Tab** arba **Enter** mygtukus, kad judintumėte žymeklį (naviguotumėte) iš vieno laukelio į kitą PrepStain sistemos ekranuose.

4.Naviguokite į antrąjį laukelį (praleiskite **OPERATOR** laukelį), įveskite apdorojamą mėginių skaičių ir paspauskite **Enter**. Mėginių skaičius turi būti keturių kartotinis.

> **Pastaba:** Jeigu apdorojamų stiklelių skaičius nesidalina iš keturių, įveskite kitą didesnį keturių kartotinį, o tada pridėkite tuščius stiklelius, BD nusėdimo kameras ir mėgintuvėlius į mėgintuvėlio stovą, kad kompensuotumėte skirtumą.

5.Naviguokite į kitą laukelį ir paspauskite **Next** patvirtinimui, kad Next Tip Position yra teisinga; arba įveskite teisingą antgalio poziciją ir tada paspauskite **Enter** (praleiskite laukelį **COMMENTS**).
6.Bus parodytas **Reenter Run Information** raginimas.

5-5 iliustracija: *Reenter Run Information meniu*

- Norėdami pakeisti mėginių skaičių arba kitą antgalio poziciją, pasirinkite **Yes**, paspauskite **Enter** ir pakartokite du paskutinius žingsnius.
- Įvesčių patvirtinimui ir perėjimui prie kito žingsnio pasirinkite **No** ir tada paspauskite **Enter**.

7.Pasirodys raginimas **CHANGE SAMPLE/STAIN PARAMETERS**.

5-6 iliustracija: *Change Sample/Stain Parameters raginimas*

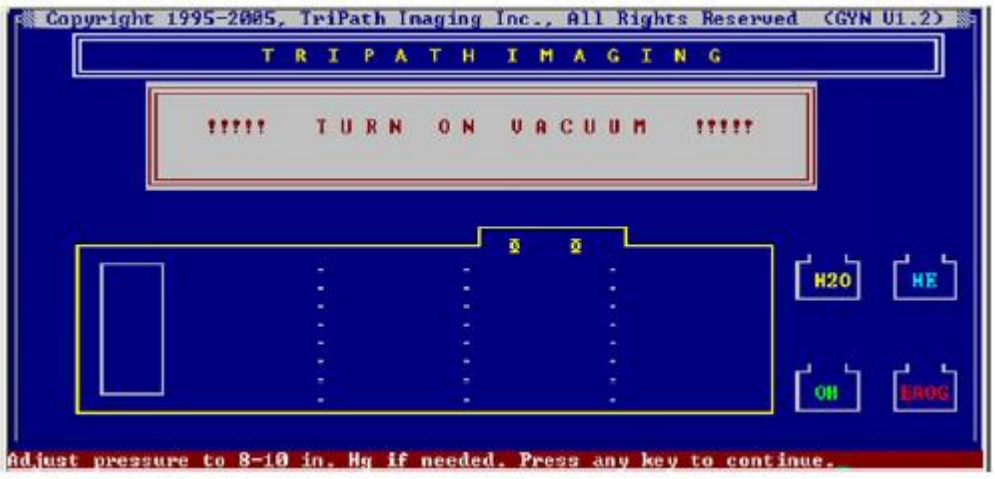
- Mėginio arba dažymo nustatymų keitimui pasirinkite **Yes**, o tada paspauskite **Enter**. Daugiau informacijos apie šias korekcijas rasite 5-15 puslapyje *Mėginio/dažymo parametrų keitimas*.
- Norėdami naudoti esamus nustatymus ir pereiti prie kito žingsnio pasirinkite **No** ir tada paspauskite **Enter**.

8.Pasirodys **SCAN BARCODES?** meniu.

5-7 iliustracija: *Scan Barcodes meniu*

- Norėdami naudoti brūkšninio kodo skanavimo įrenginį, pasirinkite **Yes**, o tada paspauskite **Enter**. Daugiau informacijos apie šios funkcijos naudojimą rasite 5-18 puslapyje *Brūkšninių kodų skanavimas (laisvai pasirenkama funkcija)*.
- Norint praleisti brūkšninių kodų programą ir pereiti prie kito žingsnio pasirinkite **No** ir tada paspauskite **Enter**.

9.Vakuumo raginimas parodomas ekrane. Taip pat girdimas aliarmo garsas. Paspauskite bet kurį mygtuką aliarmui nutildyti.



5-8 iliustracija: *vakuuminio siurblio raginimo ekranas*

10.Įjunkite vakuuminį siurblį, palaukite kelias minutes, kol jis sušils.

- Jeigu naudojate Schuco siurblį, sureguliuokite slėgį ties 8-10 colių Hg, o tada paspauskite bet kurį mygtuką, kad tęstumėte.
- Jeigu naudojate KNF siurblį, sureguliuokite slėgį ties 5-6 colių Hg, o tada paspauskite bet kurį mygtuką, kad tęstumėte.

> **Pastaba:** Siurblio slėgio nustatymas ekrano apačioje (8-10) skirtas tik mėlynam Schuco siurbliui. Naudokite 5-6 inHg, jeigu naudojate KNF siurblį su slėgio matuokliais su inHg vienetais. Naudokite 180-220 mBAR, jeigu naudojate KNF siurblį su slėgio matuokliais su mBAR vienetais.

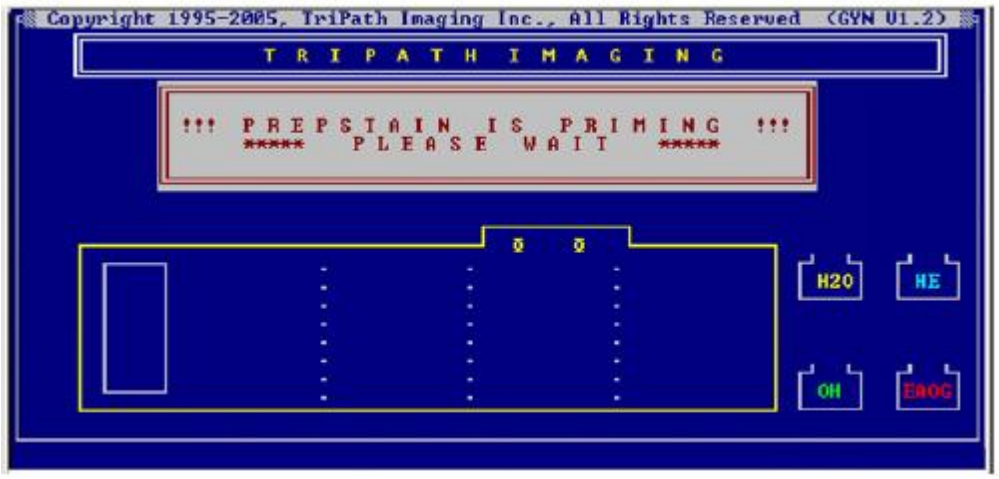
11.Pasirodys raginimas **PRIME ALL TUBING?**

5-9 iliustracija: *Prime All Tubing meniu*

- Jeigu tai yra pirmasis dienos prietaiso naudojimas, pasirinkite **Yes**, o tada paspauskite **Enter**, kad užpildytumėte sistemos vamzdelius. Sistema inicializuojasi ir švirkšto siurbliai pumpuoja du pilnus švirkšto tūrius per keturkampės atšakos vamzdelį ir į atliekų stotelę.
- Tolimesniems prietaiso naudojimams per kitas aštuonias valandas pasirinkite **No**, o tada paspauskite **Enter**, kad praleistumėte pilno užpildymo funkciją.
- Prieš kiekvieną prietaiso panaudojimą, vienas švirkšto tūris automatiškai pumpuojamas per vamzdelį, kad užtikrintų, jog sistema užpildyta.

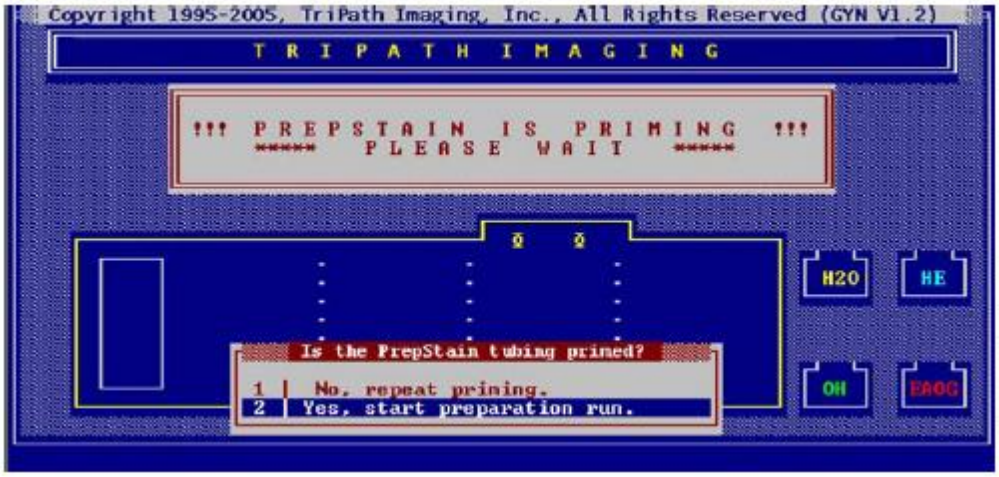
Kol sistema yra užpildoma, rodomas PrepStain System Priming ekranas.

> **Pastaba:** Praėjęs sekos laikas rodomas apatiniame kairiajame kampe. Šis ekranas rodomas kiekvienai PrepStain instrumento atliekamai užduočiai.



5-10 iliustracija: *PrepStain is Priming ekranas*

12.Kai užpildymo ciklas baigtas, ekrane pasirodo raginimas **IS THE PREPSTAIN TUBING PRIMED?**



5-11 iliustracija: *Is the tubing primed?*

- Norėdami pakartoti užpildymo seką pasirinkite **No**, o tada paspauskite **Enter**.
- Norėdami tęsti su stiklelių ruošimu ir dažymu pasirinkite **Yes**, o tada paspauskite **Enter**.

Pastaba: 13-17 žingsniai apibūdina mėginio paruošimo ir dažymo procesą. Šios sekos metu rodomas Step in Progress ekranas. Šio ekrano apibūdinimas pateikiamas 5-3 puslapyje *Ekrano Step in Progress detali informacija.*

13.DiTi lašina buferizuotą vandenį į kiekvieną BD centrifugos mėgintuvėlį, kad sumaišytų ląstelių gumulėlį. Toliau DiTi paima vienkartinį antgalį ir aspiruoja ląstelių suspensijos mėginį bei perneša į atitinkamą stiklelį ir išleidžia į nusėdimo kamerą.
14.Po to, kai mėginiai perkeliami į visus stovus, instrumentas mažiausiai 10 minučių sustoja, kol ląstelės sėda ant stiklelių.
15.Kai nusėdimo pauzės etapas pasibaigia, aliarmas įspėja vartotoją, kad atšaka tuoj pajudės.
Dažymas vienu metu atliekamas tik ant vieno stiklelio stovo. Kiekvieno dažymo ciklo metu kiekvienas stiklelis yra iš anksto nuplaunamas atitinkamame reagente (buferizuotas vanduo hematoksilinui, alkoholis EA/OG Combo Stain) ir tada nudažomas. Kiekviena nusėdimo kamera yra pilnai ištuštinama tarp dažymų ir plovimų ciklų. Atlikus dažymą stiklelis plaunamas alkoholiu.
16.Kai visi stikleliai stove yra nudažyti, PrepStain sistema skleidžia garsinį aliarmą ir tada tęsia kito stiklelio stovo dažymą.

a. Kai kiekvienas stiklelio stovas yra baigiamas, išimkite jį iš BD PrepStain™ instrumento ir nupilkite alkoholį iš kiekvienos nusėdimo kameros į tinkamą talpyklą.

Įspėjimas

- Išimdami nusėdimo kamerą, venkite ląstelių apskritimo išmetimo nuo stiklelio.
- Neleiskite stikleliams išdžiūti iki uždengimo dengiamąja plokštele. Kiekvienas stiklelis turi būti uždengiamas po vieną.
- Ilgą laiką paliekant mėginius alkoholyje galite išblukinti ląsteles.

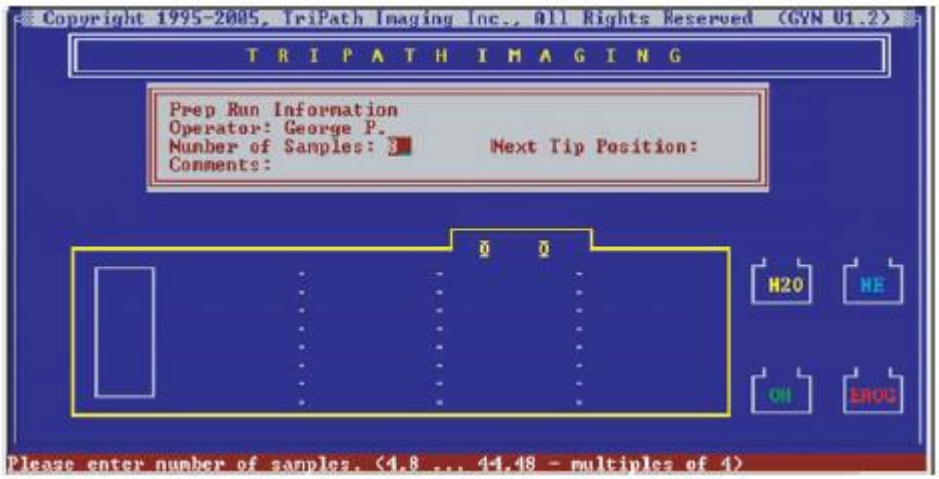
17.Kai PrepStain instrumentas baigia apdorojimą, ekrane pasirodo pranešimas **SAMPLE PREPARATION COMPLETE** ir girdimas aliarmo garsas. Paspauskite bet kurį mygtuką aliarmui nutildyti ir tęskite.
18.Kai baigiate stiklelių paruošimą ir dažymą, Jūs galite tęsti su kita partija, išeiti į DOS, nuvalyti instrumentą arba paprasčiausiai išjungti AK ir PrepStain instrumentą.

Pastaba: jeigu dėl kokios nors priežasties reikia sustabdyti instrumentą, paspauskite mygtuką **F10**. PrepStain instrumentas sustabdys procesą. Norėdami tęsti procesą sekite ekrane pateikiamą informaciją.

Tik Prep

Prieš tai, kai galėsite atlikti šią procedūrą, Jūs pirmiausia turite užbaigti paruošimo procedūras, pateikiamas ***4 skyriuje, Išankstinio apdorojimo žingsniai***. Prieiga prie **SLIDE PREPARATION** proceso suteikiama per GYN versijos tikrinimo ir GYN pagrindinio meniu ekranus. Šie ekranai nurodyti *5-1 iliustracijoje* ir *5-2 iliustracijoje*.

1.GYN taikomoji programa įsijungia automatiškai, kai Jūs paleidžiate BD PrepStain™ instrumento darbo vietą.
Jeigu darbo vieta jau veikia, tačiau GYN taikomoji programa ne:
DOS raginime įveskite **Gyn**, o tada paspauskite **Enter**. Pasirodys GYN versijos tikrinimo ekranas.
2.Meniu pasirinkite **Run Version 1.3.0.3**. Tada paspauskite **Enter**. Tokiu būdu atidarysite GYN pagrindinį meniu. Pagrindinis meniu (*5-2 iliustracija*) suteikia prieigą prie visų programos funkcijų.
3.Pasirinkite **Slide Preparation**, o tada paspauskite **Enter**. Pasirodys PrepStain Run Information ekranas.



5-12 iliustracija: *PrepStain Run Information ekranas*

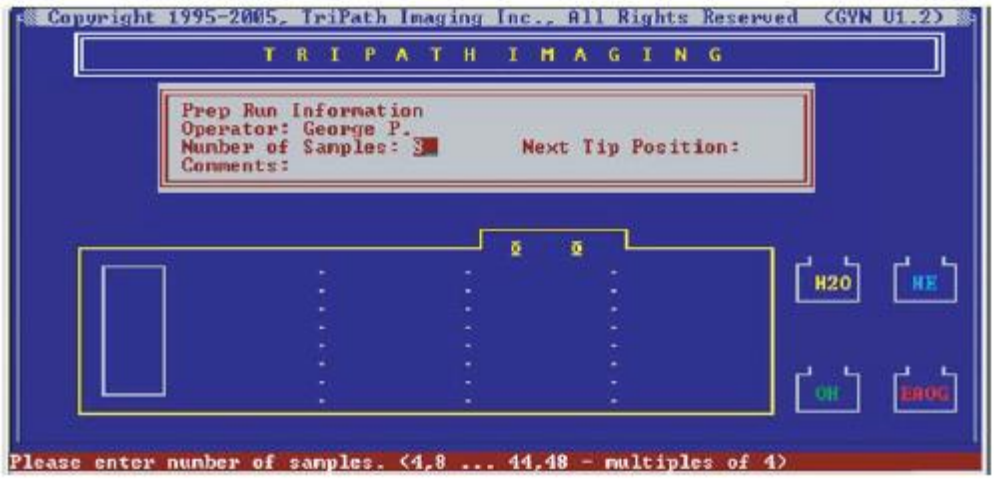
Pastaba: Jūs galite naudoti **Tab** arba **Enter** mygtukus, kad judintumėte žymeklį (naviguotumėte) iš vieno laukelio į kitą PrepStain sistemos ekranuose.

4.Įkraukite mėginius, stiklelius ir BD nusėdimo kameras, o tada patikrinkite reagento lygius. (Prisiminkite, kad nėra būtina sudėti vamzdelius į hematoksilino ir EA/OG reagento talpyklas.)
5.Sekite ekrane pateikiamas instrukcijas.
6.PrepStain instrumentas automatiškai perkels mėginius į atitinkamus stiklelius.
7.PrepStain instrumentas, baigęs apdoroti kiekvieną stovą, skelis aliarmo signalus.

8.Išimkite užbaigtą stiklelio stovą iš instrumento.
9.Apverskite stovą, kad išleistumėte skystį. Kol stovas yra apverstas, lengvai patapšnokite stiklelio stovu ant absorbuojančios medžiagos, kad nusausintumėte alkoholio perteklių iš BD nusėdimo kamerų. Palikite stovą apverstą maždaug vieną minutę, kad nusausintumėte bet kokias likusias skalavimo medžiagas.
10.Atverskite stovą statmenai ir atsargiai po vieną išimkite BD nusėdimo kameras. Nedelsdami sudėkite stiklelius į stovą, įmerktą į 95-100 proc. etanolį.
11.Pakartokite 8-10 žingsnius likusiems stiklelių stovams.
12.Pradėkite dažymo procedūrą.

Stiklelių dažymas

Prieiga prie **SLIDE STAINING** proceso suteikiama per GYN versijos tikrinimo ir GYN pagrindinio meniu ekranus. Šie ekranai nurodyti *5-1 iliustracijoje* ir *5-2 iliustracijoje*.
1.GYN taikomoji programa įsijungia automatiškai, kai Jūs paleidžiate BD PrepStain™ instrumento darbo vietą.
Jeigu darbo vieta jau veikia, tačiau GYN taikomoji programa ne:
DOS raginime įveskite **Gyn**, o tada paspauskite **Enter**. Pasirodys GYN versijos tikrinimo ekranas.
2.Meniu pasirinkite **Run Version 1.3.0.3**. Tada paspauskite **Enter**. Tokiu būdu atidarysite GYN pagrindinį meniu. Pagrindinis meniu (*5-2 iliustracija*) suteikia prieigą prie visų programos funkcijų.
3.Pasirinkite **Slide Staining**, o tada paspauskite **Enter**. Pasirodys PrepStain Run Information ekranas.



5-13 iliustracija: *PrepStain Run Information ekranas*

Pastaba: Jūs galite naudoti **Tab** arba **Enter** mygtukus, kad judintumėte žymeklį (naviguotumėte) iš vieno laukelio į kitą PrepStain sistemos ekranuose.

4.Naviguokite į antrąjį laukelį (praleiskite **OPERATOR** laukelį), įveskite apdorojamą mėginių skaičių ir paspauskite **Enter**. Mėginių skaičius turi būti keturių kartotinis.

Pastaba: Jeigu apdorojamų stiklelių skaičius nesidalina iš keturių, įveskite kitą didesnį keturių kartotinį, o tada pridėkite tuščius stiklelius, BD nusėdimo kameras ir mėgintuvėlius į mėgintuvėlio stovą, kad kompensuotumėte skirtumą.

5.Paspauskite **Enter** (praleiskite laukelį **COMMENTS**)., kad užbaigtumėte procedūrą PrepStain Run Information ekrane.
6.Bus parodytas **Reenter Run Information** raginimas.

- Norėdami pakeisti mėginių skaičių, pasirinkite **Yes**, paspauskite **Enter** ir pakartokite 4 žingsnį.
- Įvesčių patvirtinimui ir perėjimui prie kito žingsnio pasirinkite **No** ir tada paspauskite **Enter**.

7.Pasirodys raginimas **CHANGE SAMPLE/STAIN PARAMETERS**.

5-14 iliustracija: *Change Sample/Stain Parameters meniu*

- Mėginio arba dažymo nustatymų keitimui pasirinkite **Yes**, o tada paspauskite **Enter**. Daugiau informacijos apie šias korekcijas rasite 5-15 puslapyje *Mėginio/dažymo parametrų keitimas*.
- Norėdami naudoti esamus nustatymus ir pereiti prie kito žingsnio pasirinkite **No** ir tada paspauskite **Enter**.

8.Pasirodys **SCAN BARCODES?** meniu.

- Norėdami naudoti brūkšninio kodo skanavimo įrenginį, pasirinkite **Yes**, o tada paspauskite **Enter**. Daugiau informacijos apie šios funkcijos naudojimą rasite 5-18 puslapyje *Brūkšninių kodų skanavimas (laisvai pasirenkama funkcija)*.
- Norint praleisti brūkšninių kodų programą ir pereiti prie kito žingsnio pasirinkite **No** ir tada paspauskite **Enter**.

9.Vakuumo raginimas parodomas ekrane. Taip pat girdimas aliarmo garsas. Paspauskite bet kurį mygtuką aliarmui nutildyti.

10.Įjunkite vakuuminį siurblį, palaukite kelias minutes, kol jis sušils.

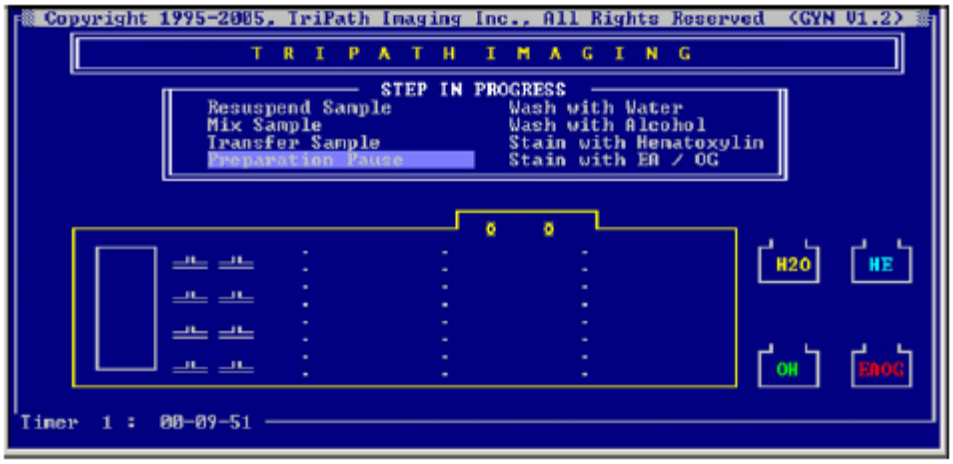
- Jeigu naudojate Schuco siurblį, sureguliuokite slėgį ties 8-10 colių Hg, o tada paspauskite bet kurį mygtuką, kad tęstumėte.
- Jeigu naudojate KNF siurblį, sureguliuokite slėgį ties 5-6 colių Hg (180-220 mBAR), o tada paspauskite bet kurį mygtuką, kad tęstumėte.

11.Pasirodys raginimas **PRIME ALL TUBING?**

- Jeigu tai yra pirmasis dienos prietaiso naudojimas, pasirinkite **Yes**, o tada paspauskite **Enter**, kad užpildytumėte sistemos vamzdelius. Sistema inicializuojasi ir švirkšto siurbliai pumpuoja du pilnus švirkšto tūrius per keturkampės atšakos vamzdelį ir į atliekų stotelę.
- Tolimesniems prietaiso naudojimams per kitas aštuonias valandas pasirinkite **No**, o tada paspauskite **Enter**, kad praleistumėte pilno užpildymo funkciją.
- Prieš kiekvieną prietaiso panaudojimą, vienas švirkšto tūris automatiškai pumpuojamas per vamzdelį, kad užtikrintų, jog sistema užpildyta.

12.Kai užpildymo ciklas baigtas, ekrane pasirodo raginimas **IS THE PREPSTAIN TUBING PRIMED?**

- Norėdami pakartoti užpildymo seką pasirinkite **No**, o tada paspauskite **Enter**.
- Norėdami tęsti su stiklelių ruošimu ir dažymu pasirinkite **Yes**, o tada paspauskite **Enter**. Pasirodys Step in Progress ekranas.



5-15 iliustracija: *Step in Progress ekranas*

Pastaba: 13-15 žingsniai apibūdina stiklelio dažymo procesą. Šios sekos metu rodomas Step in Progress ekranas. Šio ekrano apibūdinimas pateikiamas 5-3 puslapyje *Ekrano Step in Progress detali informacija.* Prisiminkite, kad pirmieji trys sąrašo elementai (Resuspend Sample, Mix Sample ir Transfer Sample) nevyksta stiklelio dažymo sekoje.

13.Dažymas vienu metu atliekamas tik ant vieno stiklelio stovo. Kiekvieno dažymo ciklo metu kiekvienas stiklelis yra iš anksto nuplaunamas atitinkamame reagente (buferizuotas vanduo hematoksilinui, alkoholis EA/OG Combo Stain) ir tada nudažomas. Kiekviena nusėdimo kamera yra pilnai ištuštinama tarp dažymų ir plovimų ciklų. Atlikus dažymą stiklelis plaunamas alkoholiu.
14.Kai visi stikleliai stove yra nudažyti, PrepStain sistema skleidžia garsinį aliarmą ir tada tęsia kito stiklelio stovo dažymą.

a. Kai kiekvienas stiklelio stovas yra baigiamas, išimkite jį iš BD PrepStain™ instrumento ir nupilkite alkoholį iš kiekvienos nusėdimo kameros į tinkamą talpyklą.

Įspėjimas

- Išimdami nusėdimo kamerą, venkite ląstelių apskritimo išmetimo nuo stiklelio.
- Neleiskite stikleliams išdžiūti iki uždengimo dengiamąja plokštele. Kiekvienas stiklelis turi būti uždengiamas po vieną.
- Ilgą laiką paliekant mėginius alkoholyje galite išblukinti ląsteles.

15.Kai PrepStain instrumentas baigia apdorojimą, ekrane pasirodo pranešimas **SAMPLE PREPARATION COMPLETE** ir girdimas aliarmo garsas. Paspauskite bet kurį mygtuką aliarmui nutildyti ir tęskite.
16.Kai baigiate stiklelių paruošimą ir dažymą, Jūs galite tęsti su kita partija, išeiti į DOS, nuvalyti instrumentą arba paprasčiausiai išjungti AK ir PrepStain instrumentą.

Mėginio/dažymo parametrų keitimas

Change Sample.Stain Parameters funkcija suteikia galimybę koreguoti mėginio paėmimo tūrius, dažymo laikus ir ląstelių nusėdimo laikus. Jūs turite galimybę pasiekit šią funkciją atlikdami stiklelių paruošimo ir dažymo, stiklelių paruošimo arba stiklelių dažymo ciklą. Bus parodytas **CHANGE SAMPLE/STAIN PARAMETERS** raginimas. Prisiminkite, kad ši funkcija pasiekiama tik įvedus slaptažodį.

Įspėjimas

Slaptažodis turi būti suteikiamas tik įgaliotiems asmenims.

5-16 iliustracija: *Change Sample/Stain Parameters meniu*

Detali procedūros informacija pateikiama toliau:
1.PrepStain proceso metu, kai specifikuojate mėginių skaičių ir kitą antgalio poziciją, Jūs turite galimybę pakeisti dažymo parametrus. Norėdami pakeisti parametrus, kurie valdo dažymo procesą, ekrane pamačius raginimą pasirinkite **Yes**. Parodomas **PASSWORD** raginimas.
2.Įveskite slaptažodį.
3.Pasirodys Sample/Stain Parameters ekranas (žr. *5-17 iliustraciją*), kur Jūs galite pakeisti parametro nustatymus.

5-17 iliustracija: *Sample/Stain Parameters ekranas*

4.Esamai aktyvus laukelis yra paryškinamas ir pažymimas mirksinčiu žymekliu. Ekrano apatinė eilutė rodo priimtinių verčių intervalą, kai Jūs judate nuo laukelio į laukelį. Naudokite mygtukus **Tab** arba **Enter**, kad naviguotumėte į laukelį, kurį norite pakeisti, ir įveskite naujas vertes. *5-2 lentelėje* pateikiama detali parametrų, kuriuos galite nustatyti šiame ekrane, informacija.

5-2 lentelė. Mėginio ir dažymo parametrų vertės

Parametro pavadinimas	Priimtinos vertės	Apibrėžimas ir numatytosios vertės
RESUSPENSION	**0 – 1000 µl**	Sumaišymo tūris yra buferizuoto dejonizuoto vandens kiekis, įlašinamas į ląstelių gumulėlį. Numatytasis kiekis yra 1000 µl.
MIX	**100 – 500 µl**	Maišymo tūris yra sumaišymo metu pumpuojamo vandens kiekis į ir iš vienkartinio antgalio gumulėlio. Numatytasis tūris yra 500 µl.
SAMPLE	**100 – 500 µl**	Mėginio turis yra perkeliamo mėginio į nusėdimo kamerą kiekis. Numatytasis tūris yra 200 µl.
DILUTION	**0 – 1000 µl**	Skiedimo tūris yra buferizuoto dejonizuoto vandens (pH 7.8-8.5) kiekis, kuris pridedamas prie mėginio tūrio po paskirstymo ant stiklelių. Numatytasis tūris yra 600 µl.
SEDIMENTATION	**0 – 1200 sek.**	Nusėdimo pauzė yra laiko kiekis, kuris suteikiamas ląstelėms nusėsti ant BD SurePath PreCoat stiklelio. Numatytoji trukmė yra 600 sek.
DRYING	**55 – 300 sek.**	Džiovinimo pauzė yra laiko kiekis, suteikiamas ląstelės džiūti ant BD SurePath PreCoat stiklelio. Numatytoji trukmė yra 60 sek.
HEMATOXYLIN	**55 – 180 sek.**	Hematoksilino inkubacija yra laiko trukmė, suteikiama ląstelėms absorbuoti dažus. Numatytoji trukmė yra 85 sek.
EA/OG	**55 – 180 sek.**	EA/OG inkubacija yra laiko trukmė, suteikiama ląstelėms absorbuoti dažus. Numatytoji trukmė yra 75 sek.
MIX	**1 – 15**	Maišymo ciklai yra kartų kiekis, kuriuo atskiestas mėginys yra pumpuojamas į ir iš vienkartinio antgalio ląstelių gumulėlio sumaišymui. Numatytasis kiekis yra 8.
WATER WASH	**1 – 9**	Vandens plovimai yra vandens ciklų kiekis, naudojamas plauti stiklelius atlikus dažymą hematoksilinu. Numatytasis kiekis yra 2 ciklai.
ALCOHOL WASH	**1 – 9**	Alkoholio plovimai yra alkoholio ciklų kiekis, naudojamas plauti stiklelius atlikus dažymą EA/OG. Numatytasis kiekis yra 3 ciklai.

Pastaba: Dešimties (10) arba didesnės įvestys yra atmetamos kaip netinkamas skalavimo ciklų kiekis vandeniui ir alkoholiui, tačiau negirdimas nei garsinis signalas, nei pateikiamas perspėjimas, kuris įspėtų apie netinkamą įvestį. Todėl, įvedus netinkamą vertę, bus priimtas tik pirmasis skaitmuo. Pavyzdžiui, Jums įvedus **10**, instrumentas priima tik **1**, arba įvedus **80**, instrumentas priima tik **8**.
Apribokite įvestis tik rekomenduojamame intervale ir visada patvirtinkite pakeistus parametrus prieš tęsdami ir/arba išsaugodami koreguotus ruošinio parametrus.

5.Kai žymeklis pabuvos kiekviename laukelyje, Jums pateikiamos 4 opcijas, kaip nurodoma *5-18 iliustracijoje*.

5-18 iliustracija: *Pasirinkite išsaugojimo opciją*

- Pasirinkite atitinkamą opciją ir tada paspauskite **Enter**.
- Jeigu pasirenkate vieną iš trijų opcijų, parametrų keitimo procedūra yra pabaigta ir pasirodo pranešimas **SCAN BARCODES**.
- Jeigu pasirenkate ketvirtą opciją, grįšite į ankstesnį žingsnį.

Brūkšninių kodų skanavimas (laisvai pasirenkama funkcija)

Jeigu centrifugos mėgintuvėliams, mėginio buteliukas ir stikleliams naudojamos brūkšninio kodo etiketės, naudokite toliau pateikiamą procedūrą, kad įvestumėte brūkšninio kodo etikečių numerius. Ši opcija suteikia papildomo identifikacinio žingsnio mėginio ruošimo procese priemonę.

1.Norint inicijuoti brūkšninio kodo skanavimo procedūrą, pranešime **SCAN BARCODES** pasirinkite opciją **Yes**.

Pasirodys Scan Barcodes ekranas. Kaip pateikiama *5-19 iliustracijoje*, ekrane yra 24 tušti laukeliai; 12 aktyviam stiklelių stovui ir 12 aktyviam mėgintuvėlių stovui.

5-19 iliustracija: *Scan Barcodes ekranas*

Pastaba: jeigu apdorojate mažiau nei pilną stiklelių stovą, ekrane vis tiek bus rodomi 24 laukeliai (12 pozicijų), tačiau bus aktyvūs tik tie laukeliai, kurie atitiks Jūsų apdorojamą kiekį. T.y. žymeklis praleis neaktyvius laukelius.

2.Naudokite brūkšninio kodo skanavimo įrenginį, kad skanuotumėte etiketę ant kiekvieno stiklelio pirmame stiklelio stove. Kai skanuojate kiekvieną etiketę, žymeklis automatiškai pereina į kitą laukelį.
3.Kai stiklelių stovo etiketės yra nuskanuojamos, žymeklis pereina į mėgintuvėlių stovą. Naudokite brūkšninio kodo skanavimo įrenginį, kad skanuotumėte etiketę ant kiekvieno mėgintuvėlio pirmame mėgintuvėlių stove.

Pastaba: skaičiai ant atitinkamų stiklelių ir centrifugos mėgintuvėlių etikečių turi atitikti. Jeigu yra nukrypimai tarp skaičių, pozicionuokite mėgintuvėlius taip, kad ištaisytumėte atitiktį, ir tada pakartotinai nuskanuokite etiketę (-es), kad išspręstumėte šią neatitiktį. Procesas negali būti tęsiamas tol, kol nebus nuskanuoti tinkamai sudėtų mėgintuvėlių stove etiketės.

4.Kai baigiate etikečių skanavimą pirmame mėgintuvėlių stove, ekranas parodo tuščius laukelius antram stiklelių stovui ir atitinkamam mėgintuvėlių stovui. Kartokite 2-3 žingsnius tiek kartų, kiek turite papildomų stovų. Kai baigiate skanuoti visus stovus, grįžkite į PrepStain apdorojimo procedūrą.

6 skyrius
Priežiūros procedūros

Šiame skyriuje pateikiamos detalios procedūros, kurios reikalingos tinkamai aptarnauti PrepStain sistemą. Tinkama priežiūra būtina BD PrepStain™ stiklelių paruošimo sistemos pastoviam kokybiškų stiklelių ruošimui. Šios informacijos nesilaikymas ilgainiui pablogins instrumento našumą. BD nėra atsakingi, pagal garantiją ar kitus įsipareigojimus, dėl žalos, patirtos nesilaikant šios informacijos.

Reikalingos medžiagos

- Negilus (maždaug 100 ml) indas/talpykla,
- Dejonizuotas (DI) vanduo,
- DI vanduo talpyklos valymui,
- Alkoholis,
- Alkoholis talpyklos valymui,
- Medžiaga be plaušelių,
- Valymo tirpalas,
- Juntamo slopintuvo keitimas.

Kasdieninė prevencinė priežiūra

Kiekvieną dieną arba po aštuonių PrepStain sistemos veikimo valandų (priklausomai kas bus pirmiau) atlikite kasdieninę prevencinę priežiūrą.
Atlikite ***Perform System clean up*** procedūrą taip, kaip nurodoma toliau.

- Įsitikinkite, kad PrepStain sistema yra išjungta.
- Jeigu instrumentas nebus naudojama daugiau nei 8 valandas, palikite sistemą užpildytą dejonizuotu vandeniu. Sudėkite visus paėmimo vamzdelius į dejonizuotą vandenį. Kiti tirpalai gali suformuoti nuosėdas, kurios gali sutrumpinti vamzdelių, vožtuvų ir švirkštų tarnavimo laiką ir paveikti instrumento tikslumą.
- Išimkite stovus iš instrumento paviršiaus. Atidžiai valykite ir sausinkite darbinį paviršių su minkštą šluoste ir valymo tirpalu.
- Ištuštinkite antgalių išmetimo talpyklą į atitinkamą biologiškai pavojingų medžiagų konteinerį.
- Patikrinkite visus švirkštus ir vamzdelius dėl pratekėjimų.
- Jeigu reikia, ištuštinkite vakuumo atliekų talpyklą.
- Nuvalykite pipečių paketus švaria medžiaga be plaušelių.
- Nuvalykite DiTi kūgį švaria medžiaga be plaušelių.
- Nuvalykite stovus ir darbinio stalo paviršių valymo tirpalu.

Sistemos valymo atlikimas

Prieiga prie sistemos valymo procedūros atliekama per GYN arba NonGYN taikomąsias programas.
1.Kaip nurodyta ankstesniame puslapyje, turėkite pasiruošę valymo vandens ir alkoholio atitinkamuose buteliuose. Neišimkite vamzdelių iš reagentų butelių tol, kol ekrane nebus nurodyta tai atlikti.
2.GYN taikomoji programa įsijungia automatiškai, kai Jūs paleidžiate BD PrepStain™ instrumento darbo vietą.
Jeigu darbo vieta jau veikia, tačiau GYN taikomoji programa ne:
DOS raginime įveskite **Gyn**, o tada paspauskite **Enter**. Pasirodys GYN versijos tikrinimo ekranas.
3.Meniu pasirinkite **Run Version 1.3.0.3**. Tada paspauskite **Enter**. Tokiu būdu atidarysite GYN pagrindinį meniu. Pagrindinis meniu (*5-2 iliustracija*) suteikia prieigą prie visų programos funkcijų.
4.Pasirinkite **Clean Up System**, o tada paspauskite **Enter**. PrepStain instrumentas inicializuosis ir grąžins visus reagentus iš linijų į atitinkamas reagentų talpyklas.
Raginimo linijoje pamatysite:
PLEASE WAIT FOR BACK FLUSHING TO COMPLETE.
Atlikus šį žingsnį AK darbo vietas skleis garsinį aliarmą.
5.Paspauskite bet kurį mygtuką, kad nutildytumėte aliarmą.
Raginimo linijoje pamatysite:
BACK FLUSHING COMPLETE. PRESS ANY KEY TO CONTINUE CLEAN UP.
6.Įdėkite hematoksilino liniją į valymo vandenį ir EA/OG liniją į valymo alkoholį. Paspauskite bet kurį mygtuką, kad tęstumėte.
Raginimo linijoje pamatysite:
PLEASE WAIT FOR STAIN LINE CLEANING TO COMPLETE.
7.PrepStain instrumentas skalauja kiekvieną dažo liniją su atitinkamu tirpikliu, o tada išskleidžia garsinį signalą.
8.Paspauskite bet kurį mygtuką, kad nutildytumėte aliarmą.
Raginimo linijoje pamatysite:
RINSING COMPLETE, PRESS ANY KEY TO CONTINUE CLEAN UP.
Sudėkite abi EA/OG ir alkoholio linijas į DI vandenį. Paspauskite bet kurį mygtuką, kad tęstumėte.
Raginimo linijoje pamatysite:
PLEASE WAIT FOR LINES TO FILL WITH DI WATER.
9.PrepStain instrumentas skalauja vamzdelius ir susijusius švirkštus vandeniu. Kai skalavimas baigtas, visi vamzdeliai užpildyti dejonizuotu vandeniu.
10.Naudokite adatą, kad valytumėte vakuuminių antgalių vidų.

11.AK darbo vieta skleidžia garsinį aliarmą ir ragina Jus laikyti DI vandens talpyklą po kiekvienu pipetės paketu ant keturkampės atšakos, kad skalauti vakuumines linijas. Paspauskite bet kurį mygtuką, kad nutildytumėte aliarmą, ir tada naudokite mažą talpyklą (maždaug 100 ml), kad skalautumėte vakuumines linijas maždaug 10 sekundžių.
Raginimo linijoje pamatysite:
PRESS ANY KEY TO RETURN TO MAIN MENU.
12.Kai baigiate skalauti pipetės paketus, paspauskite bet kurį mygtuką, kad grįžtumėte į pagrindinį meniu.
13.Išjunkite BD PrepStain™ sistemą ir vakuuminį siurblį.
14.Valykite pipetės paketus su medžiaga be plaušelių.
15.Valykite DiTi kūgį ir suimamą antgalį su medžiaga be plaušelių.

- Pakelkite plastikinė įvorę, kad pamatytumėte DiTi kūgį ir suimamą antgalį.
- Naudokite medžiagą be plaušelių, kad atsargiai valytumėte DiTi kūgį ir suimamą antgalį tik judesiu žemyn.

Tai užbaigia sistemos valymo procedūrą.

Kas savaitinė prevencinė priežiūra

Atlikite kas savaitinę prevencinę priežiūrą kiekvienos savaitės pabaigoje arba po 40 valandų veikimo. Šiai procedūrai atlikti reikalingos medžiagos nurodomos toliau.

- DI vanduo (mažiausiai 1 litras),
- 5 proc. valymo tirpalas (mažiausiai 1 litras),
- 4L talpykla su dangteliu.

Kas savaitinę priežiūrą sudaro toliau nurodytos procedūros:

- Dažymo ir vakuuminių linijų skalavimas valymo tirpalu,
- Z strypo valymas,
- Atliekų talpyklos ištuštinimas,
- Vamzdelių jungčių ir švirkštų tikrinimas dėl sandarumo,
- XYZ testas.

5 proc. valymo tirpalo paruošimas

1.Pripilkite 180 ml Contrad 70, Decon 90 arba baliklio į 1 galono talpyklą.
2.Pripilkite 4L talpyklą 3600 ml DI arba distiliuoto vandens.
3.Uždarykite ir švelniai vartykite, kad sumaišytumėte.

Dažymo ir vakuumo linijų skalavimas

Ši procedūra skalauja dažymo ir vakuumo linijas su 5 proc. valymo tirpalu, o tada jas skalauja vandeniu. BD PrepStain™ instrumento pagalbinė programa automatizuoja šį procesą.
1.Paruoškite butelius su valymo tirpalu iš šviežiu DI vandeniu skalavimui atlikti.

2.GYN taikomoji programa paleidžiama automatiškai, kai įjungiate PrepStain instrumento darbo vietą. Uždarykite šią taikomąją programą, kad gautumėte prieigą prie DOS, kur matytumėte PrepStain Utilities Version Check ekraną (*6-1 iliustracija*). Šis ekranas suteikia prieigą prie valymo proceso.

- Jeigu darbo vieta veikia GYN taikomojoje programoje, pasirinkite **Quit**, kad atidarytumėte DOS langą. Įveskite **UTIL**, o tada paspauskite **Enter**. Pasirodys PrepStain Utilities Version Check ekranas.
- Jeigu darbo vieta jau rodo DOS langą, įveskite **UTIL**, o tada paspauskite **Enter**. Pasirodys PrepStain meniu.

6-1 iliustracija: *pagalbinis meniu*

3.Jeigu neįjungtas, įjunkite vakuuminį siurblį. PrepStain Utilities meniu pasirinkite **Run Utility Version 1.1** ir paspauskite **Enter**.
Pasirodys Utilities meniu.
4.Pasirinkite **FLUSH TUBING WITH CLEANING SOLUTION**, o tada paspauskite **Enter**. PrepStain instrumentas inicializuosis; tada apatinėje eilutėje pasirodys pranešimas:
PLACE ALL REAGENT INTAKE TUBING INTO CLEANING SOLUTION. PRESS ANY KEY TO BEGIN FLUSHING PREP.
5.Sudėkite visas keturias linijas į valymo tirpalo talpyklą, o tada paspauskite bet kurį mygtuką, kad tęstumėte.
PrepStain instrumentas inicializuosis, o tada skalaus paėmimo vamzdelius valymo tirpalu.
Apatinėje eilutėje pasirodys pranešimas:
PLEASE WAIT FOR CLEANING SOLUTION FLUSH TO FINISH.
6.Kai skalavimas baigtas, AK darbo vieta skleis garsinį signalą ir paragins Jus paspausti bet kurį mygtuką, kad nutildytumėte aliarmą.
7.Paspauskite bet kurį mygtuką, kad nutildytumėte aliarmą.
Apatinėje eilutėje pasirodys pranešimas:
PLACE ALL REAGENT INTAKE TUBING INTO FRESH, CLEAN DI WATER. PRESS ANY KEY TO BEGIN.

8.Perkelkite visas keturias linijas į DI vandens talpyklą ir paspauskite bet kurį mygtuką.
BD PrepStain™ instrumentas skalauja visas keturias linijas su DI vandeniu. Apatinėje eilutėje pasirodys pranešimas:
PLEASE WAIT FOR DI WATER FLUSH TO FINISH.
9.Kai skalavimas baigtas, AK darbo vieta skleis garsinį signalą ir paragins Jus paspausti bet kurį mygtuką, kad nutildytumėte aliarmą:
CLEAN UP COMPLETE, PRESS ANY KEY TO SILENCE ALARM.
10.Paspauskite bet kurį mygtuką, kad nutildytumėte aliarmą, o tada laikykite mažą valymo tirpalo talpyklą po kiekvienu vakuuminiu antgaliu maždaug 10 sekundžių, kad skalautumėte vakuumines linijas su valymo tirpalu.
11.Skalaukite kiekvieną vakuuminę liniją laikydami mažą DI vandens talpyklą po kiekvienu vakuuminiu antgaliu maždaug 10 sekundžių.
Apatinėje eilutėje pasirodys pranešimas:
CLEAN UP COMPLETE, PRESS ANY KEY TO RETURN TO THE UTILITY MENU.
12.Kai baigiate pipetės paketo skalavimą, nuvalykite pipetės paketus švaria medžiaga be plaušelių ir paspauskite bet kurį mygtuką, kad grįžtumėte į pagrindinį meniu.
13.Išjunkite vakuuminį siurblį. Tai užbaigia dažymo ir vakuuminių linijų skalavimo procedūrą.

Z strypo valymas

Valykite Z strypą su audiniu be plaušelių. Nenaudokite alyvos ar tirpiklių Z strypui valyti.

Gravitacijos ir atliekų talpyklų ištuštinimas

Priklausomai nuo laboratorijos dydžio, tai daryti gali reikėti ir kiekvieną dieną.
Ištuštinkite vakuuminių ir gravitacijos atliekų talpyklas į atitinkamus biologiškai pavojingų atliekų konteinerius.

> **Pastaba:** kai pakartotinai prijungiate atliekų butelį, įsitikinkite, kad vakuuminės žarnelės yra tinkamai prijungtos, o dangtelis sandariai uždarytas.

Prevencinė priežiūra

Kiekvieną savaitę atlikite atsitiktinį X, Y, Z testą. Daugiau informacijos rasite ***9 skyriuje Nustatymas ir diagnostikos***.
BD PrepStain™ stiklelių paruošimo sistema neturi būti naudojama pacientų mėginių ruošimui, jeigu praėjo daugiau nei savaitė nuo paskutinio sėkmingai atlikto XYZ testo. Nepatvirtinę tinkamo judesio kontrolės funkcionavimo šiuo testu galite priversti įrangą netinkamai paskirstyti paciento mėginį.
Tai užbaigia savaitinį valymo procesą.

Kas mėnesinė prevencinė priežiūra

Kas mėnesį atlikite šią prevencinę priežiūrą.

Schuco vakuuminio siurblio juntamo slopintuvo keitimas

Pastaba: šis skyrius taikomas tik mėlynam Schuco siurbliui.

Norint pakeisti juntamą slopintuvą vakuuminiame siurblyje:
1.Vakuumo siurblyje raskite chromuotą oro išmetimo angą.
2.Atsukite išmetimo montažą.
3.Pakeiskite juntamo slopintuvo padelį.
4.Uždėkite išmetimo montažą.

Visų vandens butelių ir vamzdelių valymas

Naudodami 5 proc. baliklį arba Contrad 70, arba Decon 90 tirpalą, valykite visus vandens butelius. Skalaukite visus butelius, kol pašalinsite valymo tirpalą, su šiltu vandeniu iš čiaupo, o tada skalaukite su DI vandeniu. Naudodami ~100 ml gryno baliklio, valykite vakuumo butelį; pripilkite vandens ir leiskite pastovėti, kol bus švarus. Skalaukite vandeniu iš čiaupo.
Tai užbaigia kas mėnesinį valymo procesą.

BD PrepStain™ stiklelių paruošimo sistemos priežiūros įrašai

Skyrius: _____ Mėnuo: _____
Serijinis nr.: _____
Prašome užpildyti kiekvieną laukelį. Jeigu nustatote problemą, imkitės reikalingų veiksmų jai išspręsti. Kitai pagalbai gauti skambinkite BD techninei pagalbai telefonu: 1-800-638-8663.

Kasdien	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Atlikite sistemos valymą																															
Palikite vamzdelius DI vandenyje per naktį																															
Ištuštinkite antgalių išmetimo ir atliekų konteinerius																															
Patikrinkite švirkštus ir vamzdelius dėl pratekėjimo																															
Valykite pipetės paketus ir DiTi kūgį																															
Nuvalykite stovus ir darbo stalo paviršių valymo tirpalu																															
Naudokite adatą, kad valytumėte vakuuminių antgalių vidų																															

Kiekvienos procedūros žingsniai pateikti ankstesniuose šio skyriaus skyreliuose.

Kas savaitę	**1 savaitė (/ /)**	**2 savaitė (/ /)**	**3 savaitė (/ /)**	**4 savaitė (/ /)**	**5 savaitė (/ /)**
Pagalbinės programos naudojimas skalavimo procedūrai					
Z strypo valymas su audiniu be plaušelių					
Atsitiktinio X, Y, Z testo atlikimas					
Ištuštinkite vakuumo ir gravitacijos atliekų talpyklas (pagal poreikį, priklausomai nuo laboratorijos dydžio gali reikėti atlikti kasdien)					
Patikrinkite vamzdelių jungtis ir švirkštus dėl sandarumo					

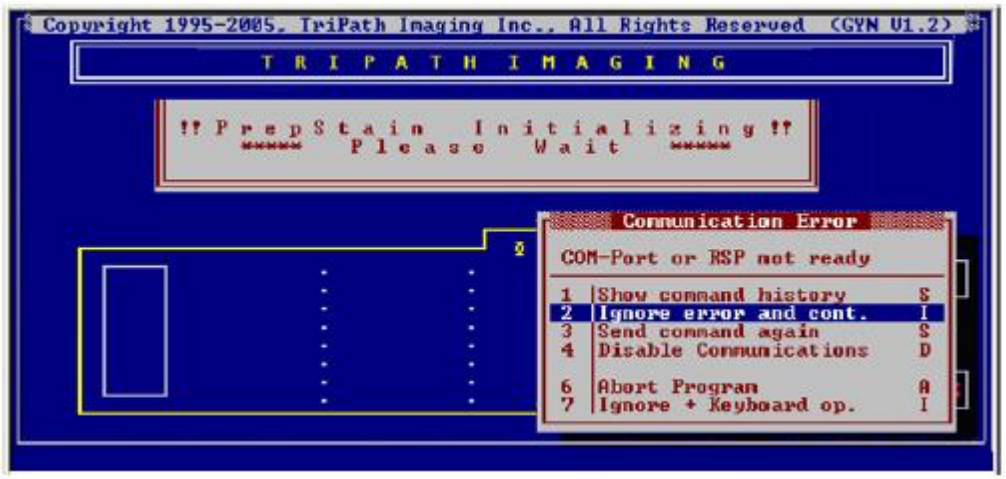
Kas mėnesį	**(/ /)**
Juntamo slopintuvo ir filtro keitimas (jeigu yra) vakuuminiame siurblyje	
Atliekų butelių keitimas arba valymas su dezinfekuojančiu tirpalu	
Vamzdelių valymas su dezinfekavimo tirpalu naudojant pagalbinę programinę įrangą	

7 skyrius
Trikčių šalinimas

Šiame skyriuje pateikiamos procedūros, kurias galite naudoti, kad izoliuotumėte ir išspręstumėte problemas su BD PrepStain™ stiklelių paruošimo sistema.
Naudodami šiame skyriuje esančią informaciją galite ištaisyti daugumą darbinių problemų, su kuriomis gali susidurti PrepStain sistema. Pasižymėdami klaidos kodą ir pranešimą, kurie pasirodo kompiuterio ekrane, ir naudodami problemų ir sprendimų lentelę Jūs galite patys išspręsti daugumą problemų. Skambindami BD techninei pagalbai nurodykite tikslią problemą, įskaitant klaidos kodo informaciją ir sprendimo veiksmus, kuriuos bandėte atlikti. BD techninės pagalbos telefonas: 800-638-8663, arba susisiekite su vietiniu BD atstovu.

Klaidų kodai ir pranešimai

PrepStain instrumentas gali aptikti įvairias klaidas. Kai viena iš šių klaidų aptinkama, AK vaizduoklio ekranas parodo klaidos pranešimą, kaip pateikiama *7-1 iliustracijoje*.



7-1 iliustracija: *klaidos pranešimas ekrane*

Toliau pateiktoje lentelėje rasite klaidų kodų, kurie gali būti rodomi, santrauką. Jeigu rodomas vienas iš šių kodų, pasižymėkite jį ir kreipkitės į BD techninę pagalbą.

Bendrų klaidų pranešimų kodai

***7-1 lentelė**. Bendrų klaidų pranešimų kodai*

Kodo nr.	Pranešimas
1	Initialization Error
2	Invalid Command
3	Invalid Operand
4	Invalid Command Sequence
5	Device Not Implemented
6	Time-out Error
7	Device Not Initialized
8	Command Overflow
9	Plunger Overload/No Liquid Detected
10	Valve Blocked/Z-position Overrun
11	Not Enough For Liquid Sampling
12	No Liquid Detected
13	Not Enough Liquid Detected
17	Arm Collision Avoided
20	Step loss detected on X-axis
21	Step loss detected on Y-axis
22	Step loss detected on Z-axis
24	ALIDUM pulse time out

Švirkšto pompos klaidų atvejai

Toliau nurodyti klaidos kodai gali būti sužadinami švirkšto pompų. Jeigu rodomas vienas iš šių kodų, pasižymėkite jį ir kreipkitės į BD techninę pagalbą.

***7-2 lentelė**. Švirkšto pompos klaidų atvejai*

Kodo nr.	Galimos priežastys
1	Sugedęs skiedimo įrenginio vožtuvas Sugedęs švirkštas Vožtuvo pavaros gedimas Stūmoklio gedimas
2	Programinės įrangos problemos Netinkama eilutės komanda
3	Netinkamas nustatymas Programos problema Netinkamas operacijos komponentas eilutės komandoje

***7-2 lentelė**. Švirkšto pompos klaidų atvejai (tęsinys)*

Kodo nr.	Galimos priežastys
4	Programinės įrangos problema
5	Skiedimo įrenginio gedimas CPU87 gedimas
6	Nusidėvėjęs vožtuvas Skiedimo įrenginio gedimas
7	Prietaisas neinicializuotas Skiedimo įrenginio gedimas
8	Vienoje eilutėje naudojama per daug komandų
9	Švirkštas pernelyg sandarus Vožtuvas užsikišęs Skiedimo įrenginio greitis pernelyg didelis Skiedimo įrenginio gedimas
10	Inicializacijos klaida

Robotizuotos atšakos klaidų kodai

Toliau pateiktus klaidų kodus gali sužadinti problemos su robotizuota atšaka. Jeigu rodomas vienas iš šių kodų, žr. *Klaviatūros inicializacija atšakos klaidoms*. Daugiau informacijos gausite iš BD techninės pagalbos nurodydami jiems klaidos kodą.

***7-3 lentelė**. Robotizuotos atšakos klaidų kodai*

Kodo nr.	Galimos priežastys
1	Netinkamas nustatymas Atšaka užblokuota
2	Programinės įrangos problema
3	Netinkamas nustatymas Programinės įrangos problema
4	Programinės įrangos problema
7	Prietaisas neinicializuotas
8	Vienoje eilutėje naudojama per daug komandų
9	Švirkštas pernelyg sandarus Vožtuvas užsikišęs Skiedimo įrenginio greitis pernelyg didelis Skiedimo įrenginio gedimas
17	Atšaka neinicializuota
21	Aptiktas X žingsnio praradimas
22	Aptiktas Y žingsnio praradimas
23	Aptiktas Z žingsnio praradimas
24	ALIDUM jungties arba ADRI plokštės gedimas

Klaviatūros inicializacija atšakos klaidoms
1.Pasirinkite opciją **IGNORE + KEYBOARD OP.** Žr. 7-1 iliustraciją 7 opciją sąraše (ne visada gali būti 7 opcija).
2.Atsidarys naujas langas. **COMMAND** eilutėje įveskite **LOAD** ir paspauskite **Enter**.
3.Atsidarys naujas langas. Iššokančiame lauke pasirinkite **APS LIQUID SYS**.
4.Kitoje **COMMAND** eilutėje įveskite **SETUP** ir paspauskite **Enter**.
5. Kitoje **COMMAND** eilutėje paspauskite mygtuką **F8** ir įveskite **PI** (ekrane pasirodys **#18PI**). Paspauskite **Enter** atšakos atstatymui.
6.Paspauskite mygtuką **Esc**, kad tęstumėte procedūrą nuo ten, kur įvyko klaida.

Problemos ir sprendimai

Toliau pateikiamoje lentelėje rasite situacijas, kurios gali įvykti apdorojant su BD PrepStain™ instrumentu. Jeigu įvyko viena iš šių problemų, pabandykite išspręsti ją patys. Tokiu būdu sutaupysite savo laiko. Jeigu to padaryti nepavyksta, kreipkitės į BD techninę pagalbą.

7-4 lentelė. *Trikčių šalinimo pasiūlymai*

Simptomas	Galima priežastis	Taisymo veiksmų seka
Visos BD nusėdimo kameros neišsituština	• Neįjungtas vakuuminis siurblys.	Įjunkite vakuuminį siurblį.
	• Vakuumo atliekų butelio dangtelis atsisukęs.	1.Jeigu nesenai pakeitėte vakuumo atliekų butelį, įsitikinkite, kad tinkamai uždėjote dangtelį. 2.Patikrinkite, ar visos vamzdelių jungtys tinkamai prijungtos.
	• Vakuumo slėgis pernelyg žemas.	1.Patikrinkite visas vakuumo montažo jungtis. Reguliuokite vakuumo slėgį iki 8-10 inHg Schuco siurbliui ar 5-6 inHg (180-220 mBar) KNF siurbliui. 2.Kreipkitės į BD techninę pagalbą.
	• Vakuumo linija užsikišo.	1.Izoliuokite vakuumo liniją, kuri kelia problemas. 2.Naudokite adatą, kad atkištumėte vakuumo linija. 3.Jeigu užsikišimo pašalinti nepavyksta, kreipkitės į BD techninę pagalbą.
	• Atliekų montažas yra užsikišęs.	Kreipkitės į BD techninę pagalbą.

7-4 lentelė. *Trikčių šalinimo pasiūlymai (tęsinys)*

Simptomas	Galima priežastis	Taisymo veiksmų seka
Makroskopiškai matomos skylės stiklelyje	• Vakuumo paketas liečia stiklelio paviršių.	Kreipkitės į BD techninę pagalbą.
	• Vakuumo slėgis yra pernelyg didelis.	Reguliuokite vakuumo slėgį iki 8-10 inHg Schuco siurbliui ar 5-6 inHg (180-220 mBar) KNF siurbliui.
Lašai susiformuoja DiTi antgalio galiuke arba pipetės dažymo pakete		1.Priveržkite visas skysčių jungtis. 2.Jeigu oras matomas vamzdelyje, priveržkite vamzdelių jungtis. 3.Priveržkite švirkšto jungtį. 4.Kreipkitės į BD techninę pagalbą.
Nepavyksta paimti antgalio		Kreipkitės į BD techninę pagalbą.
Pernelyg mažai ląstelių	Pasibaigęs Tris buferizuoto vandens galiojimo laikas.	Pagaminkite naują Tris buferizuoto vandens partiją.
	BD SurePath PreCoat stikleliai nebuvo naudojami.	Naudokite tik BD SurePath PreCoat stiklelius optimaliems rezultatams gauti.
	Mėginiui fiksuoti naudojama netinkama fiksacinė medžiaga.	Optimaliems rezultatams gauti naudokite BD SurePath Preservative Fluid.
	Vakuumo slėgis pernelyg didelis.	Reguliuokite vakuumo slėgį iki 8-10 inHg Schuco siurbliui ar 5-6 inHg (180-220 mBar) KNF siurbliui.
	BD SurePath PreCoat stiklelių galiojimo laikas pasibaigęs.	Išmeskite pasibaigusio galiojimo BD SurePath PreCoat stiklelius. Naudokite tik BD SurePath PreCoat stiklelius, kurių galiojimo laikas nepasibaigęs.
Branduolys yra per tamsus	Mėginiui fiksuoti naudojama netinkama fiksacinė medžiaga.	Optimaliems rezultatams gauti naudokite BD SurePath Preservative Fluid.
	Hematokslino dažymo laikas pernelyg ilgas.	Sumažinkite dažymo laiko sekundes.
	Džiovinimo artefaktai.	Nusėdimo kamera buvo išimta ir ląstelių paviršius išdžiuvo prieš montavimo terpės ir dengiamosios stiklinės plokštelės uždėjimą.
Obstrukcija	Vienas iš vakuumo antgalių užsikišo.	1.Izoliuokite vakuumo antgalį, kuris sukelia obstrukciją. 2.Naudokite adatą, kad atkištumėte vakuumo antgalį. 3.Valykite antgalio išorinę dalį su alkoholine šluoste. 4.Jeigu obstrukcijos pašalinti nepavyksta, kreipkitės į BD techninę pagalbą.

7-4 lentelė. *Trikčių šalinimo pasiūlymai (tęsinys)*

Simptomas	Galima priežastis	Taisymo veiksmų seka
Viena nusėdimo kamera neišsituština	Vakuumo linija nušovė nuo dažymo paketo.	Pakeiskite liniją ir tada skambinkite BD techninei pagalbai
	Tai įprastai sukeliama užsikišimu vakuumo pipetėje.	1.Izoliuokite vakuumo pipetę, kuri sukelia obstrukciją. 2.Naudokite adatą, kad atkištumėte vakuumo pipetę. 3.Valykite pipetės išorinę dalį su alkoholine šluoste. 4.Jeigu obstrukcijos pašalinti nepavyksta, kreipkitės į BD techninę pagalbą.
Viena nusėdimo kamera neužsipildo	Tai sukelia užsikišimas montaže arba paskirstymo pipetėje.	1.Izoliuokite montažą arba pipetę, kuri sukelia obstrukciją. 2.Naudokite adatą, kad atkištumėte. 3.Valykite montažo arba pipetės išorinę dalį su alkoholine šluoste. 4.Jeigu obstrukcijos pašalinti nepavyksta, kreipkitės į BD techninę pagalbą.
Rožiniai taškai	Stiklelio keturkampės atšakos Z maks. pernelyg aukštas.	Dėl sureguliavimo kreipkitės į BD techninę pagalbą.
	Paskirstymo antgaliai laša.	Patikrinkite visas vamzdelių jungtis.
Pipetės antgaliai nepataiko į tikslą		1.Patikrinkite, ar stiklelio stovas tinkamai įstatytas darbiniame stale ir, jeigu reikia, sureguliuokite. 2.Kreipkitės į BD techninę pagalbą. 3.Atlikite **Slide Preparation and Staining** arba **Slide Preparation** ir patvirtinkite, kad pipetės antgalis yra paimtas.
Dauguma ląstelių yra už 13 mm apskritimo krašto	Naudojama netinkama fiksacinė medžiaga. Tik ne GYN.	Optimaliems rezultatams naudokite BD SurePath Preservative Fluid.
	Nusėdimo kameros nėra sandarios ant stiklelio.	Naudokite tik BD SurePath PreCoat stiklelius ir pakartotinai nenaudokite nusėdimo kamerų.
	BD SurePath PreCoat stikleliai nebuvo naudojami.	Naudokite tik BD SurePath PreCoat stiklelius.
	Z paskirstymo nustatymas yra neteisingas.	Kreipkitės į BD techninę pagalbą.
	Pipetės paketo pozicija yra neteisinga.	Kreipkitės į BD techninę pagalbą.
Dažymo kokybė nepastovi	Viena iš pipečių pipetės pakete yra užsikišusi.	1.Izoliuokite pipetę, kuri sukelia obstrukciją. 2.Naudokite adatą, kad atkištumėte pipetę. 3.Valykite pipetės išorinę dalį su alkoholine šluoste. 4.Jeigu obstrukcijos pašalinti nepavyksta, kreipkitės į BD techninę pagalbą.
	Vienas arba keli reagentų butelių lygis pernelyg žemas.	Patikrinkite visų reagentų butelių lygius prieš pradėdami stiklelio paruošimą.
Dažymo nutraukimai		Išimkite dalinai nudažytą stovą. Kadangi sistema dažo vieną stovą vienu metu, turi būti tik vienas toks stovas.

7-4 lentelė. *Trikčių šalinimo pasiūlymai (tęsinys)*

Simptomas	Galima priežastis	Taisymo veiksmų seka
Antgalis nėra išmetamas		Kreipkitės į BD techninę pagalbą.
Antgalis iškrenta transportavimo metu		Kreipkitės į BD techninę pagalbą.
Perkėlimo nutraukimai		1.Išimkite centrifugos mėgintuvėlius, kurie turi mėginį, kuris nebuvo perkeltas. 2.Pakeiskite „senus“ stiklelius (stikleliai viršija kitą didžiausią keturių kartotinį). 3.Palaukite dešimt minučių, kol visos ląstelės nusės ant stiklelio. 4.Pasirinkite Slide Staining ir tęskite mėginių perkėlimą. 5.Pakeiskite mėginius, kurie neperkelti ant PrepStain padėklų. 6.Pakeiskite ištirpinimo tūrį į 10 µl. Žr. 5-15 puslapį *Mėginio/dažymo parametrų keitimas*. 7.Šiems mėginiams atlikite **Slide Preparation and Staining**. Sudėkite tuščius stiklelius ir BD nusėdimo kameras nelyginėse stiklelių vietose.
Skiriasi skirstomo reagento tūris		1.Jeigu oras matomas vamzdelyje, priveržkite vamzdelių jungtis. 2.Patikrinkite lygius reagentų talpyklose. 3.Kreipkitės į BD techninę pagalbą.

8 skyrius
Terminų žodynėlis

Remkitės toliau pateikiamais apibūdinimais, kurie nurodo mechaninius komponentus, sudarančius BD PrepStain™ stiklelių paruošimo sistemą, ir terminais, naudojamais procese.

Terminas	**Apibūdinimas/funkcija**
Brūkšninio kodo skanavimo įrenginys	• Tik opcija. • Skanuoja ir nuskaito etiketes su brūkšniniais kodais. • Naudojamas patvirtinti stiklelio ir mėgintuvėlio poziciją; t.y. jis neįveda paciento informacijos.
Pagrindinis įrenginys	• Robotizuotas mėginio apdorojimo įrenginys • Mikroprocesoriumi valdomų skysčio tvarkymo komponentų sistema.
BD EA/OG	• Vienas citoplazminių Papanicolaou dažų komponentas. • Mišinys turi modifikuoto Eosin-50 ir Orange G.
BD hematoksilino dažas	• Sukurtas specialiai PrepStain instrumentui. • Suderinamas naudojimui su stikleliais, kurie turi būti paruošiami ant FocalPoint stiklelio profiliavimo.
BD nusėdimo kameros	• Prisukamas ant stiklelio stiklelių stove. • Apdorojimo metu laiko mėginius ir kitus skysčius.
BD SurePath konservanto skystis	• Patentuotas skystis, naudojamas surinkti ir konservuoti ginekologinius mėginius.
Centrifugavimas	• Procesas, kurio metu išcentrinės jėgos pagalba atskiriami skysčiai ir kietosios dalys.
Centrifuga	• PrepStain atliekų stotelė ir PrepMate mėginio stovas sukurti tikti į centrifugos indelių formą.
Centrifugos indų dangčiai	• Apsauginis dangtis, kuris užsideda ant mažo centrifugos indo viršaus, kad centrifugavimo metu būtų išvengta išsiliejimų arba aerozolių susidarymo.

Terminas	**Apibūdinimas/funkcija**
Kompiuteris (CPU)	• Techninis komponentas, kuriame saugomos programinės įrangos taikomosios programos (programos) ir duomenys.
Kompiuterio vaizduoklis	• Vaizduoklis, kuris rodo programos ekranus, kurie padeda vartotojui naudotis taikomąja programa.
Dekantavimas (išleidimas)	• Paviršiuje plūduriuojančio skysčio išpylimas.
DiTi (vienkartinio antgalio) montažas	• Plastikinė pipetė, kuri naudojama maišyti ir paskirstyti ląstelių tirpalą ant objektinio stiklelio.
Easy Aspirator	• 12 pozicijų blokas, prijungtas prie vakuuminio siurblio, naudojamas aspiruoti skystį iš centrifugos mėgintuvėlių. • Naudojami vienkartiniai pipetės antgaliai.
Mikroskopo stikleliai	• Skaidrūs stikliai nurodyto dydžio stikleliai ir iš anksto padengti didelio molekulinio svorio katijonine plėvele. Naudoja prekės ženklą, žinomą kaip BD SurePath PreCoat stikleliai. • Ląstelių mėginiai yra paskirstomi ant stiklelio paviršiaus.
Montavimo terpė	• Tolueno arba ksileno pagrindo tirpalas, naudojamas prilipinti dengiamąją plokštelę ant mikroskopo objektinio stiklelio.
Pipetės paketas	• Sumontuotas ant keturkampės atšakos. • Sudarytas iš keturių paskirstymo antgalių, sumontuotų apie didesnį vakuuminį antgalį. • Paskirsto dažus, alkoholį ir vandenį.
Keturkampė atšaka	• Pipetės paketų, vamzdelių ir montažų, įdiegtų ant BD PrepStain™ stiklelių paruošimo sistemos sistema. • Vienu metu ant keturių mėginių leidžia atlikti dažymo procedūrą. • Reagentai paskirstomi per keturias pipetes, o atliekos pašalinamos per vakuuminę pipetę. • Gali judėti dėka keturkampio sujungimo rakto ant Z strypo rankenos. Žr. *1-14 iliustraciją*.
Keturkampis sujungimo raktas	• Sukabina keturkampę rankeną.
Keturkampis montažas	• Keturi plastikiniai korpusai, sumontuoti ant keturkampės atšakos. • Vamzdelis iš švirkšt į pipetės paketus.

Terminas	Apibūdinimas/funkcija
Stiklelio stovas	• Metalinis stovas, pagamintas su dvylika kvadratinių išpjovų, sukurtų specialiai mikroskopo stiklelių laikymui. • Kiekviena išpjova turi bėgelį, kuris naudojamas nusėdimo kameros laikymui ant stiklelio paviršiaus. • Keturi stovai tvirtinami ant darbinės BD PrepStain™ stiklelio paruošimo sistemos platformos. • Laiko iki 12 stiklinių stiklelių 4x3 matricoje.
Tirpikliui atsparus žymeklis	• Rašiklis/žymeklis su rašalu, kuris neištirpsta alkoholyje, vandenyje arba ksilene/ksileno pakaitale.
Švirkšto pompa	• Mikroprocesoriumi valdoma pompa su švirkštu ir 2 krypčių vožtuvu.
Švirkštai	• Prietaisas, naudojamas aspiruoti, o tada išleisti skystą tirpalą. • BD PrepStain™ instrumente 4 švirkštai naudojami judinti vandenį, alkoholį, hematoksiliną ir EA/OG (Eosin-50 ir Orange G). • BD PrepMate automatizuotas priedas naudoja dvylika švirkštų tam, kad sumaišytų, o tada paskirstytų ląstelių mėginio tirpalą ant BD tankio reagento.
Mėginio indelis	• Centrifugos indelis, kuriame telpa: 2, 50 ml centrifugos mėgintuvėliai arba 12, 12 ml centrifugos mėgintuvėlių 3x4 formatu.
Vakuuminis siurblys	• Elektrinis siurblys, kuris turi būti įjungiamas, kad vyktų aspiracija. • PVC vamzdelio linijos turi būti saugiai fiksuotos, kad būtų tinkamai naudojamos.
Maišyklė	• Elektrinis vibruojantis prietaisas, naudojamas sumaišyti ląstelių gumulėlius į tyrimų mėgintuvėlius ir centrifugos mėgintuvėlių stovus.
Atliekų konteineriai (talpyklos)	• Buteliai, naudojami surinkti skystas atliekas, naudojamas mėginio apdorojimo metu.
Atliekų stotelė	• Sudaryta iš atliekų latako, atliekų antgalio konteinerio, antgalio laikiklio ir centrifugos indo laikiklio. Žr. *1-13 iliustraciją*. • Užpildant arba valant, bet koks skysčiaus perteklius išleidžiamas į lataką. • Latakas per drenažo vamzdelį išleidžiamas į atliekų konteinerį.
Darbinė platforma	• Reguliuojama kvadratinė metalinį plokštelė ant PrepStain stiklelių paruošimo sistemos. • Laiko stiklelių stovus.
Z strypas	• Vertikalus dantytas strypas, kurį pakelia arba nuleidžia Z žingsninis variklis • Laiko DiTi montažo komponentus. • Z judėjimo mechanizmas.

9 skyrius
Nustatymas ir diagnostikos

Šis priedas apibūdina, kaip pasiekti ir atlikti BD PrepStain™ instrumento nustatymus ir diagnostinius testus.

Įspėjimas
BD PrepStain sistemą naudokite kaip nurodyta. Slaptažodžiai reikalingi tam tikroms funkcijoms atlikti. Šis skyrius bus naudojamas tik, kai nurodo serviso personalas, arba nurodoma kasdieniniame naudojime ir priežiūroje.

Sistemos nustatymas

Prieiga prie sistemos nustatymų funkcijų suteikiama per System Setup opcija GYN pagrindiniame meniu.
1.GYN pagrindiniame meniu pasirinkite **System Setup**, kaip parodyta *9-1 iliustracijoje*.

9-1 iliustracija: *pagrindinio meniu ekranas*

2.Kai Jūs pasirenkate System Setup, pasirodo Enter Password ekranas.

9-2 iliustracija: *ekranas Enter Password*

3.Įveskite savo slaptažodį, o tada paspauskite **Enter**. Pasirodys System Setup ekranas.

9-3 iliustracija: *System Setup ekranas*

4.Iš System Setup ekrano turite prieigą prie **MACHINE SETUP, IMPLEMENT RACKS, COMPUTER SETUP** ir **PASSWORD SETUP** funkcijų. Visos iki vienos opcijos turi būti naudojamos tik prižiūrint BD serviso atstovui.

Įrenginio nustatymas

Nustato BD PrepStain™ instrumento robotizavimo parametrus. Šie parametrai yra nustatomi BD serviso atstovo prieš arba įdiegimo metu.

> **Pastaba:** netinkami parametrų nustatymai sugeneruos klaidas, jeigu tarp keturkampės atšakos ar DiTi montažo ir DiTi antgalių, centrifugos mėgintuvėlių ar nusėdimo kamerų nebus tinkamo kontakto.

Priemonių stovai

Nustato BD PrepStain™ instrumento robotizavimo parametrus. Šie parametrai yra nustatomi BD serviso atstovo prieš arba įdiegimo metu.

> **Pastaba:** netinkami parametrų nustatymai sugeneruos klaidas, jeigu tarp keturkampės atšakos ar DiTi montažo ir DiTi antgalių, centrifugos mėgintuvėlių ar nusėdimo kamerų nebus tinkamo kontakto.

Kompiuterio nustatymas

Nustato AK darbo vietą, vaizduoklį ir spausdintuvą bei priskiria pakatalogį duomenų saugojimui. Šie parametrai yra nustatomi BD serviso atstovo prieš arba įdiegimo metu.

Slaptažodžio nustatymas

Šis ekranas leidžia Jums pakeisti slaptažodį. Slaptažodis reikalingas norint pakeisti parametrus ir pasiekti System Setup meniu. Kol galėsite sukurti naują slaptažodį, Jums reikės pateikti esamą slaptažodį. Jeigu reikia, susisiekite su BD serviso atstovu.
1.Pasirinkite **Password Setup** ir paspauskite **Enter**. Pasirodys Password Setup ekranas.

9-4 iliustracija: *Password Setup ekranas*

2.Laukelyje **Current Password** įveskite esamą BD PrepStain™ sistemos slaptažodį ir paspauskite **Enter**. Jūsų įvedami simboliai rodomi žvaigždutėmis.

3.Ekranas paragins Jus suteikti naują slaptažodį. Laukelyje **New Password** įveskite naują slaptažodį. PrepStain sistemos slaptažodį turi sudaryti 8 skaičių simbolių slaptažodis. Raidės ir kiti simboliai negali būti naudojami.
4.**Confirm New Password** laukelyje dar kartą įveskite slaptažodį, kad patvirtintumėte, jog įvedėte tai, ką norėjote.

- Jeigu padarysite klaidą, ekrane pasirodys pranešimas, nurodantis slaptažodį įvesti dar kartą.
- Kai tinkamai patvirtinate naują slaptažodį, pasirodys Confirm Password Change meniu.

9-5 iliustracija: *Confirm Password Change meniu*

5.Pasirinkite atitinkamą opciją:

- Norint pakeisti esamą slaptažodį nauju, pasirinkite **Change to new password** ir paspauskite **Enter**.
- Norėdami specifikuoti kitą slaptažodį esamo slaptažodžio keitimui, pasirinkite **Enter another password** ir paspauskite **Enter**.
- Norėdami išlaikyti esamą slaptažodį ir atmesti naujai įvestą, pasirinkite **Keep old password** ir paspauskite **Enter**.

Tai užbaigia slaptažodžio keitimo procedūrą.

Diagnostikos

Diagnostikos meniu suteikia prieigą prie klaviatūros procedūrų, atsitiktinio XYZ testo ir DiTi testų.
Norėdami atidaryti diagnostikos meniu, GYN pagrindiniame meniu pasirinkite **Diagnostics** ir paspauskite **Enter**. Pasirodys Diagnostics meniu.

9-6 iliustracija: *Diagnostics meniu*

Klaviatūros veikimas

Šis pagalbinis meniu turi būti naudojamas tik prižiūrint BD atstovui arba įgaliotam asmeniui.

Atsitiktinis XYZ testas

Atsitiktinis XYZ testas automatiškai valdo robotizuotą atšaką į atsitiktines vietas instrumento darbo stale. Taip pat vienu metu įrašo informaciją apie klaidas, praleistus žingsnius ir esamo testo ciklo parametrus.
Šis testas taip pat naudojamas per kas savaitinės priežiūros procedūras. Daugiau informacijos rasite 6 skyriuje.

1.Diagnostikos meniu pasirinkite **Random XYZ Test** ir paspauskite **Enter**. Pasirodys Random XYZ Test ekranas.

9-7 iliustracija: *Atsitiktinis XYZ: ekranas Number of Moves*

2.Ekranas paragina Jus įvesti judesių testui skaičių. Reikšmingam testui rekomenduojame 540 judesius. Įveskite norimą judesių skaičių ir paspauskite **Enter**. Pasirodys pasirinkto testo greičio meniu.

9-8 iliustracija: *Atsitiktinis XYZ: Select test speed ekranas*

3.Pasirinkite **Normal** ir paspauskite **Enter**. Sistema skelis garsinį aliarmą ir paragins Jus patikrinti DiTi dėl vienkartinių antgalių. Jeigu yra, išimkite, ir paspauskite **Enter**, kad pradėtumėte testą.
4.Sistema atlieka Random XYZ testą ir tada ekrane parodo gautus rezultatus.

9-9 iliustracija: *Atsitiktinis XYZ: ekranas Results*

5.*9-9 iliustracija* iliustruoja tipinį rezultatų ekraną. Žemiau pateikiamos priimtinos testo vertės kiekvienam parametrui.

Parametras	Priimtinas rezultatas
Moves Done	Bendras judesių kiekis, atliktas atšakos. Mažiausiai 540 judesių, kad būtų užbaigtas atsitiktinis testas.
Inits Done	Bendras atšakos atliktų inicializacijų kiekis. Reikšmingam rezultatui rekomenduojama mažiausiai dvidešimt inicializacijų.
Last Steps Lost	Prarastų žingsnių tarp dviejų inicializacijų skaičius. Šis skaičius neturi viršyti trijų.
Max Steps Lost	Maksimalus prarastų žingsnių skaičius viso testo metu. Šis skaičius neturi viršyti trijų.
Init Errors	Inicializacijos ciklo metu įvykusių klaidų skaičius. Šis skaičius turi būti nulis.

6.BD PrepStain™ stiklelių paruošimo sistema neturi būti naudojama ruošiant paciento mėginius, jeigu sistema susiduria su bet kokiomis inicializacijos klaidomis. Susisiekite su BD technine pagalba, kad išspręstumėte neišlaikyto testo problemas. Tik po sėkmingai mažiausiai 540 judesių testo prietaisas paruoštas naudoti vieną savaitę. Po to kas savaitę testas turi būti kartojamas, kad būtų užtikrintas tęstinis trijų judėjimo variklių funkcionalumas. Nepatvirtinus tinkamo judesio kontrolės funkcionavimo šiuo testu, sistema gali susidurti su netinkamai paskirstomų paciento mėginių problema.

Tai užbaigia atsitiktinį XYZ testą.

DiTi testai

DiTi testai naudojami įvertinti DiTi ir jo komponentų našumą. Naudojami trys testai: antgalio tvarkymo, Z strypo atstatymo ir kontaktinės spyruoklės atstatymo. Norint atidaryti DiTi testų meniu, diagnostikos meniu pasirinkite **DiTi Test**.

Tip handling testas (antgalio tvarkymo testas)
Antgalio tvarkymo testas įrašo prarastus žingsnius, susijusius su antgalio paėmimais ir išmetimais.
1.Diagnostikos meniu pasirinkite **DiTi Tests** ir paspauskite **Enter**. DiTi Test ekrane pasirodys DiTi Test Options meniu.

9-10 iliustracija: *DiTi Test Options*

2.DiTi Tests meniu pasirinkite **Tip Handling** ir paspauskite **Enter**. Atisdarys Tip Handling Test ekranas.

9-11 iliustracija: *DiTi Tip Handling Test*

3.Žymeklis pasirodo **Tips Tested** laukelyje. Įveskite antgalių paėmimo testui skaičių ir paspauskite **Enter**. Žymeklis juda į laukelį **First Test Tip**.
4.Įveskite pirmojo antgalio paėmimui pozicijos numerį ir paspauskite **Enter**, kad pradėtumėte testą.
Sistema paima vienkartinį antgalį, pradedant pirmuoju testo antgaliu, ir tada išmeta jį į antgalių atliekų talpyklą. DiTi atlieka testą, kad aptiktų žingsnio praradimus po kiekvieno išmetimo. Žingsnio praradimas turi būti 8 arba mažiau.

5.Kai testas yra atliktas, pakartotinai parodomas Test optikon meniu kartu su testo rezultatais. Jūs galite pakaroti testą arba išeiti ir grįžti į DiTi Tests meniu.

Z-Rod recovery (Z strypo atstatymas)
Z strypo atstatymo testas tikrina Z strypo spyruoklės atsistatymą po išsiplėtimo.
1.Diagnostikos meniu pasirinkite **DiTi Tests** ir paspauskite **Enter**. DiTi Test ekrane pasirodys DiTi Test Options meniu.

9-12 iliustracija: *DiTi Test Options*

2.Iš DiTi Tests meniu pasirinkite **Z Rod Recovery** ir tada paspauskite **Enter**. Pasirodys Z Rod Recovery ekranas.

9-13 iliustracija: *Z Rod Recovery Test Start*

3.Įveskite testo bandymų skaičių šiam testui ir paspauskite **Enter**, kad pradėtumėte testą.

4.Sistema atlieka testą ir tada parodo testo rezultatus bei Repeat Test Option Meniu.

9-14 iliustracija: *Z Rod Recovery Test Start*

5.Maksimalus pasikeitimas turi būti 5 arba mažiau. Tai užbaigia Z strypo atstatymo testą.

Contact spring recovery (kontaktinės spyruoklės atstatymas)
Contact Spring Recovery testas tikrina, ar kontaktinė spyruoklė ant DiTi po suspaudimo atsistato į savo poziciją.
1.Diagnostikos meniu pasirinkite **DiTi Tests** ir paspauskite **Enter**. DiTi Test ekrane pasirodys DiTi Test Options meniu.

9-15 iliustracija: *DiTi Test Options*

2.Iš DiTi Tests meniu pasirinkite **Contact Spring Recovery** ir tada paspauskite **Enter**. Pasirodys Contact Spring Recovery ekranas.

9-16 iliustracija: *Contact Spring Recovery Test Start*

3.Paspauskite **Enter**, kad pradėtumėte testą. Ekranas paragins Jus rankiniu būdu pakelti DiTi plastikinę įvorę ir leisti jai laisvai nukristi į savo poziciją penkis kartus.

9-17 iliustracija: *Raginimas Manually Compress Spring*

Atlikus penkis numetimus, paspauskite **Enter**, kad tęstumėte testą. DiTi pakartotinai inicializuos Z ašį, kad patikrintų dėl žingsnių praradimo.

4.Kai testas yra baigtas, pasirodys rezultatai ir Repeat Test Option meniu.

9-18 iliustracija: *Repeat Test Option meniu*

5.Pasirinkite **Repeat Trial**, kad tikrintumėte kontaktinę spyruoklę dar kartą. Pasirinkite **Quit**, kad išeitumėte į DiTi Tests meniu. Tai užbaigia kontaktinės spyruoklės atstatymo testą.

Kai pasirenkate **Quit** opciją viename iš DiTi testų rezultatų ekranų, pasirodo DiTi Tests meniu. Norint išeiti iš šio ekrano, paspauskite mygtuką **Esc**. Pasirodys Diagnostics meniu. Norint grįžti į pagrindinį meniu, dar kartą paspauskite mygtuką **Esc**. Norint grįžti į DOS eilutę, pasirinkite **Quit** ir paspauskite **Enter**, arba dar kartą paspauskite mygtuką **Esc**.

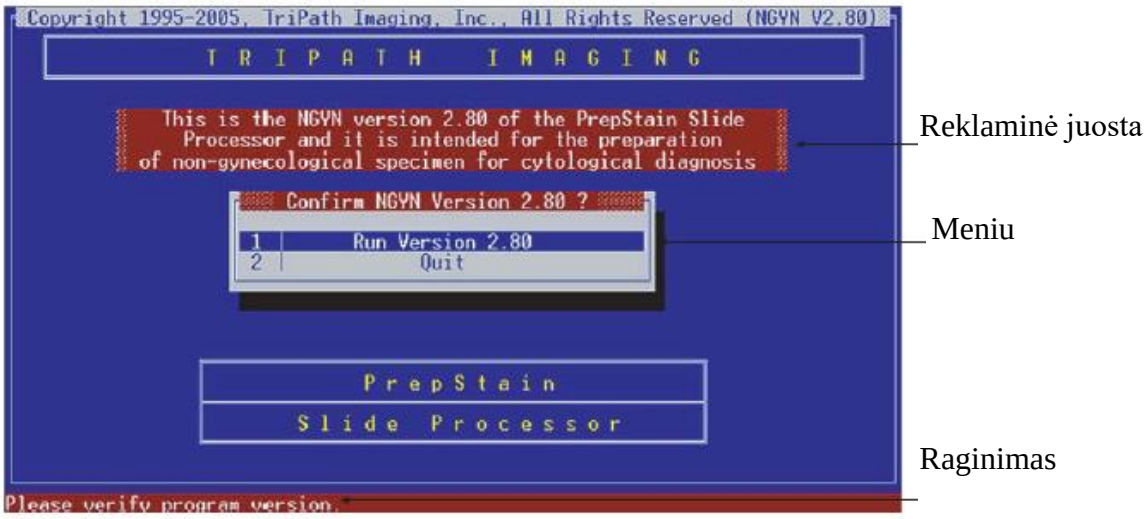
10 skyrius
Ne GYN stiklelių apdorojimas

Visos BD PrepStain™ instrumento funkcijos valdomos naudojant kompiuterinę darbo vietą. Prieiga prie programų, kurios valdo PrepStain instrumentą, atliekama per tris DOS pagrindo meniu principo taikomąsias programas.
Naudodami darbo vietos meniu Jūs komunikuojate su instrumentu ir stebite stiklelio paruošimo progresą. Šiame skyriuje aprašomas ne GYN taikomosios programos procesas paruošiant ne GYN mėginių stiklelius.

PrepStain ne GYN programa

Programos bendra informacija

10-1 iliustracija: iliustruoja pasisveikinimo ir versijos tikrinimo ekraną, kuris rodomas Jums atidarius Non-GYN programą.



10-1 iliustracija: *PrepStain sistemos Non-GYN versijos meniu*

Ekranai Non-GYN taikomojoje programoje yra padalinti į tris dalis, kaip nurodyta *10-1 iliustracijoje*.

a. Viršutinė (reklaminės juostos) dalis rodo tekstinį pranešimą keliose linijose. Šie pranešimai nurodo Jums, kokį veiksmą atlieka sistema, ar kokį ruošiasi atlikti.
b. Vidurinė (meniu) dalis rodo meniu raginimus, kuriuos naudojate sistemos valdymui.
c. Apatinė (raginimo) dalis rodo tekstinius pranešimus vienoje linijoje. Šie pranešimai nurodo Jums, kas vyksta ir ką reikia daryti toliau.

Ne GYN pagrindinis meniu

Kai pasirenkate pirmąją opciją Non- GYN versijos meniu, pasirodys Non-GYN pagrindinis meniu. Šis ekranas pateiktas *10-2 iliustracijoje*.

10-2 iliustracija: *Non-GYN pagrindinis meniu*

Šiame skyriuje aptariamos **SAMPLE PREPARATION** opcijos. **CLEAN UP SYSTEM** opcija aptariama ***6 skyriuje Priežiūros procedūros***. **SYSTEM SETUP** ir **DIAGNOSTICS** opcijos aptariamos ***9 skyriuje Nustatymas ir diagnostikos***.

Ne ginekologinių (ne GYN) mėginių apdorojimas

1.GYN taikomoji programa paleidžiama automatiškai, kai įjungiama BD PrepStain™ instrumento darbo vieta. Išeikite iš šios taikomosios programos, kad atidarytumėte DOS langą, iš kurio galėsite atidaryti Non-GYN versijos tikrinimo meniu (*10-1 iliustracija*). Šis ekranas suteikia prieigą prie visų programos funkcijų.

- Jeigu darbo vieta jau veikia su GYN taikomąją programa, pasirinkite **Quit**, kad atidarytumėte DOS langą. Įveskite **NONGYN** ir paspauskite **Enter**. Pasirodys Non-GYN Version Check meniu (*10-2 iliustracija*).
- Jeigu darbo vieta jau rodo DS langą, įveskite **NONGYN** ir paspauskite **Enter**. Pasirodys Non-GYN Version Check meniu (*10-2 iliustracija*).

2.Meniu pasirinkite **Run Version 2.80**. Tada paspauskite **Enter**. Tokiu būdu atidarysite Non-GYN pagrindinį meniu. Pagrindinis meniu (*10-2 iliustracija*) suteikia prieigą prie visų programos funkcijų.
3.Pasirinkite **Sample Preparation**, o tada paspauskite **Enter**. Pasirodys Number of Samples ekranas (*10-3 iliustracija*).

10-3 iliustracija: *Number of Samples ekranas*

Pastaba: Šiame ir visuose kituose PrepStain sistemos ekranuose Jūs galite naudoti **Tab** arba **Enter** mygtukus, kad judintumėte žymeklį (naviguotumėte) iš vieno laukelio į kitą.

4.Pirmame laukelyje įveskite apdorojamų mėginių skaičių ir paspauskite **Enter**. Mėginių skaičius turi būti keturių kartotinis.

> **Pastaba:** Jeigu apdorojamų stiklelių skaičius nesidalina iš keturių, įveskite kitą didesnį keturių kartotinį, o tada pridėkite tuščius stiklelius, BD nusėdimo kameras ir mėgintuvėlius į mėgintuvėlio stovą, kad kompensuotumėte skirtumą.

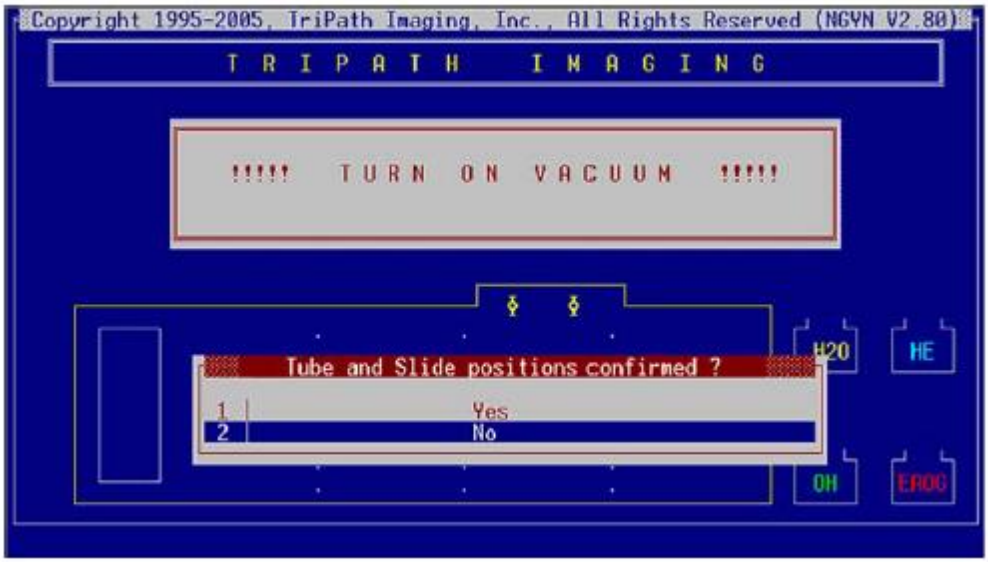
5.Naviguokite į kitą laukelį ir įveskite stiklelių, kuriuos norite sukurti kiekvienam mėginiui, skaičių. Pavyzdžiui, Jūs galite norėti sukurti tris stiklelius kiekvienam mėginiui centrifugos mėgintuvėlyje.
6.Naviguokite į kitą laukelį ir įveskite stiklelių, kuriuos norite dažyti kiekvienam mėginiui, skaičių. Pavyzdžiui, Jūs sukuriate tris stiklelius kiekvienam mėginiui, tačiau norite dažyti tik vieną iš jų su esamais mėginio ir dažymo nustatymais.
7.Naviguokite į kitą laukelį ir paspauskite **Enter** arba paspauskite **Next** patvirtinimui, kad Next Tip Position yra teisinga; arba įveskite teisingą antgalio numerį ir tada paspauskite **Enter**.
8.Bus parodytas **Reenter Run Information** raginimas.

- Norėdami pakeisti bet kokias atliktas įvestis, pasirinkite **Yes**, paspauskite **Enter** ir pakartokite du paskutinius žingsnius.
- Įvesčių patvirtinimui ir perėjimui prie kito žingsnio pasirinkite **No** ir tada paspauskite **Enter**.

9.Pasirodys raginimas **CHANGE SAMPLE/STAIN PARAMETERS**.

- Mėginio arba dažymo nustatymų keitimui pasirinkite **Yes**, o tada paspauskite **Enter**. Daugiau informacijos apie šias korekcijas rasite 5-15 puslapyje *Mėginio/dažymo parametrų keitimas*.
- Norėdami naudoti esamus nustatymus ir pereiti prie kito žingsnio pasirinkite **No** ir tada paspauskite **Enter**.

10.Pasirodys Turn on Vcuum ekranas (*10-4 iliustracija*).



10-4 iliustracija: *ekranas Turn on Vacuum*

- Patvirtinkite, kad mėginio mėgintuvėlių ir atitinkamų stiklelių pozicijos atitinka viena kitą.
- Pasirinkite **Yes** ir paspauskite **Enter**.

11.Vakuumo raginimas parodomas ekrane. Taip pat girdimas aliarmo garsas. Paspauskite bet kurį mygtuką aliarmui nutildyti.
12.Įjunkite vakuuminį siurblį, palaukite kelias minutes, kol jis sušils.

- Jeigu naudojate Schuco siurblį, sureguliuokite slėgį ties 8-10 colių Hg, o tada paspauskite bet kurį mygtuką, kad tęstumėte.
- Jeigu naudojate KNF siurblį, sureguliuokite slėgį ties 5-6 colių Hg (180-220 mBAR), o tada paspauskite bet kurį mygtuką, kad tęstumėte.

13.Pasirodys raginimas **PRIME ALL TUBING?**

- Jeigu tai yra pirmasis dienos prietaiso naudojimas, pasirinkite **Yes**, o tada paspauskite **Enter**, kad užpildytumėte sistemos vamzdelius. Sistema inicializuojasi ir švirkšto siurbliai pumpuoja du pilnus švirkšto tūrius per keturkampės atšakos vamzdelį ir į atliekų stotelę.
- Tolimesniems prietaiso naudojimams per kitas aštuonias valandas pasirinkite **No**, o tada paspauskite **Enter**, kad praleistumėte pilno užpildymo funkciją.
- Prieš kiekvieną prietaiso panaudojimą, vienas švirkšto tūris automatiškai pumpuojamas per vamzdelį, kad užtikrintų, jog sistema užpildyta.

14.Kai užpildymo ciklas baigtas, ekrane pasirodo raginimas **IS THE PREPSTAIN TUBING PRIMED?**

- Norėdami pakartoti užpildymo seką pasirinkite **No**, o tada paspauskite **Enter**.
- Norėdami tęsti su stiklelių ruošimu ir dažymu pasirinkite **Yes**, o tada paspauskite **Enter**.

15.DiTi lašina buferizuotą vandenį į kiekvieną BD centrifugos mėgintuvėlį, kad sumaišytų ląstelių gumulėlį. Toliau DiTi paima vienkartinį antgalį ir aspiruoja ląstelių suspensijos mėginį bei perneša į atitinkamą stiklelį ir išleidžia į nusėdimo kamerą.

16.Po to, kai mėginiai perkeliami, BD PrepStain™ paskirsto papildomą buferizuoto vandens kiekį. Kai mėginiai perkeliami į visus stovus, instrumentas mažiausiai 10 minučių sustoja, kol ląstelės sėda ant stiklelių.
17.Kai nusėdimo pauzės etapas pasibaigia, aliarmas įspėja vartotoją, kad atšaka tuoj pajudės.
Dažymas vienu metu atliekamas tik ant vieno stiklelio stovo. Kiekvieno dažymo ciklo metu kiekvienas stiklelis yra iš anksto nuplaunamas atitinkamame reagente (buferizuotas vanduo hematoksilinui, alkoholis EA/OG Combo Stain) ir tada nudažomas. Po dažymo stiklelis nuplaunamas alkoholiu. Kiekviena nusėdimo kamera yra pilnai ištuštinama tarp dažymų ir plovimų ciklų.
18.Kai visi stikleliai stove yra nudažyti, BD PrepStain™ sistema skleidžia garsinį aliarmą ir tada tęsia kito stiklelio stovo dažymą.

a. Kai kiekvienas stiklelio stovas yra baigiamas, išimkite jį iš BD PrepStain™ instrumento ir nupilkite alkoholį iš kiekvienos BD nusėdimo kameros į tinkamą talpyklą.

Įspėjimas

- Išimdami nusėdimo kamerą, venkite ląstelių apskritimo išmetimo nuo stiklelio.
- Neleiskite stikleliams išdžiūti iki uždengimo dengiamąja plokštele. Kiekvienas stiklelis turi būti uždengiamas po vieną.
- Ilgą laiką paliekant mėginius alkoholyje galite išblukinti ląsteles.

19.Kai BD PrepStain™ instrumentas baigia apdorojimą, ekrane pasirodo pranešimas **SAMPLE PREPARATION COMPLETE** ir girdimas aliarmo garsas. Paspauskite bet kurį mygtuką aliarmui nutildyti ir tęskite.
20.Kai baigiate stiklelių paruošimą ir dažymą, Jūs galite tęsti su kita partija, nuvalyti instrumentą arba paprasčiausiai išeiti į DOS, kad paleisti vieną iš kitų PrepStain taikomųjų programų.

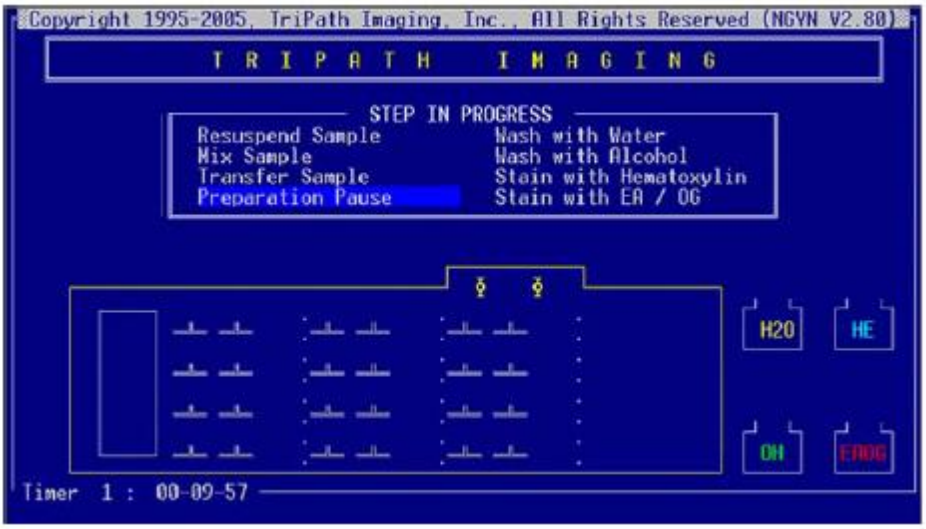
Stiklelių sutvarkymas daugialypiams stikleliams

Kai kiekvienam mėginiui ruošiate kelis stiklelius (taip pat, kai ruošiate vieną stiklelį kiekvienam mėgintuvėliui), pirmasis mėginys iš kiekvieno mėgintuvėlio yra pristatomas į atitinkamą stiklelį ant pirmojo stovo, pradedant nuo to stovo priekinio kairiojo kampo ir judant link galinės dalies. Tolimesni mėginiai, sukurti iš to mėgintuvėlio, yra pristatomi į atitinkamą stiklelį kitame stove. Kai kurie pavyzdžiai pateikti *10-5, 10-6* ir *10-7 iliustracijose*.

Du stikleliai iš aštuonių mėginių
Norint apdoroti 8 mėginius ir kiekvienam sukurti 2 stiklelius, Steps in Progress ekranas atrodys kaip *10-5 iliustracijoje*. Pavyzdžiui, mėginys iš 6 mėgintuvėlio bus perkeltas į dvi vietas: 1 stovo 6 stiklelio poziciją ir 2 stovo 6 stiklelio poziciją.

3-5 iliustracija: *du stikleliai iš aštuonių mėginių*

Trys stikleliai iš aštuonių mėginių
Norint apdoroti 8 mėginius ir kiekvienam sukurti 3 stiklelius, Steps in Progress ekranas atrodys kaip *10-6 iliustracijoje*. Pavyzdžiui, mėginys iš 6 mėgintuvėlio bus perkeltas į tris vietas: 1 stovo 6 stiklelio poziciją, 2 stovo 6 stiklelio poziciją ir 3 stovo 6 stiklelio poziciją.



10-6 iliustracija: *trys stikleliai iš aštuonių mėginių*

Du stikleliai iš šešiolikos mėginių

Norint apdoroti 16 mėginių ir kiekvienam sukurti 2 stiklelius, Steps in Progress ekranas atrodys kaip *10-7 iliustracijoje*. Šiuo atveju yra pernelyg daug mėginių, kuriamų iš kiekvieno mėgintuvėlio, kad perkelti antrąją kopiją į 2 stovą, todėl antras stiklelių rinkinys sukuriamas pradedant nuo kito galimo stovo. Šiuo atveju 3 stovo.

10-7 iliustracija: *du stikleliai iš šešiolikos mėginių*

Jūs galite sukurti 2 stiklelius per mėginį apdorojant iki 24 mėginių. Galite sukurti iki 4 stiklelių per mėginį apdorojant 12 arba mažiau mėginių.

Priedas: Pagalbiniai tyrimai iš BD SurePath surinkimo buteliuko

Alikvotinė mėginio dalis (iki 0.5 mL) gali būti pašalinama iš BD SurePath surinkimo buteliuko pagalbiniams tyrimams *prieš* BD SurePath PAP testo procesą.
Norint atlikti *Chlamydia trachomatis (CT)* ir/arba *Neisseria gonorrhoeae (GC)* tyrimus naudojant BD ProbeTec™ *Chlamydia trachomatis (CT)* Q^x ir *Neisseria gonorrhoeae (GC)* Q^x amplifikacinius DNR tyrimus iš BD SurePath surinkimo buteliuko, būtina laikytis specifinių apdorojimo žingsnių, kaip pateikiama šiame skyriuje.

Procedūra

Pastaba: pakankamas tūris gaunamas iš BD SurePath surinkimo buteliuko, kuris leidžia pašalinti 0.5 mL homogeninio ląstelių mišinio ir skysčio pagalbiniams tyrimams atlikti. Likusio kiekio pakanka atlikti PAP testą su BD PrepStain sistema (reikalauja 8.0 ± 0.5 mL).

Pastaba: prieš apdorojant BD SurePath™ PAP testą galima pašalinti iki 0.5 mL alikvotinės dalies. Prieš atliekant PAP testą, nepriklausomai nuo alikvotinės dalies tūrio, iš BD SurePath surinkimo buteliuko galima pašalinti tik vieną alikvotinę dalį.

1.Norint užtikrinti homogenišką mišinį, BD SurePath surinkimo buteliukas turi būti 10-20 sekundžių maišomas, o alikvotinė dalis turi būti paimama per vieną minutę nuo maišymo pabaigos.
2.Alikvotinės dalies paėmimui naudokite polipropileno aerozolinio barjero pipetės antgalį, kurio dydis atitinka ištraukiamą tūrį. *Pastaba:* serologinės pipetės neturi būti naudojamos. Siekiant išvengti teršalų patekimo į BD SurePath surinkimo buteliuką arba alikvotinę dalį, laikykitės geros laboratorinės praktikos procedūrų. Alikvotinės dalies paėmimas turi būti atliekamas atitinkamoje vietoje, kitoje nei bus atliekama amplifikacija.
3.Vizualiai tikrinkite alikvotinės dalies medžiagą pipetėje dėl didelių arba pusiau kietų dalelių. Tokios medžiagos identifikavimas paimant alikvotinę medžiagą priverčia grąžinti visą mėginio medžiagą į mėginio buteliuką ir nutraukti mėginio naudojimą pagalbiniams tyrimams prieš atliekant PAP testą.

4.Alikvotinės dalies apdorojimo su BD ProbeTec™ *Chlamydia trachomatis (CT)* Q^x ir *Neisseria gonorrhoeae (GC)* Q^x amplifikaciniais DNR tyrimais informacija tyrimo gamintojo pateikiama pakuotės įdėtiniuose lapuose.

Procedūros apribojimai

BD SurePath PAP testo apdorojimui laboratorijoje reikalingas 8.0 ± 0.5 mL ginekologinio mėginio, surinkto į BD SurePath surinkimo buteliuką, tūris.

Bendros atsargumo priemonės pagalbiniams tyrimams iš BD SurePath surinkimo buteliuko

Kol nėra įrodymų, kad alikvotinės dalies pašalinimas iš BD SurePath surinkimo buteliuko paveikia mėginio citiloginiams tyrimams kokybę, retais atvejais šio proceso metu gali įvykti prastos susijusios diagnostinės medžiagos gavimas. Sveikatos priežiūros teikėjams gali reikėti paimti naują mėginį, jeigu rezultatai nekoreliuoja su klinikine paciento istorija. Taip pat, citologija apima skirtingas klinikines dalis nei lytiniu keliu plintančių lygų (STD) tyrimus; todėl tam tikrais klinikiniais atvejais alikvotinės dalies paėmimas gali būti netinkamas. Jeigu reikia, STD tyrimams paimkite atskirą mėginį, o ne alikvotinę dalį iš BD SurePath surinkimo buteliuko. Alikvotinės dalies paėmimas iš mažo ląstelių kiekio mėginių gali palikti nepakankamai medžiagos BD SurePath surinkimo buteliuke patenkinamam BD SurePath PAP testo paruošimui.

Naudojami simboliai


Gamintojas


Sunaudoti iki


Katalogo numeris


Įgaliotas atstovas Europos Bendrijoje


In vitro diagnostinis medicinos prietaisas


Temperatūros ribos


Partijos kodas (LOT)


Pakanka <n> testų


Žr. naudojimo instrukcijas


Pakartotinai nenaudoti


Serijinis numeris


Tik IVD našumo įvertinimui / JAV: Tik tiriamajam naudojimui


Apatinė temperatūros riba


Kontrolė


Teigiama kontrolė

Neigiama kontrolė

Sterilizacijos metodas: etileno oksidas

Sterilizacijos metodas: apšvitinimas


Biologinės rizikos


Įspėjimas, žr. akomponuojančią dokumentaciją


Viršutinė temperatūros riba


Laikyti sausai


Paėmimo laikas


Nuplėšti čia


Perforacija


Nenaudoti, jeigu pakuotė pažeista


Laikyti toliau nuo karščio šaltinių


Kirpti čia


Paėmimo data


µL per testą


Laikyti toliau nuo šviesos šaltinių

Išskiriamos vandenilio dujos

Paciento ID numeris

Užsakymų informacija

Žemiau pateikiamas komponentų ir rinkinių, naudojamu su BD PrepStain™ sistema, sąrašas.

Produkto apibūdinimas	Katalogo numeris
BD PrepStain stiklelių paruošimo sistema	490100
BD Prepmate automatizuotas priedas	491103
BD aspiratoriaus antgaliai, 96/dėžutėje	490510
BD PrepStain perkėlimo antgaliai, 96/dėžutėje	490513
BD centrifugos mėgintuvėliai, 480/maišelyje	490515
Tris buferizuoto druskos tirpalo pakuotė	490518
BD alkoholio mišinys skalavimui, 1700 mL	491121
BD SurePath PreCoat stikleliai, 96/dėžutėje	491248
BD PrepStain Slide Library rinkinys *Sudarytas iš:* 491248 BD SurePath PreCoat stikleliai, 96/dėžutėje 491329 BD nusėdimo kameros, 96/maišelyje 490513 BD PrepStain perkėlimo antgaliai, 96/dėžutėje	491267
BD PrepStain Consumables rinkinys *Sudarytas iš*: 491248 BD SurePath PreCoat stikleliai, 5x96/dėžutėje 491330 BD nusėdimo kameros, 2x240/maišelyje 490513 BD PrepStain perkėlimo antgaliai, 5x96/dėžutėje	491311
BD PrepMate Consumables rinkinys *Sudarytas iš:* 491332 BD tankio reagentas, 4x480 mL 490515 BD centrifugos mėgintuvėliai, 480/maišelyje 491331 BD švirkščiančios pipetės, 2x240/dėžutėje 490510 BD aspiratoriaus antgaliai, 5x96/dėžutėje	491313
BD nusėdimo kameros, 96/maišelyje	491329
BD nusėdimo kameros, 2x240/maišelyje	491330
BD švirkščiančios pipetės, 240/dėžutėje	491331
BD tankio reagentas, 480 mL	491332

Produkto apibūdinimas	Katalogo numeris
BD Cytology Stain rinkinys *Sudarytas iš:* 491338 BD Hematoxylin dažas 0.75, 480 mL 491328 BD EA/OG Combo dažas, 480 mL	491334
BD SurePath konservanto skystis, 3600 mL	491337
Rankoje laikomas brūkšninio kodo skanavimo įrenginys – 1D/2D	491340
BD paskirstymo įrenginys, 4 mL	490516
BD Clamshell, 88/dėžutėje	490625

Papildomi komponentai arba rinkiniai ne ginekologiniam naudojimui su BD PrepStain sistema.

Produkto apibūdinimas	Katalogo numeris
BD CytoRich Clear Preservative	490719
BD PrepStain Non-GYN testo rinkinys *Sudarytas iš:* 490514 BD centrifugos mėgintuvėliai, 2x96/maišelyje 491248 BD SurePath PreCoat stikleliai, 2x96/dėžutėje 491329 BD nusėdimo kameros, 2x96/maišelyje 490513 BD PrepStain perkėlimo antgaliai, 2x96/dėžutėje	491303
BD Non-GYN Stain rinkinys *Sudarytas iš:* 491327 BD Hematoxylin dažas 0.5, 480 mL 491328 BD EA/OG Combo dažas, 480 mL	491333
BD CytoRich Blue Preservative, 3600 mL	491335
BD CytoRich Red Preservative, 3600 mL	491336