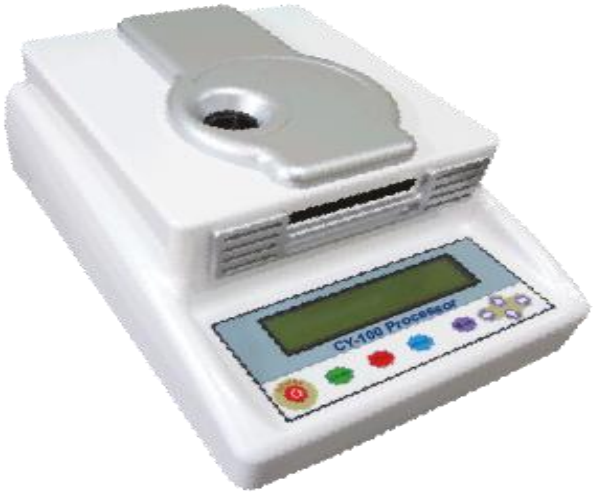
CY-100 Processor

THE NEXT GENERATION LIQUID CYTOLOGY PREPARATION SYSTEM USING DUAL FILTRATION TECHNOLOGY

USER MANUAL



HANDLE MATERIAL IN COMPLIANCE WITH YOUR LABORATORY REQUIREMENTS AND YOUR LOCAL AND FEDERAL STANDARDS.

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CY-PREP® System (Dual Filtration Technology)
The Next Generation Liquid Cytology Preparation System

Name and Intended Use

The CY-PREP® System makes use of the fluidic principles of cell collection and preservation, and dual filtration and absorption principles, and the natural binding qualities of cells in the preparation of cytology samples.

The CY-PREP® System comprises of (i) a CY-100 Processor, a liquid cytology processing device, (ii) a vial of 20 ml Preservation Solution transport medium, with a sterile Cervix-Brum® cell sampling device, and (iii) a Filter-Slide Pack, a dual filter membrane and charged slide for the cells transfer process.

Thin layer cytological slides are prepared using the automated CY-100 Processor from specimens collected using the sterile Cervix-Brum® cell sampling device rinsed into the Preservation Solution transport medium.

Ordering Information

Instrument & Reagents Required for the CY-PREP® Pap Test

CY-100 Processor (Basic Unit)	Cat no. CY10-0PRO
CY-PREP® Pap Test (300 Tests /box)	Cat no. 6888-0300
CY-PREP® Preservation Solution (300 packs /box)	Cat no. 6886-0300
CY-PREP® Filter-Slides Pack (300 packs /box)	Cat no. 6887-0300
CY-PREP® Lysis Solution (2 x 300 ml/bottle)	Cat no. 6881-2300

Summary And Explanation

One of the most common uses of cytology slides is for the screening and diagnosis of cervical sample. Carcinoma of the cervix is one of the most common malignancies in women. Worldwide, cervical cancer comprises approximately 12% of all cancers in women. The global estimates are 452,000 new cases and more than 234,000 deaths from cervical cancer each year (Ferlay et al., 1998; Parkin et al., 1999). Approximately 60% of these cases are associated with the absent or deficient screening. Approximately 25% of the screening failures are the result of errors in cervical sampling or smear interpretation (Sawaya et al., 1999).

Screening for precancerous or cancerous changes of the uterine cervix traditionally involves microscopic assessment of the cervical smears, called Pap smears. This traditional method for screening requires scrapping a woman's cervix with a sampling device, such as a cotton applicator stick, spatula or brush, and smearing this sample onto a slide for review by a medical lab professional. The specimen is gently spread across a slide to evenly distribute the cell sample. The slide is then fixed, stained, and examined under a light microscope for cellular abnormalities.

In carrying out this operation, the portion of the cell sample that is smeared onto the slide may contained blood, mucus, inflammatory cells, and clumps of cells. Accurate interpretation of up to 40% of conventional Pap smears are compromised by presence of blood, mucus, obscuring inflammatory cells, scant cellular material and air-drying artifacts (Davey et al., 1992). The presence of these contaminants can obscure many cells, causing important precancerous lesions to be missed when slide is reviewed at the lab or alternatively, making the entire slide unreadable.

One of the problems with the conventional Pap smear is how quickly the sample dries out once it is smeared on the slide. With the conventional Pap smear, the sample must be fixed immediately in order to avoid the drying out of the cells, which ruins the sample.

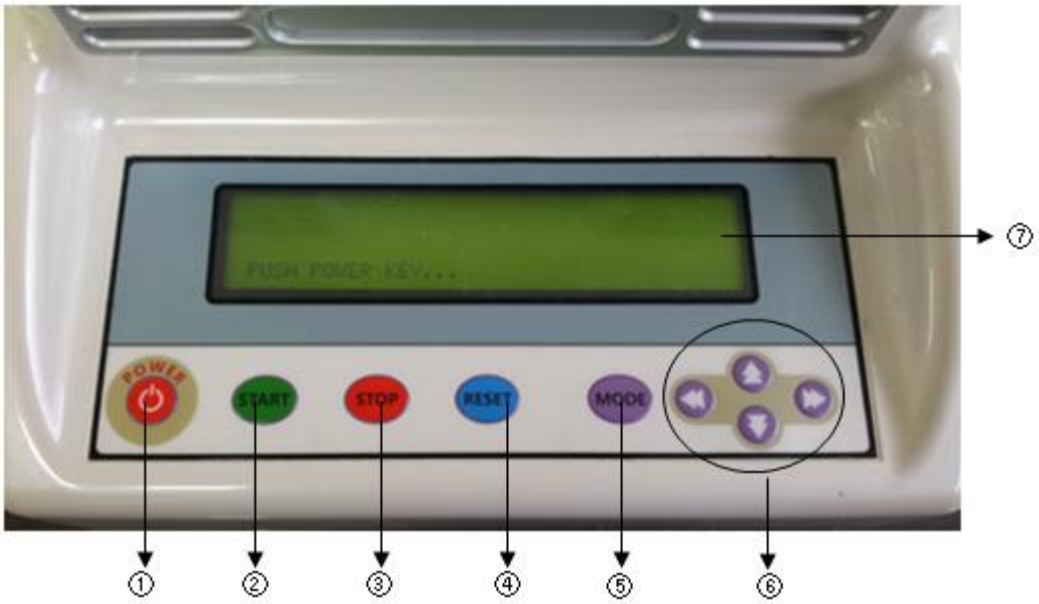
Another problem with the conventional Pap smear is the frequent inaccuracy of the test result. Common inaccuracies include both false positive and false negative Pap test results. A false positive Pap test occurs when a patient is told she has abnormal cells when the cells are actually normal. A false positive result may require a woman to undergo unnecessary and costly medical procedures. A false negative Pap test result occurs when a specimen is called normal, but the woman has a lesion. A false negative Pap test may delay the diagnosis and treatment of a precancerous or even cancerous condition.

The conventional Pap smear has a false negative rates ranging from 10-50%, with up to 90% of those false negatives due to limitations of sampling or slide preparation (Van der Graaf et al., 1987). To decrease false negative rates associated with interpretation error, re-screening a portion of the negative smear or recalling the patient for another sample is required.

Concern over the frequency of false-negative results of the traditional Pap smear has led to the development of a variety of other technologies or clinical strategies, such as Liquid Based Pap Preparation systems, to improve Pap testing.

Hence, the CY-PREP® Pap Test, using the state-of-the-art dual filtration technology for Liquid Cytology Preparation was developed to provide for a better quality prepared thin layer cytology slide having a more even distribution of cells with less interference from debris than the conventional Pap method, while offering an easier, quicker and more economical procedure.

CY-100 Processor Control Panel



No	Function	Description
①	Board ON-OFF Switch	Board's power ON-OFF switch
②	Operation Starting Switch	Start switch for clinical specimen
③	Emergency Stop Switch	Emergency switch to stop the equipment if malfunction takes place
④	Reset Switch	Equipment’s initialization switch after emergency stop
⑤	Operation Selection Switch (Main Menu)	Mode to select the required operation MODE1. Gynecologic Sample Preparation - Genecology measuring mode MODE2. Fine Needle Aspirates - FNA measuring mode MODE3. Mucoid Specimens - Mucilage clinical measuring mode MODE4. Body FLUID - Body fluid measuring mode MODE5. Superficial Brushings and Scrapings - Measuring mode of clinical specimen on the surface of body. MODE6. ECT - Different clinical specimen measuring mode arbitrarily by user MODE7. Manual - Equipment’s operation test measuring mode

⑥	Operation Selection and Adjusting Switch [redacted]	Switch for moving to the desired operation and values. ◀,▶switch: inhale time→inhale pressure→smear time→smear pressure in order, selection by left and right button. ▲,▼switch: Inhale time(0~60 sec), Inhale pressure(0~99), Smear time(0~20sec), Smear pressure(0~99) to be incremented or decremented by 1 unit number, by pushing up/down button
⑦	Display window	Indicating equipment's operation state.

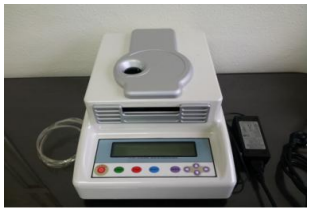
2. Dimension and weight

(1) Equipment

① Dimension : (W)390 × (D)270 × (H)210 (Unit : mm)

② Weight : ~ 10 Kg

3. Product Components

No	Item	Name	Description
1		Processor	Display PCB Assembly unit with power cord, & Waste Container with tubing.
2		Dual Filter Membrane	For processing of liquid cytology specimen
3		Preservation Solution	For storage of cytology specimen
4		Cervix-Brúm® Or Spatula + Cytobrush	For cervical cells collection

(1) Product Feature

① Tested against electric shock : 1st grade, B-type equipment

② Operation principle

Power cord voltage rated for 220V, 60Hz input, 5V and 12V conversion by SMPS, 5V is used as driving power of micro controller and 12 V is used as driving power of motor and sensor.

Specimen for investigation is poured onto the upper housing of the dual filter, where suction operation of the processor will sieve out unwanted debris at the 1st filter membrane layer, while retaining the cells of interest for investigation on the 2nd filter membrane layer, for the cell transfer process onto a glass slide.

③ Safety feature

Cut-off current : Electric fuse (250V, 2A) is installed in Power cable

4. Product performance and purpose of use

(1) Performance

①Input voltage : AC220V 60Hz

②Output voltage : DC12V, 4A

③Power consumption : 37W

④Detection range : material of 5micron and over

⑤Display type : LED 8 Digit

⑥Protection type and degree against electric shock: 1st grade, B-type

(2) Purpose of use

For cytology preparation from fluid specimen

5. Processor Operation

(1) Checklist :

① Users are advised to read the user manual prior to operating the processor.

② Check exterior of the processor for faults and connection, and ensure that the waste tubing is properly connected to the Waste Container, i.e. one end of the tubing is to be connected to the underneath base of the processor, by inserting it into the opening valve (blue), and the other end to the opening valve (blue) of the Waste Container. The Waste Container should be placed below the level of the processor.

③ Processor should be placed in an appropriate environment away from the direct sun and vibration.

(2) Operating the Processor :

① Plug power cord into power supply source of 220V.

② Turn on processor, the moving glass slide holder arm will move upfront. Place a glass slide with the white frosted end facing downwards onto the slide holder.

③ Insert the filter onto the filter holder, and turn it clockwise to lock it.

④ Before introducing the specimen onto the upper housing of the membrane, mix each cervical specimen collected in the Preservation Solution vial by either vortexing it for 5 seconds on a vortexer (preferably) or shaking vial by turning it upside down . This is to ensure homogeneity of the sample.

⑤ Pour about 2 -3 ml of specimen onto the dual filter, and press the start button to initiate the inhale (suction) mode of the specimen for about 8 -10 seconds. After which the dual filter will be separated apart inside the processor, with the glass slide holder arm moving inwards to the filter area for the cell transferring process. Upon completion of the cell transfer, the glass slide holder arm will move back upfront.

⑥ Remove the processed slide with the cells on it from the glass slide holder arm, and also the used filter from the filter holder by turning it anti-clockwise.

⑦ REPEAT Step 2-6 for the next sample. The whole cycle to process a sample takes less than 30 seconds.

6. Operation on the display panel

A) Function of front LCD display panel

① "POWER" Key : Board's On/Off

② "START" Key : Operation start

③ "STOP" Key: Temporary stop of operation

④ "RESET" Key : Initialization of operation

⑤ "MODE" Key : Main Menu selection

MODE1. Gynecologic Sample Preparation – Gynaecology measuring mode

MODE2. Fine Needle Aspirates – FNA measuring mode

MODE3. Mucoid Specimens – Mucus measuring mode

MODE4. Body FLUID – Body fluid measuring mode

MODE5. Superficial Brushings and Scrapings – Measuring mode of clinical specimen on the surface of body.

MODE6. ECT – Different clinical specimen measuring mode arbitrarily by user

MODE7. Manual – Equipment's operation test measuring mode

⑥ ▲,▼ UP/DOWN Key : can change the setting values of Inhale time(0~60 sec), Inhale pressure(0~99), Smear time(0~20sec), Smear pressure(0~99) to be incremented or decremented by 1 unit number, by pushing up/down button

⑦ ◀,▶ LEFT/RIGHT Key : Sub Menu selection

Inhale time → Inhale pressure→ Smear time→ Smear pressure, in order of sequence, by pushing left/right button to be selected

B) State of the processor when in power OFF mode

Designation	Slide Loader	Vertical Motor	Pin
State	IN	Descent	IN

C) State of processor when power ON

Designation	Slide Loader	Vertical Motor	Pin
State	OUT	Rising	IN

① At LCD display window, "Push Power Key" is displayed

② When Power button is pressed, the following of Main Menu(1~7) caption is displayed.

③ By pressing MODE Key, select as follows – Toggle Mode

MODE1. Gynecologic Sample Preparation - Gynecology measuring mode

MODE2. Fine Needle Aspirates - FNA measuring mode

MODE3. Mucoid Specimens - Mucilage clinical measuring mode

MODE4. Body FLUID - Body fluid measuring mode

MODE5. Superficial Brushings and Scrapings - Measuring mode of clinical specimen on the surface of body.

MODE6. ECT - Different clinical specimen measuring mode arbitrarily by user

MODE7. Manual - Equipment's operation test measuring mode

④ By using ◀,▶ Key, Inhale time → Inhale pressure→ Smear time→ Smear pressure MENU to be selected.

⑤ By using ▲,▼ Key, setting value can be changed or fixed.

⑥ Filter container's lower projecting part need to be mounted like shape along with pushing and turning clockwise to 90 degree and fix it.

⑦ Slide needs to be installed with smear part downwards

⑧ Clinical specimen within the container divided into proper amount(1~3 ml) depending on its specific gravity.

⑨ Push Start Key

⑩ After operation is completed, buzzer sound is generated.

⑪ After discharging liquefied thru inhale device, remove Container and Slide.

⑫ When operation completed, press the MODE Key and Power Key to Power Off

C) Storage condition & Precautions

① When processor is not in used, keep it in a place with low humidity, and not exposed to vibration and shock etc….If not used for long time, please make sure to power-off by unplugging the power cord.

② Operation of processor at room temperature

③ Processor should be operated by trained personnel.

④ Processor should not disassemble or repair by non expert personnel

⑤ Damaged power code should not be used.

⑥ Processor should be used according to its purpose.

Recommended Staining Protocol

Staining of CY-PREP®™ prepared slides could either be stained using existing laboratory Pap staining protocol or the protocol below :

1	80% Ethyl Alcohol	10-15 dips
2	70% Ethyl Alcohol	10-15 dips
3	50% Ethyl Alcohol	10-15 dips
4	Distilled Water	10-15 dips
5	HARRIS'S HEMATOXILIN	1 minute
6	Running Water	2 minute
7	0.5% HCL in distilled water	2 dips
8	Running Water	2 minutes
9	50% Ethyl Alcohol	10-15 dips
10	70% Ethyl Alcohol	10-15 dips
11	80% Ethyl Alcohol	10-15 dips
12	100% Ethyl Alcohol	10-15 dips
13	OG 6	1 dip
14	100% Ethyl Alcohol	10-15 dips
15	100% Ethyl Alcohol	10-15 dips
16	100% Ethyl Alcohol	10-15 dips
17	EA 31	1 minute
18	100% Ethyl Alcohol	10 dips
19	100% Ethyl Alcohol	10 dips
20	100% Ethyl Alcohol	10 dips
21	100% Ethyl Alcohol	10 dips
22	50/50 Xylene and Alcohol	10-15 dips
23	Xylene	10-15 dips
24	Xylene	10-15 dips
25	Xylene	10-15 dips
26	Xylene	10-15 dips

Troubleshooting Guide

Because there is biological variability in collection methods, standard processing may not always yield satisfactory and uniformly distributed preparation on the first slide. Occasionally, cervical samples containing excessive blood, inflammation, or mucus may be rendered unsatisfactory for evaluation. For a conventional Pap smear this necessitates that a second sample must be collected from the patient, delaying diagnosis for at least 3 months. CY-PREP® specimens are preserved in Preservation Solution and are thus available for additional processing if the initial CY-PREP® slide is determined to be unsatisfactory.

The troubleshooting procedures described below will usually yield a second slide that is satisfactory for evaluation.

1. Observation : **Hemorrhagic Smear**, as with the conventional Pap smear, the excess of erythrocytes may limit and impair the morphological analysis. Erythrocytes seen on the CY-PREP® prepared slides does not appear complete as in the conventional Pap slides, but, of varied degrees of fragmentation instead.

   Solution : Pipette out 1 ml of the residual specimen into another tube and add to it 100 µl of 5% glacial acetic solution (the equivalent of 10 parts of specimen sample + 1 part of 5% acetic solution. Vortex it thoroughly before centrifuging it at 2,900 ± 150 x g for 15 ± 2 minutes to get a cell pallet. Decant the supernatant and resuspend the cell pallet with 1 ml of Preservation Solution. Prepare a new thin layer slide using the cell suspension.

2. Observation : **Smear with few cells**, the cellular scarcity can be related to :

   Specimen may actually have too few cells due to conditions inherent to the patient or inadequate cell collection.

   Solution : Preferably to collect a new specimen from the patient, and if this is not possible, concentrate the residual specimen by centrifuging it at 2,900 ± 150 x g for 15± 2 minutes into a cell pallet. Decant the supernatant and re-suspend the cell pallet in 600 µl Preservation Solution. Prepare a new thin layer slide using this suspension.

Additional Testing for sample collected with the CY-PREP® Preservation Solution

Besides the Liquid Cytology for thin layer cytology slide from cervical sample collected with the CY-PREP® Preservation Solution, residual specimen can also be used to perform DNA tests for Human Papillomavirus (HPV), Chlamydia trachomatis (CT), and Neisseria gonorrhoeae (GC).

- **Refer to manufacturers' guide on the processing of DNA assays**

- **See procedure for using HC2 Sample Conversion Kit to prepare cervical cells collected in CY-PREP® Preservation Solution media on page 17, of this operation manual.**

Procedure for using Digene (Qiagen) HC2 Sample Conversion Kit to prepare cervical cells collected in the CY-PREP® Preservation Solution for testing using digene HC2 DNA tests.

The cervical cells are first collected in CY-PREP® Preservation Solution vial. Once the cervical cells have been collected, the Digene (Qiagen) HC2 Sample Conversion Kit can be used to pellet, resuspend, and denature them in preparation for testing.

After the CY-PREP™ Pap Test slides have been prepared, the remaining specimen volume is used to perform Digene (Qiagen) HC2 DNA testing. To have adequate specimen volume for the Digene (Qiagen) HC2 DNA tests, there must be at least 4 ml of the CY-PREP® Preservation Solution remaining in the vial after the preparation of the Pap test slide. Samples with less than 4 ml after the CY-PREP® Pap Test has been prepared, may contain insufficient material and could be falsely negative with the hc2 High-Risk HPV DNA Test.

Processing a 4 ml aliquot of CY-PREP® Preservation Solution produces enough material for 2 tests, when tested manually.

Note : Sample that do not have a visible pellet after centrifugation are not acceptable for testing and should be discarded.

The protocol and volumes of reagents used from the HC2 Sample Conversion Kit for processing Digene (Qiagen) HC2 HPV DNA test using CY-PREP® Preservation Solution, is similar to the listed protocol for PreservCyt Solution in the HC2 Sample Conversion Kit.

Maintenance Procedure

Daily maintenance of the CY-100 Processor

At the completion of the sample processing cycle for each day, a simple flushing of the processor's tubing with 95% ethanol is encouraged.

- Use a new dual filter and have it marked as flushing filter, dedicated for flushing the processor for maintenance purposes. This flushing filter will be reused until signs of tear and wear.

- Insert this marked flushing filter onto the filter holder, and turn it clockwise to lock it. Either use a squeeze bottle that is filled with 95% ethanol or a disposable pipette dropper to dispense out 5-6 ml of 95% ethanol onto the upper housing of the marked flushing filter and perform a test run similar to running of an actual sample.

- Upon completion of the maintenance flushing above, remove the marked flushing filter from the filter holder, and use a clean cloth or blotting paper tissue to dry and clean up the moisture from the processor filter holder. Ensure no paper tissue debris is left behind in the processor filter holder, before powering off the processor.

Limitations of the Procedure

1. For In Vitro Diagnostic Use.

2. The CY-PREP® Pap Test Procedure, Staining and the Interpretation of Specimen Smears must be followed closely to obtain reliable results.

3. It is important to vortex or shake each sample thoroughly to ensure homogeneity. Failure to do so could result in errorneous test results.

4 All other limitations as described for the preparation of sample for the DNA assays may applied.

Warranty

This product is warranted to perform as described in the labeling and in Fjord Diagnostics literature. Fjord Diagnostics disclaims any implied warranty of merchantability of fitness for any other purpose and in no event will Fjord Diagnostics be liable for any in consequential damages arising out of the aforesaid express warranty.

APPENDIX

- Optimization Protocol

- Procedures for processing Gyn & Non-Gyn samples

Optimization protocol for CY-PREP® processed slide quality per user's preference

CY-100 PROCESSOR : GYN PROCESSING PARAMETERS SET IN MACHINE

Duration of Suction	Suction Pressure	Duration of Cell Transfer	Cell Transfer Pressure
8	60	3	60

1. Process a cervical sample together with user, using only 2-3 ml* of sample (enough to cover the area of the filter membrane). Show the processed slide to user whether it's acceptable with the quality of the slide in term of thickness or thinness ? If user is OK with the quality of the processed slide as above, leave the standard parameters setting as such.

2. If user commented the processed slide is too thick for his/her liking from step (1), decrease the last parameter "Cell Transfer Pressure" by 5 units, i.e. from 60 → 55. Upon changing to the new parameter, process a new slide with the same cervical sample. Check /confirm slide quality with user on the new processed slide whether the quality is acceptable. If user is OK with the thickness quality of the new slide, then this will be the new parameters setting for the processor. However, if user still find the thickness still not to his/her liking, i.e. still find the cell too thick, decrease the last parameter "Cell Transfer Pressure" again by another 5 units, i.e. from 55 → 50, and then process a new slide with the same cervical sample. Repeat the step if needed further reduction of the last parameter "Cell Transfer Pressure" setting to get to the slide quality acceptable by the user.

3. Likewise, if user commented the processed slide is too thin for his/her liking from step (1), increase the last parameter "Cell Transfer Pressure" by 5 units, i.e. from 60 → 65. Upon changing to the new parameter, process a new slide with the same cervical sample. Check /confirm slide quality with user on the new processed slide whether the thickness quality is acceptable. If user is OK with the thickness quality of the new slide, then this will be the new parameters setting for the processor. However, if user still find the thickness still not to his/her liking, i.e. still find the cell too thin, increase the last parameter "Cell Transfer Pressure" again by another 5 units, i.e. from 65 → 70, and then process a new slide with the same cervical sample. Repeat the step if needed further increase of the last parameter "Cell Transfer Pressure" setting to get to the slide quality acceptable by the user.

*Recommended sample volume used for processing of CY-PREP® slide is 2-3 ml, however, if a particular sample processed having hardly any cells seen on the processed slide, place the same slide back into the slide holder, and without removing the used filter, pour in another 2-3 ml of sample into the filter and re-run the sample. And if the cell is still hardly to be seen on the 2nd processing, then the issue is that sample collected by the doctor/nurse has too few cells in it.

Procedure for processing Gynecological specimen with the CY-100 Processor

Gynecological specimen

1. Rinse cervical specimen collected with Cervix-Brúm® or Spatula+CytoBrush sampling devices into CY-PREP® Preservation Solution, refer to CY-PREP® Pap Test Quick Reference Guide.

2. Vortex specimen and leave standing for 15 minutes.

3. Record patient's name and/or identification number on the white frosted end of the slide, and place it into the CY-100 Processor slide holder.

4. Insert the gynecological filter into CY-100 Processor filter holder, and screw it in a clockwise dirction to lock it.

5. Pour 2-3 ml of the collected cervical specimen into the gynaecological filter and press the START button on the CY-100 Processor to process a CY-PREP® slide.

6. Remove the processed CY-PREP® slide, and immediately immersed it into a 95% ethanol solution bath to fix the slide.

7. Proceed to staining and cover slipping.

Troubleshooting Guide :

Bloody or mucoid gynaecological samples

1. Pour the full volume of the cervical specimen collected (bloody or mucoid sample) into a 50 ml centrifuge tube, and spin it down for 10 minutes at 1,800-2,000 rpm to palletise the specimen.

2. Decant the supernatant, leaving the pellet cells at the bottom of the centrifuge tube.

3. If the pellet cells is observed to be reddish or mucoid, add 15 ml of the CY-PREP® Lysis Solution (cytolytic mixture solution) to suspend the pellet cells by votexing for 5-8 seconds. Centrifuge sample mixture for 10 minutes at 1,800-2,000 rpm as in step (1), repeat this step, if necessary, until a less pinkish to whitish pellet cells is achieved .
4. Transfer the pellet cells into the CY-PREP™ Preservation Solution vial, and leave it stand for 15 minutes.

5. Process the sample mixture with the CY-100 Processor, use 2-3 ml to make slide.

Procedure for processing Non-Gynaecological specimen with the CY-100 Processor

Non-Gynaecological Specimens

A) Sputum

1. Pour the full volume from the conical tube of the CY-PREP® Preservation Solution specific for Sputum into the sputum collected specimen container. Vortex specimen mixture for 5-10 seconds to help break up the mucus. Pour mixture back into the empty conical tube, cap tightly and spin mixture for 10 minutes at 1,800-2,000 rpm.

2. Decant supernatant, leaving the sputum residue content in the bottom of the conical tube.

3. Add 5-8 ml of the CY-PREP® Preservation Solution, depending on the size of the residue pellet into the conical tube with the sputum residue content to suspend the sputum specimen by vortexing for 5-8 seconds. Let sample mixture stand for 15 minutes before processing.

4. Process the sample mixture with the CY-100 Processor, use 2-3 ml to make a slide.

B) Fine Needle Aspirate (FNA)

1. Collect FNA specimen directly into a conical tube containing the CY-PREP® Preservation Solution specific for FNA.

2. Vortex tube for 5-8 seconds, before placing tube into a centrifuge to spin mixture for 10 minutes at 1,800-2,000 rpm.

3. Decant supernatant, leaving the FNA residue content in the bottom of the conical tube.

4. If bloodiness is still observed in the FNA concentrated cells pellet, again add 15 ml of CY-PREP® Lysis Solution (cytolytic solution mixture) and perform the centrifugation process as in Step (2). Otherwise skip to step (5).

5. Add 3 ml of the CY-PREP® Preservation Solution into the conical tube with the FNA residue content to suspend the FNA specimen by vortexing for 5-8 seconds, if the size of the residue pellet is very small or hardly visible by the naked eye. Let sample mixture stand for 15 minutes before processing.

   Or

6. Add 5 ml of the CY-PREP™ Preservation Solution into the conical tube with the FNA residue content to suspend the FNA specimen by vortexing for 5-8 seconds, if the size of the residue pellet is visible by the naked eye. Let sample mixture stand for 15 minutes before processing.

7. Process the sample mixture with the CY-100 Processor, use 2-3 ml to make a slide.

C) Bronchial brushing

1. Rinse bronchial brushing specimen directly into the CY-PREP® Preservation Solution conical tube, by immersing the brush and rubbing it against the sides of the conical tube. Discard brush and cap the conical tube tightly.

2. If sample is observed to be bloody, centrifuge the bronchial specimen at 1,800-2,000 rpm for 10 minutes.

3. Decant supernatant, leaving about the brochial residue content in the bottom of the conical tube.

4. If bloodiness is still observed, repeat step (2) & (3), by adding 15 ml of CY-PREP® Lysis Solution (cytolytic mixture solution) into the conical tube with bronchial residue content. Vortex specimen residue content for 5-8 seconds to suspend the residue pellet, before spinning for another 10 minutes at 1,800-2,000 rpm. Decant the supernatant, and if a pinkish to whitish residue pellet is achieved, proceed to Step (5) or (6). If residue pellet is still reddish, repeat Step (4) until a pinkish to whitish pellet is achieved.

5. Add 3 ml of the CY-PREP® Preservation Solution into the conical tube with the bronchial brushing residue content to suspend the bronchial brushing specimen by vortexing for 5-8 seconds, if the size of the residue pellet is hardly visible by the naked eye.

   Or

6. Add 5 ml of the CY-PREP® Preservation Solution into the conical tube with the bronchial brushing residue content to suspend the bronchial brushing specimen by vortexing for 5-8 seconds, if the size of the residue pellet is visible by the naked eye. Let sample mixture stand for 15 minutes before processing.

7. Process the sample mixture with the CY-100 Processor, use 2-3 ml to make a slide.

(D) Urine

- There is the naturally released urine, the urine obtained by catheterization, the urine obtained from bladder lavage, the urine obtained from outside of bladder etc.

- For the naturally released urine, collect midstream clean catch urine into a container for examination.

1. Transfer urine specimen into a 50ml centrifuge tube, and spin it for 10 minutes at 1,800-2,000 rpm.

2. Decant supernatant, leaving the urine residue content in the bottom of the centrifuge tube.

3. If bloodiness is observed in the urine concentrated cell pellet, add 15 ml of the CY-PREP® Lysis Solution (cytolytic solution mixture). Vortex for 5-8 seconds to to suspend the pellet before spinning it as in Step (1). Otherwise skip to step 4.

4. Add 5-8 ml of the CY-PREP® Preservation Solution, depending on the size of the residue pellet into the centrifuge tube with the urine residue content to suspend the urine specimen by vortexing for 5-8 seconds. Let sample mixture stand for 15 minutes before processing.

5. Process the sample mixture with the CY-100 Processor, use 2-3 ml to make a slide

(E) Body fluid

- It should be carried in fresh state and if the immediate examination is not possible, it should be stored in refrigerator.

1. Transfer body fluid specimen into a 50ml centrifuge tube, and spin it for 10 minutes at 1,800-2,000 rpm.

2. Decant supernatant, leaving the body fluid residue content in the bottom of the centrifuge tube.

3. If bloodiness is observed in the urine concentrated cell pellet, add 15 ml of the CY-PREP® Lysis Solution (cytolytic solution mixture). Vortex for 5-8 seconds to to suspend the pellet before spinning it as in Step (1). Otherwise skip to step 4.

4. Add 5-8 ml of the CY-PREP® Preservation Solution, depending on the size of the residue pellet into the centrifuge tube with the body fluid residue content to suspend the body fluid specimen by vortexing for 5-8 seconds. Let sample mixture stand for 15 minutes before processing.

5. Process the sample mixture with the CY-100 Processor, use 2-3 ml to make a slide.