

ThinPrep[®] CytoLyt[®] Solution

INSTRUCTIONS FOR USE



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DANGER
POISON

(F, T, R10, R39/23/24/25,
S2, S7, S16, S37/39, S45)

INTENDED USE

CytoLyt[®] Solution is a water-based, buffered cell wash solution designed to lyse red blood cells, prevent protein precipitation, dissolve mucus, and preserve morphology of general cytology cellular samples prior to slide preparation with the ThinPrep 2000 Processor or the ThinPrep 5000 Processor.

SUMMARY AND EXPLANATION

CytoLyt Solution is designed for use with the ThinPrep[®] Processor, a cytologic preparation device that produces slides for microscopic examination. CytoLyt Solution enables the transport and preservation of cells for up to eight days at 15°-30° C.

PRINCIPLES OF PROCEDURE

CytoLyt Solution is a media used for collection and lysing of red blood cells. When used on the ThinPrep 2000 Processor or the ThinPrep 5000 Processor, it allows transfer of cells onto a microscope slide, providing a thin, uniform layer of cells suitable for cytologic evaluation.

COMPOSITION

Methanol based, buffered cell wash solution.

WARNINGS

For In Vitro Diagnostic use.
Not for external or internal use in humans or animals.
DANGER! May be fatal if swallowed.
Vapor may be harmful if inhaled; use with adequate ventilation.
May cause blindness.
May cause eye and skin irritation.
Cannot be made nonpoisonous.

PRECAUTIONS

Wear gloves and eye protection when handling solution. Wash hands thoroughly after handling. Keep container closed when not in direct use. Keep away from heat, sparks and flame. Do not use if primary packaging is damaged.

When transporting a CytoLyt Solution vial containing cells, make sure that the vial is tightly sealed. Align the mark on the cap with the mark on the cup or tube to prevent leakage. Dispose according to local regulations.

As with all laboratory procedures, universal precautions should be followed.

PRETREATMENT

No reconstitution, mixing or dilution is required.

STORAGE

Store CytoLyt Solution without cytologic samples at 15°C to 30°C. Do not use CytoLyt Solution beyond the expiration date marked on the container. Close 946 ml bottle after each use.

APPEARANCE AND INTEGRITY

Clear, non-sterile solution

SPECIMEN COLLECTION AND PREPARATION

Collect non-gynecological samples in a routine manner and refer to the ThinPrep Processor Operator's Manual for preparation instructions. Record required patient information in the space provided. (See figure below).

Figure



Storage and Handling

CytoLyt Solution preserves cells for up to eight days at temperatures between 15° C (59° F) and 30° C (86° F).

PROCESSING INSTRUCTIONS

Cytological specimens collected in CytoLyt Solution are further prepared with PreservCyt[™] Solution and then processed on a ThinPrep 2000 Processor or a ThinPrep 5000 Processor according to instructions in the ThinPrep Processor Operator's Manual.

LIMITATIONS OF PROCEDURE

CytoLyt Solution cannot be substituted with any other solution for specimen collection, preparation and processing on any ThinPrep Processor.

PERFORMANCE CHARACTERISTICS

Refer to the ThinPrep Processor Operator's Manual.

FIRST AID MEASURES

If ingested, seek medical assistance immediately. If inhaled, remove person to fresh air. If symptoms arise, seek medical assistance.

AW-03338-001 Rev. 002

ThinPrep CytoLyt® Solution

NAUDOJIMO INSTRUKCIJOS



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PAVOJINGA
NUODAI

(F, T, R10, R39/23/24/25,
S2, S7, S16, S37/39, S45)

PASKIRTIS

CytoLyt® Solution yra vandens pagrindo, buferizuotas ląstelių praplovimo tirpalas, skirtas eritrocitų lizavimui, baltymų nusėdimo prevencijai, gleivių tirpdymui ir citologinių mėginių morfologijos išlaikymui prieš stiklelio paruošimą su ThinPrep 2000 procesoriumi arba ThinPrep 5000 procesoriumi.

SANTRAUKA IR PAAIŠKINIMAS

CytoLyt Solution yra naudojamas su ThinPrep® procesoriumi, citologinių ruošinių prietaisu, kuris paruošia stiklelius mikroskopiniam įvertinimui. CytoLyt Solution suteikia galimybę transportuoti ir laikyti ląsteles iki aštuonių dienų prie 15°-30°C.

PROCEDŪROS PRINCIPAS

CytoLyt Solution yra terpė, skirta eritrocitų surinkimui ir lizavimui. Naudojant su ThinPrep 2000 procesoriumi ar ThinPrep 5000 procesoriumi, ląsteles galima perkelti ant mikroskopinio stiklelio, paruošiant ploną bei tolygų ląstelių sluoksnį, tinkamą citologiniam įvertinimui.

SUDĖTIS

Metanolio pagrindo, buferizuotas ląstelių praplovimo tirpalas.

ĮSPĖJIMAI

Tik In Vitro diagnostiniam naudojimui.

Ne išoriniam ar vidiniam žmonių ar gyvūnų naudojimui.

PAVOJINGA! Prarijus gali būti mirtinas.

Garų įkvėpimas gali būti pavojingas; užtikrinkite tinkamą vėdinimą.
Gali sukelti aklumą.
Gali dirginti akis ir odą.
Negali būti padaromas nenuodingu.

ATSARGUMO PRIEMONĖS

Naudojant tirpalą, dėvėkite pirštines ir akių apsaugą. Po darbo kruopščiai nusiplaukite rankas. Nenaudojant, konteinerį laikykite sandariai uždarytą. Laikykite atokiai nuo karščio, žiežirbų ir ugnies. Nenaudokite, jei pirminė produkto pakuotė yra pažeista. Transportuojant CytoLyt Solution buteliuką su ląstelėmis, užtikrinkite, jog jis yra sandariai uždarytas. Norint išvengti pratekėjimo, žymą, esančią ant kamštelio, sulygiuokite su žyma, esančia ant mėgintuvėlio. Utilizuokite laikydamiesi vietinių reikalavimų.

Kaip ir atliekant visas laboratorijos procedūras, laikykitės universaliųjų atsargumo priemonių.

IŠANKSTINIS APDOROJIMAS

Nereikia skiesti, maišyti ar kitaip paruošti tirpalo.

LAIKYMAS

CytoLyt Solution be citologinių mėginių laikykite prie 15°C-30°C. Nenaudokite CytoLyt Solution pasibaigus jo galiojimo laikui, pažymėtam ant konteinerio. Po kiekvieno naudojimo, sandariai uždarykite 946 ml buteliuką.

IŠVAIZDA IR INTEGRALUMAS

Skaidrus, nesterilus skystis.

MĖGINIŲ SURINKIMAS IR PARUOŠIMAS

Neginekologinius mėginius surinkite rutiniu būdu, o dėl paruošimo, skaitykite ThinPrep procesoriaus naudotojo vadove pateikiamas instrukcijas. Tam skirtoje vietoje pažymėkite informaciją apie pacientą (žr. žemiau pateiktą paveikslėlį).



Naudojimas ir laikymas

CytoLyt Solution išsaugo ląsteles iki aštuonių dienų, jei yra laikomas prie 15° C (59° F) - 30° C (86° F) temperatūros.

APDOROJIMO INSTRUKCIJOS

Citologiniai mėginiai, surinkti į CytoLyt Solution, toliau yra ruošiami su PreservCyt™ Solution tirpalu ir vėliau yra apdorojami ThinPrep 2000 procesoriuje ar ThinPrep 5000 procesoriuje, laikantis instrukcijų, pateikiamų ThinPrep procesoriaus naudotojo vadove.

PROCEDŪROS APRIBOJIMAI

CytoLyt Solution negali būti keičiamas kitu tirpalu surenkant, ruošiant ir apdorojant mėginius su bet kuriuo ThinPrep procesoriumi.

VEIKSMINGUMO CHARAKTERISTIKA

Skaitykite ThinPrep procesoriaus naudotojo vadovą.

PIRMOSIOS PAGALBOS PRIEMONĖS

Prarijus, nedelsiant kreipkitės medicininės pagalbos. Įkvėpus, nukentėjusįjį išveskite į gryną orą. Atsiradus simptomams, kreipkitės medicininės pagalbos.

AW-03338-001 Perž. 002

Tikslus dokumento vertimas į lietuvių kalbą

Vertėja Akvilė Gegelevičienė

Data 2017-04-08

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PreservCyt® Solution

INSTRUCTIONS FOR USE

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INTENDED USE

PreservCyt® Solution is designed for use with the ThinPrep® 2000 System, which includes the ThinPrep 2000 and 3000 Processors. PreservCyt Solution is a methanol-based reagent that serves as a transport, preservative, and antibacterial medium for gynecologic samples.

The PreservCyt Solution component of the ThinPrep 2000 System is an alternative collection and transport medium for gynecologic specimens tested with the Digene Hybrid Capture® System HPV DNA and Gen-Probe APTIMA COMBO 2® CT/NG assays. Refer to the respective manufacturer's package inserts for instructions for using PreservCyt Solution for collection, transport, and preparation of specimens for use in those systems.

The PreservCyt Solution component of the ThinPrep 2000 System is also an alternative collection and transport medium for gynecologic specimens tested with the Roche Diagnostics COBAS AMPLICOR CT/NG assay. Refer to Hologic's labeling (Document #86013-001) for instructions for using PreservCyt Solution for collection, transport, and preparation of specimens and to the Roche Diagnostics COBAS AMPLICOR CT/NG package insert for instructions for use of that system.

SUMMARY AND EXPLANATION

PreservCyt Solution is designed for use with the ThinPrep Processor, a cytologic preparation device that produces slides for microscopic examination. PreservCyt Solution enables the transport and preservation of cells.

The ThinPrep process begins with the patient's gynecologic sample being collected by the clinician using a cervical sampling device which, rather than being smeared on a microscope slide, is immersed and rinsed in a PreservCyt Solution vial.

The ThinPrep sample vial is then capped, labeled, and sent to a laboratory equipped with a ThinPrep Processor.

PRINCIPLES OF PROCEDURE

PreservCyt Solution is a media used for collection and preservation of cells and DNA of patient samples. When used on the ThinPrep Processor, it allows transfer of cells onto a microscope slide, providing a thin, uniform layer of cells suitable for cytologic evaluation. When used for the Digene Hybrid Capture System HPV DNA, Roche Diagnostics COBAS AMPLICOR CT/NG, and Gen-Probe APTIMA COMBO 2 CT/NG assays, it allows for detection of target DNA.

COMPOSITION

Methanol based, buffered preservative solution.

WARNINGS

For In Vitro Diagnostic use.

Not for external or internal use in humans or animals.

DANGER! May be fatal if swallowed.

Vapor may be harmful if inhaled; use with adequate ventilation.

May cause blindness.

May cause eye and skin irritation.

Cannot be made nonpoisonous.

PRECAUTIONS

Wear gloves and eye protection when handling solution. Wash hands thoroughly after handling. Keep container closed when not in direct use. Keep away from heat, sparks and flame. Do not use if tamper evident seal on vial is broken or missing or if primary packaging is damaged. Dispose according to local regulations.

Do not use wooden and other non-plastic devices for specimen collection. Do not detach the head of a broom-type collection device and place the head into the vial or leave the collection device standing in the solution.

When transporting a PreservCyt Solution vial containing cells, make sure the vial is tightly sealed. Align the mark on the cap with the mark on the vial to prevent leakage (see Figure 1).



PreservCyt Solution was challenged with a variety of microbial and viral organisms. Table 1 presents the starting concentrations of viable organisms and the number of viable organisms found after 15 minutes in PreservCyt Solution. The log reduction of viable organisms is also presented. As with all laboratory procedures, universal precautions should be followed.

PRETREATMENT

No reconstitution, mixing or dilution is required.

STORAGE

Store PreservCyt Solution without cytologic samples at 15°C to 30°C (59°F to 86°F). Do not use PreservCyt Solution beyond the expiration date marked on the vial.

APPEARANCE AND INTEGRITY

Clear, non-sterile solution.



SPECIMEN COLLECTION AND PREPARATION

Collect gynecologic samples using a broom-type cervical collection device or endocervical brush/spatula combination collection device. Record required patient information in the space provide (see Figure 2).

Brush/Spatula Collection Devices

Collect specimens according to applicable instructions for use for the brush/spatula sampling device being used.

Broom-Type Collection Device

Collect specimens according to applicable instructions for use for the broom-type sampling device being used.

Known Interfering Substances

The use of lubricants (e.g. KY Jelly) should be minimized prior to specimen collection. Lubricants can adhere to the filter membrane and may cause poor cell transfer to the slide.

Storage and Handling

Store PreservCyt Solution with cytologic sample intended for ThinPrep Pap testing between 15°C (59°F) and 30°C (86°F) for up to 6 weeks.

PROCESSING INSTRUCTIONS

Cytologic specimens collected in PreservCyt Solution are to be processed on a ThinPrep 2000 or 3000 Processor according to instructions in the ThinPrep 2000 or 3000 Processor Operator's Manual.

LIMITATIONS OF PROCEDURE

PreservCyt Solution cannot be substituted with any other solution for specimen collection, preparation, or processing on a ThinPrep Processor.

Samples already processed on a ThinPrep 3000 Processor should not be tested for Chlamydia trachomatis and Neisseria gonorrhoeae using the Roche Diagnostics COBAS AMPLICOR CT/NG or Gen-Probe APTIMA COMBO 2 CT/NG assays.

PERFORMANCE CHARACTERISTICS

Refer to the ThinPrep 2000 or 3000 Processor Operator's Manual.

FIRST AID MEASURES

If ingested, seek medical assistance immediately. If inhaled, remove person to fresh air. If symptoms arise, seek medical assistance.

TABLE 1

Organism	Initial Concentration	Concentration after 15 min.	Log Reduction
Candida albicans	1.1 x 10 ⁶ CFU/ml	<10 CFU/ml	>5.0
Aspergillus niger	6.7 x 10 ⁶ CFU/ml	<10 CFU/ml	>4.8
Escherichia coli	5.5 x 10 ⁶ CFU/ml	<10 CFU/ml	>5.7
Staphylococcus aureus	5.0 x 10 ⁶ CFU/ml	<10 CFU/ml	>5.7
Pseudomonas aeruginosa	1.1 x 10 ⁶ CFU/ml	<10 CFU/ml	>5.3
Mycobacterium tuberculosis	7.0 x 10 ⁶ CFU/ml	<100 CFU/ml	>4.8
Rabbitpox virus	1.2 x 10 ⁶ PFU/ml	<20 PFU/ml	>6.8
HIV-1	5.8 x 10 ⁶ TCID ₅₀ /ml	≤3 TCID ₅₀ /ml	>7.3

AW-03339-001 Rev. 001

ThinPrep® PAP TEST

PreservCyt® Solution

NAUDOJIMO INSTRUKCIJOS



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(F, T, R-11, R23/24/25,
R39/23/24/25,
S16, S23, S24/25, S37/38)

PASKIRTIS

PreservCyt® Solution yra naudojamas kartu su ThinPrep® 2000 sistema, kurioje yra ThipPrep 200 ir 3000 procesoriai. PreservCyt Solution yra metanolio pagrindo reagentas, naudojamas kaip transportavimo, saugojimo ir antibakterinė terpė ginekologiniams mėginiams.

ThinPrep 2000 sistemos komponentas PreservCyt Solution yra alternatyvi ginekologinių mėginių, tiriamų su Digene Hybrid Capture® sistema HPV DNA ir Gen-Probe APTIMA COMBO 2® CT/NG tyrimais, surinkimo ir transportavimo terpė. Dėl PreservCyt Solution naudojimo surenkant, transportuojant ir ruošiant mėginius tyrimui su šiomis sistemomis, skaitykite atitinkamo sistemos gamintojo instrukcijas naudotojo vadove.

ThinPrep 2000 sistemos komponentas PreservCyt Solution taip pat yra alternatyvi surinkimo ir transportavimo terpė mėginiams, tiriamiems su Roche Diagnostics COBAS AMPLICOR CT/NG tyrimu. Skaitykite Hologic žymose (dokumentas #86013-001) pateiktas instrukcijas dėl PreservCyt Solution naudojimo surenkant, transportuojant ir ruošiant mėginius bei Roche Diagnostics COBAS AMPLICOR CT/NG pakuotės aprašymą dėl produkto naudojimo su šia sistema.

SANTRAUKA IR PAAIŠKINIMAS

PreservCyt Solution yra naudojamas su ThinPrep procesoriumi, citologinių ruošinių prietaisu, kuris paruošia stiklelius mikroskopiniam įvertinimui. PreservCyt Solution yra skirtas ląstelių transportavimui ir laikymui.

ThinPrep procesas prasideda nuo ginekologinio mėginio paėmimo iš paciento, naudojant gimdos kaklelio mėginių surinkimo priemonę, kuri yra įmerkama į PreservCyt Solution buteliuką ir praskalaujama, vietoje tepinėlio ant stiklelio atlikimo.

Tada ThinPrep mėginio buteliukas yra uždaromas ir siunčiamas į laboratoriją, kurioje yra ThinPrep procesorius.

PROCEDŪROS PRINCIPAS

PreservCyt Solution yra terpė, skirta pacientų mėginių ląstelių ir DNR surinkimui ir laikymui. Naudojant su ThinPrep procesoriumi, ląsteles galima perkelti ant mikroskopinio stiklelio, paruošiant ploną bei tolygų ląstelių sluoksnį, tinkamą citologiniam įvertinimui. Naudojant su Digene Hybrid Capture sistema HPV DNA, Roche Diagnostics COBAS AMPLICOR CT/NG ir Gen-Probe APTIMA COMBO 2 CT/NG tyrimais, galima atlikti taikinio DNR aptikimą.

SUDĖTIS

Metanolio pagrindo, buferizuotas konservantinis tirpalas.

ĮSPĖJIMAI

Tik In Vitro diagnostiniam naudojimui.

Ne išoriniam ar vidiniam žmonių ar gyvūnų naudojimui.

PAVOJINGA! Prarijus gali būti mirtinas.

Garų įkvėpimas gali būti pavojingas; užtikrinkite tinkamą vėdinimą.

Gali sukelti aklumą.

Gali dirginti akis ir odą.

Negali būti padaromas nenuodingu.

ATSARGUMO PRIEMONĖS

Naudojant tirpalą, dėvėkite pirštines ir akių apsaugą. Po darbo kruopščiai nusiplaukite rankas. Nenaudojant, konteinerį laikykite sandariai uždarytą. Laikykite atokiai nuo karščio, žiežirbų ir ugnies. Nenaudokite, jei buteliuko užsandarinimas yra pažeistas arba jo nėra ir jei pirminė produkto pakuotė yra pažeista. Utilizuokite laikydamiesi vietinių reikalavimų.

Mėginio surinkimui nenaudokite medinių ar kitų neplastikinių priemonių. Nenuimkite šluotelės tipo priemonės galvutės ir nedėkite jos į buteliuką bei nepalikite surinkimo priemonės stovėti tirpale.

Transportuojant PreservCyt Solution buteliuką su ląstelėmis, užtikrinkite, jog jis yra sandariai uždarytas. Norint išvengti pratekėjimo, žymą, esančią ant kamštelio, sulygiuokite su žyma, esančia ant mėgintuvėlio (žr. pav. 1).

Pav.1



Linijos, esančios ant kamštelio ir buteliuko, turi sutapti ar nežymiai persidengti.

PreservCyt Solution buvo tiriamas su įvairiais mikrobais ir virusais. 1 lentelėje yra pateikiamos pradinės gyvybingų organizmų koncentracijos ir gyvybingų organizmų, aptiktų po 15 minučių PreservCyt tirpale, skaičius. Taip pat yra pateikiamas gyvybingų organizmų logaritmo sumažėjimas. Kaip ir atliekant visas laboratorijos procedūras, laikykitės universaliųjų atsargumo priemonių.

IŠANKSTINIS APDOROJIMAS

Nereikia skiesti, maišyti ar kitaip paruošti tirpalo.

LAIKYMAS

PreservCyt Solution be citologinių mėginių laikykite prie 15°C-30°C. Nenaudokite PreservCyt Solution pasibaigus jo galiojimo laikui, pažymėtam ant buteliuko.

IŠVAIZDA IR INTEGRALUMAS

Skaidrus, nesterilus skystis.

MĖGINIŲ SURINKIMAS IR PARUOŠIMAS

Ginekologinius mėginius surinkite šluotelės tipo mėginių paėmimo priemone ar gimdos kaklelio šepetėlio/mentelės priemone. Tam skirtoje vietoje pažymėkite informaciją apie pacientą (žr. pav.2).



Pav.2

Šepetėlio/mentelės tipo mėginio paėmimo priemonė

Mėginius surinkite laikydamiesi naudojamos šepetėlio/mentelės tipo mėginio paėmimo priemonės naudojimo instrukcijų.

Šluotelės tipo mėginio paėmimo priemonė

Mėginius surinkite laikydamiesi naudojamos šluotelės tipo mėginio paėmimo priemonės naudojimo instrukcijų.

Žinomos interferuojančios substancijos

Lubrikantų (pvz., KY Jelly) naudojimas prieš mėginio paėmimą turi būti sumažintas. Lubrikantai gali prikibti prie filtro membranos ir sumažinti ląstelių perkėlimo ant stiklelio kokybę.

Naudojimas ir laikymas

PreservCyt Solution su citologiniu mėginiu, skirtu ThinPrep tyrimui, laikykite prie 15° C (59° F) - 30° C (86° F) temperatūros iki 6 savaičių.

APDOROJIMO INSTRUKCIJOS

Citologiniai mėginiai, surinkti į PreservCyt Solution, yra apdorojami ThinPrep 2000 procesoriuje ar ThinPrep 5000 procesoriuje, laikantis instrukcijų, pateikiamų ThinPrep 2000 ar 3000 procesoriaus naudotojo vadove.

PROCEDŪROS APRIBOJIMAI

PreservCyt Solution negali būti keičiamas kitu tirpalu surenkant, ruošiant ir apdorojant mėginius su bet kuriuo ThinPrep procesoriumi.

Mėginiai, apdoroti su ThinPrep 3000 procesoriumi negali būti tiriami dėl *Chlamydia trachomatis* ir *Neisseria gonorrhoeae*, naudojant Roche Diagnostics COBAS AMPLICATOR CT/NG ar Gen-Probe APTIMA COMBO 2 CT/NG tyrimus.

VEIKSMINGUMO CHARAKTERISTIKA

Skaitykite ThinPrep 2000 ar 3000 procesoriaus naudotojo vadovą.

PIRMOSIOS PAGALBOS PRIEMONĖS

Prarijus, nedelsiant kreipkitės medicininės pagalbos. Įkvėpus, nukentėjusį išveskite į gryną orą. Atsiradus simptomams, kreipkitės medicininės pagalbos.

1 LENTELE

Organizmas	Pradinė koncentracija	Koncentracija po 15 min.	Log sumažėjimas
<i>Candida albicans</i>	1.1x10 ⁶ CFU/ml	<10 CFU/ml	>0.5
<i>Aspergillus niger</i>	6.7x10 ⁵ CFU/ml	<10 CFU/ml	>4.8
<i>Escherichia coli</i>	5.5x10 ⁶ CFU/ml	<10 CFU/ml	>5.7
<i>Staphylococcus aureus</i>	5.0x10 ⁶ CFU/ml	<10 CFU/ml	>5.7
<i>Pseudomonas aeruginosa</i>	2.1x10 ⁶ CFU/ml	<10 CFU/ml	>5.3
<i>Mycobacterium tuberculosis</i>	7.0x10 ⁶ CFU/ml	<100 CFU/ml	>4.8
<i>Rabbitpox virusas</i>	1.2x10 ⁸ PFU/ml	<20 PFU/ml	>6.8
ŽIV-1	5.6x10 ⁷ TCID ₅₀ /ml	<3 TCID ₅₀ /ml	>7.3

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Tikslus dokumento vertimas į lietuvių kalbą

Vertėja Akvilė Gegelevičienė

Data 2017-02-09

UAB Diamedica

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Rinse Solution

INSTRUCTIONS FOR USE



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Intended Use

ThinPrep® Rinse Solution is intended to be used in a Papanicolaou staining procedure in conjunction with ThinPrep Nuclear Stain, ThinPrep Bluing Solution, ThinPrep Orange G Solution, and ThinPrep EA Solution.

Summary and Explanation

ThinPrep Rinse Solution is an aqueous, detergent solution that removes excess ThinPrep Nuclear Stain from cellular components on slide preparations for cytologic evaluation.

Principles of Procedure

When used in conjunction with the ThinPrep staining solutions and cytologic slide preparations, ThinPrep Rinse Solution will remove excess ThinPrep Nuclear Stain from cellular components, enhancing nuclear staining and clarifying cytoplasm.

Composition

An aqueous solution of propriety surfactant.

Warnings

For In Vitro Diagnostic Use.
Not for external or internal use in humans or animals.
May cause eye irritation on contact.

Precautions

Avoid contact with eyes.
Wear gloves and eye protection when handling solution.
Keep container closed when not in direct use.
Results with non-ThinPrep cytology samples have not been evaluated.
Do not use if primary packaging is damaged.

Pretreatment

No reconstitution, mixing or dilution is required.

Storage

Store unused ThinPrep Rinse Solution at 15°C (59°F) to 30°C (86°F) in the container provided. Do not use ThinPrep Rinse Solution beyond the expiration date marked on the container.

Appearance and Integrity

Clear, non-sterile solution.

Specimen Collection and Preparation

For use with gynecologic cytology samples that have been processed on any ThinPrep Processor.

Procedure

See the ThinPrep Stain User's Manual for specific staining protocols.

Limitations of Procedure

Must be used according to the instructions provided in the ThinPrep Stain User's Manual. ThinPrep Rinse Solution cannot be substituted with any other solution.

Performance Characteristics

When used as directed on cytologic slide preparations, ThinPrep Rinse Solution removes excess ThinPrep Nuclear Stain from cellular components.

First Aid Measures

No ill effects are anticipated. See www.hologicmsds.com for the entire Material Safety Data Sheet or Safety Data Sheet (MSDS or SDS).

Ordering Information

Package of one 4-liter container

70779-001

ThinPrep® Stain

Rinse Solution

NAUDOJIMO INSTRUKCIJOS



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Paskirtis

ThinPrep® Rinse tirpalas yra naudojamas Papanicolaou dažymo metu kartu su ThinPrep Orange G tirpalu, ThinPrep Nuclear dažais, ThinPrep Bluing tirpalu ir ThinPrep EA tirpalu.

Santrauka ir paaiškinimas

ThinPrep Rinse tirpalas yra vandens pagrindo detergentinis tirpalas, kuris pašalina ThinPrep Nuclear dažų perteklių nuo ląstelės komponentų stiklelių ruošiniuose, skirtuose citologiniam įvertinimui.

Procedūros principas

Naudojamas kartu su ThinPrep dažymo tirpalais ir citologiniais ruošiniais ant stiklelių, ThinPrep Rinse tirpalas pašalina ThinPrep Nuclear dažų perteklių nuo ląstelės komponentų, išryškinant nusidažymą ir klarifikuojant citoplazmą.

Sudėtis

Vandeninis tirpalas su patentuotais surfaktantais.

Įspėjimai

Tik In Vitro diagnostiniam naudojimui.

Ne išoriniam ar vidiniam žmonių ar gyvūnų naudojimui.

Gali dirginti akis ir odą.

Atsargumo priemonės

Venkite kontakto su akimis.

Naudojant tirpalą, dėvėkite pirštines ir akių apsaugą.

Nenaudojant, konteinerį laikykite sandariai uždarytą.
Rezultatai, gauti su ne ThinPrep citologiniais mėginiais, nebuvo vertinami.
Nenaudokite, jei pirminė produkto pakuotė yra pažeista.

Išankstinis apdorojimas

Nereikia skiesti, maišyti ar kitaip paruošti tirpalo.

Laikymas

ThinPrep Rinse tirpalą laikykite prie 15°C (59°F) - 30°C (86°F) originaliame konteineryje.
Nenaudokite ThinPrep Rinse tirpalo pasibaigus jo galiojimo laikui, pažymėtam ant konteinerio.

Išvaizda ir integralumas

Skaidrus, nesterilus skystis.

Mėginių surinkimas ir paruošimas

Naudojamas su ginekologiniais citologiniais mėginiais, apdorotais su ThinPrep procesoriumi.

Procedūra

Dėl specifinio dažymo protokolo skaitykite ThinPrep Stain naudotojo vadovą.

Procedūros apribojimai

Produktas turi būti naudojamas laikantis instrukcijų, pateikiamų ThinPrep Stain naudotojo vadove.
ThinPrep Rinse tirpalas negali būti keičiamas kitu tirpalu.

Veiksmingumo charakteristika

Naudojamas su citologiniais ruošiniais ant stiklelių, ThinPrep Rinse tirpalas pašalina ThinPrep Nuclear dažų perteklių nuo ląstelės komponentų.

Pirmosios pagalbos priemonės

Susirgimo simptomai nėra tikėtini. Medžiagos saugos duomenų lapą (MSDS) ar saugos duomenų lapą (SDL) rasite apsilankę tinklalapyje www.hologicmsds.com.

Užsakymo informacija

4 litrų konteinerio pakuotė.

70780-001

AW-04349-001 Perž. 002

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Vertėja Akvilė Gegelevičienė

Data 2017-02-09

UAB Diamedica

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ThinPrep[®] Urine Collection Kit

UROCYTE

with PreservCyt[®] Solution

INSTRUCTIONS FOR USE



Read all instructions, warnings and precautions prior to use.



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(F, T, R-11, R 23/24/25,
R 39/23/24/25, S16, S23, S24/25, S37/38)

NOTE:

The ThinPrep[®] Urine Collection Kit is intended to be used in a healthcare environment. If the healthcare provider requires the specimen to be collected at home, the provider must review these instructions for use with the patient and provide the patient with any necessary protective equipment.

INTENDED USE

To collect, preserve and transport urine specimens for cytological examination using the ThinPrep[®] 2000 Processor or the ThinPrep[®] 5000 Processor and UroCyt[®] Slide Preparation System or Vysis[®] UroVysion[™] Bladder Cancer Kit.

PRINCIPLES OF PROCEDURE

Urine is collected in the specimen collection cup and PreservCyt Solution is added to preserve the cells and DNA of the patient's sample.

CONTENTS:

Specimen Collection Cup (blue cap)
30 ml vial (white cap) PreservCyt Solution – methanol based, buffered preservative solution
Absorbent pad
Specimen Transport Bag

WARNINGS

- For In Vitro Diagnostic use;
- Not for external or internal use in humans or animals
- DANGER: PreservCyt Solution¹:
 - may be fatal if swallowed
 - may cause blindness
 - may cause eye and skin irritation
 - may be harmful if inhaled
 - cannot be made non-poisonous
 - may be hazardous to the environment
- Urine specimens are considered biohazardous

¹Contact Hologic or go to www.hologic.com for a copy of the Material Safety Data Sheet (MSDS) for PreservCyt Solution

STORAGE AND HANDLING

- Store PreservCyt Solution without urine at 15°C – 30°C. Do not use beyond expiration date marked on the vial.
- Keep PreservCyt Solution vial and specimen collection cup closed until ready to use.
- Store PreservCyt Solution with urine specimen between 4°C and 30°C. Process sample within 48 hours

PRECAUTIONS

- Read these instructions carefully before use.
 - Inspect all contents for damage.
 - Wear gloves and eye protection when handling urine specimen or PreservCyt Solution. Wash hands thoroughly after handling. As with all laboratory procedures, universal precautions should be followed.
 - Do not use if tamper-proof seal on PreservCyt Solution vial or specimen collection cup is broken.
 - Do not use PreservCyt Solution beyond the expiration date marked on the vial.
 - Use in a well ventilated area.
 - Avoid direct contact. Do not urinate or pour specimen directly into PreservCyt Solution vial as this may cause the solution to splash or spill.
 - Minimize the use of lubricants (e.g. KY[®] Jelly) prior to specimen collection; as such substances can interfere with cell transfer.
 - Keep away from heat, sparks and flames.
 - Keep away from children and pets.
 - Keep specimen cup and PreservCyt Solution vial closed when not in use.
- Before transporting specimen, make sure the specimen collection cup is tightly sealed by turning cap until after hearing audible click.

DISPOSAL INFORMATION

- Dispose of used specimen collection cup, absorbent pad, transport bag and any remaining specimen as a biohazard
- Dispose of any remaining PreservCyt Solution according to local regulations.
- Do not use beyond the expiration date marked on the PreservCyt Solution vial.

LIMITATIONS OF PROCEDURE

- PreservCyt Solution cannot be substituted with any other solution for specimen collection, preparation and processing.
- Diagnosis can only be made by a trained medical professional.

PERFORMANCE CHARACTERISTICS

PreservCyt Solution exhibits bacteriostatic properties and prevents growth of organisms in urine specimens when used at a 2:1 ratio of urine to PreservCyt Solution at temperatures between 4°C and 30°C.

INSTRUCTIONS FOR USE

1. Inspect kit to ensure all contents are present and intact.
2. Record patient information in the space provided on the specimen collection cup
3. Collect urine in a routine manner. Note: A minimum of 33cc of urine is required for the Vysis UroVysion FISH Test. Volume measurements can be found on the side of the specimen cup.
4. If urine exceeds 60cc, pour off the excess (the total volume of urine must not exceed 60cc)
5. Carefully pour the entire contents of the PreservCyt Solution vial into the specimen cup containing urine
6. Tightly secure blue cap on specimen cup to prevent leakage (keep turning until after you hear the audible click)
7. Place specimen collection cup containing the urine/PreservCyt Solution, and the absorbent pad in the specimen transport bag. Tightly seal bag.
8. Store specimen with PreservCyt Solution between 4°C - 30°C (39°F – 86°F). Preferred storage and shipping conditions are on ice packs (e.g. blue ice in Styrofoam).
9. Process specimen within 48 hours according to appropriate instructions outlined in the ThinPrep Processor Operator's Manual or the Vysis UroVysion Instructions for Use.

FIRST AID INFORMATION

- If ingested, seek medical attention immediately. Patients using this product at home should contact their local poison control center.
- If inhaled, remove person to fresh air. If symptoms arise, seek medical attention.
- If PreservCyt Solution comes in contact with skin or eyes, flush thoroughly with cold water for 15 minutes. Seek medical attention if symptoms arise.

ThinPrep® Urine Collection Kit with PreservCyt® Solution

NAUDOJIMO INSTRUKCIJOS



Prieš naudojimą perskaitykite instrukcijas, įspėjimus ir atsargumo priemones



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PAVOJINGA
NUODAI



(F, T, R-11, R 23/24/25,
R 39/23/24/25, S16, S23, S24/25, S37/38)

PASTABA

ThinPrep® šlapimo surinkimo rinkinys yra naudojamas sveikatos priežiūros įstaigose. Jei gydantysis personalas paskiria pacientui paimti šlapimo mėginį namie, jis/ji turi būti supažindintas su naudojimo instrukcijomis ir aprūpintas visomis būtinomis apsaugos priemonėmis.

PASKIRTIS

Produktas yra skirtas šlapimo mėginių, skirtų citologiniam ištyrimui su ThinPrep® 2000 procesoriumi ar ThinPrep® 5000 procesoriumi ir UroCyte® stiklelių paruošimo sistema ar Vysis® UroVysion™ Bladder Cancer rinkiniu, surinkimui, išsaugojimui ir transportavimui.

PROCEDŪROS PRINCIPAS

Šlapimo mėginys yra surenkamas į surinkimo indelį, į kurį yra įdedama PreservCyt tirpalo paciento mėginio ląstelių ir DNR išsaugojimui.

SUDĖTIS:

Mėginio surinkimo indelis (mėlynu dangteliu).
30 ml buteliukas (baltu dangteliu) PreservCyt tirpalo – metanolio pagrindo buferizuotas konservantinis tirpalas.
Absorbentinis lapelis.
Mėginio transportavimo maišelis.

ĮSPĖJIMAI

- Tik In Vitro diagnostiniam naudojimui;
- Ne išoriniam ar vidiniam žmonių ar gyvūnų naudojimui;
- PAVOJINGA: PreservCyt tirpalas¹:
- prarijus gali būti mirtinas
- gali sukelti aklumą
- gali dirginti akis ir odą
- įkvėpus gali būti kenksmingas
- negali būti padaromas nenuodingu
- gali būti kenksmingas aplinkai
- šlapimo mėginiai yra laikomi biologiškai pavojingais

¹Dėl PreservCyt tirpalo medžiagos duomenų saugos lapo (MSDL) susisieki su Hologic arba apsilankykite tinklalapyje www.hologic.com.

LAIKYMAS IR NAUDOJIMAS

- PreservCyt tirpalą be šlapimo laikykite prie 15°C – 30°C. Nenaudokite pasibaigus ant buteliuko nurodytai galiojimo datai.
- Iki naudojimo, PreservCyt tirpalo buteliuką laikykite sandariai uždarytą.
- PreservCyt tirpalą su šlapimo mėginiais laikykite prie 4°C – 30°C. Mėginį apdorokite per 48 valandas.

ATSARGUMO PRIEMONĖS

- Prieš naudojimą atidžiai perskaitykite instrukcijas.
- Apžiūrėkite, ar komponentai nėra pažeisti.
- Naudojant šlapimo mėginius ar PreservCyt tirpalą, dėvėkite pirštines ir akių apsaugą. Po darbo kruopščiai nusiplaaukite rankas. Kaip ir visų laboratorinių procedūrų metu, laikykitės universaliųjų atsargumo priemonių.
- Nenaudokite, jei PreservCyt buteliuko užsandarinimas ar mėginio surinkimo indelis yra pažeistas.
- Nenaudokite PreservCyt tirpalo pasibaigus jo galiojimo datai, pažymėtai ant buteliuko.
- Naudokite gerai vėdinamoje patalpoje.
- Venkite tiesioginio kontakto. Mėginio nepilkite tiesiogiai į PreservCyt tirpalo buteliuką, nes tirpalas gali taškytis ar išsilieti.
- Prieš mėginio surinkimą, minimizuokite lubrikantų (pvz., KY[®] Jelly) naudojimą, nes tokio pobūdžio substancijos gali interferuoti ląstelių perkėlimą.
- Laikykite atokiai nuo karščio, žiežirbų ir ugnies.
- Saugokite nuo vaikų ir gyvūnų.
- Nenaudojant, mėginio indelį ir PreservCyt tirpalo buteliuką laikykite uždarytus.
- Prieš mėginio transportavimą, užtikrinkite, jog mėginio surinkimo indelis yra sandariai uždarytas – sukite dangtelį, kol pasigirs spragtelėjimas.

IŠMETIMO INFORMACIJA

- Panaudotą mėginio surinkimo indelį, absorbentinį lapelį, transportavimo maišelį ir likusį mėginį išmeskite kaip biologiškai pavojingas atliekas.
- Likusį PreservCyt tirpalą išmeskite laikydamiesi vietinių taisyklių.

- Nenaudokite PreservCyt tirpalo pasibaigus jo galiojimo datai, pažymėtai ant buteliuko.

PROCEDŪROS APRIBOJIMAI

- PreservCyt tirpalas negali būti keičiamas kitu tirpalu surenkant, ruošiant ir apdorojant mėginius.
- Diagnozė turi būti atliekama apmokyto profesionalaus medicinos personalo.

VEIKSMINGUMO CHARAKTERISTIKA

PreservCyt tirpalas turi bakteriostatinių savybių ir užkerta kelią organizmų augimui šlapimo mėginiuose, kai yra naudojamas santykiu 2:1 (šlapimas su PreservCyt tirpalu) prie 4°C - 30°C temperatūros.

NAUDOJIMO INSTRUKCIJOS

1. Apžiūrėkite rinkinį ir įsitikinkite, ar yra visi komponentai ir ar jie nėra pažeisti.
2. Tam skirtoje vietoje ant mėginio indelio užrašykite paciento informaciją.
3. Šlapimą surinkite rutininio būdu. Pastaba: Vysis UroVysion FISH tyrimui reikia mažiausiai 33cc šlapimo. Tūrio matavimas yra pažymėtas ant mėginio indelio šono.
4. Jei šlapimo tūris viršija 60cc, perteklių nupilkite (bendras šlapimo mėginio tūris negali viršyti 60cc).
5. Atsargiai supilkite visą PreservCyt tirpalo buteliuko turinį į mėginio indelį su šlapimu.
6. Sandariai užsukite mėginio indelio mėlyną dangtelį, kad išvengtumėte pratekėjimo (sukite, kol pasigirs spragtelėjimas).
7. Mėginio surinkimo indelį su mėginiu/ PreservCyt tirpalu ir absorbentiniu lapeliu įdėkite į transportavimo maišelį. Maišelį užsandarinkite.
8. Mėginį su PreservCyt tirpalu laikykite prie 4°C - 30°C (39°F – 86°F). Rekomenduojamos laikymo ir transportavimo sąlygos – ant ledo (pvz., ledas putų polistirole).
9. Mėginius apdorokite per 48 valandas, laikydamiesi instrukcijų, pateikiamų ThinPrep procesoriaus naudotojo vadove ar Vysis UroVysion naudojimo instrukcijose.

PIRMOSIOS PAGALBOS PRIEMONĖS

- Prarijus, nedelsiant kreipkitės medicininės pagalbos. Pacientai, naudojantys šį produktą namie, turi skambinti į vietinį apsinuodijimų centrą.
- Įkvėpus, nukentėjusį išveskite į gryną orą. Atsiradus simptomams, kreipkitės medicininės pagalbos.
- Jei PreservCyt tirpalo pateko į akis, 15 minučių kruopščiai plaukite šaltu vandeniu. Atsiradus simptomams, kreipkitės medicininės pagalbos.

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Vertėja Akvilė Gegelevičienė

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UAB Diamedica

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TABLE 16: SUMMARY OF DIRECT-TO-VIAL ENDOCERVICAL COMPONENT (ECC) STUDIES

Study	Number of Evaluable Patients	SBLB due to No Endocervical Component	Comparable Conventional Pap Smear Percentage
Direct-to-Vial Feasibility	299	9.36%	9.43% ¹
Direct-to-Vial Clinical Study	484	4.96%	4.38% ²

1. Direct-to-Vial Feasibility study compared to overall clinical investigation conventional Pap smear SBLB-No Endocervical Component rate.
 2. Direct-to-Vial Clinical study compared to site S2 clinical investigation conventional Pap smear SBLB-No Endocervical Component rate.

Direct-to-Vial HSIL+ Study

Following initial FDA approval of the ThinPrep System, Hologic conducted a multi-site direct-to-vial clinical study to evaluate the ThinPrep 2000 System versus conventional Pap smear for the detection of High Grade Squamous Intraepithelial and more severe lesions (HSIL+). Two types of patient groups were enrolled in the trial from ten (10) leading academic hospitals in major metropolitan areas throughout the United States. From each site, one group consisted of patients representative of a routine Pap test screening population and the other group made up of patients representative of a referral population enrolled at the time of colposcopic examination. The ThinPrep specimens were collected prospectively and compared against a historical control cohort. The historical cohort consisted of data collected from the same clinics and clinicians (if available) used to collect the ThinPrep specimens. These data were collected sequentially from patients seen immediately prior to the initiation of the study.

The results from this study showed a detection rate of 511 / 20,917 for the conventional Pap smear versus 399 / 10,226 for the ThinPrep slides. For these clinical sites and these study populations, this indicates a 59.7% increase in detection of HSIL+ lesions for the ThinPrep specimens. These results are summarized in Table 17.

TABLE 17: SUMMARY OF DIRECT-TO-VIAL HSIL+ STUDY

Site	Total CP (n)	HSIL+	Percent (%)	Total TP (n)	HSIL+	Percent (%)	Percent Change (%)
S1	2,439	51	2.1	1,218	26	2.1	+2.1
S2	2,075	44	2.1	1,001	57	5.7	+168.5
S3	2,034	7	0.3	1,016	16	1.6	+357.6
S4	2,043	14	0.7	1,000	19	1.9	+177.3
S5	2,040	166	8.1	1,004	98	9.8	+20.0
S6	2,011	37	1.8	1,004	39	3.9	+111.1
S7	2,221	58	2.6	1,000	45	4.5	+72.3
S8	2,039	61	3.0	983	44	4.5	+49.6
S9	2,000	4	0.2	1,000	5	0.5	+150.0
S10	2,015	69	3.4	1,000	50	5.0	+46.0
Total	20,917	511	2.4	10,226	399	3.9	59.7(p<0.001)

Percent Change (%) = ((TP HSIL+/TP Total)/(CP HSIL+/CP Total)-1) *100

GLANDULAR DISEASE DETECTION – PUBLISHED STUDIES

The detection of endocervical glandular lesions is an essential function of the Pap test. However, abnormal glandular cells in the Pap sample may also originate from the endometrium or from extrauterine sites. The Pap test is not intended to be a screening test for such lesions.

When suspected glandular abnormalities are identified, their accurate classification as true glandular versus squamous lesions is important for proper evaluation and subsequent treatment (e.g. choice of excisional biopsy method versus conservative follow-up). Multiple peer-reviewed publications⁴⁻⁹ report on the improved ability of the ThinPrep 2000 System to detect glandular disease versus the conventional Pap smear. Although these studies do not consistently address sensitivity of different Pap testing methods in detecting specific types of glandular disease, the reported results are consistent with more frequent biopsy confirmation of abnormal glandular findings by the ThinPrep Pap Test compared to conventional cytology.

Thus, the finding of a glandular abnormality on a ThinPrep Pap Test slide merits increased attention for definitive evaluation of potential endocervical or endometrial pathology.

CONCLUSIONS

The ThinPrep® 2000 System is as effective as the conventional Pap smear in a variety of patient populations and may be used as a replacement for the conventional Pap smear method for the detection of atypical cells, cervical cancer, or its precursor lesions, as well as all other cytologic categories as defined by The Bethesda System.

The ThinPrep 2000 System is significantly more effective than the conventional Pap smear for the detection of Low-grade Squamous Intraepithelial (LSIL) and more severe lesions in a variety of patient populations.

Specimen quality with the ThinPrep 2000 System is significantly improved over that of conventional Pap smear preparation in a variety of patient populations.

MATERIALS REQUIRED

MATERIALS PROVIDED

The ThinPrep 2000 System consists of the following components:

- ThinPrep Processor Instrument (Model TP 2000)
- PreservCyt® Solution vial
- ThinPrep Pap Test Filter for Gynecologic Applications
- Program Memory Card for Gynecologic Applications
- Waste bottle assembly - includes bottle, bottle cap, tubing set, fittings, waste filter
- 2 filter Caps
- 2 spare filter seal O-rings
- Power cord
- ThinPrep Microscope slides

Additional items supplied:

- ThinPrep 2000 Operator's Manual
- 10 fixative vials

MATERIALS REQUIRED BUT NOT PROVIDED

- Slide staining system and reagents
- Standard laboratory fixative
- Coverslips and mounting media
- 20 ml PreservCyt® Solution vial
- ThinPrep® Pap Test Filter for Gynecologic Applications
- Cervical collection device

STORAGE

- Store PreservCyt Solution between 15°C (59°F) and 30°C (86°F). Do not use beyond the expiration date printed on the container.
- Store PreservCyt Solution with cytologic sample intended for ThinPrep Pap testing between 15°C (59°F) and 30°C (86°F) for up to 6 weeks.
- Store PreservCyt Solution with cytologic sample intended for CT/NG testing using the Roche Diagnostics COBAS AMPLICOR CT/NG test between 4°C (39°F) and 25°C (77°F) for up to 6 weeks.

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TECHNICAL SERVICE AND PRODUCT INFORMATION

For technical service and assistance related to use of the ThinPrep 2000 System, contact Hologic:

Telephone: 1-800-442-9892

Fax: 1-508-229-2795

For international or toll-free blocked calls, please contact 1-508-263-2900.

Email: info@hologic.com

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**Hologic, Inc.
ThinPrep® 2000 System**

Instructions for Use

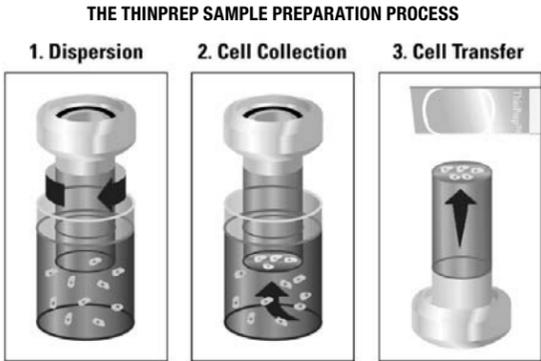
INTENDED USE

The ThinPrep® 2000 System is intended as a replacement for the conventional method of Pap smear preparation for use in screening for the presence of atypical cells, cervical cancer, or its precursor lesions (Low-grade Squamous Intraepithelial Lesions, High-grade Squamous Intraepithelial Lesions), as well as all other cytologic categories as defined by *The Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses*¹.

SUMMARY AND EXPLANATION OF THE SYSTEM

The ThinPrep process begins with the patient’s gynecologic sample being collected by the clinician using a cervical sampling device which, rather than being smeared on a microscope slide, is immersed and rinsed in a vial filled with 20 ml of PreservCyt® Solution (PreservCyt). The ThinPrep sample vial is then capped, labeled, and sent to a laboratory equipped with a ThinPrep 2000 Processor.

At the laboratory, the PreservCyt sample vial is placed into a ThinPrep 2000 Processor and a gentle dispersion step breaks up blood, mucus, non-diagnostic debris, and thoroughly mixes the cell sample. The cells are then collected on a ThinPrep Pap Test Filter specifically designed to collect diagnostic cells. The ThinPrep 2000 Processor constantly monitors the rate of flow through the ThinPrep Pap Test Filter during the collection process in order to prevent the cellular presentation from being too scant or too dense. A thin layer of cells is then transferred to a glass slide in a 20 mm-diameter circle, and the slide is automatically deposited into a fixative solution.



(1) Dispersion

The ThinPrep Pap Test Filter rotates within the sample vial, creating currents in the fluid that are strong enough to separate debris and disperse mucus, but gentle enough to have no adverse effect on cell appearance.

(2) Cell Collection

A gentle vacuum is created within the ThinPrep Pap Test Filter, which collects cells on the exterior surface of the membrane. Cell collection is controlled by the ThinPrep 2000 Processor’s software that monitors the rate of flow through the ThinPrep Pap Test Filter.

(3) Cell Transfer

After the cells are collected on the membrane, the ThinPrep Pap Test Filter is inverted and gently pressed against the ThinPrep Microscope Slide. Natural attraction and slight positive air pressure cause the cells to adhere to the ThinPrep Microscope Slide resulting in an even distribution of cells in a defined circular area.

As with conventional Pap smears, slides prepared with the ThinPrep® 2000 System are examined in the context of the patient’s clinical history and information provided by other diagnostic procedures such as colposcopy, biopsy, and human papillomavirus (HPV) testing, to determine patient management.

The PreservCyt® Solution component of the ThinPrep 2000 System is an alternative collection and transport medium for gynecologic specimens tested with the Digene Hybrid Capture™ System HPV DNA and Gen-Probe APTIMA COMBO 2® CT/NG Assays. Refer to the respective manufacturer’s package inserts for instructions for using PreservCyt Solution for collection, transport, storage, and preparation of specimens for use in those systems.

The PreservCyt Solution component of the ThinPrep 2000 System is also an alternative collection and transport medium for gynecologic specimens tested with the Roche Diagnostics COBAS AMPLICOR™ CT/NG assay. Refer to Hologic’s labeling (Document # MAN-02063-001) for instructions for using PreservCyt Solution for collection, transport, storage, and preparation of specimens and to the Roche Diagnostics COBAS AMPLICOR CT/NG package insert for instructions for use of that system.

LIMITATIONS

- Gynecologic samples collected for preparation using the ThinPrep 2000 System should be collected using a broom-type or endocervical brush/plastic spatula combination collection devices.
- Preparation of microscope slides using the ThinPrep 2000 System should be performed only by personnel who have been trained by Hologic or by organizations or individuals designated by Hologic.

- Evaluation of microscope slides produced with the ThinPrep 2000 System should be performed only by cytotechnologists and pathologists who have been trained to evaluate ThinPrep prepared slides by Hologic or by organizations or individuals designated by Hologic.

- Supplies used in the ThinPrep 2000 System are those designed and supplied by Hologic specifically for the ThinPrep 2000 System. These include PreservCyt Solution vials, ThinPrep Pap Test Filters, and ThinPrep Microscope Slides. These supplies are required for proper performance of the system and cannot be substituted. Product performance will be compromised if other supplies are used. After use, supplies should be disposed of in accordance with local, state, and federal regulations.

- A ThinPrep Pap Test Filter must be used only once and cannot be reused.
- The performance of HPV DNA and CT/NG testing on reprocessed sample vials has not been evaluated.

WARNINGS

- For In Vitro Diagnostic Use
- PreservCyt Solution contains methanol, which is poisonous and may be fatal or cause blindness if swallowed. Methanol vapor may be harmful. PreservCyt is flammable; keep away from fire, heat, sparks, and flame. Other solutions must not be substituted for PreservCyt Solution. PreservCyt Solution should be stored and disposed of in accordance with local, state, and federal regulations.

- Do not process a cerebral spinal fluid (CSF) specimen or other sample type that is suspected of possessing prion infectivity (PrPsc) derived from a person with a TSE, such as Creutzfeldt-Jakob disease, on the ThinPrep 2000 processor. A TSE contaminated processor cannot be effectively decontaminated and therefore must be properly disposed of in order to avoid potential harm to users of the processor or service personnel.

PRECAUTIONS

- Specific processing steps must be followed before and during use of the ThinPrep 2000 processor if planning to perform *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing, using the Roche Diagnostics COBAS AMPLICOR CT/NG test, on the residual specimen after a slide has been prepared using a ThinPrep 2000 processor. Follow the procedures found in Chapter 5B of the ThinPrep 2000 Operator’s Manual.

- This equipment generates, uses and can radiate radio frequency energy, and if not installed and used in accordance with the Operator’s Manual, may cause interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at his/her own expense.

- PreservCyt Solution *with* cytologic sample intended for ThinPrep Pap testing must be stored between 15°C (59°F) and 30°C (86°F) and tested within 6 weeks of collection.
- PreservCyt Solution *with* cytologic sample intended for CT/NG testing using the Roche Diagnostics COBAS AMPLICOR CT/NG test must be stored between 4°C (39°F) and 25°C (77°F) and tested within 6 weeks of collection.

- PreservCyt Solution was challenged with a variety of microbial and viral organisms. The following table presents the starting concentrations of viable organisms, and the number of viable organisms found after 15 minutes in the PreservCyt Solution. The log reduction of viable organisms is also presented. As with all laboratory procedures, universal precautions should be followed.

Organism	Initial Concentration	Log Reduction after 15 min.
Candida albicans	5.5 x 10 ⁵ CFU/mL	>4.7
Aspergillus niger*	4.8 x 10 ⁵ CFU/mL	2.7
Escherichia coli	2.8 x 10 ⁵ CFU/mL	>4.4
Staphylococcus aureus	2.3 x 10 ⁵ CFU/mL	>4.4
Pseudomonas aeruginosa	2.5 x 10 ⁵ CFU/mL	>4.4
Mycobacterium tuberculosis**	9.4 x 10 ⁵ CFU/mL	4.9
Rabbitpox virus	6.0 x 10 ⁶ PFU/mL	5.5***
HIV-1	1.0 x 10 ^{7.5} TCID ₅₀ /mL	7.0***

* After 1 hour >4.7 log reduction

** After 1 hour >5.7 log reduction

*** Data is for 5 minutes

PERFORMANCE CHARACTERISTICS: REPORT OF CLINICAL STUDIES

A prospective multi-center clinical study was conducted to evaluate the performance of the ThinPrep 2000 System in direct comparison to the conventional Pap smear. The objective of the ThinPrep clinical study was to demonstrate that gynecologic specimens prepared using the ThinPrep 2000 System were at least as effective as conventional Pap smears for the detection of atypical cells and cervical cancer or its precursor lesions in a variety of patient populations. In addition, an assessment of specimen adequacy was performed.

The initial clinical study protocol was a blinded, split sample, matched pair study, for which a conventional Pap smear was prepared first, and the remainder of the sample (the portion that normally would have been discarded) was immersed and rinsed into a vial of PreservCyt Solution. At the laboratory, the PreservCyt sample vial was placed into a ThinPrep 2000 Processor and a slide was then prepared from the patient’s sample. ThinPrep and conventional Pap smear slides were examined and diagnosed independently. Reporting forms containing patient history as well as a checklist of all possible categories of The Bethesda System were used to record the results of the screening. A single independent pathologist reviewed all discrepant and positive slides from all sites in a blinded fashion to provide a further objective review of the results.

LABORATORY AND PATIENT CHARACTERISTICS

Cytology laboratories at three screening centers (designated as S1, S2, and S3) and three hospital centers (designated as H1, H2, and H3) participated in the clinical study. The screening centers in the study serve patient populations (screening populations) with rates of abnormality (Low-grade Squamous Intraepithelial Lesion [LSIL] and more severe lesions) similar to the United States average of less than 5%.² The hospital centers in the study serve a high risk referral patient population (hospital populations) characterized by high rates (>10%) of cervical abnormality. Data on race demographics was obtained for 70% of the patients that participated in the study. The study population consisted of the following race groups: Caucasian (41.2%), Asian (2.3%), Hispanic (9.7%), African American (15.2%), Native American (1.0%) and other groups (0.6%).

Table 1 describes the laboratories and the patient populations.

TABLE 1: SITE CHARACTERISTICS

Site	Laboratory Characteristics			Clinical Study Demographics			
	Type of Patient Population	Laboratory Volume - Smears per Year	Cases	Patient Age Range	Post-Meno-pausal	Previous Abnormal Pap Smear	Convent. Prevalence LSIL+
S1	Screening	300,000	1,386	18.0–84.0	10.6%	8.8%	2.3%
S2	Screening	100,000	1,668	18.0–60.6	0.3%	10.7%	2.9%
S3	Screening	96,000	1,093	18.0–48.8	0.0%	7.1%	3.8%
H1	Hospital	35,000	1,046	18.1–89.1	8.1%	40.4%	9.9%
H2	Hospital	40,000	1,049	18.1–84.4	2.1%	18.2%	12.9%
H3	Hospital	37,000	981	18.2–78.8	11.1%	38.2%	24.2%

CLINICAL STUDY RESULTS

The diagnostic categories of The Bethesda System were used as the basis of the comparison between conventional and ThinPrep® findings from the clinical study. The diagnostic classification data and statistical analyses for all clinical sites are presented in Tables 2 through 11. Cases with incorrect paperwork, patient's age less than 18 years, cytologically unsatisfactory slides, or patients with a hysterectomy were excluded from this analysis. Few cases of cervical cancer (0.02%) were represented in the clinical study, as is typical in the United States patient population.

TABLE 2: DIAGNOSTIC CLASSIFICATION TABLE, ALL CATEGORIES
Conventional

ThinPrep		NEG	ASCUS	AGUS	LSIL	HSIL	SQ CA	GL CA	TOTAL
		NEG	5224	295	3	60	11	0	0
ASCUS	318	125	2	45	7	0	0	497	
AGUS	13	2	3	0	1	0	1	20	
LSIL	114	84	0	227	44	0	0	469	
HSIL	11	15	0	35	104	2	0	167	
SQ CA	0	0	0	0	0	1	0	1	
GL CA	0	0	0	0	0	0	0	0	
TOTAL	5680	521	8	367	167	3	1	6747	

Abbreviations for Diagnoses: *NEG* = Normal or negative, *ASCUS* = Atypical Squamous Cells of Undetermined Significance, *AGUS* = Atypical Glandular Cells of Undetermined Significance, *LSIL* = Low-grade Squamous Intraepithelial Lesion, *HSIL* = High-grade Squamous Intraepithelial Lesion, *SQ CA* = Squamous Cell Carcinoma, *GL CA* = Glandular Cell Adenocarcinoma

TABLE 3: THREE CATEGORY DIAGNOSTIC CLASSIFICATION TABLE
Conventional

ThinPrep		NEG	ASCUS/AGUS+	LSIL+	TOTAL
		NEG	5224	298	71
ASCUS/AGUS+	331	132	54	1154	
LSIL+	125	99	413	637	
TOTAL	5680	529	538	6747	

TABLE 4: TWO CATEGORY DIAGNOSTIC CLASSIFICATION TABLE,
LSIL AND MORE SEVERE DIAGNOSES
Conventional

ThinPrep		NEG/ASCUS/AGUS+	LSIL+	TOTAL
		NEG/ASCUS/AGUS+	5985	125
LSIL+	224	413	637	
TOTAL	6209	538	6747	

TABLE 5: TWO CATEGORY DIAGNOSTIC CLASSIFICATION TABLE,
ASCUS/AGUS AND MORE SEVERE DIAGNOSES

ThinPrep		NEG	ASCUS/AGUS+	TOTAL
		NEG	5224	369
ASCUS/AGUS+	456	698	1154	
TOTAL	5680	1067	6747	

The diagnostic data analysis from the sites is summarized in Table 6 and 7. When the p-value is significant (p < 0.05), the method favored is indicated in the tables.

TABLE 6: RESULTS BY SITE, LSIL AND MORE SEVERE LESIONS

Site	Cases	ThinPrep LSIL+	Convent. LSIL+	Increased Detection*	p-Value	Method Favored
S1	1,336	46	31	48%	0.027	ThinPrep
S2	1,563	78	45	73%	<0.001	ThipPrep
S3	1,058	67	40	68%	<0.001	ThinPrep
H1	971	125	96	30%	<0.001	ThinPrep
H2	1,010	111	130	(15%)	0.135	Neither
H3	809	210	196	7%	0.374	Neither

*Increased detection = $\frac{\text{ThinPrep}^{\circ} \text{LSIL+} - \text{Conventional LSIL+}}{\text{Conventional LSIL+}} \times 100\%$

For LSIL and more severe lesions, the diagnostic comparison statistically favored the ThinPrep® method at four sites and was statistically equivalent at two sites.

TABLE 7: RESULTS BY SITE, ASCUS/AGUS AND MORE SEVERE LESIONS

Site	Cases	ThinPrep ASCUS+	Convent. ASCUS+	Increased Detection*	p-Value	Method Favored
S1	1,336	117	93	26%	0.067	Neither
S2	1,563	124	80	55%	<0.001	ThinPrep
S3	1,058	123	81	52%	<0.001	ThinPrep
H1	971	204	173	18%	0.007	ThinPrep
H2	1,010	259	282	(8%)	0.360	Neither
H3	809	327	359	(9%)	0.102	Neither

*Increased detection = $\frac{\text{ThinPrep ASCUS+} - \text{Conventional ASCUS+}}{\text{Conventional ASCUS+}} \times 100\%$

For ASCUS/AGUS and more severe lesions, the diagnostic comparison statistically favored the ThinPrep method at three sites and was statistically equivalent at three sites.

One pathologist served as an independent reviewer for the six clinical sites, receiving both slides from cases where the two methods were either abnormal or discrepant. Since a true reference cannot be determined in such studies and therefore true sensitivity cannot be calculated, the use of an expert cytologic review provides an alternative to histologic confirmation by biopsy or human papillomavirus (HPV) testing as a means for determining the reference diagnosis.

The reference diagnosis was the more severe diagnosis from either of the ThinPrep or conventional Pap slides as determined by the independent pathologist. The number of slides diagnosed as abnormal at each site, compared to the reference diagnosis of the independent pathologist, provides the proportion of LSIL or more severe lesions (Table 8) and the proportion of ASCUS/AGUS or more severe lesions (Table 9). The statistical analysis allows a comparison of the two methods and a determination of which method is favored when using the independent pathologist for expert cytologic review as the adjudicator of the final diagnosis.

TABLE 8: INDEPENDENT PATHOLOGIST RESULTS BY SITE, LSIL AND MORE SEVERE LESIONS

Site	Cases Positive by Independent Pathologist	ThinPrep Positive	Conventional Positive	p-Value	Method Favored
S1	50	33	25	0.170	Neither
S2	65	48	33	0.042	ThinPrep
S3	77	54	33	<0.001	ThinPrep
H1	116	102	81	<0.001	ThinPrep
H2	115	86	90	0.876	Neither
H3	126	120	112	0.170	Neither

For LSIL and more severe lesions, the diagnostic comparison statistically favored the ThinPrep method at three sites and was statistically equivalent at three sites.

TABLE 9: INDEPENDENT PATHOLOGIST RESULTS BY SITE,
ASCUS/AGUS AND MORE SEVERE LESIONS

Site	Cases Positive by Independent Pathologist	ThinPrep® Positive	Conventional Positive	p-Value	Method Favored
S1	92	72	68	0.900	Neither
S2	101	85	59	0.005	ThinPrep
S3	109	95	65	<0.001	ThinPrep
H1	170	155	143	0.237	Neither
H2	171	143	154	0.330	Neither
H3	204	190	191	1.000	Neither

For ASCUS/AGUS and more severe lesions, the diagnostic comparison statistically favored the ThinPrep method at two sites and was statistically equivalent at four sites.

Table 10 below shows the summary for all sites of the descriptive diagnosis for all Bethesda System categories.

TABLE 10: SUMMARY OF DESCRIPTIVE DIAGNOSIS

Descriptive Diagnosis <i>Number of Patients: 6747</i>	ThinPrep		Conventional	
	N	%	N	%
Benign Cellular Changes:	1592	23.6	1591	23.6
Infection:				
Trichomonas Vaginalis	136	2.0	185	2.7
Candida spp.	406	6.0	259	3.8
Coccobacilli	690	10.2	608	9.0
Actinomyces spp.	2	0.0	3	0.0
Herpes	3	0.0	8	0.1
Other	155	2.3	285	4.2
Reactive Cellular Changes Associated with:				
Inflammation	353	5.2	385	5.7
Atrophic Vaginitis	32	0.5	48	0.7
Radiation	2	0.0	1	0.0
Other	25	0.4	37	0.5
Epithelial Cell Abnormalities:	1159	17.2	1077	16.0
Squamous Cell:				
ASCUS	501	7.4	521	7.7
favor reactive	128	1.9	131	1.9
favor neoplastic	161	2.4	140	2.1
undetermined	213	3.2	250	3.7
LSIL	469	7.0	367	5.4
HSIL	167	2.5	167	2.5
Carcinoma	1	0.0	3	0.0
Glandular Cell:				
Benign Endometrial cells in Postmenopausal Women	7	0.1	10	0.1
Atypical Glandular Cells (AGUS)	21	0.3	9	0.1
favor reactive	9	0.1	4	0.1
favor neoplastic	0	0.0	3	0.0
undetermined	12	0.2	2	0.0
Endocervical Adenocarcinoma	0	0.0	1	0.0

Note: Some patients had more than one diagnostic subcategory.

Table 11 shows the rates of detection for infection, reactive changes, and the total benign cellular changes for both the ThinPrep® and conventional methods at all sites.

TABLE 11: BENIGN CELLULAR CHANGES RESULTS

	ThinPrep		Conventional	
	N	%	N	%
Benign Cellular Changes				
Infection	1392	20.6	1348	20.0
Reactive Changes	412	6.1	471	7.0
Total*	1592	23.6	1591	23.6

* Total includes some patients that may have had both an infection and reactive cellular change.

Tables 12, 13, and 14 show the specimen adequacy results for the ThinPrep method and conventional smear method for all of the study sites. Of the 7,360 total patients enrolled, 7,223 are included in this analysis. Cases with patient's age less than 18 years or patients with a hysterectomy were excluded from this analysis.

Two additional clinical studies were conducted to evaluate specimen adequacy results when samples were deposited directly into the PreservCyt® vial, without first making a conventional Pap smear. This specimen collection technique is the intended use for the ThinPrep 2000 System.

Tables 15 and 16 present the split sample and direct to vial results.

TABLE 12: SUMMARY OF SPECIMEN ADEQUACY RESULTS

Specimen Adequacy <i>Number of Patients: 7223</i>	ThinPrep		Conventional	
	N	%	N	%
Satisfactory	5656	78.3	5101	70.6
Satisfactory for Evaluation but Limited by:	1431	19.8	2008	27.8
Air-Drying Artifact	1	0.0	136	1.9
Thick Smear	9	0.1	65	0.9
Endocervical Component Absent	1140	15.8	681	9.4
Scant Squamous Epithelial Component	150	2.1	47	0.7
Obscuring Blood	55	0.8	339	4.7
Obscuring Inflammation	141	2.0	1008	14.0
No Clinical History	12	0.2	6	0.1
Cytolysis	19	0.3	119	1.6
Other	10	0.1	26	0.4
Unsatisfactory for Evaluation:	136	1.9	114	1.6
Air-Drying Artifact	0	0.0	13	0.2
Thick Smear	0	0.0	7	0.1
Endocervical Component Absent	25	0.3	11	0.2
Scant Squamous Epithelial Component	106	1.5	47	0.7
Obscuring Blood	23	0.3	58	0.8
Obscuring Inflammation	5	0.1	41	0.6
No Clinical History	0	0.0	0	0.0
Cytolysis	0	0.0	4	0.1
Other	31	0.4	9	0.1

Note: Some patients had more than one subcategory.

TABLE 13: SPECIMEN ADEQUACY RESULTS
Conventional

ThinPrep		SAT	SBLB	UNSAT	TOTAL
		SAT	4316	1302	38
SBLB	722	665	44	1431	
UNSAT	63	41	32	136	
TOTAL	5101	2008	114	7223	

SAT=Satisfactory, SBLB=Satisfactory But Limited By, UNSAT=Unsatisfactory

TABLE 14: SPECIMEN ADEQUACY RESULTS BY SITE

Site	Cases	ThinPrep SAT Cases	Convent. SAT Cases	ThinPrep SBLB Cases	Convent. SBLB Cases	ThinPrep UNSAT Cases	Convent. UNSAT Cases
S1	1,386	1092	1178	265	204	29	4
S2	1,668	1530	1477	130	178	8	13
S3	1,093	896	650	183	432	14	11
H1	1,046	760	660	266	375	20	11
H2	1,049	709	712	323	330	17	7
H3	981	669	424	264	489	48	68
All Sites	7,223	5656	5101	1431	2008	136	114

The Satisfactory But Limited By (SBLB) category can be broken down into many subcategories, one of which is the absence of Endocervical Component. Table 15 shows the Satisfactory But Limited By category "No ECC's" for ThinPrep® and conventional slides.

TABLE 15: SPECIMEN ADEQUACY RESULTS BY SITE,
SBLB RATES FOR NO ENDOCERVICAL COMPONENT.
SBLB Due to No ECC's

Site	Cases	ThinPrep SBLB-no ECC's	ThinPrep SBLB-no ECC's (%)	Conventional SBLB-no ECC's	Conventional SBLB-no ECC's (%)
S1	1,386	237	17.1%	162	11.7%
S2	1,668	104	6.2%	73	4.4%
S3	1,093	145	13.3%	84	7.7%
H1	1,046	229	21.9%	115	11.0%
H2	1,049	305	29.1%	150	14.3%
H3	981	120	12.2%	97	9.9%
All Sites	7,223	1140	15.8%	681	9.4%

For the results of the clinical study involving a split-sample protocol, there was a 6.4 percent difference between conventional and ThinPrep methods in detecting endocervical component. This is similar to previous studies using a split sample methodology.

Direct-to-Vial Endocervical Component (ECC) Studies

For the intended use of the ThinPrep® 2000 System, the cervical sampling device will be rinsed directly into a PreservCyt® vial, rather than splitting the cellular sample. It was expected that this would result in an increase in the pick