

ThinPrep® Pap Test PreservCyt® Solution

Instructions for Use



INTENDED USE

PreservCyt® Solution is designed for use with the ThinPrep® processors. PreservCyt Solution is a methanol-based reagent that serves as a transport, preservative, and antibacterial medium for gynecologic samples.

PreservCyt Solution is also a collection and transport medium for gynecologic samples for certain tests for Human Papilloma Virus (HPV) and other sexually transmitted infections. Refer to the manufacturer's instructions for using PreservCyt Solution for collection, transport, and preparation of specimens for these tests.

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 in molecular testing, PreservCyt Solution allows for the detection of the target.

COMPOSITION

Methanol-based, buffered preservative solution. 35–55% Methanol. CAS 65-56-1

WARNINGS

Danger. Flammable. Contains Methanol.

H301 - Toxic if swallowed.

H311 - Toxic in contact with skin.

H331 - Toxic if inhaled.

H370 - Causes damage to organs.

H226 - Flammable liquid and vapour.

For In Vitro Diagnostic use. Not for external or internal use in humans or animals. Cannot be made non-poisonous. Use with proper ventilation.

ThinPrep® Pap Test PreservCyt® Solution

PRECAUTIONS

P210 - Keep away from heat/sparks/open flames/hot surfaces.

P233 - Keep container tightly closed.

P264 - Wash hands thoroughly after handling.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

Do not use if tamper-evident seal on vial is broken or missing or if the primary packaging is damaged.

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.)



Line on cap and line on vial should meet or slightly overlap.

Figure 1



Figure 2

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 provided. (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.

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PROCESSING INSTRUCTIONS

Cytologic specimens collected in PreservCyt Solution are to be processed on a ThinPrep processor according to instructions in the ThinPrep processor’s 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 used for certain molecular tests.

Refer to the instructions provided with the collection device for warnings, contraindications, and limitations associated with specimen collection.

PERFORMANCE CHARACTERISTICS

Refer to the ThinPrep processor’s operator’s manual.

DISPOSAL

Dispose in accordance with all applicable regulations.

FIRST AID MEASURES

IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell. See www.hologicds.com for the entire Safety Data Sheet.

TABLE 1

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



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Manufacturer



Consult instructions for use



In vitro diagnostic medical device



Authorised representative in the European Community



Catalogue number



Use by



Batch code



Temperature limitation

(YYYY-MM-DD)

The date in the year-month-day format: YYYY-MM-DD



Flammable



Acute Toxicity



Respiratory Sensitizer,
Target Organ Toxicity



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