

ThinPrep® PreservCyt® Solution

Instructions for Use

CE
Rx only**INTENDED USE**

PreservCyt® Solution is designed for use with a ThinPrep processor. PreservCyt Solution is a methanol-based transport medium and preservative for cytologic samples.

Note: PreservCyt Solution for non-gynecological samples cannot be used with the ThinPrep® 3000 processor.

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 for up to three weeks at room temperature.

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.

COMPOSITION

Methanol-based, buffered preservative solution. 35–55% Methanol. CAS 67-56-1

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 vapor.

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

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 primary packaging is damaged.

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.)

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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 container. Close the 946 mL bottle after each use.

APPEARANCE AND INTEGRITY

Clear, non-sterile solution.



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

Figure 1



Figure 2

SPECIMEN COLLECTION AND PREPARATION

Collect non-gynecologic 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 2.)

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

PreservCyt Solution preserves cells for up to three weeks at temperatures between 4°C (39°F) and 37°C (98°F).

PROCESSING INSTRUCTIONS

Cytologic specimens collected in PreservCyt Solution are to be processed on a ThinPrep processor according to instructions in the ThinPrep processor operator’s manual.

LIMITATIONS OF PROCEDURE

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

PERFORMANCE CHARACTERISTICS

Refer to the ThinPrep processor operator’s manual.

DISPOSAL

Dispose in accordance with all applicable regulations.

FIRST AID MEASURES

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



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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



Manufacturer



Consult instructions for use



In vitro diagnostic medical device



Authorised representative in the European Community



Catalogue number



Use by



Batch code



Temperature limitation



Flammable



Acute Toxicity



Respiratory Sensitizer, Target Organ Toxicity



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