

## ThinPrep™ PreservCyt™ Solution

## Instructions for Use

**INTENDED USE**

ThinPrep™ PreservCyt™ Solution is a transport, preservative, and antibacterial medium for non-gynecological samples and is used to prepare cytology slides using a ThinPrep™ processor as part of the ThinPrep™ System. For professional use.

**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 vapour.

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.

P260. Do not breathe dust/fume/gas/mist/vapours/spray.

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

P301 + P310. IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P303 + P361 + P353. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305 + P351 + P338. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308 + P311. IF exposed or concerned: Call a POISON CENTER or doctor.

P370 + P378. In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish.

# ThinPrep™ PreservCyt™ Solution

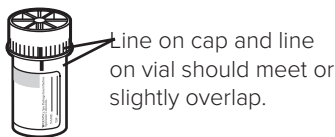
P403 + P233. Store in a well-ventilated place. Keep container tightly closed.

P501. Dispose of contents/container in accordance with local/regional/national/international regulation.

Wash hands thoroughly after handling.

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.)



**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 container. Close the 946 mL bottle after each use.

## **APPEARANCE AND INTEGRITY**

Clear, non-sterile solution.

## **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.

# ThinPrep™ PreservCyt™ Solution

## SAFETY AND PERFORMANCE CHARACTERISTICS

Refer to the ThinPrep processor operator’s manual.

If any serious incident occurs related to this device or any components used with this device, report it to Hologic Technical Support and the competent authority local to the patient and/or user.

## 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.hologicsds.com](http://www.hologicsds.com) for the entire Safety Data Sheet.

**TABLE 1**

Organism	Initial Concentration	Log Reduction After 15 Minutes
<i>Candida albicans</i>	5.5 x 10 <sup>5</sup> CFU/ml	≥4.7
<i>Candida auris</i>	2.6 x 10 <sup>5</sup> CFU/ml	≥5.4
<i>Aspergillus niger</i>	4.8 x 10 <sup>5</sup> CFU/ml	2.7*
<i>Escherichia coli</i>	2.8 x 10 <sup>5</sup> CFU/ml	≥4.4
<i>Staphylococcus aureus</i>	2.3 x 10 <sup>5</sup> CFU/ml	≥4.4
<i>Pseudomonas aeruginosa</i>	2.5 x 10 <sup>5</sup> CFU/ml	≥4.4
<i>Mycobacterium tuberculosis</i> <sup>†</sup>	9.4 x 10 <sup>5</sup> CFU/ml	4.9**
Rabbitpox virus	6.0 x 10 <sup>6</sup> PFU/ml	5.5***
HIV-1	3.2 x 10 <sup>7</sup> TCID <sub>50</sub> /ml	≥7.0***
Hepatitis B virus <sup>†</sup>	2.2 x 10 <sup>6</sup> TCID <sub>50</sub> /ml	≥4.25
SARS-CoV-2 virus	1.8 x 10 <sup>6</sup> TCID <sub>50</sub> /ml	≥3.75
<p>* After 1 hour 4.7 log reduction            ** After 1 hour 5.7 log reduction            *** Data is for 5 minutes            † Organisms were tested with similar organisms from the same genus to assess antimicrobial effectiveness.</p> <p><b>Note:</b> All log reduction values with a ≥ designation yielded undetectable microbial presence after exposure to PreservCyt Solution. The listed values represent the minimum allowable claim given the initial concentration and the detection limit of the quantitative method.</p>		

## **Revision History**

Revision	Date	Description
AW-22939-002 Rev. 001	3-2021	Clarify instructions. Add instructions regarding reporting serious incidents.



## ThinPrep™ PreservCyt™ Solution



Manufacturer



Consult instructions for use



*In vitro* diagnostic medical device



Authorised representative in the European Community



Catalogue number



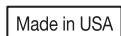
Use by



Batch code



Temperature limitation



Made in USA



Do not reuse



Flammable



Acute Toxicity



Respiratory Sensitizer,  
Target Organ Toxicity



Quantity



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