

# ThinPrep™ Pap Test PreservCyt™ Solution

## Instructions for Use



### INTENDED USE

ThinPrep™ Pap Test PreservCyt™ Solution is a transport, preservative, and antibacterial medium for gynecologic samples and is used to prepare cytology slides using a ThinPrep™ processor as part of the ThinPrep™ System.

ThinPrep Pap Test 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. 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.

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.

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## 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.

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 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.)

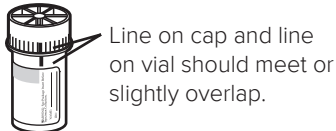


Figure 1



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.)

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## **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 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.

## **SAFETY AND PERFORMANCE CHARACTERISTICS**

Refer to the ThinPrep processor's 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 CENTRE or doctor/physician if you feel unwell. See [www.hologicds.com](http://www.hologicds.com) for the entire Safety Data Sheet.

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**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

\* 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.

**Note:** 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.

**Revision History**

Revision	Date	Description
AW-22719-002 Rev. 001	3-2021	Clarify instructions. Add instructions regarding reporting serious incidents.



Manufacturer



Consult instructions for use



*In vitro* diagnostic medical device



Authorised representative in the European Community



Catalogue number



Use by



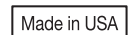
Batch code



Temperature limitation

(YYYY-MM-DD)

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



Made in USA



Do not reuse



Flammable



Acute Toxicity



Respiratory Sensitizer, Target Organ Toxicity



Quantity



Hologic, Inc. • 250 Campus Drive • Marlborough, MA 01752 USA  
 Tel: +1 (508) 263-2900 • www.hologic.com



Hologic BV • Da Vinciaan 5 • 1930 Zaventem • Belgium • Tel: +32 2 711 46 80

Australian Sponsor:

Hologic (Australia and New Zealand) Pty Ltd • Suite 302, Level 3 • 2 Lyon Park Road  
 Macquarie Park NSW 2113 • Australia • Tel: +02 9888 8000

