

## ThinPrep™ CytoLyt™ Solution

## Instructions for Use

**INTENDED USE**

ThinPrep™ CytoLyt™ Solution is a methanol-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 a ThinPrep processor. For professional use.

**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°C–30°C.

**PRINCIPLES OF PROCEDURE**

CytoLyt Solution is a media used for collection and lysing of red blood cells. When used on samples processed with a ThinPrep processor, the process 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. CAS 67-56-1

**WARNINGS**

**Danger.** Flammable. Contains Methanol.

H302. Harmful if swallowed.

H312. Harmful in contact with skin.

H332. Harmful if inhaled.

H370. Causes damage to organs.

H226. Flammable liquid and vapor.

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

**PRECAUTIONS**

P210. Keep away from heat/sparks/open flames/hot surfaces.— No smoking

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

P280. Wear protective gloves and eye/face protection

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

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

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P302 + P352. IF ON SKIN: Wash with plenty of soap and water

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

P370 + P378. In case of fire: Use dry sodium carbonate 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 primary packaging is damaged.

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

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 (59°F to 86°F). Do not use CytoLyt 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.)

## **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**

Cytologic specimens collected in CytoLyt Solution are further prepared with PreservCyt™ Solution and then processed on a ThinPrep processor according to instructions in the ThinPrep processor's operator's manual.



Figure

## ThinPrep™ CytoLyt™ Solution

### LIMITATIONS OF PROCEDURE

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

### SAFETY AND PERFORMANCE CHARACTERISTICS

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.

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

### Revision History

Revision	Date	Description
AW-24657-002 Rev. 001	3-2022	Clarify instructions. Add instructions regarding reporting serious incidents.



Manufacturer



Consult instructions for use



*In vitro* diagnostic medical device



Authorised representative in the European Community



Made in USA



Catalogue number



Use by



Batch code



Temperature limitation



Quantity



Do not reuse



Flammable



Irritant, Respiratory Tract Irritation, Dermal Sensitizer



Respiratory Sensitizer, Target Organ Toxicity



Product meets the requirements for CE marking in accordance with EU-IVD Regulation 2017/746



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