

## ThinPrep® PreservCyt® Solution

## Instructions for Use

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.)

# ThinPrep® PreservCyt® Solution

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

# ThinPrep® PreservCyt® Solution

**TABLE 1**





Organism	Initial Concentration	Log Reduction after 15 min.
<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





<sup>†</sup> 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.




Following is an explanation of the symbols that may appear on your product.

Symbol	Title	Description	Standard information
	Manufacturer	Indicates the medical device manufacturer, as defined in the EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.1
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.  When used to indicate an instruction to consult an electronic instructions for use (eIFU), this symbol is accompanied by an eIFU indicator. This indicator may represent the manufacturer’s eIFU website or an appropriate indication on the use of eIFU. The indicator may be placed either alongside, beneath or surrounding the symbol.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.3
	<i>In vitro</i> diagnostic medical device	Indicates a medical device that is intended to be used as an <i>in vitro</i> diagnostic medical device	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.5.1
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.6

## ThinPrep® PreservCyt® Solution

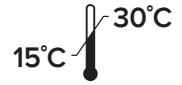
Symbol	Title	Description	Standard information
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.4
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.5
	Temperature limit	Indicates the upper and lower limit of temperature to which the medical device can be safely exposed.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.3.7
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.2

And this product is marked with the following pictograms:

Symbol	Title
	Flammable
	Respiratory Sensitizer, Target Organ Toxicity
	Acute Toxicity

# ThinPrep® UroCyt® PreservCyt® Solution

## Instructions for Use



### **INTENDED USE**

To preserve and transport urine specimens for cytological examination using a ThinPrep® processor and UroCyt® Slide Preparation System or Vysis® UroVysion® Bladder Cancer Kit and Urine Cytology.

### **SUMMARY AND EXPLANATION**

PreservCyt® Solution enables the transport and preservation of urine.

### **PRINCIPLES OF PROCEDURE**

PreservCyt Solution is a media used to preserve the cells and DNA of urine specimens.

### **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.

H370—Causes damage to organs.

H331—Toxic if inhaled.

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.

### **PRECAUTIONS**

Read these instructions carefully before use.

Inspect all contents for damage.

P210—Keep away from heat, spark, open flames/hot surfaces.

P233—Keep container tightly closed.

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

Wash hands thoroughly after handling.

As with all laboratory procedures, universal precautions should be followed.

# ThinPrep® UroCyt® PreservCyt® Solution

Do not use if tamper-proof seal is broken.

Use in a well ventilated area.

Avoid direct contact.

## **PRETREATMENT**

No reconstitution, mixing or dilution is required.

## **STORAGE AND HANDLING**

Store unused PreservCyt Solution at 15°C–30°C. Do not use beyond expiration date. Keep PreservCyt Solution vial and specimen collection cup closed until ready to use.

Store PreservCyt Solution with urine specimen between 4°C and 30°C. Process sample within 48 hours.

## **APPEARANCE AND INTEGRITY**

Clear, non-sterile solution.

## **PERFORMANCE CHARACTERISTICS**

PreservCyt Solution exhibits bacteriostatic properties and prevents growth of organisms in urine specimens when used at a 2:1 ratio of urine to PreservCyt Solution at temperatures between 4°C and 30°C. Refer to the ThinPrep processor operator's manual for additional information.

## **PROCESSING INSTRUCTIONS**

Note: A minimum of 33 cc of urine, which was collected in a routine manner, is required for the Vysis UroVysion Bladder Cancer Kit.

1. Carefully pour the entire contents of the PreservCyt Solution vial into the specimen cup containing urine. Tightly secure specimen cup to prevent leakage.
2. Store specimen with PreservCyt Solution between 4°C–30°C. Preferred storage and shipping conditions are on ice packs (e.g., blue ice in Styrofoam).
3. Process specimen within 48 hours according to the instructions in the ThinPrep processor operator's manual, or the manufacturer's instructions for use for the Vysis UroVysion Bladder Cancer Kit.

## **DISPOSAL INFORMATION**

Dispose of used specimen collection cup, absorbent pad, transport bag and any remaining specimen as a biohazard. Dispose in accordance with all applicable regulations.

## **LIMITATIONS OF PROCEDURE**










PreservCyt Solution cannot be substituted with any other solution for specimen collection, preparation and processing. Minimize the use of lubricants (e.g., KY® Jelly) prior to specimen collection, as such substances can interfere with cell transfer.

## **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.


## ThinPrep® UroCyt® PreservCyt® Solution

Following is an explanation of the symbols that may appear on your product.

Symbol	Title	Description	Standard information
	Manufacturer	Indicates the medical device manufacturer, as defined in the EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.1
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.  When used to indicate an instruction to consult an electronic instructions for use (eIFU), this symbol is accompanied by an eIFU indicator. This indicator may represent the manufacturer's eIFU website or an appropriate indication on the use of eIFU. The indicator may be placed either alongside, beneath or surrounding the symbol.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.3
	<i>In vitro</i> diagnostic medical device	Indicates a medical device that is intended to be used as an <i>in vitro</i> diagnostic medical device	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.5.1
	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.2
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.6
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.4
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.5
	Temperature limit	Indicates the upper and lower limit of temperature to which the medical device can be safely exposed.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.3.7
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.2

And this product is marked with the following pictograms:

	Flammable		Respiratory Sensitizer, Target Organ Toxicity		Acute Toxicity
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## ThinPrep® CytoLyt® Solution

## Instructions for Use

Rx only

**INTENDED USE**

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 the ThinPrep® processor.

**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.

Store in a well-ventilated place. Keep container tightly closed. Wear gloves and eye protection when handling solution. 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.



# ThinPrep® CytoLyt® Solution

## **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.

## **LIMITATIONS OF PROCEDURE**

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



Figure

# ThinPrep® CytoLyt® Solution

Following is an explanation of the symbols that may appear on your product.

Symbol	Title	Description	Standard information
	Manufacturer	Indicates the medical device manufacturer, as defined in the EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.1
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.  When used to indicate an instruction to consult an electronic instructions for use (eIFU), this symbol is accompanied by an eIFU indicator. This indicator may represent the manufacturer's eIFU website or an appropriate indication on the use of eIFU. The indicator may be placed either alongside, beneath or surrounding the symbol.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.3
	<i>In vitro</i> diagnostic medical device	Indicates a medical device that is intended to be used as an <i>in vitro</i> diagnostic medical device	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.5.1
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.6
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.4
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.5
	Temperature limit	Indicates the upper and lower limit of temperature to which the medical device can be safely exposed.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.3.7
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.2

And this product is marked with the following pictograms:

Symbol	Title
	Flammable
	Irritant, Respiratory Tract Irritation, Dermal Sensitizer
	Respiratory Sensitizer, Target Organ Toxicity