HOLOGIC®

ThinPrep® PreservCyt® Solution

Instructions for Use

℞ 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® NON-GYN

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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.hologicsds.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
Candida auris	2.6 x 10^5 CFU/mL	≥5.4
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	3.2 x 10^7 $TCID_{50}$/mL	≥7.0***
Hepatitis B virus†	2.2 x 10^6 $TCID_{50}$/mL	≥4.25
SARS-CoV-2 virus	1.8 x 10^6 $TCID_{50}$/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.

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
	*In vitro* diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro 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

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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 intented 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

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