ThinPrep® CytoLyt® Solution

Instructions for Use

℞ 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 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
	*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
	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
	Irritant, Respiratory Tract Irritation, Dermal Sensitizer
	Respiratory Sensitizer, Target Organ Toxicity

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