HOLOGIC®

ThinPrep® UroCyte® PreservCyt® Solution

Instructions for Use

INTENDED USE

To preserve and transport urine specimens for cytological examination using a ThinPrep® processor and UroCyte® 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® UroCyte® 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.hologicsds.com for the entire Safety Data Sheet.

ThinPrep® UroCyte® 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
	*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
	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 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

Symbol	Title
	Respiratory Sensitizer, Target Organ Toxicity

Symbol	Title
	Acute Toxicity

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