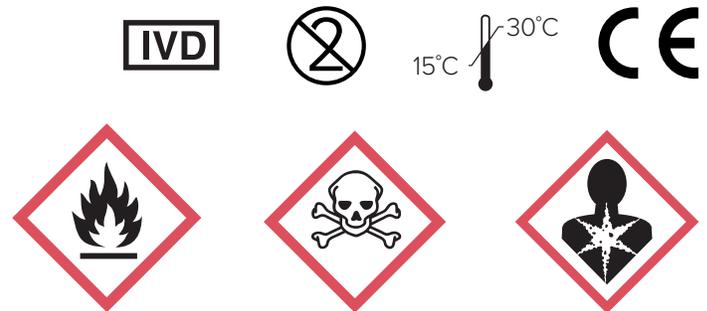


ThinPrep™ UroCyt™ PreservCyt™ Solution

Instructions for Use



INTENDED USE

ThinPrep™ UroCyt™ PreservCyt™ Solution is a transport and preservative medium for urine samples and is used to prepare cytology slides using a ThinPrep™ processor as part of the ThinPrep™ System. For professional use.

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/sparks/open flames/hot surfaces.

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

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

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

P303 + P361 + P353. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

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

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

P370 + P378. In case of fire: Use dry sand, dry chemical or alcohol-resistant foam 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.

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

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.

SAFETY AND 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.

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.

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.

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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.hologic.com for the entire Safety Data Sheet.

Revision History

Revision	Date	Description
AW-22938-002 Rev. 001	3-2021	Clarify instructions. Add instructions regarding reporting serious incidents.



Manufacturer



Use by



Flammable



Consult instructions for use



Batch code



Acute Toxicity



In vitro diagnostic medical device



Temperature limitation



Respiratory Sensitizer, Target Organ Toxicity



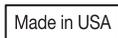
Authorised representative in the European Community



Do not reuse



Catalogue number



Made in USA



Quantity



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