

ThinPrep® UroCyt® PreservCyt® Solution

Instructions for Use

R_xonly

IVD



15°C 30°C



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.

Note: UroCyt PreservCyt Solution is not for use with the ThinPrep® 3000 processor.

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.hologicsds.com for the entire Safety Data Sheet.

ThinPrep® UroCyt® PreservCyt® Solution



Manufacturer



Consult instructions for use



In vitro diagnostic medical device



Authorised representative in the European Community



Catalogue number



Use by



Batch code



Temperature limitation



Do not reuse



Flammable



Acute Toxicity



Respiratory Sensitizer,
Target Organ Toxicity



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