ThinPrep® UroCyte® Urine Collection Kit with PreservCyt® Solution

Instructions for Use

Read all instructions, warnings and precautions prior to use.

NOTE:

The ThinPrep® Urine Collection Kit is intended to be used in a healthcare environment. If the healthcare provider requires the specimen to be collected at home, the provider must review these instructions for use with the patient and provide the patient with any necessary protective equipment.

INTENDED USE

To collect, preserve and transport urine specimens for cytological examination using the ThinPrep® processor and UroCyte® Slide Preparation System or Vysis® UroVysion® Bladder Cancer Kit.

SUMMARY AND EXPLANATION

PreservCyt® Solution enables the transport and preservation of urine.

PRINCIPLES OF PROCEDURE

Urine is collected in the specimen collection cup and PreservCyt Solution is added to preserve the cells and DNA of the patient's sample.

COMPOSITION

Methanol-based, buffered preservative solution. 35–55% methanol. CAS 67-56-1

CONTENTS:

Specimen Collection Cup (blue cap)

30 ml vial (white cap) PreservCyt Solution—methanol based, buffered preservative solution

Absorbent pad

Specimen Transport Bag

WARNINGS

Danger. Flammable. Contains Methanol.

H226. Flammable liquid and vapor.

H301. Toxic if swallowed.

H311. Toxic in contact with skin.

H370. Causes damage to organs.

H331. Toxic if inhaled.

For *In Vitro* Diagnostic use.

Not for external or internal use in humans or animals.

Cannot be made non-poisonous.

Urine specimens are considered biohazardous.

PRECAUTIONS

Read these instructions carefully before use.

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.

Do not use if tamper-proof seal on PreservCyt Solution vial or specimen collection cup is broken.

Use in a well ventilated area.

Avoid direct contact. Do not urinate or pour specimen directly into PreservCyt Solution vial as this may cause the solution to splash or spill.

Minimize the use of lubricants (e.g., KY® Jelly) prior to specimen collection, as such substances can interfere with cell transfer.

Keep away from children and pets.

Before transporting specimen, make sure the specimen collection cup is tightly sealed by turning cap until after hearing audible click.

PRETREATMENT

No reconstitution, mixing or dilution is required.

STORAGE AND HANDLING

Store PreservCyt Solution without urine at 15˚C–30˚C. Do not use beyond expiration date marked on the vial.

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.

INSTRUCTIONS FOR USE

1. Inspect kit to ensure all contents are present and intact.
2. Record patient information in the space provided on the specimen collection cup.
3. Collect urine in a routine manner. Note: A minimum of 33 cc of urine is required for the Vysis UroVysion FISH Test. Volume measurements can be found on the side of the specimen cup.
4. If urine exceeds 60cc, pour off the excess. (The total volume of urine must not exceed 60 cc.)
5. Carefully pour the entire contents of the PreservCyt Solution vial into the specimen cup containing urine.
6. Tightly secure blue cap on specimen cup to prevent leakage. (Keep turning until after you hear the audible click.)
7. Place specimen collection cup containing the urine/PreservCyt Solution, and the absorbent pad in the specimen transport bag. Tightly seal bag.
8. Store specimen with PreservCyt Solution between 4˚C–30˚C (39˚F–86˚F). Preferred storage and shipping conditions are on ice packs (e.g., blue ice in Styrofoam).
9. Process specimen within 48 hours according to appropriate instructions outlined in the ThinPrep processor operator's manual or the Vysis UroVysion Instructions for Use.

LIMITATIONS OF PROCEDURE

PreservCyt Solution cannot be substituted with any other solution for specimen collection, preparation and processing. Diagnosis can only be made by a trained medical professional.

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.

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.

FIRST AID INFORMATION

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. See www.hologicsds.com for the entire Safety Data Sheet.

SYMBOLS

The following symbols may appear on your product:

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, ISO 15223-1:2012(E) Section 5.1.4
	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, ISO 15223-1:2012(E) Section 5.1.6
	In vitro diagnostic medical device	Indicates a medical device that is intended to used as an in vitro diagnostic mecial device	ISO 15223-1 Medical devices—Symbols to be used with edical device labeling and information to be supplied, ISO 15223-1:2012(E) Section 5.5.1
 hologic.com/ifu	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, ISO 15223-1:2012(E) Section 5.4.3
	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, ISO 15223-1:2012(E) Section 5.1.5
	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, ISO 15223-1:2012(E) Section 5.1.1
	Temperature limitation	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, ISO 15223-1:2012(E) 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
	Acute Toxicity	Toxic if swallowed. Toxic in contact with skin. Toxic if inhaled.	United States Department of Labor Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard (HCS), Appendix C to §1910.1200, Sections C.4.1, C.4.2, C.4.3 (Classified in Accordance with Appendix A.1)
	Flammable	Flammable liquid and vapor	OSHA's HCS, Appendix C to §1910.1200, Section C.4.19 (Classified in Accordance with Appendix A.1)
	Respiratory Sensitizer, Target Organ Toxicity	Causes damage to organs	OSHA's HCS, Appendix C to §1910.1200, Section C.4.11 (Classified in Accordance with Appendix A.1)