PreservCyt® Solution Sample Collection and Transport Medium for use with

The ThinPrep® Pap Test

℞ only

HOLOGIC®

Intended Use for Gynecologic Applications

PreservCyt® Solution is designed for use with the ThinPrep® 2000 System, the ThinPrep 3000 Processor, and the ThinPrep 5000 Processor. PreservCyt Solution is an alcohol-based, preservation solution that serves as a transport, preservative, and antibacterial medium for gynecologic samples.

The PreservCyt Solution component of the ThinPrep 2000 System is an alternative collection and transport medium for gynecologic specimens tested with the Cervista® HPV HR Test, the Cervista® HPV 16/18 Test, the Roche cobas® HPV Test and the Digene Hybrid Capture® System HPV DNA. Refer to the respective manufacturer's package inserts for instructions for using PreservCyt Solution for collection, transport, storage, and preparation of specimens for use in those systems.

The PreservCyt Solution component of the ThinPrep 2000 System is an alternative collection and transport medium for gynecologic specimens tested with the BD ProbeTec™ CT Qx Amplified DNA Assay, Hologic APTIMA COMBO 2® CT/NG Assays and the Hologic APTIMA® Trichomonas vaginalis Assay. Refer to the respective manufacturer's package inserts for instructions for using PreservCyt Solution for collection, transport, storage, and preparation of specimens for use in those systems.

The PreservCyt Solution component of the ThinPrep 2000 System is also an alternative collection and transport medium for gynecologic specimens tested with the Roche Diagnostics COBAS® AMPLICOR CT/NG assay. Refer to Hologic's labeling (Document # MAN-02063-001) for instructions for using PreservCyt Solution for collection, transport, storage, and preparation of specimens and to the Roche Diagnostics COBAS AMPLICOR CT/NG package insert for instructions for use of that system.

Summary and Explanation of the ThinPrep System

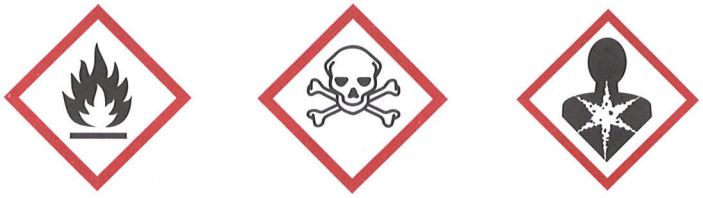
The ThinPrep process begins with the patient's gynecologic sample being collected by the clinician using a cervical sampling device which, rather than being smeared on a microscope slide, is immersed and rinsed in a vial filled with PreservCyt Solution. The ThinPrep sample vial is then capped, labeled, and sent to a laboratory equipped with a ThinPrep Processor.

At the laboratory, the PreservCyt sample vial is placed into a ThinPrep Processor and a gentle dispersion step breaks up blood, mucus, non-diagnostic debris, and thoroughly mixes the cell sample. The cells are then collected on a ThinPrep Pap Test Filter specifically designed to collect diagnostic cells. The ThinPrep Processor constantly monitors the rate of flow through the ThinPrep Pap Test Filter during the collection process in order to prevent the cellular presentation from being too scant or too dense. A thin layer of cells is then transferred to a glass slide in a 20 mm-diameter circle, and the slide is automatically deposited in or sprayed with a fixative solution.

Reagents

For In Vitro Diagnostic Use. Contains buffered methanol. CAS 67-56-1

Warnings



Danger. Flammable. Contains Methanol.

H301 – Toxic if swallowed.
H311 – Toxic in contact with skin.
H331 – Toxic if inhaled.
H370 – Causes damage to organs.
H226 – Flammable liquid and vapor.
NOT FOR EXTERNAL OR INTERNAL USE IN HUMANS OR ANIMALS. CANNOT BE MADE NON-POISONOUS. Use with adequate ventilation.
P210 – Keep away from heat/sparks/open flames/hot surfaces.
P233 – Keep container tightly closed.
P264 – Wash hands thoroughly after handling.
P280 – Wear protective gloves/protective clothing/eye protection/face protection.

First Aid

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

Storage

Store PreservCyt Solution between 15°C (59°F) and 30°C (86°F). Do not use beyond the expiration date printed on the container.

Store PreservCyt Solution with cytologic sample intended for ThinPrep Pap testing between 15°C (59°F) and 30°C (86°F) for up to 6 weeks.

Disposal

Dispose in accordance with all applicable regulations.

Specimen Collection for Gynecologic Samples

Collect samples in the routine manner (e.g., CLSI guideline GP-15A3) and rinse in PreservCyt Solution following recommended technique (see reverse for appropriate sample collection technique).

Aliquot Removal (Optional)

Testing for certain sexually transmitted diseases (STD) and for Human Papilloma Virus (HPV) in conjunction with cytology may be performed using the residual specimen remaining in the PreservCyt sample vial after preparation of the ThinPrep Pap Test slide. Such testing may also be enabled by the removal of an aliquot of up to 4 mL (Aliquot Removal) from the PreservCyt sample vial before preparing the ThinPrep Pap Test slide.

Because cytology/HPV testing and STD testing address different clinical questions, Aliquot Removal may not be suitable for all clinical situations. Physicians and other persons responsible for ordering clinical tests should be familiar with the following:

- There is no evidence of degradation of cytology results by Aliquot Removal, however, this cannot be ruled out for all specimens. As with any subsampling step in anatomic pathology, chance misallocation of diagnostic cells may occur if they are very rare. If negative results from the specimen do not fit with the clinical impression, a new specimen may be necessary.
- Aliquot Removal from low-cellularity specimens may leave insufficient material in the PreservCyt sample vial for preparation of a satisfactory ThinPrep Pap Test slide.
- Aliquot Removal may leave insufficient material In the PreservCyt sample vial for performance of ancillary testing (e.g., reflexive HPV testing) using the residual specimen following preparation of a ThinPrep Pap Test slide.
- Co-collection of separate samples for the ThinPrep Pap Test and STD testing may be considered in lieu of Aliquot Removal.
- When opting for concurrent cytologic and STD testing, providers should consider risk and clinical history (e.g., disease prevalence, patient age, sexual history or pregnancy) as well as specimen suitability (e.g., exudates or bleeding) that can impact diagnostic reliability.

Sexually Transmitted Diseases Treatment Guidelines 2002 (Centers for Disease Control and Prevention, MMWR 2002: 51(No. RR-6)) provides clinical guidance for the management and treatment of individual patients, including use of Pap testing.

If ancillary testing is to be performed, laboratory personnel must follow specific instructions (refer to the Operator's Manual for the ThinPrep processor) to appropriately remove the desired aliquot volume and prepare the PreservCyt sample vial for the ThinPrep Pap Test. Adherence to these instructions must be maintained to ensure there is no adverse effect on the ThinPrep Pap Test result.

Materials Required but Not Supplied

- ThinPrep Pap Test Filters (clear) for gynecologic slide preparation
- Microscope slides
- Cover slips
- Staining reagents

Specific Performance Characteristics

When used and stored as described, PreservCyt Solution will preserve a cytologic sample for up to 6 weeks.

PreservCyt Solution is bactericidal. PreservCyt Solution has been shown to cause greater than 99.999 percent inactivation within 15 minutes for the following bacteria: Candida albicans, Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Mycobacterium tuberculosis (determined according to the United States Pharmacopeia preservative antimicrobial effectiveness test, U.S.P. XXII,51). As with all laboratory procedures, universal precautions should be followed.

Limitations of Procedure

Always use good sampling techniques when collecting samples. Poor sampling techniques will produce inadequate samples. Sampling is limited to broom-like and endocervical brush/plastic spatula combination collection devices. Consult sampling instructions below for specific techniques.

Warranty

This product is warranted to perform as described in the labeling and in Hologic's literature. Hologic disclaims any implied warranty of merchantability of fitness for any other purpose and in no event will Hologic be liable for any inconsequential damages arising out of the aforesaid express warranty. Distributed by Hologic, Inc., 250 Campus Drive, Marlborough, MA 01752 USA, Phone: 1 (800) 442-9892 or (508) 263-2900.

Figure 1

Line on cap passes line on vial

SAMPLE COLLECTION TECHNIQUE USING BRUSH/SPATULA COLLECTION DEVICES:

STEP 1 Sample ectocervix with a plastic spatula.

STEP 2 Rinse spatula in the PreservCyt Solution vial by swirling vigorously 10 times. Place cap on vial until step 4. Discard collection device.

STEP 3 Sample endocervix with an endocervical brush.

STEP 4 Rinse the brush in the PreservCyt Solution by rotating the device in the solution 10 times while pushing against the PreservCyt vial wall. Swirl the brush vigorously to further release material. Discard the collection device.

STEP 5 Tighten the PreservCyt sample vial cap so that the torque line on the cap passes the torque line on the vial. See Figure 1.

SAMPLE COLLECTION TECHNIQUE USING BROOM-LIKE COLLECTION DEVICE:

STEP 1 Obtain a sample from the cervix using a broom-like device.

STEP 2 Rinse the collection device into a PreservCyt Solution vial by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to further release cellular material. Discard the collection device.

STEP 3 Cap the PreservCyt sample vial tightly. Tighten the cap of the vial so that the black torque line on the cap passes the black torque line on the vial. See Figure 1.

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
REF	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
IVD	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
	Caution, consult instructions for use	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, ISO 15223-1:2012(E) Section 5.4.4
	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
LOT	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
	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)