PreservCyt™ Collection Medium

Instructions for Use

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INTENDED USE

PreservCyt™ Collection Medium is a methanol-based reagent that serves as a transport, preservative, and antibacterial medium for molecular testing of gynecologic samples.

Refer to the respective manufacturer's package inserts for instructions for using PreservCyt Collection Medium for collection, transport, and preparation of specimens for use in their specific molecular tests.

For professional use.

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.

H331. Toxic if inhaled.

H370. Causes damage to organs.

H226. Flammable liquid and vapour.

For In Vitro Diagnostic use. Not for external or internal use in humans or animals. Cannot be made non-poisonous. Use with proper ventilation.

PRECAUTIONS

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.

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.

Do not use if tamper-evident seal on vial is broken or missing, or if primary packaging is damaged.

PreservCyt® COLLECTION MEDIUM

PreservCyt™ Collection Medium

Do not use wooden and other non-plastic devices for specimen collection. Do not detach the head of a broom-type collection device and place the head into the vial or leave the collection device standing in the solution.

When transporting a PreservCyt Collection Medium vial containing cells, make sure the vial is tightly sealed. Align the mark on the cap with the mark on the vial to prevent leakage. (See Figure 1.)

Figure 1

Figure 2

PreservCyt Collection Medium was challenged with a variety of microbial and viral organisms. Table 1 presents the starting concentrations of viable organisms and the number of viable organisms found after 15 minutes in PreservCyt Collection Medium. The log reduction of viable organisms is also presented. As with all laboratory procedures, universal precautions should be followed.

PRETREATMENT

No reconstitution, mixing or dilution is required.

STORAGE

Store PreservCyt Collection Medium without cytologic samples at 15°C to 30°C (59°F to 86°F). Do not use PreservCyt Collection Medium beyond the expiration date marked on the vial.

APPEARANCE AND INTEGRITY

Clear, non-sterile solution.

SPECIMEN COLLECTION AND PREPARATION

Collect gynecologic samples using a broom-type cervical collection device or endocervical brush/spatula combination collection device. Record required patient information in the space provided. (See Figure 2.)

Brush/Spatula Collection Devices

Collect specimens according to applicable instructions for use for the brush/spatula sampling device being used.

Broom-Type Collection Device

Collect specimens according to applicable instructions for use for the broom-type sampling device being used.

Known Interfering Substances

The use of lubricants (e.g., KY® Jelly) should be minimized prior to specimen collection. Lubricants can adhere to labware and may cause poor or undesired results.

Storage and Handling

Store PreservCyt Collection Medium with gynecologic cytologic sample between 15°C (59°F) and 30°C (86°F) for up to 6 weeks.

PROCESSING INSTRUCTIONS

Refer to the respective manufacturer's package inserts for instructions for using PreservCyt Collection Medium for collection, transport, and preparation of specimens for use in their specific molecular tests.

LIMITATIONS OF PROCEDURE

Refer to the instructions provided with the collection device for warnings, contraindications, and limitations associated with specimen collection.

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SAFETY AND PERFORMANCE CHARACTERISTICS

Refer to the instructions provided with the molecular test.
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.

DISPOSAL

Dispose in accordance with all applicable regulations.

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.

TABLE 1

Organism	Initial Concentration	Log Reduction After 15 Minutes
Candida albicans	5.5 x 10^5 CFU/ml	≥4.7
Candida auris	2.6 x 10^5 CFU/ml	≥5.4
Aspergillus niger	4.8 x 10^5 CFU/ml	2.7*
Escherichia coli	2.8 x 10^5 CFU/ml	≥4.4
Staphylococcus aureus	2.3 x 10^5 CFU/ml	≥4.4
Pseudomonas aeruginosa	2.5 x 10^5 CFU/ml	≥4.4
Mycobacterium tuberculosis†	9.4 x 10^5 CFU/ml	4.9**
Rabbitpox virus	6.0 x 10^6 PFU/ml	5.5***
HIV-1	3.2 x 10^7 $TCID_{50}$/ml	≥7.0***
Hepatitis B virus†	2.2 x 10^6 $TCID_{50}$/ml	≥4.25
SARS-CoV-2 virus	1.8 x 10^6 $TCID_{50}$/ml	≥3.75

* After 1 hour 4.7 log reduction
** After 1 hour 5.7 log reduction
*** Data is for 5 minutes
† Organisms were tested with similar organisms from the same genus to assess antimicrobial effectiveness.

Note: All log reduction values with a ≥ designation yielded undetectable microbial presence after exposure to PreservCyt Collection Medium. The listed values represent the minimum allowable claim given the initial concentration and the detection limit of the quantitative method.

Revision History

Revision	Date	Description
AW-23087-002 Rev. 001	3-2021	Clarify instructions. Add instructions regarding reporting serious incidents.

PreservCyt™ Collection Medium

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		Made in USA		Quantity	
Catalogue number		Do not reuse			

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