

COLLECT • INACTIVATE • STABILIZE • PRESERVE

Product Information

INTENDED USE: PrimeStore Molecular Transport Medium[®] (PS-MTM) is intended for stabilization, transportation, and inactivation of infectious unprocessed nasal washes, nasopharyngeal, oral/throat swabs* suspected of containing Influenza A virus RNA. PS-MTM is also intended for the stabilization, transportation, and inactivation of infectious unprocessed sputum samples suspected of containing *Mycobacterium tuberculosis* (MTB) DNA from human samples.

BACKGROUND: PS-MTM consists of a 4 mL cryovial tube containing 1.5 mL of a proprietary solution for inactivation of Influenza A and MTB, and the stabilization of Influenza A RNA and MTB DNA. It is intended for storage and transport of Influenza A RNA and MTB DNA in a closed tube. Performance characteristics for PS-MTM have only been established with Influenza A RNA and MTB DNA. The user is responsible for establishing additional PS-MTM performance characteristics.

SUMMARY AND EXPLANATION: Specimen collection and transport is a key component in molecular detection of Influenza A and MTB. PS-MTM is a self-contained, 'ready-to-use' system that allows for the stabilization and safe transport of clinical samples at ambient temperature from the collection site to the laboratory.

DEVICE DESCRIPTION: The PS-MTM device is a sterile, plastic, cryogenic tube with an O-ring and lip seal containing 1.5 mL of the stabilization solution. These components inactivate Influenza A and MTB, lyse cells, disrupt/lyse lipid membranes, denature proteins and enzymes, and preserve and stabilize Influenza A RNA and MTB DNA.

REAGENTS: Guanidine thiocyanate*, TCEP, Sodium citrate, N-Lauroylsarcosine sodium (NLS), Antifoam A, TRIS, EDTA, Ethanol (molecular grade), HCl, Nuclease-free water.

* Guanidine thiocyanate is a standard chemical used in lysis buffers and nucleic acid purification kits. Bleach should never be used to clean or disinfect Guanidine thiocyanate solutions

PRECAUTIONS:

- Not to be used with the Hologic Panther because of bleach step specific to that platform
- To be used by trained and qualified professionals.
- Read the information in this package insert and follow directions carefully.
- Do NOT insert swab into solution before collecting patient specimen.
- Do NOT drink, touch or remove PS-MTM from collection tube.
- Do NOT transfer PS-MTM into other tubes.
- Do NOT pool PS-MTM into larger volumes, or leave tubes uncapped for more than 10 minutes.
- For specimen in PS-MTM follow state, local and institution guidelines for the handling and disposition of biohazard waste.

STORAGE TEMPERATURE PRIOR TO USE: Optimal storage temperature is 36-77°F (2-25°C). Shelf life prior to use is 24 months.

SPECIMEN COLLECTION PROCEDURE:

- 1) Non-invasive collection of suitable clinical/biological samples including nasal washes and sputum samples.
- 2) Unscrew cap of the PS-MTM tube.
- 3) Collect clinical/biological specimens using standard clinical procedures. For MTB sputum collection, swirl a submerged flocked swab five times in clinical sputum sample and transfer swab to PS-MTM tube. The volume of sputum sample absorbed onto a flocked swab is typically 0.1 to 0.2 mL. Influenza specimens should be collected by standard methods using a throat swab, NP swab, or nasal washing. Up to 0.5 mL of nasal wash can be added to each PS-MTM tube. A second sample should be collected if there is a requirement directed by protocol, state or federal law to submit samples to the United States Center for Disease Control (CDC).
- 4) If collection is by NP or oral swab, insert flocked swab containing collected sample directly into PS-MTM collection tube and break off excess swab handle at the indicated breakpoint.
- 5) Place cap on PS-MTM tube and close tightly.
- 6) Store at room temperature until ready to ship to diagnostic laboratory. MTB DNA from samples collected and stored in PS-MTM is stable for up to 30 days at ambient temperature (50-78.8°F/10-26°C). Influenza A RNA from samples collected and stored in PS-MTM is stable for up to 7 days at ambient temperature (78.8 °F/26°C) or can be refrigerated for up to 28 days.
- 7) Proceed with RNA/DNA extraction after letting specimen sit in PS-MTM for a minimum of 60 minutes. Vortex sample before use. Extract the RNA/DNA using extraction kit or an automated platform validated for use with PS-MTM.

QUALITY CONTROL: Each lot of PS-MTM is tested for pathogen inactivation to ensure reproducible performance.

RESULTS: Accuracy of molecular testing depends on proper specimen collection, integrity of nucleic acid, extraction and PCR amplification.

LIMITATIONS:

- Performance characteristics of PS-MTM have been demonstrated for Influenza RNA and MTB DNA. The user is responsible for validating PS-MTM with all diagnostic assays to include those used in this submission.
- Performance characteristics of PS-MTM have been demonstrated for Influenza RNA from nasal washes and MTB DNA from sputum.
- The user is responsible for establishing appropriate system performance characteristics for other specimen types and tissues.
- The PS-MTM system is a collection, preservation, transport, and storage system for Influenza RNA and MTB DNA. Extraction and purification of nucleic acids have been validated on several manual spin column kits (PrimeXtract[™], RNAqueous Micro Kit, Viral RNA Mini Kit, QiaAMP DNA Mini Kit), and automated magnetic bead extraction kits (NucleiSens EasyMAG and MagNA Pure 96 System using the DNA Bacterial/Viral small volume kit). The user is responsible for validating additional extraction and purification kits and platforms.

PrimeStore[®] is registered under United States Patent Nos. 8,084,443; 8,293,467; 8,415,330; 8,060,645-IPC; 8,669,240; 8,080,645; 8,097,419; South Africa Patent Nos. 2010/02174, 2011/07624; Australia Patent No. 2008 343745; Europe Patent Nos. 2195466; 2421993; Israel Patent No. 204756; and New Zealand Patent No. 584308.

*Documented in accordance with 'Deciding When to Submit a 510(k) for a Change to an Existing Device', October 25, 2017 Section (A1.5).

