PrimeStore MTM®

MOLECULAR TRANSPORT MEDIUM (MTM) FOR NUCLEIC ACID TESTING & MOLECULAR DIAGNOSTICS

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 2 mL cryovial tube containing 1.0mL 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 1.0 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 break-point.
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 (NucliSENS 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).*

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