

## COLLECT • INACTIVATE • STABILIZE • PRESERVE

### Product Information

**INTENDED USE:** PrimeStore Molecular Transport Medium<sup>®</sup> (PS-MTM) is intended for inactivation of infectious samples and stabilization and transportation of microbial RNA and DNA.

**BACKGROUND:** PS-MTM consists of a tube containing a proprietary solution for inactivation of infectious samples and the stabilization of nucleic acids. It is intended for storage and transport of viral RNA and DNA in a closed tube. Performance characteristics for PS-MTM have been established with the US Food and Drug Administration for Influenza A RNA and MTB DNA. Data on additional sample types and pathogens can be found in peer reviewed publications. <https://lhvnd.com/publications>

**SUMMARY AND EXPLANATION:** Specimen collection and transport is a key component in molecular detection of microbes. PS-MTM is a self-contained 'ready-to-use' system that allows for the inactivation, 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 plastic tube with lip seal containing the inactivation/stabilization solution. These components inactivate microbes, lyse cells, disrupt/lyse lipid membranes, denature proteins and enzymes, and preserve and stabilize RNA and DNA.

**REAGENTS:** Guanidine thiocyanate, TCEP, sodium citrate, N-Lauroylsarcosine sodium (NLS), antifoam A, TRIS, EDTA, ethanol (molecular grade), HCl, nuclease-free water.

**PRECAUTIONS:** Read the information in this package insert and follow directions carefully. To be used by trained and qualified professionals.

**WARNING:** Guanidine Thiocyanate forms very toxic gases on contact with acids! Keep away from acidic or alkaline products and oxidizing agents.

- Do NOT use bleach for cleaning or disinfection. Not to be used with lab automation systems that use bleach including the Hologic Panther and Fusion systems.
- Do NOT breathe vapors.
- Avoid contact with eyes and skin.
- 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 specimens in PS-MTM follow state, local and institution guidelines for the handling and disposal of biohazard waste.

**NOTE:** Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

**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 and oral swabs, nasal washes and sputum samples.
- 2) Unscrew the 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 a government agency (e.g. United States Center for Disease Control (CDC)).
- 4) If collection is by NP or oral swab, insert the flocked swab containing the collected sample directly into the PS-MTM collection tube and break off the excess swab handle at the indicated breakpoint.
- 5) Place the cap on the PS-MTM tube and close tightly, being careful not to over-torque the cap.
- 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 (50-78.8°F/10-26°C) or can be refrigerated (36-46°F/2-8°C) for up to 28 days. While unnecessary, samples can also be frozen prior to extraction and testing.
- 7) Proceed with RNA/DNA extraction after incubating the specimen in PS-MTM for a minimum of 10 minutes for suspected RNA samples and 60 minutes for sputum suspected of MTB. Vortex sample before extraction. Extract the RNA/DNA using either an 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 correct specimen collection, integrity of nucleic acid, extraction and PCR amplification.

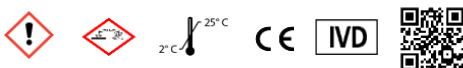
#### LIMITATIONS:

- The user is responsible for establishing appropriate system performance characteristics for non-respiratory 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 (PrimeExtract™, 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<sup>®</sup> 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.

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