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 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://lhnvd.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 (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.

Longhorn Vaccines and Diagnostics LLC, 2 Bethesda Metro Center, Suite 910, Bethesda, MD 20814, USA.

EC REP Emergo Europe, Prinsessgracht 20, 2514 AP The Hague, The Netherlands.

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LONGHORN VACCINES & DIAGNOSTICS

www.lhnvd.com
info@lhnvd.com

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