PRODUCT INFORMATION

PrimeStore® MTM

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.

Intended use

PrimeStore® Molecular Transport Medium (PS-MTM) is intended for stabilization, transportation, and inactivation of infectious unprocessed nasal washes, nasopharyngeal, and 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.

Veterinary sample types compatible with MTM include:

blood, serum, oral fluids, feces, urine, respiratory swabs and washes, processing fluids, skin, homogenized tissue, whole insects, mask punches, environmental swabs, wastewater liquids, and more.

Specimen collection procedure

To ensure proper inactivation and preservation of sample material, the working ratio of MTM to Sample is 3 : 1. Each prefilled tube/vial contains 1.5 mL of MTM which allows for up to 500 µL maximum added sample volume.

- The 5 mL prefilled tube currently sold allows for break-off of swab shaft and swab to be left in tube.
- For high throughput testing labs, leaving the swab behind may be undesirable due to robot automation. In this case, the "saturated swab delivery principle" may be implemented (see step 2 below).

1. Select appropriate tube

The appropriate tube for MTM transport and storage is of a thick-walled plastic cryovial construction with a tight-fitting screw cap lid (preferably threaded with gasket for tight seal).

Snap cap tubes are not recommended as they do not seal well enough to prevent leakage and evaporation of the MTM reagent. Appropriate tubes also ensure safety for sample collectors and testing staff.

Note: If MTM is purchased in bulk, we recommend aliquoting MTM into the smallest tube that allows for addition of the sample without overloading or exceeding the 3:1 MTM to sample ratio.

Larger tubes may be used to allow for swab and swab shaft to be broken off inside tube.



2. Collect sample

Use flocked swabs of man-made materials (AVOID cotton tips and wooden shafts).

For swine oral fluids and other liquid veterinary sample types, **submerge and swirl a flocked swab five times** in liquid biological sample.

The volume of sputum liquid sample absorbed onto a flocked swab is typically 0.1 to 0.3 mL, which will safely avoid exceeding the 0.5 mL maximum sample volume for a 1.5 mL volume of MTM.

- Although pipetting is also acceptable, the "saturated swab delivery principle" avoids extra time, supplies, and labor in the field. Use of a typical synthetic flocked swab will consistently deliver enough sample for successful PCR detection or sequencing. Note: Pools of swabs will require larger tubes and more volume of MTM (3-5 mL). Contact us for more information.
- Influenza and other respiratory infectious specimens should be collected using a throat swab, NP/OP swab, or nasal washing.
- 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 Department of Agriculture or other entity.

3. Insert sample and incubate

Up to 0.5 mL of pipetted liquid OR material from one loaded swab can be added to each tube containing 1.5 mL of MTM.

- Insert the flocked swab containing sample directly into PS-MTM tube and swirl five times in the MTM. The excess swab handle may be broken off at break point OR the entire swab discarded.
- If pipetting liquid sample, insert the pipet directly into PS-MTM tube and deliver sample liquid gently into the MTM liquid.
- Screw cap onto tube tightly and mix by inversion for 3-5 seconds.
- Incubate samples in PS-MTM for a **minimum of 60 minutes** prior to downstream sample processing.

Samples are Stable for 7 days at ambient temperature and stable for 28 days at 2-8°C. Samples can be bio-banked for long term storage. It should be noted that samples will not be affected by multiple freeze-thaw cycles. Studies have shown longer stability for RNA at both ambient and high temperatures from time of collection to time of nucleic acid extraction compared with other transport media.

4. Nucleic acid extraction

Due to certain components of the PrimeStore® MTM solution, you must first undertake a nucleic acid extraction process before you conduct a RT-PCR or PCR assay.

The procedure is specific to the extraction kit being used and not specific to PrimeStore® MTM.

Samples should be vortexed for 3-5 seconds prior to DNA and RNA extraction.

(Exception: you can place a sample from PrimeStore® MTM into the Cepheid GeneXPert cartridge along with the Cepheid PBS solution without first performing an extraction step.)





Limitations

- 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.
- PS-MTM has been used for ASFv, CSFv, and FMDv by USDA-FADDL and FLI in Germany. The user is responsible for validating PS-MTM with all diagnostic assays and extraction methods.
- 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 NucliSENSE 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.

Precautions

- ✓ 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 mix PS-MTM with bleach

- 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.
- ✓ Shelf life: 24 months from manufacture.
- ✓ Store at room temperature
- ✓ Avoid excessive exposure to open air

Ingredients

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

