

## COLLECT • STABILIZE • PRESERVE

### Product Information

**INTENDED USE:** PrimeStore Analyte Transport Medium® (PS-ATM) is intended for the preservation, stabilization and transportation of specimens for downstream protein, antibody, analyte, and nucleic acid (DNA/RNA) analysis. Suitable specimens include nasal washes, nasopharyngeal swabs, oral/throat swabs, buccal swabs, urine, and cultured cells.

**BACKGROUND:** PS-ATM consists of a cryogenic tube containing 1.5 mL of a proprietary solution for stabilization of proteins, analytes, and nucleic acids (DNA/RNA). It is intended for storage and transport of specimens in a closed tube. Performance characteristics for PS-ATM have been established with Influenza RNA and adenovirus DNA using qPCR and rapid antigen testing. The user is responsible for establishing additional PS-ATM performance characteristics.

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

**DEVICE DESCRIPTION:** The PS-ATM device is a sterile, plastic, cryogenic tube containing 1.5 mL of the stabilization solution. These components are designed to preserve and stabilize RNA and DNA and maintain the integrity of proteins, antibodies, and analytes for downstream molecular-based assays.

#### 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-ATM from collection tube.
- Do NOT transfer PS-ATM into other tubes.
- Do NOT pool PS-ATM into larger volumes, or leave tubes uncapped for extended periods.
- For specimen in PS-ATM 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 respiratory or nasopharyngeal swabs, nasal washes, buccal samples, urine, and cultured cells.
- 2) Unscrew cap of the PS-ATM tube.
- 3) Collect clinical/biological specimens using standard clinical procedures. Respiratory 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-ATM tube.
- 4) If collection is by NP or oral swab, insert flocked swab containing collected sample directly into PS-ATM collection tube and break off excess swab handle at the indicated break-point.
- 5) Place cap on PS-ATM tube and close tightly.
- 6) Store specimen at room temperature until ready to ship to diagnostic laboratory. Specimens stored in PS-ATM are stable for up to 7 days at ambient temperature (78.8°F/26°C) or can be refrigerated (36-46°F/2-8°C) for 30 days. For long-term storage, samples collected in PS-ATM should be held at -20°C or below.
- 7) Proceed with RNA/DNA extraction after letting specimen sit in PS-ATM for a minimum of 30 minutes. Vortex sample before use. Extract the RNA/DNA using commercial extraction kits (PrimeXtract™, Qiagen, etc.) or an automated platform.
- 8) For Extraction-less PCR for viral pathogen testing, directly add PS-ATM to the qPCR well in the equivalent ratio of extracted sample to qPCR reagent.

**QUALITY CONTROL:** Each lot of PS-ATM is tested for pathogen detection to ensure reproducible performance. PS-ATM is certified RNASE/DNASE-free.

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

#### LIMITATIONS:

- Performance characteristics of PS-ATM have been demonstrated for Influenza RNA and other respiratory pathogens using qPCR and rapid antigen testing. The user is responsible for validating PS-ATM with all diagnostic assays.
- Performance characteristics of PS-ATM have been demonstrated for Influenza RNA and adenovirus DNA.
- The user is responsible for establishing appropriate system performance characteristics for other specimen types and tissues.
- The PS-ATM system is a collection, preservation, transport, and storage system for nucleic acids and proteins. Extraction and purification of nucleic acids have been validated on several manual spin column kits (MagMax, 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, as well as extraction-less protocols.

