



APTIMA[®] Urine Specimen Transport Tubes

For *in vitro* diagnostic use

Intended Use

The APTIMA urine specimen transport tubes are for use with APTIMA assays. The APTIMA urine specimen transport tube is intended to be used for the collection and transport of male or female urine specimens.

Materials Provided

APTIMA Urine Specimen Transport Tubes (Cat. No. 105575)

| Component | Quantity | Description |
|-------------------------|----------|--|
| Specimen transport tube | 100 each | Tube containing 2 mL of APTIMA urine transport medium. |

Materials Required But Not Provided

Disposable pipette for the transfer of 2 mL of urine from the primary collection container to the APTIMA urine specimen transport tube.

Warnings and Precautions

- Do not apply the transport medium directly to skin or mucous membranes or take internally.

Storage Requirements

Store urine specimen transport tubes at room temperature (15°C to 30°C).

Urine Specimen Performance

The assay performance characteristics of the male and female urine specimens are provided in the appropriate APTIMA assay package insert. The APTIMA assay package inserts may be referenced online at www.gen-probe.com. The table below identifies acceptable specimen types for each of the APTIMA assays.

| APTIMA Assay for | Female Urine Specimens | Male Urine Specimens |
|--|------------------------|----------------------|
| <i>Chlamydia trachomatis</i> | Yes | Yes |
| <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> (APTIMA Combo 2 Assay) | | |
| <i>Neisseria gonorrhoeae</i> | | |

Specimen Collection and Handling

- The patient should not have urinated for at least 1 hour prior to specimen collection.
- Direct patient to provide a first-catch urine (approximately 20 mL to 30 mL of the initial urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in rRNA target dilution that may reduce test sensitivity. Female patients should not cleanse the labial area prior to providing the specimen.

3. Remove the cap and transfer 2 mL of urine into the urine specimen transport tube using a disposable pipette. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine specimen transport tube label.
4. Re-cap the urine specimen transport tube tightly. This is now known as the processed urine specimen.

Specimen Transport and Storage

After collection, transport the processed urine specimens in the APTIMA urine specimen transport tube at 2°C to 30°C and store at 2°C to 30°C until tested. Processed urine specimens should be assayed with the APTIMA assay within 30 days of collection. If longer storage is needed, refer to the appropriate APTIMA assay package insert.

Urine samples that are still in the primary collection container must be transported to the lab at 2°C to 30°C. Transfer the urine sample into the APTIMA urine specimen transport tube within 24 hours of collection. Store at 2°C to 30°C and test within 30 days of collection.

Note: Specimens should be transported in compliance with Federal regulations for transport of etiological agents. Please refer to HHS Publication No. CDC 93-8395 or latest revision.

Limitations

- A. Use this specimen transport tube only with the APTIMA assays. Performance has not been established with other products.



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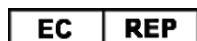
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