Aptima™ Urine Specimen Transport Tubes

Instructions for Use
For *in vitro* diagnostic use
For US export only

Intended Use

The Aptima™ urine specimen transport tubes are for use with Aptima assays and other Hologic products. 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 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

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

***Note**: Hazard communication reflects the EU Safety Data Sheets (SDS) classifications. For hazard communication information specific to your region, refer to the region specific SDS on the Safety Data Sheet Library at www.hologicsds.com.*

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 assay package insert. The assay package inserts may be referenced online at www.hologic.com. The performance of the male urine specimen has not been established for all Aptima assays.

Specimen Collection and Handling

Note: If the tube contents are spilled, discard and replace with a new Aptima urine specimen transport tube.

1. The patient should not have urinated for at least 1 hour prior to specimen collection.
2. 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 must be shipped in accordance with applicable national and international transportation regulations.

Limitations

A. Use this specimen transport tube only with the Aptima assays and other Hologic products. Performance has not been established with other products.

B. The performance of male urine specimens has not been established for the Aptima Trichomonas vaginalis assay.

Contact Information and Revision History

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For country-specific Technical Support and Customer Service email address and telephone number, visit www.hologic.com/support.

This product is intended for use only in the field of human *in vitro* diagnostics.

In case of serious incident, please notify the Manufacturer and Competent Authority in your region.

AW-26250-001 Rev. 001
2022-05

Revision History	Date	Description
AW-26250-001 Rev. 001	May 2022	• Created Aptima Urine Specimen Transport Tubes IFU AW-26250-001 Rev. 001 based on 501935EN Rev. 005 for regulatory compliance with IVDR • Added Instructions for Use • Updated Intended Use section and Limitations section with a reference to "... other Hologic products” • Updated Warnings and Precautions section with Global GHS notification • Updated contact information including: EC Rep, CE Mark, Australian Rep information, and technical support