

Aptima[®] Urine Collection Kit

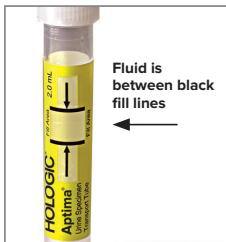
Collection procedure guide

Collection for male and female urine specimens

Patient should not have urinated for at least 1 hour prior to specimen collection.



Direct patient to provide **first-catch** urine (approximately 20 to 30 mL of initial urine stream) into urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity. Female patients should not cleanse labial area prior to providing specimen.



Remove cap from urine specimen transport tube and transfer 2 mL of urine into urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on urine specimen transport tube label.



Re-cap urine specimen transport tube tightly. This is now known as the “processed urine specimen.”

Urine specimen collection guide for:

- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (NG)
- *Mycoplasma genitalium* (MG)
- *Trichomonas vaginalis* (TV) for female only
- *Zika virus* (Zika)
(collect alongside a blood sample)

Confirm with your laboratory if these samples types are acceptable.



Specimen transport and storage

- Urine samples still in primary collection container must be transported to the lab between 2°C to 30°C. Transfer urine sample into Aptima urine specimen transport tube within 24 hours of collection for Aptima Combo 2[®] assay for CT/NG, Aptima[®] Mycoplasma genitalium assay or Aptima[®] Trichomonas vaginalis assay and within 72 hours for Aptima[®] Zika virus assay.
- Transport and store processed urine specimens in the Aptima urine specimen transport tube between 2°C to 30°C until tested.
- Processed urine specimens should be assayed for Aptima Combo 2[®] assay for CT/NG, Aptima[®] Mycoplasma genitalium assay, Aptima[®] Trichomonas vaginalis assay and Aptima[®] Zika virus assay within 30 days of collection.
- If longer storage is needed, freeze between -20°C to -70°C. Consult package inserts for allowable duration.

The Aptima Zika Virus assay:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Hologic provides this collection procedure guide as a general informational tool only; it is not an affirmative instruction or guarantee of performance. It is the sole responsibility of the clinician/ laboratory to read and understand the appropriate package insert and comply with applicable local, state and federal rules and regulations.

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