

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 undersection 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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Clinician collection procedure guide

For rectal swab specimens



Partially open swab package and remove swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima Multitest Swab Specimen Collection Kit. **Hold swab, placing thumb and forefinger in the middle of shaft covering score line.** Do not hold shaft below score line.



Carefully insert swab into the rectum about 1-2 inches (3-5 cm) past the anal margin (the outside of the anus) and **gently rotate swab clockwise for 5-10 seconds.** Withdraw swab without touching skin.



While holding swab in hand, unscrew tube cap. Do not spill tube contents. If tube contents are spilled, discard and replace with a new Aptima Multitest Swab Specimen Collection Kit.





Immediately place swab into transport tube so score line is at top of tube. Align the score line with top edge of tube and carefully break shaft. Discard top portion of shaft.







Note: Do NOT insert score line below top edge of vial. Do NOT push swab to bottom of vial.





Tightly screw cap onto tube. When collecting multiple specimens from the same patient, the tube label provides a specimen source field for unique identification for specimen location.

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Clinician collection procedure guide

For throat swab specimens



Partially open swab package and remove swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima Multitest Swab Specimen Collection Kit. **Hold swab, placing thumb and forefinger in the middle of shaft covering score line.** Do not hold shaft below score line.



Carefully insert the swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue.



While holding swab in hand, unscrew tube cap. Do not spill tube contents. If tube contents are spilled, discard and replace with a new Aptima Multitest Swab Specimen Collection Kit.





Immediately place swab into transport tube so score line is at top of tube. Align the score line with top edge of tube and carefully break shaft. Discard top portion of shaft.



Note: Do NOT insert score line below top edge of vial. Do NOT push swab to bottom of vial.





Tightly screw cap onto tube. When collecting multiple specimens from the same patient, the tube label provides a specimen source field for unique identification for specimen location.

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Clinician collection procedure guide

For vaginal swab specimens



Partially open swab package and remove swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima Multitest Swab Specimen Collection Kit. Hold swab, placing thumb and forefinger in the middle of shaft covering score line. Do not hold shaft below score line.



Carefully insert swab into opening of the vagina, about 2 inches (5 cm), and gently rotate swab for 10 to 30 seconds. Make sure swab touches the vagina walls so that moisture is absorbed by the swab. Withdraw swab without touching skin.



While holding swab in hand, unscrew tube cap. Do not spill tube contents. If tube contents are spilled, discard and replace with a new Aptima Multitest Swab Specimen Collection Kit.





Immediately place swab into transport tube so score line is at top of tube. Align the score line with top edge of tube and carefully break shaft. Discard top portion of shaft.







Note: Do NOT insert score line below top edge of vial. Do NOT push swab to bottom of vial.





Tightly screw cap onto tube. When collecting multiple specimens from the same patient, the tube label provides a specimen source field for unique identification for specimen location.

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Patient collection procedure guide

For penile meatal swab specimens





Wash hands before starting. If you have any questions about this procedure, please ask your healthcare provider.

Partially open swab package and remove swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima Multitest Swab Specimen Collection Kit. **Hold swab, placing thumb and forefinger in the middle of swab shaft over score line.**



Hold the penis with your free hand (hand with no swab). If you are uncircumcised, you will have to roll the foreskin down before collection. Using your other hand (with the swab), roll swab just at the tip or outside the opening to the penis through which you pass urine (pee). Be sure to roll swab completely around the opening to get the best sample. It is not necessary to put the swab deep inside the opening of the penis.



While holding swab in your hand, unscrew tube cap. Do not spill tube contents. If tube contents are spilled, request a new Aptima Multitest Swab Specimen Collection Kit.





Immediately place swab into transport tube so score line is at top of tube. Align score line with top edge of tube and carefully break swab shaft.







Note: Do NOT insert score line below top edge of vial. Do NOT push swab to bottom of vial.





Discard top portion of shaft. Tightly screw cap onto tube. Return tube as instructed by your healthcare provider.

Translations for the collection guide may be available. Please check with your Hologic rep for all collection guides.

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Patient collection procedure guide

Collection for vaginal swab specimens



Wash hands before starting. If you have any questions about this procedure, please ask your healthcare provider.

Partially peel open the swab package and remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, laid down or dropped, request a new Aptima Multitest Swab Specimen Collection Kit. Hold the swab, placing thumb and forefinger in the middle of the shaft over the black score line.



Carefully insert the swab into the opening of the vagina, about 2 inches (5 cm), and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the vaginal walls so that moisture is absorbed by the swab. Withdraw the swab without touching the skin.





While holding the swab in your hand, unscrew the tube cap. Do not spill the tube contents. If the tube contents are spilled, request a new Aptima Multitest Swab Specimen Collection Kit. Immediately place the swab into the transport tube so the black score line is at the top of the tube. Align the score line with the top edge of the tube and carefully break the swab shaft. The swab will drop to bottom of the vial. Discard the top portion of the shaft.



Tightly screw the cap onto the tube. Return the tube as instructed by your healthcare provider.

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