

Maryland Department of Health
Division of Virology and Immunology
Chlamydia Laboratory
Lab phone: 443-681-3937 Lab fax: 443-681-3844

Collection instructions for CT/GC testing using the Hologic Aptima® Combo 2 Assay



Urine specimens sample collection, transport, and storage:

- Male and female urine specimen collection should be **first catch of the void**. Not mid-stream or first of day.
- Collect approximately **20-30mL** into a preservative-free sterile collection cup. Larger volumes may result in dilute specimens and reduced test sensitivity.
- Female patients should **not** cleanse labia area prior to providing specimen.
- Gently swirl urine cup, and transfer **2mL** of urine into the urine transport tube, using the disposable pipette provided. Final volume of the tube should be **between the two black fill lines**. Under- or over-filling a transport tube can yield invalid results.
- Specimen must be transferred to the transport tube **within 24 hours** of collection.
- Re-cap transport tube **tightly**.
- Users should wash their hands and re-glove between specimen collections if collecting a specimen from more than one anatomic site.

All Urine specimens: After collection, transport the specimen transport tube at **2°C to 30°C** until tested. Specimens must be assayed with the APTIMA COMBO 2 Assay within **30 days** of collection. If longer storage is needed, freeze at -20°C to -70°C for up to 12 months after collection.

Aptima[®] urine collection kit

Collection procedure guide

Collection for male and female urine specimens

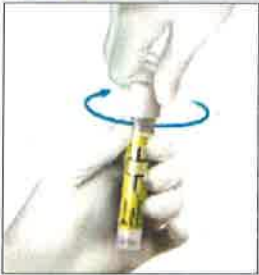
Patient should not have urinated for at least 1 hour prior to specimen collection.



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* (GC)
- *Trichomonas vaginalis* (TV) for female only



Specimen transport and storage

- After collection, 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 with the Aptima assay for CT, GC and/or TV within 30 days of collection.
- If longer storage is needed, freeze between -20°C to -70°C for up to 12 months after collection in the Aptima assay for CT and/or GC. For the Aptima assay for TV, freeze at < -20°C for up to 12 months.
- 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.
- Store between 2°C to 30°C and test within 30 days of collection.

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HOLOGIC[®]

Collection instructions for CT/GC testing using the Hologic Aptima® Combo 2 Assay

Unisex (Blue swab) specimens sample collection, transport, and storage:



Male Urethra:

- **Discard** white cleaning swab.
- **Blue unisex** collection swab should be inserted **2cm to 4cm** into the urethra.
- Gently rotate swab clockwise for **2 to 3 seconds** to ensure adequate sampling. Withdraw swab carefully.
- Place swab into the **unisex** specimen tube, carefully break swab shaft **at the score line** and re-cap **tightly**.
- Users should wash their hands and re-glove between specimen collections if collecting a specimen from more than one anatomic site.

Endocervical swabs:

- Endocervical collection **require use of a cleaning swab** prior to collection. Use the white cleaning swab to remove excess mucus from cervical and surrounding mucosa.
- **Discard** this swab.
- Insert the **blue unisex** collection swab into cervical canal. Gently rotate the swab clockwise for **10 to 30 seconds** to ensure adequate sampling. Withdraw swab carefully to avoid contact with vaginal mucosa.
- Place swab into the **unisex specimen** tube, carefully break swab shaft **at the score line** and re-cap **tightly**.
- Users should wash their hands and re-glove between specimen collections if collecting a specimen from more than one anatomic site.

All Unisex (Blue swab) specimens: After collection, transport and store the swab in the labeled swab specimen transport tube at **2°C to 30°C** until tested. Specimens must be assayed with the APTIMA COMBO 2 Assay within **60 days** of collection. If longer storage is needed, freeze at **-20°C** to **-70°C** for up to 12 months after collection.

Aptima® unisex swab kit

Female collection procedure guide

Collection for endocervical swab specimens



Use cleaning swab (white shaft swab with red printing) to remove excess mucus from cervical os and surrounding mucosa. Discard this swab.



Insert collection swab (blue shaft swab with green printing) into endocervical canal. Gently rotate swab clockwise for 10 to 30 seconds to help ensure adequate sampling. Withdraw swab carefully; avoid any contact with vaginal mucosa.



While holding swab in hand, unscrew the tube cap. Do not spill tube contents. **If the tube contents are spilled, discard and replace with a new Aptima unisex swab transport tube.** Carefully break the swab shaft at the score line against the side of the tube. Discard top portion of swab shaft.



Re-cap swab specimen transport tube tightly.

Swab specimen collection guide for:

- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (GC)
- *Trichomonas vaginalis* (TV)

Specimen Transport and Storage

- After collection, transport and store swab in unisex specimen transport tube between 2°C to 30°C until tested.
- Specimens must be assayed with the Aptima assay for CT, GC and /or TV within 60 days of collection.
- If longer storage is needed, freeze between -20°C to -70°C for up to 12 months after collection in the Aptima assay for CT and/or GC. For the Aptima assay for TV, freeze at < -20°C for up to 12 months.

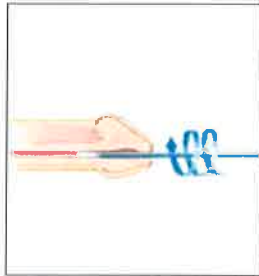


Aptima® unisex swab device

Male collection procedure guide

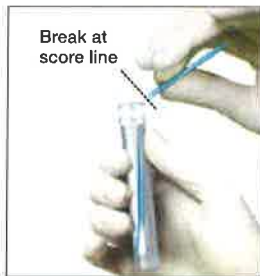
Collection for male urethral swab specimens

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



Discard cleaning swab (white shaft with red print on label). The cleaning swab is NOT needed for male specimen collection.

Insert specimen collection swab (blue shaft swab with green printing) 2 cm to 4 cm into urethra. Gently rotate swab clockwise for 2 to 3 seconds in urethra to help ensure adequate sampling. Withdraw swab carefully.



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 unisex swab transport tube.** Carefully break the swab shaft at the score line against the side of the tube. Discard top portion of swab shaft.



Re-cap swab specimen transport tube tightly.

Swab specimen collection guide for:

- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (GC)

Specimen Transport and Storage

- After collection, transport and store swab in unisex specimen transport tube between 2°C to 30°C until tested.
- Specimens must be assayed with the Aptima assay for CT and/or GC within 60 days of collection.
- If longer storage is needed, freeze between -20°C to -70°C for up to 12 months after collection.

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Collection instructions for CT/GC testing using the Hologic Aptima® Combo 2 Assay

Multi-test (Pink swab) specimens sample collection, transport, and storage:

Vaginal specimens:

- Vaginal **pink** collection swab should be inserted **2 inches** into the opening of the vagina.
- Gently rotate swab clockwise for **10 to 30 seconds** to ensure adequate sampling. Ensure swab touches the walls of the vagina so moisture is absorbed by the swab. Withdraw swab carefully without touching the skin.
- Place swab into the **orange multi-test** specimen tube, carefully break swab shaft **at the score line** and re-cap **tightly**.
- Users should wash their hands and re-glove between specimen collections if collecting a specimen from more than one anatomic site.



Rectal swabs:

- Insert **pink multi-test** swab **3 to 5 cm** into the anus and rotated for **5–10 seconds**. (If needed prior to insertion, the swab can be moistened with water or saline solution).
- Place swab into the **orange multi-test specimen tube**, carefully break swab shaft **at the score line** and re-cap **tightly**.
- Users should wash their hands and re-glove between specimen collections if collecting a specimen from more than one anatomic site.

Pharyngeal swabs:

- Use **pink unisex** swab to make contact with five key anatomic landmarks: bilateral tonsils, bilateral posterior walls, and the uvula.
- Place swab into the **orange multi-test specimen tube**, carefully break swab shaft **at the score line** and re-cap **tightly**.
- Users should wash their hands and re-glove between specimen collections if collecting a specimen from more than one anatomic site.

All Multi-test (Pink swab) specimens: After collection, transport and store the swab in the labeled swab specimen transport tube at **2°C to 30°C** until tested. Specimens must be assayed with the APTIMA COMBO 2 Assay within **60 days** of collection. If longer storage is needed, freeze at **-20°C** to **-70°C** for up to 12 months after collection.

Aptima® Multitest Swab Specimen Collection Kit

Patient collection procedure guide



Collection for vaginal swab specimens

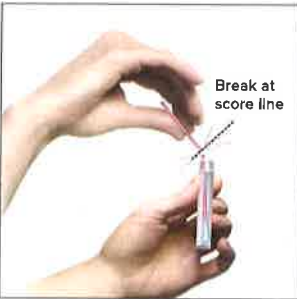


Wash hands before starting. If you have any questions about this procedure, please ask your healthcare provider.

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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Aptima® Multitest Swab Specimen Collection Kit

Clinician collection procedure guide



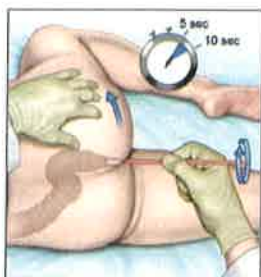
Collection for rectal swab specimens



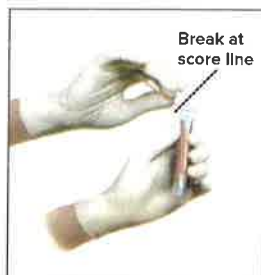
Partially open the swab package and remove the swab. Do not touch the soft tip or lay the swab down. **If the soft tip is touched, laid down, or dropped, discard and use a new Aptima Multitest Swab Specimen Collection Kit.** Hold the swab, placing thumb and forefinger in the middle of the shaft covering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

Swab specimen collection guide for:

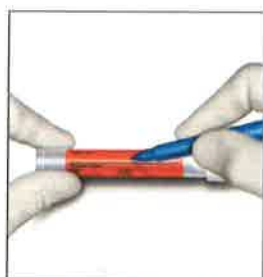
- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (NG)



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



While holding the swab in hand, unscrew the tube cap. Do not spill the tube contents. **If the tube contents are spilled, discard and replace with 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 shaft. The swab will drop to the bottom of the tube. Discard the top portion of the swab shaft.



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



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Aptima® Multitest Swab Specimen Collection Kit

Clinician collection procedure guide



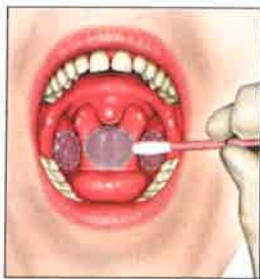
Collection for throat swab specimens



Partially 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, discard and get a new Aptima Multitest Swab Specimen Collection Kit.** Hold the swab, placing thumb and forefinger in the middle of the shaft covering the black score line. Do not hold the shaft below the score line.

Swab specimen collection guide for:

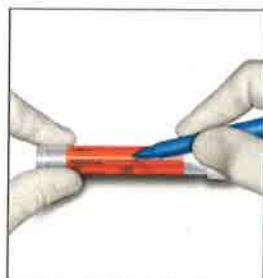
- *Chlamydia trachomatis (CT)*
- *Neisseria gonorrhoeae (NG)*



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 the swab in hand, unscrew the tube cap. Do not spill the tube contents. **If the tube contents are spilled, discard and replace with 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 shaft. The swab will drop to the bottom of the tube. Discard the top portion of the swab shaft.



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



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Aptima® Multitest Swab Specimen Collection Kit

Specimen processing guide



Collection for multitest swab specimens



Improper sample processing will result in sample rejection.

Swab specimen collection guide for:

- *Chlamydia trachomatis* (CT)
- *Trichomonas vaginalis* (TV)
- *Neisseria gonorrhoeae* (NG)
- *Herpes simplex virus 1 & 2* (HSV)

ACCEPT ✓

After collection, immediately hold the swab in 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 the bottom of the vial. Screw the cap on tightly and send to the lab.



REJECT ✗

DO NOT break above the score line.



DO NOT cut.



DO NOT fold in half.



Visually inspect to confirm the swab is broken at the score line.

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