

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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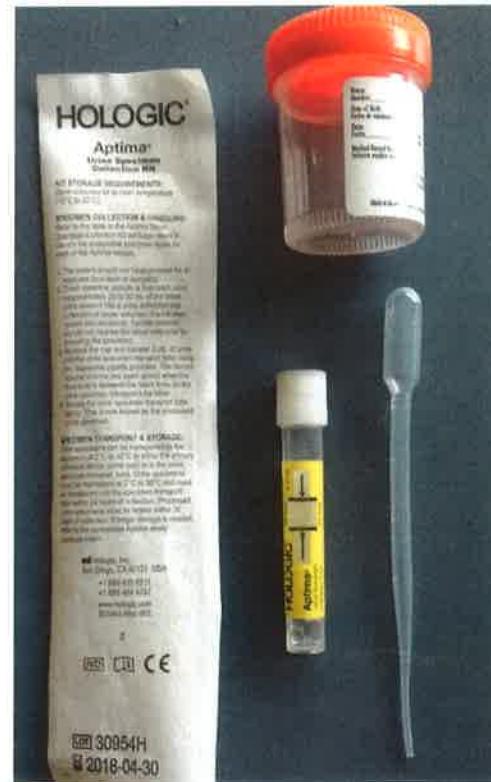
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Chlamydia Laboratory
1770 Ashland Avenue Baltimore, MD 21205
Lab phone: 443-681-3937 Lab fax: 443-681-3844*

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.
- After collection, transport the labeled urine specimen transport tube at **2°C to 30°C** until tested.
- Specimens must be assayed with the APTIMA COMBO 2 Assay **within 7 days** of collection. If longer storage is needed, freeze at **-20°C to -70°C** for up to 12 months after collection.



Aptima® vaginal swab device

Clinician collection procedure guide

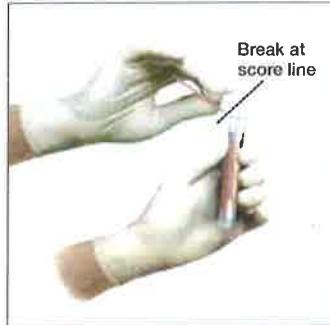
Collection for vaginal swab specimens



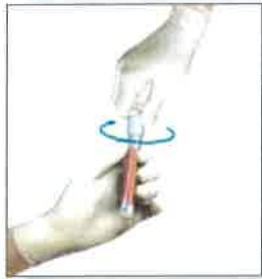
Partially open swab package and remove the swab. Do not touch the soft tip or lay the swab down. **If the soft tip is touched, laid down, or dropped, discard and get a new Aptima vaginal swab specimen collection kit.** Hold swab, placing thumb and forefinger in the middle of the swab shaft covering the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



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



While holding the 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 vaginal swab specimen collection kit.** Immediately place swab into 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 swab shaft. Swab will drop to bottom of the vial. Discard the top portion of the swab shaft.



Tightly screw cap onto tube.



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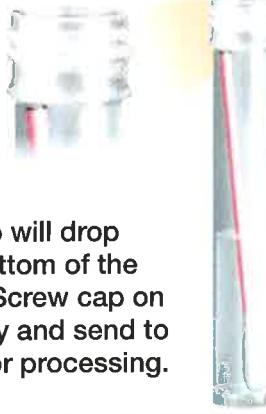
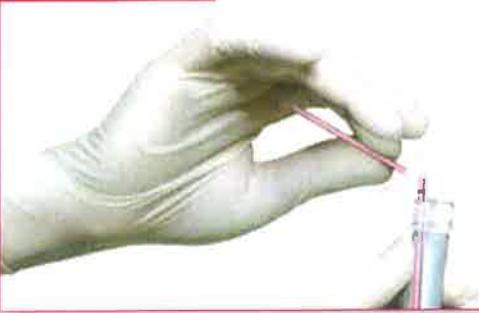
Aptima® vaginal swab

Specimen processing guide

Improper sample processing will result in sample rejection.

Swab specimen collection guide for:

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

ACCEPT	<p>After sample collection, immediately hold swab in the transport tube so the black score line is at top of the tube.</p> 	<p>Align the score line with the top edge of the tube and carefully break swab shaft.</p> 	 <p>Swab will drop to bottom of the vial. Screw cap on tightly and send to lab for processing.</p>
REJECT	<p>DO NOT break above score line.</p> 	<p>DO NOT cut.</p> 	<p>DO NOT fold swab in half.</p> 

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

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Aptima® vaginal swab device

Patient collection procedure guide

Collection for vaginal swab specimens

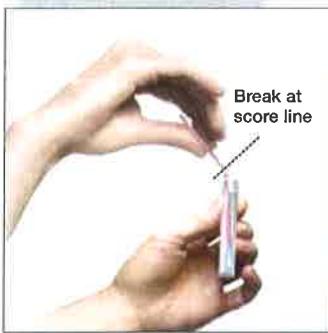


Wash hands before starting. If you have any questions about this procedure, please ask your doctor, nurse, or care provider.

Partially peel open 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 vaginal swab specimen collection kit.** Hold swab, placing thumb and forefinger in the middle of the swab shaft over the black score line.



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



While holding the swab in your hand, unscrew the tube cap. Do not spill tube contents. **If the tube contents are spilled, request a new Aptima vaginal swab specimen collection kit.** Immediately place swab into 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 swab shaft. Swab will drop to bottom of the vial. Discard the top portion of the swab shaft.



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

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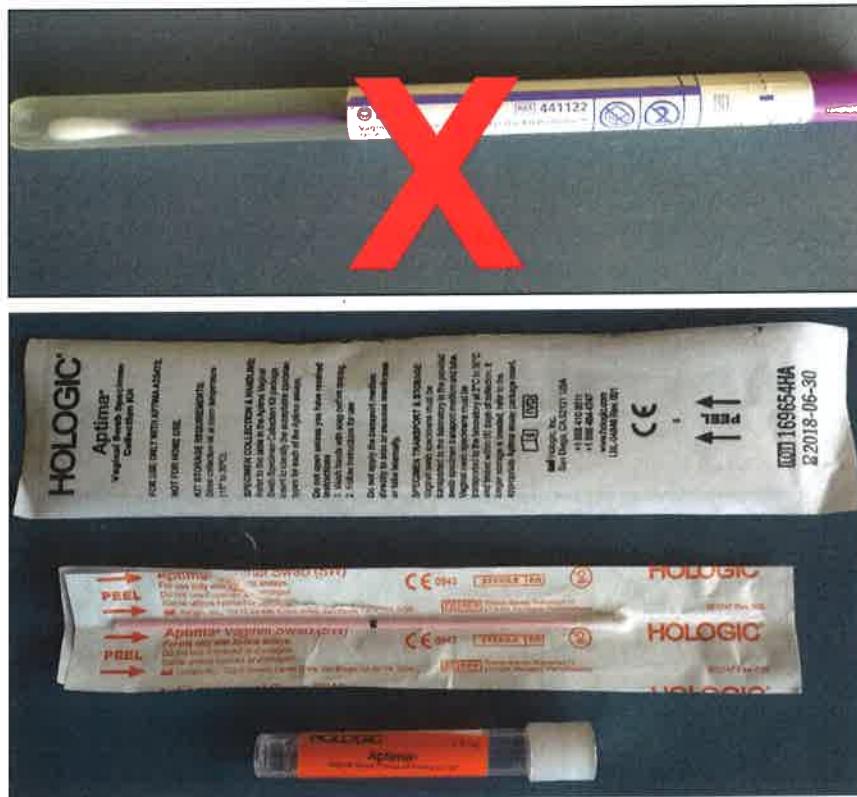
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Collection instructions for CT/GC testing using the Hologic Aptima® Combo 2 Assay

Vaginal specimens sample collection, transport, and storage:

- 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** 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.
- 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.

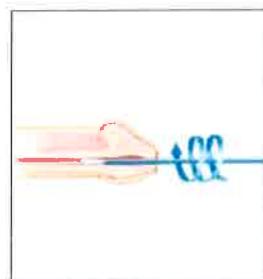


Aptima® unisex swab device

Male collection procedure guide

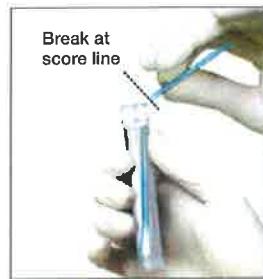
Collection for male urethral swab specimens

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

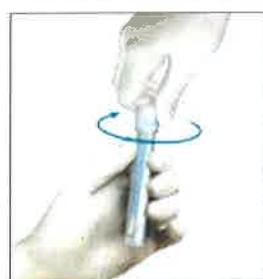


Discard cleaning swab (white shaft with red print on label). The cleaning swab is NOT needed for male specimen collection.

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

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.
- 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.

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.
- 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



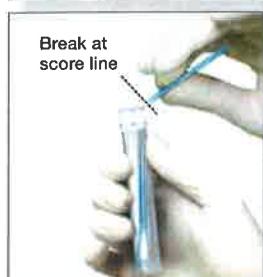
Use cleaning swab (white shaft swab with red printing) to remove excess mucus from cervical os and surrounding mucosa. Discard this swab.

Swab specimen collection guide for:

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



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.



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.

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

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

Rectal swabs:

Discard white cleaning swab.

Insert **blue unisex** 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 **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.

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 7 days** of collection. If longer storage is needed, freeze at **-20°C to -70°C** for up to 12 months after collection.

Pharyngeal swabs:

Discard white cleaning swab.

Use **blue unisex** swab to make contact with five key anatomic landmarks: bilateral tonsils, bilateral posterior walls, and the uvula.

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.

After collection, transport and store the swab in the labeled swab specimen transport tube at **2°C to 30°C** until tested.

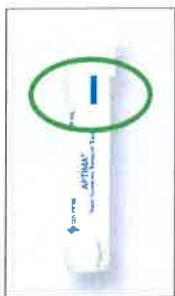
Specimens must be assayed with the APTIMA COMBO 2 Assay **within 7 days** of collection. If longer storage is needed, freeze at **-20°C to -70°C** for up to 12 months after collection.



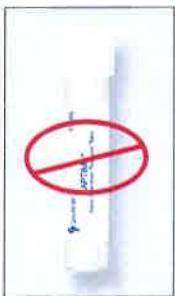
Aptima® unisex swab

Specimen processing guide

Improper sample collection will result in sample rejection.



One blue swab = **ACCEPT**



White swab = **REJECT**



Two swabs = **REJECT**

Swab specimen processing guide for:

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

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