

**Specimen Requirements for Chlamydia Trachomatis/Neisseria Gonorrhoeae by
Nucleic Acid Amplification Testing (NAAT)**
Revised on August 13, 2025

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Methodology: Target amplification nucleic acid probe test.

The Aptima Combo 2 Assay is a target amplification nucleic acid probe test that utilizes target capture for the *in vitro* qualitative detection and differentiation of ribosomal RNA (rRNA) from *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (GC) in clinician-collected endocervical, vaginal, throat, rectal, and male urethral swab specimens; patient-collected vaginal, female and male urine, throat and rectal specimens.

The HI Department of Health State Laboratories Division has verified the use of this product with patient-collected throat and rectal specimens.

Performed: SLD (Four to Five Times Weekly as needed)

Turn-Around-Time: Specimens are tested in batches. Results are routinely reported within 2-5 business days, from date of receipt.

Specimen (type) required: Clinician-collected endocervical, vaginal, throat, rectal, and male urethral swab specimens; patient-collected vaginal, female and male urine, throat, and rectal specimens. Testing not performed on patients less than 14 years of age.

Specimen Collection and Stability:

Avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of organisms. Ensure that specimen containers DO NOT contact one another, and discard used materials without passing over open containers. Change gloves if they come into contact with specimen.

Swab specimens in their appropriate transport tube can be stored at 2° to 30°C for 60 days after collection. If longer storage is needed, freeze at -20° to -70°C within 7 days of collection for up to 12 months.

Note: Throat and rectal swabs are stable at 4° to 30 °C, or -20° to -70°C for 60 days after collection.

Urine samples that are still in the primary collection container must be transported to the laboratory at 2°C to 30°C. The urine sample should be transferred into the HOLOGIC Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens within 24 hours of collection by the submitter.

Processed urine specimens in the HOLOGIC Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens can be stored at 2° to 30°C until tested. Processed urine specimens should be assayed with the Aptima Combo 2 Assay within 30 days of collection. If longer storage is needed, freeze at -20° to -70°C within 7 days of collection for up to 12 months.

Only the swabs and the specimen transport tube contained in the Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens can be used to collect the patient swab specimens. A unisex swab is used for both male and female specimens. The Aptima Multitest Swab Specimen Collection Kit is used for clinician-collected and patient-collected vaginal, rectal, and throat specimens. The Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens is used for urine specimens.

Instructions for collection:

1. Endocervical swab specimens

- a. Remove the excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white shaft swab in the package with red printing). **Discard this swab.**

Note: To remove excess mucus from the cervical os, a large - tipped swab (not provided) may be used.

- b. Insert the specimen collection swab (blue shaft swab in the package with green printing) into the endocervical canal.
- c. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling.
- d. Withdraw the swab carefully; avoid any contact with the vaginal mucosa.
- e. Remove the cap from the swab specimen transport tube and immediately place the collection swab into the transport tube.
- f. Carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft; use care to avoid splashing of contents.
- g. Re-cap the swab specimen transport tube tightly.

2. Male urethral swab specimens
 - a. The patient should not have urinated for at least one hour prior to sample collection.
 - b. Insert the specimen collection swab (blue shaft swab in the package with the green printing) 2 to 4 cm into the urethra.
 - c. Gently rotate the swab clockwise for 2 to 3 seconds in the urethra to ensure adequate sampling.
 - d. Withdraw the swab carefully.
 - e. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the specimen transport tube.
 - f. Carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft; use care to avoid splashing of contents.
 - g. Re-cap the swab specimen transport tube tightly.
3. Rectal swab specimens
 - a. Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection Kit.
 - b. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
 - c. Carefully insert the swab into the rectum about 1-2 inches (3-5 cm) past the anal margin and **gently rotate the swab clockwise** for 5 to 10 seconds. Withdraw the swab without touching the skin.
 - d. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection Kit.
 - e. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
 - f. Carefully break the swab shaft at the score line against the side of the tube.
 - g. Immediately discard the top portion of the swab shaft.
 - h. Tightly screw the cap onto the tube.
4. Throat swab specimens
 - a. Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection Kit.

- b. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
- c. 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.
- d. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection Kit.
- e. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
- f. Carefully break the swab shaft at the score line against the side of the tube.
- g. Immediately discard the top portion of the swab shaft.
- h. Tightly screw the cap onto the tube.

5. Vaginal swab specimens

- a. Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection Kit.
- b. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
- c. Carefully insert the swab into the vagina about 2 inches (5 cm) past the introitus and gently rotate the swab clockwise for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching skin.
- d. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection Kit.
- e. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
- f. Carefully break the swab shaft at the score line against the side of the tube.
- g. Immediately discard the top portion of the swab shaft.
- h. Tightly screw the cap onto the tube.

6. Urine specimens
 - a. The patient should not have urinated for at least one hour prior to specimen collection.
 - b. Direct the patient to provide a first-catch urine (approximately 20 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.
 - c. Remove the cap and transfer 2 mL of urine into the urine 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 the urine specimen transport tube label.

Urine samples must be transferred into the Aptima Urine Specimen transport tube within 24 hours of collection.

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

Specimen transport and
storage before testing:

1. Transport each sample in their own biohazard bag. If a patient has more than one sample, all samples from that patient can be in the same biohazard bag.

2. Swab Specimens:

After collection, transport and store the swab in the swab specimen transport tube at 2° 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° to -70°C within 7 days of collection for up to 12 months.

Note: Throat and rectal swabs are stable at 4° to 30 °C, or -20° to -70°C for 60 days after collection.

3. Urine Specimens:

- a. The submitting facility will transfer the urine sample into the Aptima urine specimen transport tube within 24 hours of collection. This is now known as the *processed urine specimen*.

- b. Processed urine specimens should be stored and transported at 2 - 30°C and assayed with the Aptima Combo 2 Assay within 30 days of collection. If longer storage is needed freeze at -20° to -70°C within 7 days of collection for up to 12 months.

Ship specimens in the appropriate HOLOGIC Aptima transport tubes to the Medical Microbiology Branch for testing. Follow current instructions in compliance with the U.S. Department of Transportation (U.S. DOT) and International Air Transport Association (IATA) for packing and shipping.

Specimen submission: Submitters (Authorized by the STD Prevention Program of the HARM Reduction Services Branch).

Submit samples through the Hawaii SLD LabOnline portal:

<https://cln-lab-prod-statelab.doh.hawaii.gov>

The CHLAMYDIA/GONORRHEA LAB FORM, Nucleic Acid Amplification Test, provided by the STD Prevention Program of the HARM Reduction Services Branch may be used with pre-approved permission from the Hawaii State Laboratories Division.

**Labeling Hologic
Aptima Swab Specimen
or Urine Specimen
Transport Tube:**

1. Legibly write on the Transport label using smear-proof ink:
 - a. The Patient Name,
 - b. Specimen Type,
 - c. Date of Collection,
 - d. Patient ID# or other unique identifier (i.e. Date of Birth)
2. **DO NOT** cover the Fill Area window on the urine specimen transport tubes and the Expiration Date of the transport tube with tape or a label.

**Unacceptable conditions:
(Rejection Criteria)**

- Specimen is received in a container that is leaking;
- Wrong swab(s);
- No swab (except urine specimen);
- Specimen is not collected in a proper container or handling instruction is not followed;
- Specimen transport tubes from different patients packaged together in one biohazard bag;
- Improperly packaged specimen(s) NOT in properly labeled packaging/containers (i.e. biohazard label);

- Urine specimens in their primary containers.
- Incorrect volume of urine (fluid level is not between the black fill lines on the urine transport tube label);
- Unable to verify the volume of liquid in the specimen transport tube;
- Specimen quantity is insufficient to perform the tests;
- Unlabeled specimens;
- Improperly/Illegible filled requisition form (provided by STD Prevention Program of the HARM Reduction Services Branch);
- Missing Date of Birth (DOB) and/or Age of Patient;
- Age of Patient is younger than 14 years (the performance of the Aptima Combo 2 assay has not been evaluated in adolescents less than 14 years of age).;
- Specimen label does not match the submitted request;
- Expired transport tube;
- Unable to verify the expiration date of specimen transport tube;
- No submitting facility listed;
- Specimen improperly submitted through Hawaii SLD LabOnline.

Normal Value: Negative for *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*.

Result Notification: Laboratory results are reported via the Hawaii SLD LabOnline and/or through the STD Prevention Program of the HARM Reduction Services Branch.

Disclaimer: Gonorrhea (GC)/Chlamydia (CT) Nucleic Acid Amplification – off label for patient-collected throat and rectal specimens:

The off-label (not cleared or approved by the U.S. Food and Drug Administration) use of this test on these specimen types was verified by the State Laboratories Division.

Test performed at: Virology Section, Medical Microbiology Branch
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2725 Waimano Home Road, 2nd Floor
Pearl City, Hawaii 96782

Contact: Roland Lee, Supervisor, Virology
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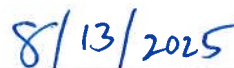
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Edward P. Desmond, Ph.D.
Administrator, State Laboratories Division



Date

Instructions for Using the Aptima® Multitest Swab Specimen Collection Kit for Patient-Collected Specimens

PATIENT INFORMATION REGARDING SELF-COLLECTED SPECIMENS

- A self-collected swab is one way to test for sexually transmitted infections (STIs). Other options are available. If you have questions about the self-collected swab, other sample collection options, or about STIs, consult your health care provider.
- Self-collection is an option in clinical settings if you agree to perform the procedure. Counseling from your health-care provider is available for the self-collection procedure.
- Carefully read the swab self-collection instructions below. If you feel you can perform this self-collection procedure and wish to use this method of testing for STIs, inform your health-care provider.
- Do not take the collection kit or your self-collected specimen out of the clinic.
- Some self-collected specimen types are not available with all assays. Refer to the appropriate assay package insert for appropriate specimen types.

GENERAL INSTRUCTIONS FOR ALL COLLECTION METHODS

Carefully follow procedures for reliable results. If you have any questions about any procedure, ask your health-care provider.

- Wash your hands before starting.
- In the privacy of the examination room or restroom, you will need to undress, as necessary. You will need to comfortably position yourself to maintain balance during the collection procedure.
- Open kit package. Remove the swab and the tube. Set the tube aside before beginning instructions below to collect the specimen or specimens requested by your health-care provider. **WARNING: If at any time the contents of the tube are spilled on your skin, wash the affected area with soap and water. If the contents of the tube are splashed in your eyes, immediately flush your eyes with water. Notify your health-care provider if irritation develops. If the contents of the tube are spilled, request a new Aptima Multitest Swab Specimen Collection Kit. Do not take internally.**

VAGINAL SWAB SPECIMEN COLLECTION

- Before proceeding, read the patient information and general instructions above.
- Partially peel open the swab package as shown in Diagram 1. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is tied down, or the swab is dropped, request a new Aptima Multitest Swab Specimen Collection Kit.
- Hold the swab in your hand as shown in Diagram 2, placing your thumb and forefinger in the middle of the swab shaft covering the score line (black line). Do not hold the swab shaft below the score line (black line).
- Carefully insert the swab into your vagina about 2 inches (5 cm) inside the opening of the vagina (as shown in Diagram 3) and gently rotate the swab clockwise for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin.
- While holding the swab in the same hand, unscrew the cap from the tube as shown in Diagram 4. Do not spill the contents of the tube. If the contents of the tube are spilled, request a new Aptima Multitest Swab Specimen Collection Kit.
- Immediately place the swab into the transport tube so that the score line (black line) is at the top of the tube as shown in Diagram 5.
- Carefully break the swab shaft at the score line (black line) against the side of the tube as shown in Diagram 6.
- Immediately discard the top portion of the swab shaft as shown in Diagram 7.
- Tightly screw the cap onto the tube as shown in Diagram 8. Return the tube as instructed by your health-care provider.

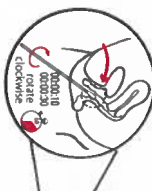
Important Information to Consider

If YOU ARE PREGNANT, PLEASE INFORM YOUR HEALTH-CARE PROVIDER.

Before you collect a vaginal swab specimen, inform your health-care provider if you have:

- recent pelvic pain
- pain with sexual intercourse
- unusual vaginal discharge or bad odor

These symptoms can be due to pelvic inflammatory disease (PID). Prompt diagnosis and treatment of PID can help prevent infertility and ectopic pregnancy associated with PID.



Vaginal Swab Specimen Collection

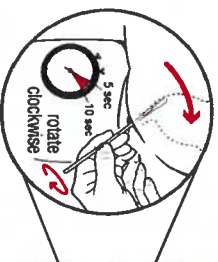
Instructions for Using the Aptima® Multitest Swab Specimen Collection Kit for Patient-Collected Specimens

RECTAL SWAB SPECIMEN COLLECTION

- Before proceeding, read the patient information and general instructions on page 1.
- Partially peel open the swab package as shown in Diagram 1. Remove the swab.
Do not touch the soft tip or lay the swab down.
- Hold the swab as shown in Diagram 2, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
- Caressfully insert the swab into your rectum about 1-2 inches (3-5 cm) past the anal margin (the outside of the anus) and gently rotate the swab clockwise for 5 to 10 seconds as shown in Diagram 3.
- While holding the swab in the same hand, unscrew the cap from the tube as shown in Diagram 4. Do not spill the contents of the tube.
- Immediately place the swab into the transport tube so that the score line is at the top of the tube as shown in Diagram 5.
- Caressfully break the swab shaft at the score line against the side of the tube as shown in Diagram 6.
- Immediately discard the top portion of the swab shaft as shown in Diagram 7.
- Tightly screw the cap onto the tube as shown in Diagram 8. Return the tube as instructed by your health-care provider.

THROAT SWAB SPECIMEN COLLECTION

- Before proceeding, read the patient information and general instructions on page 1.
- Partially peel open the swab package as shown in Diagram 1. Remove the swab.
Do not touch the soft tip or lay the swab down.
- If the soft tip is touched, the swab is laid down, or the swab is dropped, request a new Aptima Multitest Swab Specimen Collection Kit.
- Hold the swab as shown in Diagram 2, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
- Caressfully insert the swab into your mouth as shown in Diagram 3, ensuring contact with bilateral tonsils (the tonsils on both sides of your mouth, unless your tonsils have been removed) and the back of your throat, then withdraw the swab without touching the inside of your cheeks or tongue.
- While holding the swab in the same hand, unscrew the cap from the tube as shown in Diagram 4. Do not spill the contents of the tube.
- If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection Kit.
- Immediately place the swab into the transport tube so that the score line is at the top of the tube as shown in Diagram 5.
- Caressfully break the swab shaft at the score line against the side of the tube as shown in Diagram 6.
- Immediately discard the top portion of the swab shaft as shown in Diagram 7.
- Tightly screw the cap onto the tube as shown in Diagram 8. Return the tube as instructed by your health-care provider.



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.
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AW-28254-001 Rev.001

| Revision History | Date | Description |
|-----------------------|--------------|--|
| AW-28254-001 Rev. 001 | January 2022 | <ul style="list-style-type: none"> Added Aptima Multitest Swab Specimen Collection Kit for Patient-Collected Specimens (UAW-28254-001 Rev.001) based on AW-19988 Rev. 005 for regulatory compliance with IVD. Updated contact information including EC Rep, Australian Rep information, and technical support. |

Rectal Swab Specimen Collection



Throat Swab Specimen Collection

