Aptima CT/NG Assay



The Aptima Chlamydia trachomatis (CT)/Neisseria gonorrhoeae (NG) 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) to aid in the diagnosis of chlamydial and/or gonococcal disease in symptomatic and asymptomatic individuals.

A. Specimen collection

Note: Handle all specimens as if they contain potentially infectious agents. Use Universal Precautions.

Note: Take care to avoid cross-contamination during sample handling steps. For example, discard used material without passing over open tubes.

The following specimen types are acceptable for the Aptima CT/NG Assay:

- Clinician-collected PreservCyt[®] Solution liquid Pap specimen. For collection instructions refer to ThinPrep Pap Test Quick Reference Guide Endocervical Brush/Spatula Protocol or Broom-Like Device Protocol.
- 2. Vaginal swab specimen collected with the Aptima Multitest Swab Specimen Collection Kit. The Aptima Multitest Vaginal Swab Specimen Collection instructions are as follows:



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 black score line**. Do not hold shaft below score line.



Carefully insert swab into the vagina about 2 inches (5 cm) past the introitus and gently **rotate swab for 10 to 30 seconds**. Make sure swab touches vaginal walls so that moisture is absorbed by 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 black 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.

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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If you have any questions or need more information, contact Cytology at Pathology Services Laboratory by phone at 479-968-6781 or 1-800-874-4904 or by email at PSLab@pathologyserviceslab.com.

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- 3. Female and male urine specimens.
 - a. The patient should not have urinated for at least 1 hour prior to specimen collection.
 - b. Direct 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. Within 24 hours of collection, transfer 2 mL of urine into the 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 the urine specimen transport tube label.
 - d. Re-cap the urine specimen transport tube tightly.
- 4. Endocervical swab specimen collected with the Aptima Unisex Swab.
 - a. Remove 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 the 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 specimen 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
- 5. Male urethral swab specimen collected with the Aptima Unisex Swab.
 - a. The patient should not have urinated for at least 1 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 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
- 6. Rectal swab specimen collected with the Aptima Multitest Swab.
 - 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.

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- 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.

B. Specimen transport and storage before testing:

- PreservCyt solution liquid Pap specimens intended for CT and/or GC testing must be processed for cytology and/or transferred to an Aptima specimen transfer tube within 30 days of collection when stored at 2°C to 30°C.
- Aptima Multitest Swab specimens in transport tubes can be stored at 2°C to 30°C for up to 60 days.
- Maintain urine specimens at 2°C to 30°C after collection and transfer to the Aptima urine specimen transport tube within 24 hours of collection. Urine specimens in the Aptima urine specimen transport tube can be stored at 2°C to 30°C for up to 30 days.
- Aptima Unisex Swab specimens in transport tubes can be stored at 2°C to 30°C for up to 60 days.