



NEISSERIA GONORRHOEAE

INDICATIONS:

Gonorrhea is a purulent infection of the mucous membrane surfaces caused by Neisseria gonorrhoeae. N gonorrhoeae is spread by sexual contact or through transmission during childbirth. The Centers for Disease Control (CDC) recommends that all patients with gonorrheal infection also be treated for presumed co-infection with Chlamydia trachomatis.

SPECIMEN:

1. Thin Prep Based Pap Test
2. Aptima Swab Collection (Vaginal)
3. Aptima Swab Collection (Endocervical / Male Urethra)
4. Urine

SUPPLIES:

1. Cervical sampling:
 - CytoBrush & Spatula or Broom in Thin Prep or Liquid Based Collection Vial [Adjunct to Pap]
2. Vaginal sampling:
 - APTIMA vaginal specimen collection swab and tube
3. Unisex sampling:
 - APTIMA unisex specimen collection swab and tube
4. Urine sampling:
 - APTIMA urine specimen collection tube
5. Specimen Requisition
6. Specimen Bag with a biohazard label

COLLECTION PROCEDURE:

Thin Prep Liquid Based Pap Test:

One specimen will be used to provide samples for both the Pap test and/or the Neisseria gonorrhoeae (NG) test. Follow the appropriate Pap collection instructions for testing of NG. This test can be performed adjunctively from the Pap vial.

APTIMA Vaginal Swab Collection [Separate from Pap]:

1. Partially peel-open the swab package. 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 Vaginal Swab Specimen Collection Kit.





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2. Remove the swab.
3. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft.
4. Carefully insert the swab into the vagina about two inches and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab.
5. Withdraw the swab without touching the skin.
6. 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 Vaginal Swab Specimen Collection Kit.
7. Immediately place the swab into the transport tube so that the tip of the swab is visible below the tube label.
8. Carefully break the swab shaft at the score-line against the side of the tube and discard the top portion of the swab shaft. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Vaginal Swab Specimen Collection Kit.
9. Tightly screw the cap onto the tube.

APTIMA Endocervical / Male Urethra Swab Collection [Separate from Pap]:

Endocervical swab specimens:

1. 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.
2. Insert the specimen collection swab (blue shaft swab in the package with the green printing) into the endocervical canal.
3. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling.
4. Withdraw the swab carefully; avoid any contact with the vaginal mucosa.
5. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
6. Carefully break the swab shaft against the side of the tube at the score-line and discard the top portion of the swab shaft; use care to avoid splashing of contents.
7. Re-cap the swab specimen transport tube tightly.





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Male urethral swab specimens:

1. The patient should not have urinated for at least 1 hour prior to sample collection.
2. Insert the specimen collection swab (blue shaft swab in the package with the green printing) 2 to 4 cm into the urethra.
3. Gently rotate the swab clockwise for 2 to 3 seconds in the urethra to ensure adequate sampling.
4. Withdraw the swab carefully.
5. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
6. Carefully break the swab shaft against the side of the tube at the score-line and discard the top portion of the swab shaft; use care to avoid splashing of contents.
7. Re-cap the swab specimen transport tube tightly.

Urine Collection:

1. The patient should not have urinated for at least 1 hour prior to specimen collection.
2. 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.
3. Remove the cap and 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.
4. Re-cap the urine specimen transport tube tightly. The specimen is now known as the processed urine specimen.

STORAGE REQUIREMENTS:

- Cervicovaginal – Thin Prep liquid based Pap vial at 2 to 30 degrees C.
Vaginal – APTIMA swab specimen transport tube at 2 to 30 degrees C.
Endocervical – APTIMA swab specimen transport tube at 2 to 30 degrees C.
Urethral – APTIMA swab specimen transport tube at 2 to 30 degrees C.
Urine – APTIMA urine specimen transport tube at 2 to 30 degrees C.





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STABILITY REQUIREMENTS:

Cervicovaginal, Vaginal, & Endocervical – APTIMA swab specimen transport tube or liquid based Pap preservative vial – 3 weeks from collection.

Urine – APTIMA urine specimen transport tube – 3 weeks from collection.

Note: Urine samples that are still in the primary collection container must be transported to the lab and transferred into the APTIMA urine specimen transport tube within 24 hours of collection.

STORAGE REQUIREMENTS – Room Temperature

STABILITY REQUIREMENTS – 72 hours

Submit all patient information following the procedure for "Completing a Gynecologic Cytology Requisition".

Complete test requisition including last and first name of patient, patient's date of birth and social security number, body site and source of specimen collected. Label specimen container (using the labels provided on the requisition) with patient's first name and last name, and body site/source. The container must have at least two (2) unique identifiers. Examples of unique identifiers: patient name, DOB, unique bar code, etc. Include pertinent clinical information, i.e., previous malignancy, radiation therapy, drugs, etc. Place container in a specimen bag with a biohazard label. Place the requisition in the side pocket of the specimen bag.

