

Virology/Special Chemistry Policy 830 Bayou Pines West · Lake Charles, La. 70601

GENPROBE APTIMA COMBO 2 CT/GC

Specimen Collection Guidelines

Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) Testing

Specimens other than those collected with the following specimen collection kits have not been cleared for use on the PANTHER system:

- Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens
- Aptima Urine collection kit for male and female urine specimens
- Aptima Vaginal Swab Specimen Collection Kit
- Aptima Specimen Transfer Kit (for use with gynecologic samples collected in PreservCyt Solution)

A. Instructions for Collection:

- 1) Aptima Urine Collection Kit: (Provided to the off-site offices)
- ** Please Note: If a urine culture is needed, you must <u>first</u> collect GC/CT specimen in a cup, then follow proper procedures to collect a clean catch specimen for culture.
 - 1. The patient should not have urinated for at least 1 hour prior to specimen collection.
 - 2. 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.
 - 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. This is now known as the processed urine specimen.

2) Aptima Vaginal Swab Collection Kit:

- 1. 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 Vaginal Swab Specimen Collection Kit.
- 2. 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.
- 3. Carefully insert the swab into the 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 walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin.

- 4. 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.
- 5. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
- 6. Carefully break the swab shaft at the score line against the side of the tube.
- 7. Immediately discard the top portion of the swab shaft; use care to avoid splashing of contents.
- 8. Tightly screw the cap onto the specimen transport tube.

3) Aptima Unisex Swab Collection Kit:

a) Endocervical swab:

- 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.
 - **Please 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. Tightly re-cap the swab specimen transport tube.

b) Male urethral swabs:

- 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. Tightly re-cap the swab specimen transport tube.

B. Specimen Transport and Storage before Testing:

1) Swab specimens:

a) 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 for up to 12 months after collection.

2) PreservCyt Solution liquid pap specimens:

a) 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 to 30 °C.

3) Urine specimens:

- a) **From Offsite:** Urine samples that are still in the primary collection container must be transported to the lab at 2 to 30 °C. Transfer the urine sample into the Aptima urine specimen transport tube within 24 hours of collection. Store at 2 to 30 °C and test within 30 days of collection.
- b) **Collected In-House:** After collection, transfer the processed urine specimens into the Aptima urine specimen transport tube and store 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 for up to 12 months after collection.