

**Specimen Requirements for Chlamydia Trachomatis/Neisseria
Gonorrhoeae by Nucleic Acid Amplification Testing (NAAT)**

Revised on June 12, 2007

- Methodology:** Target amplification nucleic acid probe test.
- Performed:** 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* and/or *Neisseria gonorrhoeae* in clinician-collected endocervical and male urethral swab specimens, and in female and male urine specimens.
- Turn-Around-Time:** Specimens are tested in batches. Results are reported out in 7 calendar days (Oahu) to 10 calendar days (Neighbor Islands).
- Specimen (type) required:** Clinician-collected endocervical and male urethral swab specimens, and female and male urine specimens.
- Specimen Collection:** 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 for up to 90 days after collection.
- Processed urine specimens in the GEN-PROBE APTIMA urine specimen transport tube can be stored 2° to 30°C for 30 days after collection. If longer storage is needed, freeze at -20° to -70°C for up to 90 days after collection.
- Only the swabs and the specimen transport tubes contained in the APTIMA Unisex Swab Specimen Collection Kit for Endocervical and 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 Unisex Swab Specimen Collection Kit for Endocervical and Urethral Swab Specimens, APTIMA Urine Specimen Collection Kit for Male and Female Urine Specimens, PACE Specimen Collection Kit for Urethral or Conjunctival Specimens in conjunction with the APTIMA Adapter Kit, and PACE Specimen Collection Kit for Endocervical Specimens are intended to be

used only with the GEN-PROBE APTIMA Combo 2 Assay.

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 cleaning swab (not provided) may be used. Discard swab after use.

- 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 swab collection swab into the transport tube.
 - f. Carefully break the swab shaft at the scoreline; use care to avoid splashing of the 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 specimen 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 at the scoreline; use care to avoid splashing of the contents.
 - g. Re-cap the swab specimen transport tube tightly.
3. 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 specimen 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 with the fluid level is between the black fill lines on the urine tube label.
 - d. Re-cap the urine specimen transport tube tightly. This is now known as the *processed urine specimen*.

Specimen storage, packing and transport:

Specimen transport and storage before testing:

1. 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 for up to 90 days after collection.

2. Urine Specimens:

- a. After collection, transport the processed urine specimens in the GEN-PROBE APTIMA urine specimen transport tube at 2° to 30°C 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 90 days after collection.
- b. 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.
- c. Urine specimens will be transferred to the GEN-PROBE specimen transport tube by the submitting facility and transported to the Medical Microbiology Branch for testing.

Ship specimens in the appropriate Gen-Probe APTIMA transport tubes. Follow instructions for Class B – Biological Substance of the U.S. Department of Transportation (U.S. DOT) and International Air Transport Association (IATA) for packing and shipping.

Specimen submission: Submitters (Authorized by STD Control Program of the STD/AIDS Branch).

Unacceptable conditions:

- Specimen is received in a container that is leaking;
- Wrong swab;
- Specimen is not collected in a proper container or handling instruction is not followed;
- 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);
- Specimen quantity is insufficient to perform the tests;

- Unlabeled specimens;
- Improperly filled requisition form (provided by STD Control Program);
- Specimen label does not match the requisition;
- Expired transport tube.

Stability: 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 for up to 90 days after collection.

Processed urine specimens in the GEN-PROBE APTIMA urine specimen transport tube can be stored 2° to 30°C for 30 days after collection. If longer storage is needed, freeze at -20° to -70°C for up to 90 days after collection.

Requisition Form: Provided by the STD Control Program of the DOH STD/AIDS Branch.

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

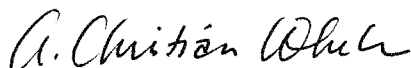
Result Notification: Laboratory results are reported to the STD Control Program of the DOH STD/AIDS Branch.

Test performed at: Virology Section, Medical Microbiology Branch
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Approved by:



A. Christian Whelen, Ph.D.
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June 15, 2007