Specimen Requirements for Chlamydia Trachomatis/Neisseria Gonorrhoeae by Nucleic Acid Amplification Testing (NAAT)
Revised on December 22, 2016

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 and male urethral swab specimens, clinician-collected or patient-collected vaginal specimens, female and male urine specimens, oral (pharyngeal) and rectal specimens for *Neisseria gonorrhoeae*, and rectal specimens for *Chlamydia trachomatis*.

The HI Department of Health State Laboratories Division has verified the use of this product with female urine specimens; oral and rectal GC specimens; and rectal CT specimens.

Performed: SLD (Two to Three Times Weekly as needed)

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, clinician-collected/or patient-collected vaginal specimens, female and male urine specimens, oral and rectal specimens for *Neisseria gonorrhoeae*, and rectal specimens for *Chlamydia trachomatis.* Testing not performed on patients less than 14 years of age.

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 12 months after collection. *Note: Oral (Pharyngeal) and rectal swabs are stable at 2° to 30°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 APTIMA urine specimen tube within 24 hours of collection by the submitter. Store at 2°C to 30°C and test within 30 days of collection

Processed urine specimens in the GEN-PROBE APTIMA urine specimen transport tube 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 for up to 12 months 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 including oral and rectal specimens. A unisex swab is used for both male and female specimens. The APTIMA Vaginal Swab Specimen Collection Kit is used for clinician-collected and patient-collected vaginal specimens. The APTIMA Urine Collection Kit for Male and Female Urine Specimens is used for urine specimens.

The HI Department of Health State Laboratories Division has verified the use of this product with female urine specimens; oral and rectal GC specimens; and rectal CT specimens.

Instructions for collection:

1. Endocervical swab specimens

    a. Remove the excess mucus from the cervical os and surrounding mucosa using the *Female* 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 *Female* cleaning swab (provided in the collection package) 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 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. Rectal swab specimens
   a. Insert the blue shaft specimen collection swab into the anal canal.
   b. Rotate for 15-30 seconds.
   c. Withdraw the swab carefully and place into the specimen transport tube.
   d. Carefully break the swab shaft at the score line; use care to avoid splashing of the contents.
   e. Recap the tube tightly.
   f. Specimens are stable at 2° to 30°C for 60 days after collection.

4. Oral (pharyngeal) swab specimens
   a. Instruct the patient to tilt head backwards, open mouth, and say "ah".
   b. A tongue depressor may be used to facilitate seeing the pharynx.
   c. Insert the blue shaft specimen collection swab without touching lips, teeth, tongue, or cheeks.
   d. Gently and quickly, swab the tonsillar area side to side.
   e. Withdraw the swab carefully and place into the specimen transport tube.
   f. Carefully break the swab shaft at the score line; use care to avoid splashing of the contents.
   g. Recap the tube tightly.
   h. Specimens are stable at 2° to 30°C for 60 days after collection.

5. 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 when the fluid level is between the black fill lines on the urine 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 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 12 months after collection.

   Note: Oral (Pharyngeal) and rectal swabs are stable at 2° to 30°C for 60 days after collection.

2. 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 for up to 12 months after collection.

Ship specimens in the appropriate Gen-Probe 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).

Labeling Gen-probe Aptima Swab Specimen Transport Tube or Urine Specimen Transport:

1. Legibly write on the Transport label using smear-proof ink:
   a. The Patient Name,

b. Date of Collection,
c. Patient ID# or other unique identifier

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;
- 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/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 endocervical, vaginal, male urethral, urine, oral, and rectal swab specimens and PreservCyt Solution liquid Pap specimens has not been evaluated in adolescents less than 14 years of age).;
- 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 12 months after collection.

Note: Oral (Pharyngeal) and rectal swabs are stable at 2° to 30°C for 60 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 12 months after collection.

Requisition Form: Provided by the STD Prevention Program of the HARM Reduction Services Branch.

CHLAMYDIA/GONORRHEA LAB FORM, Nucleic Acid Amplification Test, 9" X 7" Form.

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

Result Notification:	Laboratory results are reported to the STD Prevention Program of the HARM Reduction Services Branch or sent electronically by a secure electronic reporting system (Dashboard, SharePoint).
Disclaimer:	Gonorrhea (GC)/Chlamydia (CT) Nucleic Acid Amplification – off label for oral/rectal GC, rectal CT specimens and female urine CT/GC 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 State Laboratories Division Department of Health 2725 Waimano Home Road, 2nd Floor Pearl City, Hawaii 96782
Contact:	Roland Lee, Supervisor, Virology (808) 453-6705 Rebecca Kanenaka, Supervisor, Viral Isolation and Antigen Detection Unit (808) 453-6705 Gail Y. Kunimoto, Chief, Medical Microbiology (808) 453-6700

Approved by:

A. Christian Whelen, Ph.D.
State Laboratories Division Administrator December 22, 2016