Neisseria gonorrhoeae and *Chlamydia trachomatis* Gen-Probe Aptima Combo 2 Assay

Chlamydia (C.) trachomatis is the most common treatable sexually transmitted infection affecting females of reproductive age in the United States today, with an estimated four million new cases each year. Up to 80% of infected females have few or no symptoms. Asymptomatic infection in females can persist for up to 15 months. Complications of untreated chlamydial infection in females include acute pelvic inflammatory disease, ectopic pregnancy, chronic pelvic pain, and infertility.

Gonorrhea affects both males and females with symptoms ranging from purulent discharge to very mild symptoms. Symptoms may pass unnoticed with the health consequence that asymptomatic carriers contribute significantly to the public health problem of gonorrhea.

The Serology Section uses the Gen-Probe Aptima Combo 2 Assay to detect both chlamydia and gonorrhea infections utilizing urine from either males or females, or female endocervical swabs, male urethral swabs, vaginal swabs, pharyngeal swabs and rectal swabs or liquid pap solution.

This method is not recommended for medicolegal cases. The SDPHL will also continue to perform culture tests for *N. gonorrhoeae* under these circumstances if requested. Antimicrobial tests are not performed. The South Dakota Public Health Laboratory does not perform culture tests for *Chlamydia.*

Only swabs supplied with the specimen collection systems should be used for specimen collection.

Specimen Collection and Storage

The APTIMA Combo 2 Assay is designed to detect the presence of *C. trachomatis* and *N. gonorrhoeae* in endocervical and male urethral specimens, and in female and male urine specimens. The SDPHL can also test vaginal, rectal, urine, pharyngeal and liquid pap specimens in Aptima transport medium. Only the swabs and the specimen transport tubes contained in the APTIMA Combo 2 Assay Unisex Swab Specimen Collection Kit for Endocervical and Urethral Swab Specimens should be used to collect patient swab specimens. A unisex swab is used for both male and female specimens. These collection kits are intended to be used only with the Hologic APTIMA Combo 2 Assay. Performance has not been established with other products.

Swab specimens must be transported to the laboratory in the swab specimen transport medium and tube. Swab specimens must be transported to the laboratory at 2°- 30°C and tested within 60 days of collection.

Urine specimens must be transferred into the Hologic specimen transport tube within 24 hours of collection. Once transferred, urine specimens can be stored at 2°- 30°C for up to 30 days after collection.

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A. Instructions for collection:

1. Endocervical swab specimens:

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.**

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 specimen collection swab into the transport tube.

f. Carefully break the swab shaft at the score line; 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 - 4 cm into the urethra.

c. Gently rotate the swab clockwise for 2 - 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 score line; 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 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 transport tube label.

d. Re-cap the urine specimen transport tube tightly. This is now known as the processed urine specimen.

4. Rectal or Vaginal Swabs:

a. Insert the specimen collection swab (blue shaft swab in the package with green printing) into the vagina or rectum.

b. Gently rotate the swab clockwise for 10 - 30 seconds in the rectum or vaginal canal to ensure adequate sampling.

c. Withdraw the swab carefully.

d. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.

e. Carefully break the swab shaft at the score line; use care to avoid splashing of the contents.

f. Re-cap the swab specimen transport tube tightly.

5. Pharyngeal Swabs:

a. Insert the specimen collection swab (blue shaft swab in the package with green printing) into back of the throat.

b. Gently rotate the swab clockwise for 10 to 30 seconds at the back of the throat to ensure adequate sampling.

c. Withdraw the swab carefully.

d. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.

e. Carefully break the swab shaft at the score line; use care to avoid splashing of the contents.

f. Re-cap the swab specimen transport tube tightly.

B. Storage before testing:

1. Swab specimens:

Once collected, transport and store the swab in the swab specimen transport tube at 2°-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:**
   After collection, transport the processed urine specimens in the Hologic APTIMA Combo 2 urine specimen transport tube 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.

Specimen Identification

1. Complete **all** the provider and patient information areas.

2. Label each specimen with the date of collection and the patient's first and last name. Unlabeled specimens or specimens where the patient identifier on the specimen does not match the identifier on the form will not be tested.

Reporting and Interpretation of Results

The goal of the Serology Section is to test and report all Chlamydia/Gonorrhea Probe specimens within a 24 hour turnaround period, except for borderline or equivocal specimens which will take 48 hours. Copies of all positive Chlamydia and Gonorrhea reports are sent to the Sexually Transmitted Disease (STD) Program.

Results are reported as follows:

POSITIVE – Positive for Chlamydia trachomatis and/or Neisseria gonorrheae.

NEGATIVE – Negative for Chlamydia trachomatis and/or Neisseria gonorrheae.

EQUIVOCAL – Borderline for Chlamydia trachomatis and/or Neisseria gonorrheae. Submit another specimen.

UNSATISFACTORY – Specimen comprised in some manner making it unsatisfactory for testing. The reason for each "Unsatisfactory" specimen will be detailed on the report.

Criteria for Unacceptable Specimens

1. The specimen was not labeled.

2. The patient identifier on the specimen did not match the identifier on the form.

3. The specimen was collected by use of swabs and/or tubes (collection kit) other than by the Hologic kit.

4. The specimen was collected from a site other than endocervical, urethral or urine, rectal, vaginal or pharyngeal.

5. The specimen was too old for testing.

6. The specimen had no collection swab in the transport tube upon receipt in the laboratory.

7. The specimen had two collection swabs in the transport tube.

8. The specimen was received in an out-of-date collection kit.

9. The media had leaked in transport or something has been added to the tube for example the tube was too full or was a strange color.
10. The specimen did not arrive in appropriate temperature transport range.