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PUBLIC HEALTH LABORATORY**
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Test Order Chlamydia / Gonorrhea TMA

Specimen Collection and Storage for Chlamydia and Gonorrhea Testing (using the APTIMA® Transcription Mediated Amplification / TMA Molecular Detection Assay)

Background: The APTIMA® Transcription Mediated Amplification Assay for chlamydia and gonorrhea is a sensitive and specific FDA-approved assay for the detection of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* infection for the following specimen sources: endocervical, vaginal, male urethral, and urine. In addition, the San Francisco Public Health Laboratory has validated this assay for the detection *N. gonorrhoeae* and *C. trachomatis* in pharyngeal and rectal sources. Conjunctival, or any other sources, are not validated for this assay, and cannot be tested. The assay detects the presence of ribosomal RNA (rRNA) of *N. gonorrhoeae* and *C. trachomatis* in patient samples, negating the need for culture methods.

Materials for specimen collection, and acceptable specimen sources:

APTIMA® Unisex Swab Collection Kit: for endocervical, male urethral, rectal, and pharyngeal sources

APTIMA® Urine Collection Kit: for urine specimens

APTIMA® Vaginal Swab Collection Kit: for vaginal sources

San Francisco Public Health Laboratory Requisition Form:

<http://sfdcpc.org/document.html?id=1035>

Procedures for specimen collection and submission:

1) Specimen Collection

Urine specimens: Transfer, at the clinic, within 24 hours of urine collection using the disposable pipette provided in the APTIMA® urine kit, the first-catch urine specimen from a urine collection cup to an APTIMA® urine transport tube bringing the final volume in the APTIMA® tube **to within the marked fill area**. Tightly re-cap the APTIMA® urine transport tube, and make sure the specimen is labeled with the following required information: first and last name of patient (or patient medical record number). Urine specimens properly transferred to a urine APTIMA® transport tube within 24 hours of urine collection can be stored at 2°C to 30°C for up to 30 days before being submitted to the laboratory.

Endocervical swab specimens: Using the APTIMA® Unisex Swab Collection Kit, remove excess mucus from the cervical os and surrounding mucosa with the cleaning swab (white shaft swab). **Discard this swab.** Insert the cervical specimen collection device (blue shaft swab) into the endocervical canal. Rotate the device clockwise three full turns to ensure adequate sampling. Withdraw the device carefully; avoid any contact with the vaginal mucosa. Remove the cap from the unisex specimen transport tube and immediately place the specimen collection device into the transport tube. Break the swab shaft at the scoreline, and recap the tube, leaving the lower half of the blue swab in the tube. Use care to avoid spilling of contents. Make sure the specimen is labeled with the following required information: first and last name of patient (or patient medical record number), and specimen source. After collection, cervical specimens can be stored at 2°C to 30°C for 60 days until tested.

Male urethral swab specimens: The patient should not have urinated for at least 1 hour prior to sample collection. Using the APTIMA® Unisex Swab Collection Kit, insert the specimen collection swab (blue shaft swab) 2 to 4 cm into the urethra. Gently rotate the swab clockwise for 2 to 3 seconds in the urethra to ensure adequate sampling. Withdraw the swab carefully. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft against the side of the tube at the

scoreline and discard the top portion of the swab shaft; use care to avoid splashing of contents. Re-cap the swab specimen transport tube tightly and make sure the specimen is labeled with the following required information: first and last name of patient (or patient medical record number), and specimen source. After collection, male urethral specimens can be stored at 2°C to 30°C for up to 60 days until tested.

Vaginal swab specimens: Peel open the APTIMA® Vaginal Swab Collection Kit. Remove the swab (pink shaft swab). 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. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. Immediately place the swab into the transport tube so that the score line is at the top of the tube. Carefully break the swab shaft at the score line against the side of the tube. Discard the top portion of the swab shaft. Tightly screw the cap onto the tube, and make sure the specimen is labeled with the following required information: first and last name of patient (or patient medical record number). After collection, vaginal specimens can be stored at 2°C to 30°C for up to 60 days until tested.

Rectal swab specimens: From the APTIMA® Unisex Swab Collection Kit, use only the blue shaft specimen collection swab for specimen collection. **Do not use the white cleaning swab for specimen collection.** For asymptomatic collection: moisten the swab with sterile saline and insert into the anus and rectum—leave for 20 seconds. For symptomatic collection: swab rectal mucosa using a sterile anoscope. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft. Use care to avoid spilling of contents. Re-cap the swab specimen transport tube tightly and make sure the specimen is labeled with the following required information: first and last name of patient (or patient medical record number), and specimen source. After collection, rectal specimens can be stored at 2°C to 30°C for up to 60 days until tested.

Pharyngeal (throat) swab specimens: From the APTIMA® Unisex Swab Collection Kit, use only the blue shaft specimen collection swab for specimen collection. **Do not use the white cleaning swab for specimen collection.** Swab the area between the tonsillar pillars and the region posterior to the pillars. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft. Use care to avoid spilling of contents. Re-cap the swab specimen transport tube tightly and make sure the specimen is labeled with the following required information: first and last name of patient (or patient medical record number), and specimen source. After collection, pharyngeal specimens can be stored at 2°C to 30°C for up to 60 days until tested.

Notes on specimen collection:

- The fluids that are contained within the APTIMA® transport tubes act as a preservative and a cell lysis buffer for specimens. Urine specimens with a final volume higher than the marked fill area could lead to reduced sensitivity upon testing, and will be rejected upon arrival to the laboratory.
- Unprocessed urine specimens submitted in urine collection cups will **always** be rejected upon receipt.
- APTIMA® swab transport tubes that do not have a swab in the tube upon receipt at the laboratory will not be processed. Swabs should remain in the tubes as indication of specimen collection (to prevent the likelihood producing false-negative results).
- APTIMA® swab transport tubes that contain the white cleaning swab provided in the kit upon receipt at the laboratory will not be processed. These swabs can damage the testing machine if left in the transport tube upon processing.
- The patient identification must match between the specimen tube label and the test request form. Mismatches in identification between specimens and forms will not be tested.
- Do not puncture the foil caps of the APTIMA® transport tubes. The machine that processes these specimens punctures the foil cap upon testing. Specimen collection tubes received with punctured foil-caps can leak in transit, and will not be processed.

2) Completion of Test Request Form for Chlamydia/Gonorrhea TMA

The following information must be included on the test request form, or the specimen will not be processed:

- The name and address of the ordering clinic

- The ordering clinician's name and **CHN number, legible** (effective 1/2016, the San Francisco Public Health will no longer test specimens that are accompanied with test request forms that do not include an ordering clinician's legible CHN number).
- The patient's first and last name (or unique identifier).
- The patient's gender.
- The patient's date of birth (or age).
- The test to be performed, i.e. "chlamydia TMA," "gonorrhea TMA" (this must be indicated on the request form).
- The source of the specimen.
- The date of specimen collection.

Request forms that fail to include any of these information cannot be tested (according to testing regulations), and calls cannot be made to the clinic to request this information.

Results

The turnaround time for specimen testing is 7 business days (Monday through Friday) from specimen receipt, however, results are usually made available within a shorter time period. If you would like to expedite a specimen for testing, please contact the laboratory directly (see contact information below), and we will do our best to expedite the testing of a certain specimen.

Specimens resulted as "unsatisfactory" are the result of sometimes unknown qualities of a specimen that caused the testing machine to reject the specimen in duplicate. The most frequent causes of assay rejection by the machine, which lead to "unsatisfactory" results are: too low of volume in the APTIMA® transport tube, caused by a spilling or pouring out of fluid volume during specimen collection; and crystallized substances in urine specimens that we were unable to dissolve upon warming of specimens. Please recollect a specimen in these instances.

Specimens resulted as "inconclusive" were tested in duplicate, and were found to be inconclusive in the presence of chlamydia or gonorrhea ribosomal RNA. Please resubmit a specimen for testing.

Updated 1/15/2016