

Chlamydia trachomatis / *Neisseria gonorrhoeae* – Transcription Mediated Amplification

Use

To screen symptomatic or asymptomatic males and females for the presence of *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG), also referred to as gonococcus (GC). Intended for clinical management of patients. Not intended for use in monitoring therapeutic efficacy or medical legal applications.

Clinical Significance

CT and GC are the most common bacterial causes of sexually transmitted diseases in the U.S. Screening reduces rates of transmission and overall prevalence and potentially reduces the incidence of severe and debilitating complications associated with symptomatic infections.

Further background information, fact sheets, statistics and educational resources may be found at the OSDH Infectious Disease Services [website](#).

Methodology

Hologic Aptima Combo 2® *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Assay; Transcription Mediated Amplification (TMA) using the Panther platform.

Specimen Type

- Urine in Aptima® Urine Specimen Transport Tube (USTT, yellow)
- Vaginal, throat or rectal swab in Aptima® Multitest Swab Specimen Transport Tube (MSSTT, orange)

Minimum Volume/Size

- Urine – fill USTT to level within fill indicator lines on tube
- One swab in MSSTT

Collection Instructions

Urine

1. Instruct patient to collect 20-30 mL of first-voided (not mid-stream) urine in a sterile collection cup free of any preservatives. Excessive urine collection may dilute specimen and reduce test sensitivity. Patient should not have urinated for at least 1 hour prior to collection. Female patients should not cleanse the labial area prior to urine collection.
2. Urine should be transferred from the collection cup to an Aptima® Urine Specimen Transport Tube (USTT; provided in the Aptima® Urine Specimen Collection Kit) within 24 hours of collection at 2-30°C.
3. Label a USTT with two patient identifiers (e.g., patient's name and DOB) and date collected. Align barcode labels along the length of the tube with 1/4" or more clear space above the bottom of the tube and below the cap to aid with scanning. Do not cover-up expiration date or fill-line indicators on tube.
4. Twist the cap on the USTT to break the seal.
5. Using the disposable transfer pipette provided in the kit, transfer urine from cup to USTT until the level is between the two black indicator lines on the fill window (approx. 2 mL). Do not over-fill or under-fill.
6. Immediately replace cap and tightly secure.
7. Place tube in sealed specimen bag separate from other patient specimens.
8. Store specimen refrigerated or at room temperature (2-30°C).

For further information on collection of urine using the Aptima® Urine Specimen Collection Kit, see <https://hologicwomenshealth.com/wp-content/uploads/2020/09/Aptima-Urine-Collection-Guide.pdf>

Multitest Swabs

1. Label the MSSTT with two patient identifiers (e.g., patient's name and DOB) and date collected. Align any barcodes along the length of the tube to aid with scanning.
2. Open the swab packaging, being careful not to contaminate the swab.
3. Hold the swab near the middle of the shaft so that your thumb and forefinger touch the score line. Do not hold it between the line and swab tip.
4. Collect the sample by holding the swab at the score line to avoid breaking the shaft during collection:
Vaginal: Insert the swab approximately 2 inches (5 cm) past the introitus and gently rotate the swab, ensuring contact with vaginal walls, for 10 to 30 seconds. Withdraw the swab, avoiding contact with the skin. See clinician collection video at <https://www.youtube.com/watch?v=DMGmniL-7uI>
Throat: Insert the swab into the throat ensuring to make contact with the bilateral tonsils (if present) and the posterior pharyngeal wall. Withdraw the swab, making sure to avoid contact with the tongue or inner cheeks. See clinician collection video at <https://www.youtube.com/watch?v=DPuPIpN5drU>
Rectal: Insert the swab approximately 1-2 inches (3-5 cm) past the anal margin and gently rotate the swab for 5-10 seconds. Withdraw the swab avoiding contact with the skin. See clinician collection video at <https://www.youtube.com/watch?v=vOnQqQO2LE>
5. Unscrew the cap on the MSSTT.
6. Place the swab in the collection tube so that the score line is at the top of the tube. Gently flex the shaft against the tube to break at the score line, then dispose the top of the shaft. Do not break above the score line or cut or fold the shaft.
7. Tightly secure the cap.
8. Place tube in sealed specimen bag separate from other patient specimens.
9. Store specimen refrigerated or at room temperature (2-30°C).

Common Causes for Rejection

- Patient less than 14 years old
- Inappropriate collection device
- Tube with no or multiple swabs
- Over- or under-filled urine specimen tube
- Specimens from multiple patients placed in the one specimen bag
- Raw urine
- Specimens collected using expired collection kits
- MSSTT received > 60 days from date of collection (DOC)
- USTT received > 30 days from DOC

Shipping and Storage

Important: When shipping multiple patient samples, place each patient's sample in an individual specimen bag. CT/GC-positive specimens can contain extremely high levels of organisms and any contamination of the outside of the primary container may contaminate other specimens.

- **Urine:** Store and ship samples at refrigerated or ambient temperatures (2-30°C). Deliver to the laboratory within 30 days from DOC.
- **Swab** in MSSTT: Store and ship samples at refrigerated or ambient temperatures (2-30°C). Deliver to the laboratory within 30 days from DOC.

Turn-around Time

Within 7 working days from receipt

Reference Range

- Presumed negative for CT rRNA
- Presumed negative for GC rRNA

Reportable Results

- Presumed negative for CT rRNA
- Presumed negative for GC rRNA
- Positive for CT rRNA
- Positive for GC rRNA
- Indeterminate, a new specimen should be collected
- Invalid

Interpretation

- A positive result indicates successful amplification/detection of rRNA sequence(s) for CT and/or GC.
- A negative result indicates an inability to amplify/detect rRNA for CT and GC and the sample is presumed negative.
- An equivocal result indicates that a determination of either analyte could not be made, and collection of a new sample is recommended.
- An invalid result indicates that the instrument encountered processing issues with the specimen; the most likely reason is the presence of debris in the sample preventing successful processing by the analyzer. Collection of a new sample is recommended.

Limitations/Interferences

- A negative result does not preclude the presence of CT and/or GC infection.
- A positive result does not infer viability and/or infectivity for CT and/or GC since target rRNA for these organisms may persist in the patient in the absence of viable organisms (e.g., following antimicrobial therapy).
- Test results may be affected by improper specimen collection or transport, presence of low levels of organisms, presence of plasmid-free variants of *C. trachomatis*, presence of inhibitors, technical errors, and treatment status of the patient.
- The test is not appropriate for testing cases associated with sexual assault, abuse or other medico-legal implications.
- Culture is the recommended procedure for diagnosing CT/GC infections in medico-legal cases, testing of conjunctival, rectal and nasopharyngeal specimens, and evaluating gonorrhea treatment failure.
- This test cannot be used to assess therapeutic success or failure.
- The results of this test should not be used as the sole basis for diagnosis or patient management decisions.

CPT Code

87491, 87591

Notes

This test has been cleared for *in vitro* diagnostic use by the U.S. Food and Drug Administration.