

**CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE BY  
NUCLEIC ACID AMPLIFICATION (GEN-PROBE)  
#800307**

**EXPLANATION:** Mayo Medical Laboratories is pleased to announce that our Jacksonville Laboratory will be adding *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by Nucleic Acid Amplification (GEN-PROBE), to their test menu.

**NOTE:** This test will be replacing Jacksonville test #800158 *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by Nucleic Acid Amplification (BD Probe Tec ET Amplified DNA) which will become obsolete effective April 21, 2011.

**PROFILE INFORMATION:**

Unit Code	Reporting Name	Available Separately	Always Performed
800308	C. Trachomatis Amplified RNA	Yes	Yes
800309	N. Gonorrhoeae Amplified RNA	Yes	Yes

**USEFUL FOR:** Diagnosing *Chlamydia trachomatis* or *Neisseria gonorrhoeae* infections.

**METHODOLOGY:** Transcription Mediated Amplification

**REFERENCE VALUES:**

*Chlamydia trachomatis*  
Negative

*Neisseria gonorrhoeae*  
Negative

**SPECIMEN REQUIREMENTS:**

**Submit only 1 of the following specimens:**

**Swab specimens must be collected** using an APTIMA Collection Unisex Swab or APTIMA Collection Vaginal Swab. These swabs are contained in the APTIMA Collection Kit.

**Endocervix (Females Only)**

**Container/Tube:** APTIMA Swab Collection System (Supply T583)

**Specimen Volume:** Swab

**Collection Instructions:**

1. Use cleaning swab (white shaft) to remove excess mucus from endocervix and discard.
2. Insert second swab (blue shaft) 1 cm to 1.5 cm into endocervical canal, and rotate swab gently for 30 seconds. Avoid touching vaginal wall when removing swab.
3. Place second swab into transport tube provided in collection kit. Snap off swab at score line so swab fits into closed tube.
4. Cap tube securely, and label tube with patient's entire name, and date and time of collection.

**Note: Specimen source is required.**

**Urethra (Males Only)****Container/Tube:** APTIMA Swab Collection System (Supply T583)**Specimen Volume:** Swab**Collection Instructions:**

1. Patient should not have urinated for at least 1 hour prior to collection.
2. With a rotating movement, insert swab (blue shaft) 2 cm to 4 cm into urethra.
3. Once inserted, rotate swab gently at least 1 full rotation using sufficient pressure to ensure swab comes into contact with all urethral surfaces. Allow swab to remain inserted for 2 to 3 seconds.
4. Place swab in transport tube provided in collection kit. Snap off swab at score line so swab fits into closed tube.
5. Cap tube securely, and label tube with patient's entire name, and date and time of collection.

**Note: Specimen source is required.****Urine (Males and Females)****Container/Tube:** APTIMA Urine Specimen Transport Tube (Supply T582)-**Midstream specimen is not acceptable.****Specimen Volume:** 15 mL to 20 mL from a random urine collection**Collection Instructions:**

1. Patient should not have urinated for at least 1 hour prior to specimen collection.
2. Patient should collect first portion of a voided urine (first part of stream) into a sterile, plastic, preservative-free container.
3. Transfer 2 mL of urine into the urine specimen transport tube using the disposable pipette provided within 24 hours of collection. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine transport tube.

**Note: Specimen source is required.****CAUTIONS:**

- This report is intended for use in clinical monitoring or management of patients; it is not intended for use in medico-legal applications.
- Appropriate specimen collection and handling is necessary for optimal assay performance.
- Results should be interpreted in conjunction with other laboratory and clinical information.
- A negative test result does not exclude the possibility of infection. Improper specimen collection, concurrent antibiotic therapy, presence of inhibitors, or low numbers of organisms in the specimen (ie, below the sensitivity of the test) may cause false-negative test results.
- In low prevalence populations, positive results must be interpreted carefully as false-positive results may occur more frequently than true positive results in this setting.
- This assay cannot be used to assess therapeutic success or failure, since nucleic acids from these organisms may persist following antimicrobial therapy.
- The presence of mucous does not interfere with this assay. However, this test requires endocervical cells, and if excess mucous is not removed prior to collection, adequate numbers of these cells may not be obtained.
- No interference is expected due to:
  - Blood (urine and swab) specimens
  - Lubricants and spermicides (swab)

- The effects of use of tampons, douching, specimen types other than those listed in Specimen Required, and specimen collection variable have not been determined.
- Testing of urine specimens with this method is not intended to replace cervical exam and endocervical sampling for diagnosis of urogenital infection; infections may result from other causes or concurrent infections may occur.
- Testing urine specimens as the sole test for identifying female patients with chlamydial or gonococcal infections may miss some infected individuals.
- Performance estimates for urine specimens are based on evaluation of urine obtained from the first part of the urine stream; performance on midstream collections has not been determined.
- This assay **does** detect plasmid-free variants of *Chlamydia trachomatis*.
- This assay does not detect *Chlamydia pneumoniae*.

**MML LIST FEE:** \$ 207.60

**CPT CODE:**

87491-*Chlamydia trachomatis*

87591-*Neisseria gonorrhoeae*

**ANALYTIC TIME:** 1 day

**DAY(S) SET-UP:** Monday through Saturday

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager  
Greg Renkly, Mayo Medical Laboratories' Technologist Support  
Telephone: 800-533-1710