CT/NG  Chlamydia/Gonorrhea by TMA - Qualitative

GA Test Code  3333/0180

Note: GA recommends ordering these assays together because patients infected with *C. trachomatis* may be co-infected with *N. gonorrhoeae*.

Method  
**FDA-approved** Aptima Combo 2® Assay for CT/NG, performed on the Panther® system from Hologic®

Specimens  
**ThinPrep:** 2.0 mL (1.0 mL), store and ship ambient (up to 3 months).
**SurePath:** 1.0 mL (0.5 mL), store and ship ambient (14 days).
**G Swab®:** G Swab kits are provided by GA. Collect vaginal specimen with swab and place in tube with liquid media. Break-off swab (pre-scored) and seal tube for transport. Sample is stable for 30 days at room temperature (15-30°C).
**G Swab® - Urine:** G Swab kits include a urine collection pipette. Use pipette to add 1.0 mL only of first catch urine to red fill line on media tube. Sample is stable for 30 days at room temperature (15-30°C).
**Swab:** from any site, place in 1-2 mL viral transport medium, store/ship ambient or refrigerated (14 days). If longer storage is needed, store frozen (90 days).
**Urine:** 4.0 mL (2.0 mL). Collect first-catch (not mid-stream) urine in sterile, leakproof container. The patient should not have urinated for 2 hours prior to collection. Immediately refrigerate urine and ship within 24 hours on cold pack.

Note: The presence of blood, mucus, some spermicidal agents, feminine powder sprays, and treatments for vaginal conditions such as yeast infection may interfere with nucleic acid test based assays.

Causes for Rejection  
Quantity not sufficient (QNS); time and/or temperature instructions not followed; G Swab urine filled above 3 mL (red line).

Reference Range  
Not Detected

Turnaround Time  
24-48 hours

CPT Codes  
87491, 87591

Clinical Utility  
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 *Neisseria gonorrhoeae* (NG) to aid in the diagnosis of chlamydial and/or gonococcal urogenital disease. Cell culture was once considered to be the “gold standard” for detection of CT and NG. Culture is quite specific, but scientific studies have demonstrated that the NAAT DNA probe technologies have a higher clinical sensitivity than culture. Due to its lower clinical sensitivity and variable performance between laboratories, culture has been replaced in many laboratories by direct DNA probe and NAATs. Since a specific diagnosis of either urogenital disease may improve treatment compliance and enhance partner notification, the use of these highly sensitive and specific tests is strongly recommended.


---

*Genetic Assays, Inc.*  
4711 Trousdale Drive, Ste 209  •  Nashville, TN 37220  •  (615) 781-0709  •  (800) 390-5280  •  FAX (615) 781-0766  
[www.geneticassays.com](http://www.geneticassays.com)  
Directory of Services – updated October 2017