GENETIC ASSAYS
A Molecular Diagnostics Laboratory

CT/NG Chlamydia/Gonorrhea by rPCR - 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	Real-time PCR
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). **eSwab**® 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). **eSwab®- 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	24-72 hours
CPT Codes	87491, 87591

Clinical Utility

This test was developed and its performance characteristics determined by Genetic Assays. It has not been cleared nor approved by the U.S. FDA. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. Genetic Assays is certified under CLIA as qualified to perform high-complexity testing.The CT/NG assay is an in vitro polymerase chain reaction (PCR) assay for the direct, qualitative detection of the plasmid DNA of *Chlamydia trachomatis* and the genomic DNA of *Neisseria gonorrhoeae*. PCR does not differentiate between dead and live organisms; therefore, a patient being treated with drug therapies can remain positive for weeks after the initiation of such treatments. Thus, this assay should not be used as a "test of cure". Positive results for asymptomatic patients should be confirmed with repeat PCR analysis and/or culture. A negative result only indicates that a detectable level of CT and/or NG DNA was not present in the sample submitted.

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.

Sexually transmitted diseases treatment guidelines, 2010. *MMWR*, December 17, 2010/Vol. 59/No. RR-12, 44-55.