GENETIC ASSAYS
A Molecular Diagnostics Laboratory

CT/NG Chlamydia/Gonorrhea by PCR - 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*** Abbott RealTi*m*e in vitro polymerase chain reaction (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). **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 90 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 90 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**: 10.0 mL (5.0 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 Code	87491, 87591

Description

The Abbott RealTi*m*e 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*. The assay uses PCR technology with homogeneous real-time fluorescence detection.

Clinical Utility

The CT/NG assay is used for the dual detection of the sexually transmitted disease pathogens, *C. thrachomatis* and *N. gonorrhoeae.* Cell culture used to detect *C. trachomatis* has been replaced by more sensitive nucleic acid tests. Since a specific diagnosis of chlamydia may improve treatment compliance and enhance partner notification, the use of these highly sensitive and specific tests is strongly recommended. Culture is commonly used for the detection of *N. gonorrhoeae*. Presumptive diagnosis of gonorrhea is based on the morphological examination, Gram stain, and oxidase measurement of the culture isolate. Nucleic acid tests are widely available for definitive identification of *N. gonorrhoeae.*

Performance characteristics of the Abbott RealTi*m*e CT/NG assay were established in a multi-center clinical study. The overall sensitivity and specificity for CT was 95.2% and 99.3%, respectively. The overall sensitivity and specificity for NG was 97.5% and 99.7%, respectively.

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

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