



CT/NG Chlamydia/Gonorrhea by PCR - Qualitative

GA Test Code	3333/0180 <i>Note:</i> GA recommends ordering these assays together because patients infected with <i>C. trachomatis</i> may be co-infected with <i>N. gonorrhoeae</i> .
Method	Abbott RealTime in vitro polymerase chain reaction (PCR) assay - Qualitative
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 (28 days). Genital Swab or Urine (Abbott multi-Collect Specimen Collection Kits): Kits are provided by GA. Collect swab or urine specimen in accordance with package instructions. Transport and store transport tube ambient or refrigerated for up to 14 days. If longer storage is needed, store frozen (90 days). 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. <i>Note:</i> 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/temperature instructions not followed.
Reference Range	Not Detected
Turnaround Time	24-48 hours
CPT Code	87491, 87591

Description

The Abbott RealTime 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. trachomatis* 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 Cell culture used to detect *C. trachomatis* has been replaced by more sensitive nucleic acid tests.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 RealTime 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.

MMWR. Sexually transmitted diseases treatment guidelines 2002. *Morb Mortal Wkly Rep* [serial online] 2002;51 (RR-06). Available at <http://www.cdc.gov/STD/treatment/4-2002TG.htm>.

Johnson RE, Newhall WJ, Papp JR, et al. Screening tests to detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections-2002. *MMWR Recomm Rep* 2002;51 (RR-15):1-27.

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