

## ***Chlamydia trachomatis and Neisseria gonorrhoeae DNA Testing***

***Test Update  
March 5, 2008***

### **Overview**

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*Chlamydia trachomatis* and *Neisseria gonorrhoeae* are the most common causes of sexually transmitted disease. An estimated 3 million *Chlamydia trachomatis* infections occur annually among sexually active adolescents and young adults in the United States (1). The majority of persons with *C. trachomatis* and *N. gonorrhoeae* infection are not aware of their infection because they are asymptomatic (1, 2).

Untreated disease can lead to serious complications including pelvic inflammatory disease and infertility in women. *C. trachomatis* and *N. gonorrhoeae* infection during pregnancy can lead to infant conjunctivitis and pneumonia as well as maternal postpartum endometritis. Among men, urethritis and epididymitis are the most common illnesses resulting from *C. trachomatis* infection. Consequently, screening is necessary to identify and treat these infections. The US Preventive Services Task Force strongly recommends routine *C. trachomatis* and *N. gonorrhoeae* screening for all sexually active women 25 years of age or younger, as well as for pregnant women and others at increased risk (2).

Culture testing for *C. trachomatis* and *N. gonorrhoeae* has been the reference standard against which all other tests have been compared.

However, other tests are needed because culturing for *C. trachomatis* is difficult to standardize, technically demanding, and expensive. In addition, culturing of either agent is associated with problems in maintaining the viability of organisms during transport and storage (2, 3).

PathGroup Lab is offering a reliable, sensitive and specific method for detection of *C. trachomatis* and *N. gonorrhoeae*; Gen-Probe TIGRIS (APTIMA 2®). The TIGRIS (APTIMA 2®) assay uses transcription mediated technology (TMA) and tests for the target that is most abundant, ribosomal RNA. In a single cell, ribosomal RNA copies are present thousands of times more than DNA offering improved sensitivity.

A second methodology, the Cobas Amplicor CT/NG testing is based on polymerase chain reaction (PCR) technology and which uses sequence specific primers and probes to amplify and detect both *C. trachomatis* and *N. gonorrhoeae*. An internal control is included to detect test inhibition and reduce false negative results.

Both technologies are FDA approved and utilize Nucleic Acid Amplification Technology (NAAT). NAAT is recognized by the CDC as the most sensitive method for detection of these infectious agents (5, 6).

### ***Clinical Utility***

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- Diagnostic screening for *Chlamydia trachomatis* infection.
- Diagnostic screening for *Neisseria gonorrhoeae* infection.
- Confirmational testing for diagnosis of *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae* infections.

**Methodology:** TIGRIS/APTIMA 2<sup>®</sup> (TMA technology)

Polymerase Chain Reaction (PCR) will be done on low volume ThinPreps

**Test Codes:** CTNG – *C. trachomatis* and *N. gonorrhoeae* by TMA

CTAPT- *C. trachomatis* by TMA

NGAPT – *N. gonorrhoeae* by TMA

**CPT Codes:** 87491 for *C. trachomatis* and 87591 for *N. gonorrhoeae*.

**Specimen Collection:** GenProbe APTIMA swab, ThinPrep<sup>™</sup> Solution, Swabs in M4 transport medium, GenProbe APTIMA Urine transport tube or Urine in sterile cup.

**Shipping and Handling:** Transported at 2-30°C. (Urine in cup should be sent refrigerated)

**Reference Ranges:** Not Detected

**Turnaround Time:** M-F Next Day

## References

1. Center for Disease Control and Prevention. Sexual transmitted disease treatment guideline. *MMWR Recomm Rep.* 2006. 55(RR11):1-95
2. Johnson RE, Newhall WJ, Papp JR, Knapp JS, Black CM, Gift TL, Steece R, Markowitz LE, Devine OJ, Walsh CM, Wang S, Gunter DC, Irwin KL, DeLisle S, Berman SM. Screening tests to detect Chlamydia trachomatis and Neisseria gonorrhoeae infection. *MMWR Recomm Rep.* 2002 Oct 18;51(RR-15):1-38; quiz CE1-4.
3. Martin DH, Nsuami M, Schachter J, Hook EW 3rd, Ferrero D, Quinn TC, Gaydos C. Use of multiple nucleic acid amplification tests to define the infected-patient "gold standard" in clinical trials of new diagnostic tests for Chlamydia trachomatis infections. *J Clin Microbiol.* 2004 Oct;42(10):4749-58.
4. Gen-Probe APTMA COMBO2<sup>®</sup> Assay. San Diego, CA: Gen-Probe Inc: 2005 Package Insert.
5. Leslie DE, Azzato F, Ryan N, Fyfe J. An assessment of the Roche Amplicor Chlamydia trachomatis/Neisseria gonorrhoeae multiplex PCR assay in routine diagnostic use on a variety of specimen types. *Commun Dis Intell.* 2003;27(3):373-9.
6. Koumans EH, Black CM, Markowitz LE, Unger E, Pierce A, Sawyer MK, Papp JR. Comparison of methods for detection of Chlamydia trachomatis and Neisseria gonorrhoeae using commercially available nucleic acid amplification tests and a liquid pap smear medium. *J Clin Microbiol.* 2003 Apr;41(4):1507-11.