LABORATORY ALLIANCE
of Central New York, LLC
1304 Buckley Road • Syracuse, NY 13212-4302
www.laboratoryalliance.com

Laboratory Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Genital Infections Using Nucleic Acid Amplification Technology

The Microbiology department of Laboratory Alliance of Central New York offers a highly sensitive, molecular-based, nucleic acid amplification assay for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in urine, urethral, and/or endocervical samples. This assay replaced the former probe test for these organisms.

Clinical Significance:
Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (GC) are the two most common bacterial causes of sexually transmitted diseases worldwide. In the United States CT and GC account for about 4 million and 2 million annual cases of genital infection respectively. Importantly, 20% of males and 40% of females are co-infected with both organisms. Individuals with CT or GC infection may present with asymptomatic disease. Undiagnosed and untreated symptomatic and asymptomatic infections can lead to disseminated infection in males and pelvic inflammatory disease in females resulting in infertility, ectopic pregnancy, and chronic pelvic pain.

The CT and GC Direct Amplified Test is a gene amplification based technology that represents one of the most sensitive methods for the detection of CT and GC in urogenital samples. This test has the important added advantage that patient urine samples may be used to reliably screen for the presence of CT and GC. As shown in the following table, clinical studies have shown that the Chlamydia/GC Assay is the most sensitive method available for detecting CT and GC infections and that urine specimens may be used to reliably screen both male and female patients for symptomatic or asymptomatic urogenital infections.

Table 1. Chlamydia/GC Assay Performance With Swab Specimens

	Males (urethral swab)		Females (endocervical swab)	
Organism	Sensitivity	Specificity	Sensitivity	Specificity
CT	95.9%	97.5%	94.2%	97.6%
GC	99.1%	97.8%	99.2%	98.7%

Table 2. Chlamydia/GC Assay Performance With Urine Specimens

	Males (first void urine)		Females (first void urine)	
Organism	Sensitivity	Specificity	Sensitivity	Specificity
CT	97.9%	98.5%	94.7%	98.9%
GC	98.5%	99.6%	91.3%	99.3%

Table 3. Overall Chlamydia/GC Assay Performance

Organism	Sensitivity	Specificity
CT	95.9%	98.2%
GC	97.8%	98.9%

Test Code: **GCAT, CHAT, GCCAT** (Battery for both tests)

CPT 4 Code: 87491 (Chlamydia) 87591 (GC)

Specimen Requirements:

Urine: First catch urine (approximately 20 to 30 ml of initial urine stream) into urine collection cup free of any preservatives. Urine samples must be transported to the laboratory at 4˚C to 30˚C within 24 hours of specimen collection.

Male Urethral Swabs: Collect urethra sample using the Blue Shaft swab in the Aptima 2 Combo Assay Kit by inserting swab 2 to 4 cm into urethra and rotating swab. Place swab in Aptima 2 specimen transport tube. Additional details provided on attached *"Swab Specimen Collection Guide."*

Endocervical Swabs: Remove excess mucus from cervical os using white shaft swab in the Aptima 2 Combo Specimen Collection Kit and discard swab. Use blue shaft swab to collect endocervical sample using standard technique. Place swab in Aptima 2 specimen transport tube. Additional details provided on attached "*Swab Specimen Collection Guide."*

Storage and Transport:

Urine: Store urines at 2˚C to 30˚C and transport to laboratory within 24 hours of collection.

Urethral or Endocervical Swabs: Store specimen transport containers at 2˚C to 30˚C until tested. Specimens are stable for up to 60 days of collection.

Schedule of Testing: Monday through Friday.

For More Information:
If you have any questions or concerns regarding this test service, please contact Mr. Russell Rawling, Microbiology Manager at 410-7060.

References:

Black CM. Current methods of laboratory diagnosis of *Chlamydia trachomatis* infections. Clin Microbiol Rev 1997; 10: 160-84.

Kirchner JT, Emmert DH. Sexually transmitted diseases in women. *Chlamydia trachomatis* and herpes simplex infections. Postgrad Med 2000; 107:55-65.

Scholes D, Stergachis A, Heidrich FE, Andrilla H, Holmes KK, Stamm WE. Prevention of pelvic inflammatory disease by screening for cervical Chlamydia infection. N Engl J Med 1996; 334: 1362-6.

Emmert DH, Kirchner JT. Sexually transmitted diseases in women. Gonorrhea and syphilis. Postgrad Med 2000, 107:181-97.

Quinn TC. Association of sexually transmitted diseases and infection with the human immunodeficiency virus: biological cofactors and markers of behavioral interventions. Int J STD AIDS 1996; 7(Suppl 2): 17-24.

Mehta SD, Rothman RE, Kelen GD, Quinn TC, Zenilman JM. Clinical aspects of diagnosis of gonorrhea and Chlamydia infection in an acute care setting. Clin Infect Disclosures 2001; 32:655-9.

Joffe A. Amplified DNA testing for sexually transmitted diseases. New opportunities and new questions. Arch Pediatr Adolesc Med 1999; 153: 111-3.

Boyadzhyan B, Yashina T, Yatabe JAH, Patnaik M. Evaluation of the Aptima Combo 2 Assay for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. [Abstract] Clin Chem 2001; 47:2082.

Martin D, Hook E 3rd, Ferrero D, et al. Comparison of three nucleic acid amplification tests (NAATs) and N gonorrhoeae (GC) culture for the detection of C. trachomatis (CT) and GC using a rotating standard. In: Kohl P, Jodi S, editors. ISSTDR '01. International Congress of Sexually Transmitted Diseases; 2001 June 24-27; Berlin, Germany, p. 75-9.