LABORATORY ALLIANCE of Central New York, LLC

Women's STD Health Panel for *Chlamydia trachomatis, Neisseria gonorrhoeae* and *Trichomonas vaginalis* using Gene Amplification Technology

The Microbiology department of Laboratory Alliance of Central New York has offered a combination nucleic acid amplification test (NAAT) for detecting *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in urine and urogenital specimens for over a decade. This NAAT is called the Aptima Chlamydia/GC combination test. Recently, the assay has been approved for use in detecting *Trichomonas vaginalis* in vaginal specimens using the same APTIMA swab specimen collector or urine container.

Healthcare providers now have the opportunity to order the APTIMA *Trichomonas vaginalis* test as part of the APTIMA Chlamydia/GC test combo by using the same APTIMA Swab or Urine Specimen Collection Device. This single specimen can then be used for detecting *C. trachomatis, N. gonorrhoeae*, and *T. vaginalis* in vaginal or urine specimens by using one of the most highly sensitive and specific gene amplification assays available. Depending on the clinical need, one may continue to order just the Aptima Chlamydia/GC combo separately or the *Trichomonas vaginalis* test alone using the Aptima swab or urine specimen collector.

Clinical Significance

Chlamydia trachomatis, Neisseria gonorrhoeae, and *Trichomonas vaginalis* are common causes of sexually transmitted disease (STD) in the United States and throughout the world. In women, *C. trachomatis* and *N. gonorrhoeae* are the leading bacterial causes of cervicitis in which infected patients may be at risk for systemic complications of pelvic inflammatory disease, septicemia, septic arthritis, and salpingitis. Most women infected with *C. trachomatis* and/or *N. gonorrhoeae* are asymptomatic for disease.

Trichomonas vaginalis, a protozoan, can cause vaginitis, cervicitis, or urethritis. Complications of *Trichomonas* genital infection can include premature labor, low-birth-weight offspring, premature rupture of membranes, and post-abortion or post-hysterectomy infection. An association with pelvic inflammatory disease, tubal infertility, and cervical cancer with previous episodes of trichomoniasis has been reported. Symptomatic women with trichomoniasis usually complain of vaginal discharge, vulvovaginal soreness, and/or irritation. Dysuria is also common. However, it has been estimated that 10% to 50% of *T. vaginalis* infections in women are asymptomatic, and in men, the proportion may even be higher. Given the systemic complications that can result from localized chlamydial, gonococcal or trichomonal genital infection, highly sensitive and reliable tests are needed for diagnosis. Although cultural methods may be used to diagnose these infections, they can be highly insensitive, cumbersome, and time-consuming.

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The APTIMA Chlamydia/GC/Trich STD panel combines technologies of target capture, transcription-medicated amplification, and hybridization protection assay. This technology represents one of the most sensitive and specific methods for detecting *C. trachomatis*, *N. gonorrhoeae,* and *T. vaginalis* in urogential specimens. The *T. vaginalis* assay and the Aptima Chlamydia/GC may also be ordered as individual tests. Providers may continue to order the Vaginitis Direct Test (order code: VAGDT) which screens for *Gardnerella vaginalis*, the major cause of bacterial vaginosis, and *Candida* species, the fungal agent responsible for vaginal moniliasis, by using the AFFIRM specimen collector provided by the laboratory.

Test Name:	T Vaginal Amplified
Test Code:	TVAT (Note: Order "GCTAT" for Chlamydia, GC and Trichomonas, Amplified)
Method:	Amplified DNA Probe
Specimen Requirements:	Endocervical or vaginal scrapings collected with Gen-Probe Aptima swab collector, or first void urine in a sterile container. Specimen collection guides are available from Customer Service at 315-461-3008 or in the Directory of Service at www.laboratoryalliance.com under the test information.
Storage and Transport:	Transport and store vaginal or endocervical specimens in Aptima collectors at 2°C to 30°C until tested. Specimens are stable for up to 60 days from time of collection.. Transport and store urine specimens submitted in a sterile container at 2°C to 30°C for 24 hours.
Unacceptable Conditions:	1. Collection devices other than Gen-Probe Aptima or other than specified from the collection kit. 2. Gen-Probe Aptima swabs that still have the white shaft (should be discarded prior to specimen submission)
Schedule of Testing:	Monday through Friday.
CPT 4 Code:	87798 for *Trichomonas vaginalis* by Amplified DNA probe 87491 for *Chlamydia trachomatis* by Amplified DNA probe 87591 for *Neisseria gonorrhoeae* by Amplified DNA probe
Billing Code:	3010385

If you have any questions or concerns regarding this test service, please contact Mr. Russell Rawling, Microbiology Manager, at 315-410-7060.

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References:

Andrea SB, Chapin KC. Comparison of Aptima *Trichomonas vaginalis* transcription mediated amplification assay and BD Affirm VPIII for detection of *T. vaginalis* in symptomatic women. Clin. Microbiol 2011;49:866-9.

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, Kichner 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 amplication tests (NAATs) and N gonorrhoeae (GC) culture for the detection of C. trachomatis (CT) and CG using a rotating standard. In: Kohl P, Jodi S, editors. ISSTDR '01. International Congress of Sexually Transmitted Diseases; 2001 June 24-27; Berlin, German, p. 75-9

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