Billings Clinic

Laboratory Communiqué

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In This Issue

Women's Health Molecular Assays

HPV Assay

Test Number:
HPV: 9324

CPT:
HPV: 87621

HPV 16, 18/45 Genotype

Test Number:
N/A - This is a Reflex Test from a Positive HPV

CPT:
HPV 16, 18/45: 87621

Women's Health Testing

This issue will be dedicated to a review of the in-house molecular testing options available in our Laboratory for women's health. We have had HPV with optional HPV 16 and 18/45 Genotyping, Chlamydia RNA and Neisseria RNA assays available on the GenProbe Panther instrument for several years. In addition to those tests, we have now added two additional molecular tests. One is a Vaginitis Panel on the BD Affirm instrument and the other is the Trichomonas RNA assay on the GenProbe Panther. We will review test information and specimen requirements for our current assays and elaborate in more detail on the new assays.

APTIMA® HPV and APTIMA® HPV 16, 18/45 Genotype

These 2 tests were implemented in February 2014 on the GenProbe PANTHER which is a random access, fully automated molecular instrument that allows continuous loading of samples and reagents.

Fourteen HPV genotypes are considered pathogenic or high risk for cervical disease. Multiple studies have linked genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 to disease progression. Women with persistent infection with one of these types have an increased risk for developing severe dysplasia or cervical carcinoma. The APTIMA® HPV qualitative assay will detect the presence of the RNA from these 14 genotypes

Worldwide, HPV types 16, 18, and 45 are associated with approximately 80% of all invasive cervical cancers. These three types are found in 75% of all squamous carcinomas, with type 16 alone found in over 60% of all squamous carcinomas. In adenocarcinomas, HPV types 16, 18, and 45 are found in 80-94% of cases, with types 18 and 45 comprising almost half of these infections.

The APTIMA® HPV 16 and 18/45 Genotype Assay can differentiate HPV 16 from HPV 18 and/or HPV 45, but does not differentiate between HPV 18 and HPV 45.

Specimen: ThinPrep® Pap Test PreservCyt® Solution specimens
Testing Performed: Monday through Friday.

CT and GC RNA

Test Numbers:
CT/GC Urine RNA: 4798
CT/GC PAP RNA: 9638
CT/GC RNA: 7072
CT RNA: 7071
CT Urine RNA: 4799
CT PAP RNA: 9642
GC RNA: 7069
GC Urine RNA: 4796
GC PAP RNA: 9644

CPT:
CT 87492
GC 87592

LOINC Codes:
GC (urethra): 53927-0
GC (endocervical):50388-8
GC (urine): 60256-5
GC (PAP): 53088-8
CT (urethra): 53925-4
CT (endocervical): 50387-0
CT (urine): 42931-6
CT (PAP): 50387-0

New Assays

Trichomonas PCR

Test Numbers:
T.*vaginalis* RNA PAP: 9007
T. *vaginalis* RNA: 9008

CPT:
Trichomonas RNA: 87761

LOINC:
Trichomonas RNA: 6154-1

NOTE: Add-on testing to specimens previously tested on the GenProbe PANTHER are restricted to the following:

PAP Vials up to 30 days
APTIMA Swabs 5 days

APTIMA® Chlamydia RNA and Neisseria RNA

These 2 tests were implemented in June 2013 on the GenProbe PANTHER. The APTIMA® Combo 2 Assay utilizes target capture for the qualitative detection and differentiation of ribosomal RNA from *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC).

Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (GC) infections are two of the most common sexually transmitted infections worldwide. *C. trachomatis* can cause nongonococcal urethritis, epididymitis, proctitis, cervicitis, acute salpingitis, and Pelvic Inflammatory Disease (PID). *C. trachomatis* infections are often asymptomatic in both males and females. Children born to infected mothers are at significantly higher risk for inclusion conjunctivitis and chlamydial pneumonia.

N. gonorrhoeae is the causative agent of gonorrheal disease. The majority of gonorrheal infections are uncomplicated lower genital tract infections and may be asymptomatic. However, if left untreated in women, infections can ascend and cause PID. PID can manifest as endometritis, salpingitis, pelvic peritonitis and tubo-ovarian abscesses. A smaller percentage of persons with gonococcal infections may develop Disseminated Gonococcal Infection (DGI).

Specimen:
1. Female Endocervical and male urethral swabs. Specimens collected using the APTIMA Collection Unisex Swab.
2. Gynecological specimens collected in the PreservCyt Solution
3. Male and female urines (”dirty catch”) collected in sterile cup or APTIMA Urine Specimen Transport Tube

Testing Performed: Monday through Friday

New Molecular Tests

The two new molecular tests are Trichomonas RNA and a Vaginitis Panel which will be discussed in detail below.

APTIMA® Trichomonas RNA Amplification

The Aptima Trichomonas vaginalis Assay involves the technologies of target capture, transcription mediated amplification (TMA), and hybridization protection assay (HPA). Specimens are collected and transferred into their respective specimen transport tubes. The transport solution in these tubes releases the rRNA target and protects it from degradation during storage. When the Aptima

Vaginitis Panel

Test: 9743

CPT Codes:
87480 Candida species
87660 T. *vaginalis*
87510 G. *vaginalis*

LOINC Codes
4700-5 Candida species
6568-0 T. *vaginalis*
6410-5 G. *vaginalis*

Trichomonas vaginalis assay is performed in the laboratory, the target rRNA is isolated from the specimens by the use of a specific capture oligomer and magnetic microparticles in a method called target capture. This assay is also performed on the GenProbe PANTHER.

Trichomonas *vaginalis* (TV) is the most common curable sexually transmitted disease (STD) agent in the United States, with an estimated 7.4 million new cases occurring annually. Infections in women cause vaginitis, urethritis, and cervicitis. Complications 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.

T*. vaginalis* may also be detected using “wet-mount” preparation by mixing vaginal secretions with saline on a slide and examining the slide under a microscope. However, the wet-mount method is only 35% to 80% sensitive compared with culture. The sensitivity of the wet-mount method is highly dependent on the experience of the microscopist as well as the time of specimen transport to the laboratory.

Specimen:
1. Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab specimen
2. Aptima Vaginal Swab Specimen Collection Kit
3. Aptima Specimen Transfer Kit (for use with gynecological samples collected in PreservCyt Solution

Interpretation:

Negative Result:	Negative for Trichomonas *vaginalis*
Positive Result:	Positive for Trichomonas *vaginalis*
Invalid:	This specimen may be grossly contaminated with mucous or another interfering substance which prevented adequate amplification. Please resubmit.
Equivocal:	Indeterminate-a second specimen should be submitted to determine infection status

Testing Performed: Monday through Friday

Billings Clinic

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Vaginitis Panel

This test is performed on the BD Affirm™ Microbial Identification System. The Affirm™ VPIII Microbial Identification Test is a DNA probe test for use in the detection and identification of *Candida* species, *Gardnerella vaginalis* and *Trichomonas vaginalis* nucleic acid in vaginal fluid specimens from patients with symptoms of vaginitis/vaginosis. The test uses two distinct single-stranded nucleic acid probes for each organism, a capture probe and a color development probe that are complementary to unique genetic sequences of the target organism.

Vaginitis, one of the most common problems in clinical medicine, accounts for more than 10 million office visits each year. The three main categories of vaginitis are bacterial vaginosis (BV), yeast vaginitis (candidiasis) and *T. vaginalis (*trichomoniasis). BV is the most common vaginal infection and accounts for 15-50% of vaginitis/vaginosis depending upon the patient population. Vaginal candidiasis is the second most common form of vaginal infection seen in varied clinical settings. Trichomoniasis, a non-reportable sexually transmitted disease has been estimated to affect 180 million annually worldwide.

Specimen: Vaginal fluid collected using the BD Affirm ATTS Swab.

Transport: Using the Affirm VPIII Ambient Transport System (ATTS): up to 72 hrs. at 15-30ºC or refrigerated at 2-8ºC.
NOTE: Transport time is critical. Test must be performed within 72 hrs. of collection.

Testing Performed: Daily

Interpretation: *Candida* species: Detected or Not Detected
Gardnerella vaginalis: Detected or Not Detected
Trichomonas vaginalis: Detected or Not Detected

For more information about Billings Clinic Laboratory please call (406) 657-4060. www.billingsclinic.com

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