



AFFIRM™ VPIII Microbial Identification Test Available

Anna Vischio M.D., MPH

The laboratory is pleased to announce effective July-----, the availability of the AFFIRM VPIII Microbial Identification Test, a DNA probe test intended 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 AFFIRM VPIII Microbial Identification Test is based on the principles of nucleic acid hybridization. The test uses two distinct single-stranded nucleic acid probes for each organism in question, a capture probe and color development probe, which are complementary to unique genetic sequences of target organisms. The test will be available for routine requests to rule out infections of the aforementioned organisms; testing schedules will be determined by the volume of tests received.

Vaginitis is one of the most common problems that affect women; approximately 10 million office visits annually. The three main categories of vaginitis include: bacterial vaginosis (BV), yeast vaginitis (candidiasis) and *Trichomonas vaginalis* (trichomoniasis). Bacterial vaginosis, which involves an increase in anaerobic bacteria and reduction in the normal Lactobacillus flora, remains the most common vaginal infection accounting for 15-50% of vaginitis/vaginosis. Although it is now known that *Gardnerella vaginalis* is not the only etiologic agent of BV, it is still considered to be the major bacteria contributing to the infection. Some of the clinical implications of BV infection include adverse pregnancy outcomes, endometritis, pelvic inflammatory disease and post hysterectomy cuff cellulitis. Vaginal candidiasis, while less ominous, is the second most common vaginal infection seen in clinical medicine. Seventy-five percent of all women will experience the infection at least once, while half of these women experience a second infection and approximately 5% have recurrent, often intractable yeast infection. Trichomoniasis, a sexually transmitted disease, is estimated to affect 180 million women annually. Women who contract *Trichomonas vaginalis* are at greater risk of premature rupture of membranes, preterm labor and birth and post-surgical gynecologic infections.

The AFFIRM VPIII provides rapid and accurate detection of all three organisms even if a patient is co-infected. This test will aid in decreasing the morbidity associated with such infections. Implementation of the AFFIRM VPIII will allow for a timely and more sensitive method of detecting the microbes involved in causing vaginitis/vaginosis than those used in standard cultures.

SPECIMEN REQUIREMENTS:

A vaginal swab must be collected using the swab provided in the AFFIRM VPIII Microbial Identification kit.

Vaginal Sample Collection: Label the Sample Collection Tube (SCT) with the patient identification information. With the patient in position for a pelvic exam, insert an UNLUBRICATED speculum (WITHOUT JELLY OR WATER) into the vagina allowing visualization of the posterior fornix. Using the sterile swab provided, obtain a sample from the posterior vaginal fornix by rolling swab against the vaginal wall two or three times. Ensure that the entire circumference of the swab touches the vaginal wall and that the lateral walls are sampled while removing the swab. Immediately place the swab into the Sample Collection Tube (SCT). With the swab touching the BOTTOM of the collection tube, grasp the pre-scored handle of the swab just above the top of the tube and bend until the swab breaks. Place the cap over the exposed end of the swab and firmly press the cap onto the tube. The cap will "snap" onto the tube when it is properly seated.

When using the AFFIRM VPIII Ambient Temperature Transport System (ATTS), the total time between sample collection and receipt in the laboratory should not exceed 48 hours. The sample should be stored at ambient temperatures (15-30° C)

TEST REQUESTS:

Requests for the test will be performed on all women experiencing clinical signs or symptoms of vaginitis/vaginosis.

EXPECTED RESULTS:

The AFFIRM VPIII Microbial Identification Test will be positive or negative for *Candida* species (*C. albicans*, *C. glabrata*, *C. kefyr*, *C. krusei*, *C. parapsilosis*, *C. tropicalis*), *G. vaginalis*, and/or *T. vaginalis*, which means the nucleic acid for these organisms is present or absent in the sample in clinically significant amounts. Since *Candida* species are part of normal vaginal flora, the Affirm VPIII test is designed to be positive when there are greater than the 1×10^4 colony forming units (CFU) per mL which is the amount required for a clinically significant infection. Since *G. vaginalis* can be present in normal vaginal flora, the Affirm VPIII test is designed to be positive when there are greater than the 2×10^5 colony forming units (CFU) per mL which is the amount required for a clinically significant infection.

REQUISITIONS FOR PATIENT TESTING:

Please remember to include the first and last name of the clinician ordering the testing so that the laboratory may ensure that reports are forwarded to the correct recipient. The first and last name of the patient is also required on the requisition as well as the medical record number, date of birth and/or social security number.

Questions regarding this test may be directed to the Microbiology section of the laboratory at 203-739-7305.