

BD Affirm™ VPIII Microbial Identification test for detection of *Candida*, *Gardnerella*, and *Trichomonas* species in Suspected cases of Vaginitis/Vaginosis

Summary and Explanation of the Test:

The University of Toledo Medical Center clinical microbiology laboratory offers the DNA probe Affirm™ VPIII Microbial Identification 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. 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* vaginitis (trichomoniasis).

BV is the most common vaginal infection, and accounts for 15 to 50% of vaginitis/vaginosis depending upon the patient population. While *G. vaginalis* is no longer thought to be the only etiologic agent of BV, it is still considered to be one of the major bacteria contributing to the infection. The complications of BV can be especially significant in pregnant women, resulting in increased risk of adverse pregnancy outcome, including pre-term labor and birth. In addition, recent data suggest BV-associated bacteria in the endometrium may be etiologic agents of endometritis and pelvic inflammatory disease.

Vaginal candidiasis is the second most common form of vaginal infection seen in varied clinical settings. Three quarters of all adult women will experience at least one episode of vaginal candidiasis during their lifetime, with 40 to 50% experiencing a second episode. Approximately 5% of the adult female population suffers from recurrent, often intractable yeast infection.

Trichomoniasis, a non-reportable sexually transmitted disease, has been estimated to affect 3 million women in the United States each year. Pregnant women positive for *T. vaginalis* are more likely to have pre-term rupture of membranes as well as pre-term labor and birth. *T. vaginalis* is a risk factor for the development of post-surgical gynecologic infections. In addition, *T. vaginalis* is a risk factor for the development of post-hysterectomy cuff cellulitis. Laboratory methods for the identification of these organisms include microscopic evaluation, amine test, Gram stain, pH, culture, and molecular methods such as the *Affirm* test.

Method:

The *Affirm* VPIII Microbial Identification Test is based on the principles of nucleic acid hybridization. It 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 organisms. The capture probes are immobilized on a bead embedded in a Probe Analysis Card (PAC), which contains a separate bead for each target organism. The color development probes are contained in a multi-well Reagent Cassette (RC). During sample preparation, the sample is treated with the Lysis Solution (L) and heated. Hybridization occurs on the PAC beads in the first and second wells of the Reagent Cassette (RC). Hybridization of the organism nucleic acid to the capture probe on the bead occurs, as well as hybridization of the color development probes (if organism is present in the sample). All unbound sample components and probes are washed away, and the enzyme conjugate binds to the captured nucleic acid. Unbound conjugate is washed away and the indicator substrate is converted to a blue-colored product if bound enzyme conjugate (and organism nucleic acid) is present on the bead.

Turn-Around-Time: 1 day

Sample Requirements:

Vaginal swab using the *Affirm* VPIII Ambient Temperature Transport System, the *Affirm* VPIII Sample Collection Set or the swabs provided in the *Affirm* VPIII Microbial Identification Test Kit. ***Separate swabs should be used for other tests, e.g. culture or microscopic slide samples.*** These sample collection kits can be obtained through our clinical microbiology laboratory by calling 419-383-6646.

Results Reporting:

A report is issued containing the results of the test (positive or negative)

References:

1) BD Affirm™ VPIII Microbial Identification test package insert, Becton, Dickinson and Company 7 Loveton Circle, Sparks, MD 21152 USA. 800-638-8663, www.bd.com/ds.

For any questions regarding this test contact the clinical microbiology laboratory at 419-383-6646 or molecular diagnostics laboratory at 419-383-5636. For further consultation regarding this test or other microbiology and molecular tests please contact the medical director ([Kenneth L. Muldrew, MD, MPH](mailto:Kenneth.L.Muldrew@utoledo.edu)) at 419-383-6444. Further information can also be found on the molecular diagnostics laboratory (<http://www.utoledo.edu/med/depts/path/moldx/index.html>) and clinical microbiology laboratory (<http://www.utoledo.edu/med/depts/path/micro/index.html>) websites.