Vaginitis Panel by DNA Direct Probe

Molecular testing using a DNA probe for the detection of
Candida species, Gardnerella vaginalis, and Trichomonas vaginalis nucleic acid

Clinical Background

Vaginitis is common and accounts for more than 10 million office visits each year. There are three infectious agents associated with vaginitis: bacterial vaginosis (BV), yeast vaginitis (candidiasis) and T. vaginalis vaginitis (trichomoniasis). BV is the most common and accounts for 15 to 50% of vaginitis/vaginosis depending upon the patient population. G. vaginalis is not the only etiologic agent of BV, but it is one of the major bacteria contributing to the infection. BV involves an increase in anaerobic bacteria and reduction in the normal Lactobacillus spp. The complications of BV can be significant in pregnant women, resulting in increased risk of adverse pregnancy outcome, including pre-term labor and birth. In addition, BV-associated bacteria in the endometrium may be etiologic agents of endometritis and pelvic inflammatory disease.

Test Performance Verification

In house test performance was compared to reference lab testing (Affirm™ VPIII Microbial Identification Test) for *Candida species* and *Gardnerella vaginalis.* The following summary table shows the performance characteristics for this direct probe nucleic acid test:

Test Variable	Candida species	Gardnerella vaginalis	Trichomonas vaginalis*
Sensitivity	100	100	NA
Specificity	97.2	92.3	100
NPV	100	100	NA
PPV	92.3	91.7	97.9

*The statistical analysis for T. vaginalis is not available (NA) due to low test numbers. There is an ongoing validation for support of sensitivity.

Test performance from the package insert (Affirm™ VPIII Microbial Identification Test) for symptomatic and asymptomatic patients compared to culture is:

Test Variable	Candida species	Gardnerella vaginalis	Trichomonas vaginalis*
Sensitivity	80.6	89.0	89.6
Specificity	98.2	99.1	98.5
Accuracy	95.3	92.6	99.9

Test Limitations

- This test is intended for use with vaginal specimens.
- A negative test result does not rule out the presence of microorganisms below the test sensitivity.
- "A negative result for Candida, Gardnerella and/or Trichomonas indicates nucleic acid from less than 1×10^4 Candida cells, 2×10^5 CFU of G. vaginalis or 5×10^3 trichomonads, respectively, may be present in the patient sample."

Methodology

The Affirm™ VPIII Microbial Identification Test is 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

Test Ordering Information

Test Name	Test Code
Vaginitis Panel, DNA Direct Probe	**5493**

Specimen Collection and Transport

Specimen Type: vaginal specimen in Affirm VPIII Ambient Temperature Transport System
Other specimen types: vaginal swab, vaginal fluid in Affirm VPIII Ambient Temperature Transport System

Specimen Stability

Ambient Stability: 72 hours
Refrigerated (2-8°C):
Frozen Stability (-20°C or lower):
Local Transport: ambient **Long Distance:** ambient

CPT Code

87480	Candida species, direct probe
87510	Gardnerella vaginalis, direct probe
87660	Trichomonas vaginalis, direct probe

References

1. Kent, HL. Am J. Obstet Gynecol; 165 (4 Pt 2): p.1168-76; Oct 1991.
2. Sobel, JD. Med Clin North Am; 74 (6) p1573-602; Nov 1990.
3. Gravett MG, HP Nelson, T DeRouen, et al. 1986. J Am Med Assoc 256:1899-1903.
4. Faro S. 1991. J Reprod Med 34:602-604. Gravett MG, D Hummel, DA Eschenbach, et al. 1986. Obstet Gynecol 67:229-237.

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