



New Test Available January 13, 2010

Vaginitis DNA Probe Panel: *Gardnerella vaginalis*, candida species, and *Trichomonas vaginalis*

We are pleased to announce a new service for our healthcare providers. Starting January 13, 2010, we will offer the FDA-approved BD Affirm Vaginitis DNA Probe Panel. This test is 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.

CLINICAL INFORMATION:

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).

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, independent of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* infection. BV is also a risk factor for the development of post-hysterectomy cuff cellulitis.

Traditional methods for the identification of these organisms include microscopic evaluation of Gram stained (*Candida* and *G. vaginalis*) and wet slide preparations (*Trichomonas*), antigen detection, and culture. The advantage of the BD Affirm Vaginitis Panel is that all three organisms can be detected from a single specimen, increased sensitivity, and detection is not subject to the one hour time limitation of the wet prep method for *Trichomonas*.

SPECIMEN INFORMATION:

Only the BD Affirm Ambient Temperature Transport system should be used.

PRODUCTION SCHEDULE: Batched Daily in the Molecular Department
SPECIMEN STABILITY: 72 Hours at Room Temperature or Refrigerated
SOFT ORDER CODE: BDAFR
CPT: 87480, 87510, 87660

CLINICAL INTERPRETATION:

The BD Affirm Vaginitis panel is designed to detect clinically significant levels of the three organisms. 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.

Possible cross-reactivity: *Cryptococcus* at concentrations greater than 1×10^8 yeast/mL, *M. mulieris* at concentrations greater than 4×10^6 bacteria/mL, and *Bifidobacterium dentium* at concentrations greater than 8×10^5 bacteria/mL may react with the BD Affirm Vaginitis Panel (*C. neoformans* and *B. dentium* are only rarely encountered in the vagina).

