



## BD Affirm™

### Vaginal Pathogens by Direct DNA Probe

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Vaginal symptoms are common and lead to frequent utilization of the health care system, accounting for more than 10 million office visits each year. A survey of women college graduates with a median age of 30 years showed that 70% had been diagnosed and treated for a vaginal yeast infection, 29% had been treated for bacterial vaginosis, and 26% had been treated for trichomoniasis. Clinical differentiation of the various types of infectious vaginitis based on genitourinary tract symptoms lacks specificity, thus requiring laboratory testing for an accurate diagnosis.

#### Trichomoniasis

Trichomoniasis is one of the most common sexually transmitted diseases in women. *Trichomonas vaginalis* causes trichomoniasis in approximately 8 million people per year in the United States, with at least 180 million cases annually worldwide. As many as 50% of *T. vaginalis* infected women are asymptomatic, suggesting that universal screening may be important in diagnosing this infection. The annual total direct cost due to trichomoniasis in the United States was estimated to be \$34.2 million in 2000, among persons aged 15 to 24 years. Importantly, *T. vaginalis* infection has been associated with pelvic inflammatory disease, adverse pregnancy outcomes, and increased acquisition of HIV. The symptoms are insufficiently unique to permit differentiation from other causes of genital infections, and about a third of the cases of trichomoniasis in women occur as a dual infection with bacterial vaginosis. *T. vaginalis* cannot survive for long outside the urogenital system. The sensitivity of wet mount microscopy compared to the gold standard of culture is between 50% and 70%, depending on the skill of the microscopist and delays between specimen collection and examination. The BD Affirm™ VP111 nucleic acid-based test has a reported sensitivity of 90% and specificity of 95% to 100% for *T. vaginalis*, with a lower limit of detection of  $5 \times 10^3$  trichomonads/mL.

#### Vulvovaginal Candidiasis

*Candida albicans* and other species of *Candida* are part of the normal vaginal flora in asymptomatic women, with 10% to 20% of women harboring yeast in the absence of symptoms. *C. albicans* is isolated from about 80% to 90% of patients with vulvovaginal candidiasis, with *C. glabrata* accounting for 10% and *C. tropicalis* for as many as 5% of the infections. There are an estimated 13 million cases annually of *Candida* vaginitis. It has been projected that as many as 75% of adult women will have at least one episode of vulvovaginal candidiasis during their lifetime, making it the most common cause of vaginitis. Microscopic examination has a sensitivity of 50%, leading to culture and a delay in diagnosis in many cases. The BD Affirm™ VP111 nucleic acid-based test has a reported sensitivity of 80% and specificity of 85% to 98% for *Candida* vaginitis, at a detection threshold of  $1 \times 10^4$  CFU/mL.

#### Bacterial Vaginosis

Many women with vaginal symptoms have a condition referred to as bacterial vaginosis. It is the most common cause of abnormal vaginal discharge in women of reproductive age and is associated with an increased susceptibility to HIV and other sexually transmitted diseases, preterm delivery, and pelvic inflammatory disease. Reports of prevalence have ranged from 5% to 30% in developed nations. It has been estimated that the population attributable risk for preterm delivery in

## Quick Facts

- ▶ DNA probe technology
- ▶ Simultaneously tests for the three major causes of vaginitis/ bacterial vaginosis Gardnerella, Trichomonas and Candida.
- ▶ Provides rapid results and increased reproducibility of results
- ▶ Identifies mixed infections that occur in 25% of cases and that are often undiagnosed.
- ▶ More sensitive than clinical examination and wet mount exam for the diagnosis of symptomatic vaginitis/ vaginosis.
- ▶ Identifies and differentiates between the three causes of vaginitis/vaginosis, leading to appropriately targeted therapy.

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the United States is 30%, at an annual cost of \$1 billion. Inflammation and perivaginal irritation are significantly milder than in trichomoniasis or candidiasis, thus leading to the designation of vaginosis. Clinical signs are neither sensitive nor specific, with clinical interpretation of the vaginal discharge associated with bacterial vaginosis tending to be poorly reproducible. "Clue cells" are seen in wet mounts of vaginal fluid from more than 90% of women with bacterial vaginosis. Culture for *Gardnerella vaginalis* is not diagnostically helpful because up to 70% of asymptomatic women also harbor the organism, with a reported predictive value for culture of 50%. *G. vaginalis* is not the sole cause of bacterial vaginosis. Bacterial vaginosis is characterized by a shift in the normal vaginal flora involving an increase in the numbers of not only *G. vaginalis* but also anaerobic organisms, in conjunction with the loss of normally present *Lactobacillus* species. An objective microscopic diagnosis can be achieved using the gold standard of the Gram stain with the Nugent scoring criteria, yielding a sensitivity of 89% and a specificity of 93%. The BD Affirm™ VP8 nucleic acid-based test has a reported sensitivity of 84% to 98% and specificity of 81% to 100% for bacterial vaginosis, with a *G. vaginalis* detection threshold of  $2 \times 10^5$  CFU/mL. To increase the specificity of the BD Affirm™, the presence of a vaginal fluid pH >4.5 or amine odor can be used in conjunction with a positive DNA probe test result for the diagnosis of bacterial vaginosis.

## Diagnostic Challenge

Current conventional diagnostic methods for vaginitis and vaginosis have clear limitations in terms of provision of a prompt diagnosis leading to appropriate treatment. Up to 25% of women will have mixed infections; thus, testing for all three syndromes should be performed. Access to rapid, objective, and reliable testing will improve the diagnosis and management of these infections. The BD Affirm™ VP8 is a semi-automated, standardized nucleic acid-based test that detects the rRNA of *G. vaginalis* as a marker for bacterial vaginosis, *T vaginalis*, and six *Candida* species in vaginal fluid specimens. A specific DNA capture-probe for each organism plus positive and negative control beads are included on each test card. Specimens must be submitted in the Affirm ambient temperature transport system that maintains sample integrity for up to 3 days at room temperature. The advantages associated with this test include rapid results, increased sensitivity, detection of multiple infections, and increased reproducibility of results. The BD Affirm™ VP8 nucleic acid-based test is a more sensitive diagnostic test for the detection and identification of symptomatic vaginitis/vaginosis compared to clinical examination and wet mount exam. Importantly, the test identifies and differentiates between the three causes of vaginitis/vaginosis, thus leading to appropriately targeted therapy.

## Test Information

**DESCRIPTION** Vaginal Pathogens by BD Affirm™ DNA Direct Probe

**METHOD** Molecular

**ORDER CODE** VPDNA

**CPT CODE** Candida – 87480  
Gardnerella – 87510  
Trichomonas – 87660

**SPECIMEN REQUIREMENTS** Vaginal swab from AFFIRM VP8 AMBIENT TEMPERATURE TRANSPORT SYSTEM. Collect vaginal sample from the posterior fornix. Store and transport at room temperature. AFFIRM VP8 AMBIENT TEMPERATURE TRANSPORT SYSTEMS available in the PAML Supply Department.

**COMMENTS** 1) Unacceptable conditions: greater than 72 hours from time of collection to time of assay and lubricants should not be used during specimen collection.

2) Stability: room temperature - 3 days, Refrigerated-3 days, Frozen-unacceptable.

3) SHMC- Microbiology Department.

**RANGES** Source Vaginal Pathogens by DNA Probe Status.  
Negative for Gardnerella vaginalis, Candida, and/or Trichomonas vaginalis detected by DNA Probe.

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