

What makes the use of the BD Affirm VPIII a better method than the wet preps (wet mounts) I'm using now?

- Affirm VPIII utilizes a standardized, rapid RNA probe technology which differentiates and confirms etiology [etiologies] of infectious vaginitis.
- The advanced technology of Affirm VPIII enables practitioners to deal with the challenges of mixed infections and difficult specimens (presence of factors that obscure microscopic interpretations; e.g., douches, lubricants, menses).
- Wet preps are only 50-75% sensitive for *Trichomonas* compared to Affirm VPIII.^{11, 12}
- Traditional testing which relies on recognition of the clue cells as an indicator for BV is highly variable. Results depend on the quality of the microscope, the quality of the specimen, and the skill of the observer.^{3, 13}
- Wet mounts for *Trichomonas* must be performed immediately.
- Over-the-counter anti-fungals, lubricants, douching and menses hamper differential diagnosis when performing wet mounts.^{14, 15}



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Helping all people
live healthy lives

Why test for vaginitis? I always treat based on symptoms, and this works fine. Why would I need the BD Affirm™ VPIII System?

- Vaginitis is the most common reason a woman visits her doctor. Vaginitis results in approximately 15 million office visits per year in the USA.¹
- Millions of dollars of unnecessary spending occur due to improper diagnosis.²
- Trichomoniasis is the most common curable STD in young, sexually active women. An estimated 5 million new cases occur each year in women and men.²⁴
- Clinical symptoms of vaginitis are nonspecific, subjective, and subtle. Diagnosis can be particularly difficult with overlapping symptoms and mixed infections.³⁻⁵
- Therapeutic regimens are different for the three major causes of infectious vaginitis - Bacterial Vaginosis (BV), Trichomoniasis and Candidiasis.
- Bacterial Vaginosis and Trichomoniasis are associated with pre-term birth. These infections may be avoided by administration of appropriate antimicrobials.^{6,7}
- Women with BV are 40-50% more likely to have pre-term or low-birth-weight babies.⁸
- Approximately 50% of women with Trichomoniasis and BV are asymptomatic.⁹
- Pregnant women with Trichomoniasis are more likely to have pre-term rupture of membranes.^{7, 10}
- BV and Trichomoniasis can increase a woman's susceptibility to HIV infection, if she is exposed to the virus.^{23, 24}
- Having BV or Trichomoniasis increases the chances that an HIV-infected woman can pass HIV to her sex partner.^{23, 24}

Responses To
Commonly Asked
Questions About

BD Affirm™ VPIII
Microbial Identification System

What does the BD Affirm VPIII test for?

- The Affirm VPIII system detects the three infectious agents that are responsible for up to 95% of infectious vaginitis cases: *Gardnerella vaginalis*, *Candida* species, and *Trichomonas vaginalis*.
- *Gardnerella vaginalis* is the most common agent causing vaginitis/vaginosis.
- *Candida* species is the second most common agent - due to yeast/fungal infection; this is often incorrectly assumed to be the most common cause of infectious vaginitis.
- *Trichomonas vaginalis* is the least common agent - a sexually transmitted disease due to a parasitic infection.^{7,10}



Can the BD Affirm VPIII handle difficult specimens?

The BD Affirm VPIII diagnosis is not hampered by factors such as douches, lubricants, or menses. These factors are present in 50% of specimens¹⁷ and will obscure microscopic examinations. The BD Affirm VPIII technology is unaffected by those factors and thus improves accuracy of diagnosis. Physician offices may benefit from the BD Affirm VPIII by:

- Reducing repeat patient visits and complications due to improper diagnosis.
- Minimizing the potential for missed diagnosis of mixed infections.
- Increasing patient satisfaction and patient retention in the practice.

I hear the BD Affirm VPIII detects clinically significant levels of vaginal pathogens. What does this mean?

- *Gardnerella vaginalis* and *Candida* species exist as normal flora in 50% of women. The BD Affirm VPIII detection threshold is set above levels of normal flora, and detects only clinically significant levels (disease state) of *Gardnerella* and *Candida* species.^{3,17-19}
- Detection thresholds as published in the Affirm VPIII package insert:
 - *Gardnerella vaginalis* - 2 X 10⁵ - CFU/mL
 - *Candida* species - 1 X 10⁴ - CFU/mL
 - *Trichomonas vaginalis* - 5 X 10³ - Trichomonads/mL

Why is it important to test for mixed infections?

- 25% of vaginal infections are mixed infections which are frequently missed by microscopy.^{11,16}
- Physicians who use the Affirm VPIII can quickly detect mixed infections and provide appropriate drug combination therapy.

What about Group B Strep, *Neisseria gonorrhoeae* and *Chlamydia*?

- Group B Strep, *N. gonorrhoeae* and *Chlamydia* diagnostic testing is best detected by amplified rather than direct probe technologies.

Organisms other than *Gardnerella vaginalis* cause BV - why don't you detect these other microbes?

- *Gardnerella vaginalis* is selected as the sentinel indicator for BV - when the population of this organism exceeds 2 X 10⁵, this is an indication of active infection caused by multiple organisms.^{3,17,20}

What does the *Candida* species probe detect?

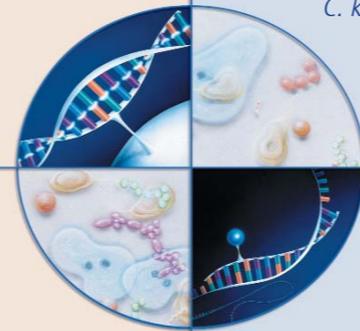
- *C. albicans*, *C. tropicalis*, *C. glabrata*, *C. kefyr*, *C. krusei*, *C. parapsilosis* - all of which are associated with vulvovaginal candidiasis.

Should I perform this test for my pregnant patients? What are the benefits?

- Screening for Bacterial Vaginosis may be considered in women at high risk for pre-term labor (women with a history of pre-term delivery, a low pre-pregnant weight of less than 50 kg, or both).^{5,21}
- The treatment of Bacterial Vaginosis in early pregnancy might reduce the incidence of premature delivery by 50%.⁶

I want to transport specimens from several offices to a central site. How do I do this?

- The Affirm VPIII Ambient Temperature Transport System (ATTS) is a sterile ready-to-use system intended for the collection, transport and preservation of vaginal specimens for use only with the Affirm VPIII Microbial Identification Test. The ATTS should be used with those specimens where transport times are expected to exceed 1 hour at ambient temperature or 4 hours refrigerated. The ATTS enables specimen transport for up to 72 hours at ambient temperature.



Why should I pay for this test?

- Affirm VPIII is the most accurate method for the differential detection of infectious vaginitis pathogens. It is based on direct nucleic acid probe technology.
- Consider the inconvenience to patients who don't get the right diagnosis and treatment the first time.
- Consider the costs and the consequences of inadequate treatment which may include unnecessary repeat office visits and treatments, pre-term low-birth-weight deliveries, pelvic inflammatory disease, post-gynecologic surgery complications and greater risk for HIV infection.
- Consider the benefit of performing the test while the patient waits in your office.

