

BD Affirm™ VPIII Microbial Identification Test

VAGINAL INFECTIONS:

The power of DNA technology for better patient care



Helping all people
live healthy lives



“Vaginitis has a broad differential diagnosis, and successful treatment frequently rests on an accurate diagnosis.”

ACOG Practice Bulletin. Clinical management guidelines for obstetrician-gynecologists, Number 72, May 2006: Vaginitis. *Obstet Gynecol* 2006;107:1195-1206.¹¹

Diagnose and treat vaginitis/vaginosis patients correctly the first time

- Avoid recurrences and possible complications
- BV and trichomoniasis during pregnancy are associated with adverse pregnancy outcomes^{4,7}
- Trichomoniasis is associated with increasing the risk of transmission of HIV by increasing the susceptibility of the HIV-uninfected partner and the infectivity of the infected individual⁸
- Unnecessary or inappropriate use of over-the-counter preparations can lead to a delay in the treatment of other vulvovaginitis etiologies, which can result in adverse clinical outcomes⁹
- A study of women who purchased over-the-counter antifungal medications showed that only 33.7% of the participants actually had candidiasis alone¹⁰

**Call 1-800-999-4951 ext. 3597 to
get started with BD Affirm today
Or email: BD_Womenshealth@bd.com**



“Even under research conditions that provided clinicians with sufficient time and materials to conduct a thorough and standardized clinical evaluation, the diagnosis ... remains difficult.”

Lowe NK, Neal JL, Ryan-Wenger NA. Accuracy of the clinical diagnosis of vaginitis compared with a DNA probe laboratory standard. *Obstet Gynecol* 2009;113:89-95.³

Accurate test results on three pathogens with DNA technology

- The BD Affirm™ VPIII Microbial Identification Test uses DNA probe technology¹
- Detection thresholds for *Candida* species and *Gardnerella vaginalis* distinguish between normal flora and clinically significant levels of organisms¹
- BD Affirm provides more accurate detection of *Trichomonas vaginalis* compared to microscopy,¹ which has been shown to be negative in up to 50% of women with culture-confirmed trichomoniasis²

BD Affirm performance data¹

	SENSITIVITY	SPECIFICITY	ACCURACY
<i>G. vaginalis</i> *	98.3%	100%	98.4%
<i>T. vaginalis</i> **	92.8%	99.9%	98.9%
<i>Candida</i> species*	82.3%	98.4%	95.2%

*Compared to culture (symptomatic patients)

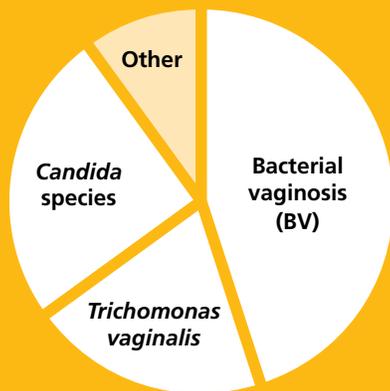
**Compared to wet mount (symptomatic and asymptomatic patients)

BD Affirm vs. clinical diagnosis

- A recent study concluded that BD Affirm is more sensitive and more specific than clinical diagnosis for bacterial vaginosis, candidiasis and trichomoniasis³
- The clinical diagnostic protocol included patient history, pelvic exam, vaginal pH, vaginal fluid amines test and wet-prep microscopy³

“Clinicians’ diagnoses were even less accurate than [the BD Affirm VPill test] when coexisting vaginal infections were present.”

Ferris DG, Hendrich J, Payne PM, et al. Office laboratory diagnosis of vaginitis: clinician-performed tests compared with a rapid nucleic acid hybridization test. J Fam Pract 1995;41:575-581.¹²



Up to 90% of vaginitis/vaginosis cases are associated with *Candida* species, bacterial vaginosis (BV) and *T. vaginalis*.⁴ In this study *G. vaginalis* is the indicator organism for BV.⁵

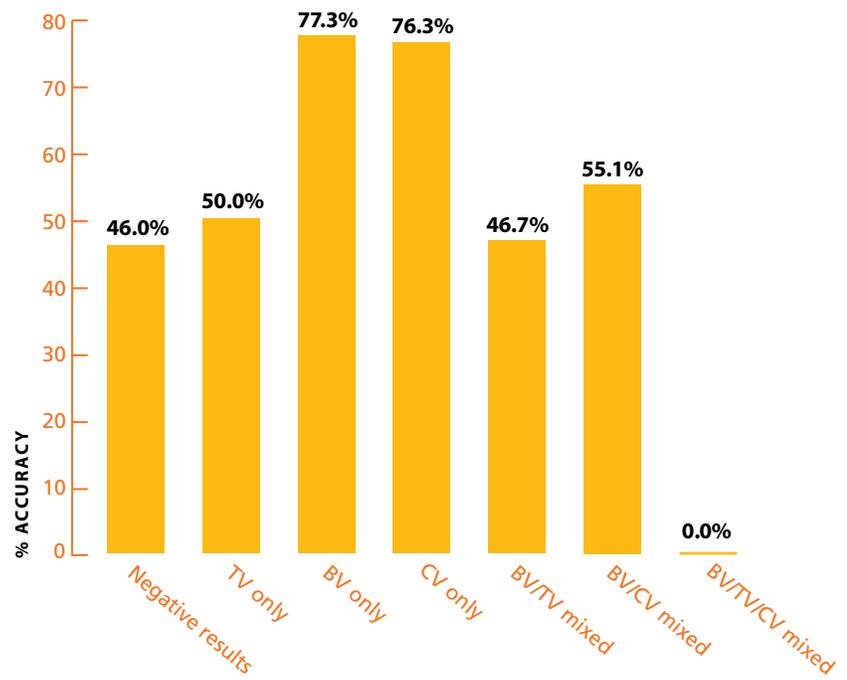
Identify mixed infections with one test

- 22% of vaginal infections are caused by two or more organisms³
- BD Affirm can identify *Candida* species, *G. vaginalis* and *T. vaginalis* with one sample and one test

Begin treatment with confidence

- DNA technology provides objective, accurate results
- All three pathogens commonly associated with vaginitis/vaginosis are included in one test

Accuracy of clinical diagnosis vs. BD Affirm³



TV = Trichomoniasis
 BV = Bacterial vaginosis
 CV = Candidiasis

Simple, convenient path to accurate diagnosis



- Just one sample for all three tests (*Candida* species, *G. vaginalis*, *T. vaginalis*)
- Streamlines sample collection; no need to collect multiple samples
- Confidence in results whether tests are performed in your office or at your reference lab
- Samples remain stable for up to 72 hours when used with the BD Affirm VPIII Ambient Temperature Transport System (ATTS)⁶

INTENDED USE: 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.¹



“Although it is tempting to treat vaginal complaints empirically based on the patient’s history alone, studies have demonstrated poor correlation between symptoms and the final diagnosis.”

Owen MK, Clenney TL. Management of vaginitis. *Am Fam Physician* 2004;70:2125-2132.²

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“Given the extraordinarily high prevalence of vaginal infections, the significant association with HIV-related risk, and adverse sexual and reproductive health outcomes, the time clearly has come to stop minimizing the impact of vaginal diseases.”

Van Der Pol B. Diagnosing vaginal infections: it's time to join the 21st century. *Curr Infect Dis Rep* 2010;12:225-230.⁷

References

- 1 BD Affirm™ VPIII Microbial Identification Test [package insert]. Sparks, MD: BD Diagnostics; 2010.
- 2 Owen MK, Clenney TL. Management of vaginitis. *Am Fam Physician* 2004;70:2125-2132.
- 3 Lowe NK, Neal JL, Ryan-Wenger NA. Accuracy of the clinical diagnosis of vaginitis compared with a DNA probe laboratory standard. *Obstet Gynecol* 2009;113:89-95.
- 4 Centers for Disease Control and Prevention. STD curriculum for clinical educators: Vaginitis module. 2010.
- 5 Fredricks DN, Fiedler TL, Marrazzo JM. Molecular identification of bacteria associated with bacterial vaginosis. *N Engl J Med* 2005;353:1899-1911.
- 6 BD Affirm™ VPIII Ambient Temperature Transport System for collection and extended transport of vaginal specimens for use in the Affirm VPIII Microbial Identification Test [package insert]. Sparks, MD: BD Diagnostics; 2009.
- 7 Van Der Pol B. Diagnosing vaginal infections: it's time to join the 21st century. *Curr Infect Dis Rep* 2010;12:225-230.
- 8 Sobel JD. What's new in bacterial vaginosis and trichomoniasis? *Infect Dis Clin N Am* 2005;19:387-406.
- 9 Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines 2006. *MMWR Recomm Rep* 2006;55:1-95.
- 10 Ferris DG, Nyirjesy P, Sobel JD, Soper D, Pavletic A, Litaker MS. Over-the-counter antifungal drug misuse associated with patient-diagnosed vulvovaginal candidiasis. *Obstet Gynecol* 2002;99:419-425.
- 11 ACOG Practice Bulletin. Clinical management guidelines for obstetrician-gynecologists, Number 72, May 2006: Vaginitis. *Obstet Gynecol* 2006;107:1195-1206.
- 12 Ferris DG, Hendrich J, Payne PM, et al. Office laboratory diagnosis of vaginitis: clinician-performed tests compared with a rapid nucleic acid hybridization test. *J Fam Pract* 1995;41:575-581.



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