

OVERVIEW

Vaginal symptoms consisting of abnormal discharge, foul odor, and vulvar itching and burning are some of the most common reasons for gynecological consultation. The three entities most frequently associated with these symptoms are *Bacterial Vaginosis (BV)*, *Trichomonas vaginalis (TV) infection*, or *Vulvovaginal Candidiasis (VVC)*.

Bacterial Vaginosis (BV) is the most common vaginal infection in women of childbearing age¹ and is the most prevalent cause of vaginal discharge or malodor in 50% of symptomatic women.² BV is characterized by the decrease or absence of protective lactobacilli which are normally present in the vagina. When lactobacilli are lacking, overgrowth of other bacteria, such as *Gardnerella vaginalis*, can occur. BV has been associated with adverse pregnancy outcomes (premature rupture of membranes, preterm labor, etc.)³ and can also lead to pelvic inflammatory disease, postprocedural infections, and increased susceptibility for HIV and Herpes simplex virus (HSV-2) infections.²

TESTING FOR VAGINITIS INFECTION

Identification of the cause of vaginitis and vaginosis is key for selection of appropriate and specific therapy. Traditional diagnostic methods include a gynecological examination, vaginal pH, wet mount and/or Gram stain, and an amine odor test.

Laboratory methods for the identification of Bacterial Vaginosis (BV) include wet mount, Gram stain (the "gold standard"), and microbiological culture. Gram staining of vaginal secretions is more reliable than wet mount, with a reported sensitivity of 93% and specificity of 70%.⁶ Cultures for *Gardnerella vaginalis* are not helpful as up to 50% of asymptomatic women may harbor this organism.⁵

Trichomonas vaginalis is diagnosed by wet mount which has a sensitivity of 55 to 60%.² Due to microscopy's limited sensitivity, culture (with a sensitivity of 90%)² or antigen testing should be used in patients where trichomoniasis is suspected but not proven.

Trichomonas vaginalis (TV) is caused by a single-celled protozoan parasite and is responsible for 7.4 million new cases each year in women and men.⁴ TV is diagnosed in 4 to 35% of women presenting with vaginal symptoms.² Inflammation caused by trichomoniasis can increase a woman's susceptibility to HIV infection when exposure to the virus occurs.⁴ In addition, pregnant women with trichomoniasis may have babies who are born early or with low birth weight (< 5.5 lbs.).⁴

Vulvovaginal Candidiasis (VVC) is present in 17 to 39% of symptomatic women.² It is estimated that 75% of women will have at least one episode of VVC, and 40 to 50% will have two or more episodes.³ Approximately 10 to 20% will have complicated VVC which includes recurrent disease, severe disease, non-albicans candidiasis, or conditions related to diabetes, debilitation, immunosuppression, or pregnancy.³ Mixed infections are common in up to 25% of patients with infectious vaginitis.⁵

Microscopic sensitivity to yeast is only around 50% and misses a substantial percentage of patients with symptomatic vulvovaginal candidiasis.² Culture is considered the standard in confirmation of yeast, but is costly and can cause a delay in diagnosis.²

As noted, conventional diagnostic methods for accurately identifying vaginitis and vaginosis have significant limitations. Because 25% of women have mixed infections, testing for all three diseases should be performed. Rapid, objective, and reliable testing can improve the diagnosis and management of these infections. The Affirm™ DNA Probe Test rapidly and simultaneously detects the presence of clinically significant levels of *Trichomonas*, *Gardnerella*, and *Candida* from vaginal specimens. It has shown to be 30% more sensitive than microscopy.⁷

Sensitivity*	Relative to Microscopy:	<i>G. vaginalis</i> – 95%, <i>T. vaginalis</i> – 93%
	Relative to Culture:	<i>Candida</i> species – 82%, <i>G. vaginalis</i> - 98%, <i>T. vaginalis</i> - 90%
Specificity*	Relative to Microscopy:	<i>G. vaginalis</i> – 100%, <i>T. vaginalis</i> – 99.9%
	Relative to Culture:	<i>Candida</i> species – 98.4%, <i>G. vaginalis</i> – 100%, <i>T. vaginalis</i> – 99.9%

*Test performance characteristics data is based on Becton Dickinson kit insert

CLINICAL UTILITY

- 30% more sensitive than in-office microscopy
- Simultaneous detection and identification of each organism from a single vaginal swab specimen
- Unaffected by “difficult specimens” (due to vaginal lubricants, etc.)
- Rapid 24-hour turnaround time

SAMPLE TYPE AND COLLECTION

BD Affirm™ VP8 Collection and Transport Kit includes BD Vaginal Swab. Please call Client Services at 877-922-7284 to request collection kits.

METHODOLOGY

DNA Probe

ORDERING INFORMATION

Test Code	Test Name
527	AFFIRM™ Microbial Identification Test for Vaginitis

Specimen/Stability	BD Vaginal Swab: Ambient temperature for 72 hours
Collection Instructions	BD Affirm™ VP8 collection and transport kit required. Call Client Services at 877-922-7284 to request collection kits.
Report	Next business day

REFERENCES

1. CDC STD Fact Sheet - Bacterial Vaginosis www.cdc.gov/std/bv/STDFact-Bacterial-Vaginosis.htm
2. ACOG Practice Bulletin: Vaginitis. *Obstetrics and Gynecology* 2006; 107:1195-1206.
3. Sexually Transmitted Diseases Treatment Guidelines. *MMWR (CDC)* Aug 4 2006;55(RR-11); 50-58.
4. CDC STD Fact Sheet - Trichomoniasis www.cdc.gov/std/trichomonas/STDFact-Trichomoniasis.htm
5. Brown HL, et al. Clinical evaluation of Affirm VP8 in the detection and identification of *Trichomonas vaginalis*, *Gardnerella vaginalis*, and *Candida* species in vaginitis/vaginosis. *Infectious Diseases in Obstetrics and Gynecology* 2004; 12:17-21.
6. Witt A, et al. DNA Hybridization Test: Rapid Diagnostic Tool for Excluding Bacterial Vaginosis in Pregnant Women with Symptoms Suggestive of Infection. *Journal of Clinical Microbiology* 2002; 40(8):3057-59.
7. Package Insert: BD Affirm™ VP8 Microbial Identification Test <http://www.bd.com/ds/productCenter/446250.asp>