

**VP**

## Vaginitis Panel

**GA Test Code** 341  
**Method** FDA-approved BD Affirm™ VPIII Microbial Identification Test, using DNA probe hybridization technology

<u>Pathogen</u>	<u>Sensitivity</u>	<u>Specificity</u>
<i>Candida</i> species	82.3%	98.4%
<i>Gardnerella vaginalis</i>	98.3%	100%
<i>Trichomonas vaginalis</i>	92.8%	99.9%

\*Source of data: BD Affirm™ VPIII Microbial Identification Test [package insert]. Sparks, MD: BD Diagnostics; 2010.

**Specimen** **BD Affirm™ VPIII Ambient Temperature Transport System (ATTS):**  
ATTS collection kits are provided by GA. Collect vaginal specimen and prepare for transport in accordance with package instructions. Sample is stable for 72 hours at ambient temperature (15-30°C) or refrigerated (2-8°C).

**Causes for Rejection** Specimens held longer than 72 hours at ambient or refrigerated conditions may cause false results. Frozen specimens are unacceptable.

**Reference Range** Not Detected

**Detection Range**  
*Candida* species >1 x 10<sup>4</sup> CFU  
*Gardnerella vaginalis* >2 x 10<sup>5</sup> CFU  
*Trichomonas vaginalis* >5 x 10<sup>3</sup> trichomonads

**Turnaround Time** Same or next day

**CPT Codes** 87480 (*Candida*), 87510 (*Gardnerella*), 87660 (*Trichomonas*)

### Description

The BD Affirm™ VPIII Microbial Identification Test is an FDA-approved DNA probe test that simultaneously detects and identifies the three pathogens that cause up to 90% of all vaginal infections: *Candida* species, *Gardnerella vaginalis*, and *Trichomonas vaginalis*. Vaginitis 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).

### Clinical Utility

Detecting and identifying the cause of vaginitis is essential when recommending pathogen-specific drug regimens. Traditional clinical methods (e.g. pelvic exam, vaginal pH, microscopy of Gram stain and/or wet mount, amine odor test) fail to support a diagnosis in approximately 30% of symptomatic patients, and very often do not detect a mixed infection. Testing with this Vaginitis Panel is more sensitive and specific than these traditional methods, and reports only clinically significant levels of organisms.

Lowe, N.K. et al. 2009. Accuracy of the clinical diagnosis of vaginitis compared with a DNA probe laboratory standard. Am. College Obst. Gyn. 113: 89-95.

Sexually transmitted diseases treatment guidelines, 2010. *MMWR*, December 17, 2010/Vol. 59/No. RR-12, 56-63.

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