



## BVP

## Bacterial Vaginosis Panel by PCR - Qual/Quant

<b>GA Test Code</b>	<b>824</b>	
<b>Method</b>	Multiplex Real-Time Polymerase Chain Reaction (rPCR) – Qualitative/Quantitative	
<b>Specimens</b>	<p><b>G Swab®:</b> G Swab kits are provided by GA. Collect vaginal/cervical specimen with swab and place in tube with liquid media. Break-off swab (pre-scored) and seal tube for transport. Sample is stable for 30 days at room temp (15-30°C).</p> <p><b>ThinPrep:</b> 4.0 mL (2.0 mL), store and ship ambient (up to 3 months).</p> <p><b>SurePath:</b> 1.0 mL (0.5 mL), store and ship ambient (14 days).</p> <p><b>BD Affirm™ VPIII Ambient Temperature Transport System (ATTS):</b> Collect vaginal specimen and prepare/transport in accordance with package instructions. Sample is stable for 7 days ambient (15-30°C) or refrigerated (2-8°C).</p> <p><i>Note:</i> The presence of blood, mucus, some spermicidal agents, feminine powder sprays, and treatments for vaginal conditions such as yeast infection may interfere with nucleic acid test based assays.</p>	
<b>Causes for Rejection</b>	Quantity not sufficient (QNS) for analysis; time and/or temperature instructions not followed. ATTS specimens held longer than 7 days may cause false results.	
<b>Reference Range</b>	<b>All targets except <i>G. vaginalis</i></b>	Not Detected
	<b><i>Gardnerella vaginalis</i></b>	Normal
	<i>Note:</i> The detection range for <i>G. vaginalis</i> is >2 x 10 <sup>5</sup> CFU. Abnormally high levels of the bacteria are deemed clinically significant and will be reported as ELEVATED at a semi-quantitative level (e.g. <b>ELEVATED 10X Normal Level</b> ).	
<b>Turnaround Time</b>	24-48 hours	
<b>CPT Codes</b>	<b><i>Candida species</i></b>	87481
	<b><i>Candida albicans</i></b>	87481
	<b><i>Gardnerella vaginalis</i></b>	87512
	<b><i>Mycoplasma genitalium</i></b>	87563
	<b><i>Mycoplasma hominis</i></b>	87798
	<b><i>Trichomonas vaginalis</i></b>	87661
	<b><i>Ureaplasma urealyticum</i></b>	87798

### **Description**

This assay uses real-time polymerase chain reaction (rPCR) for the simultaneous and multiplex amplification and detection of the DNA of the following causative pathogens of bacterial vaginosis: *Candida species* (*C. albicans*, *C. glabrata*, *C. kefyr*; *C. krusei*, *C. parapsilosis*, *C. tropicalis*), *Candida albicans*, *Gardnerella vaginalis*, *Mycoplasma genitalium*, *Mycoplasma hominis*, *Trichomonas vaginalis*, and *Ureaplasma urealyticum*.

### **Clinical Utility**

A positive PCR result for any target indicates the presence of the respective organism in the specimen. A “not detected” result indicates that target’s DNA was below detectable levels or not present in the specimen, but it does not completely rule out infection with these or other non-target pathogens. *Gardnerella vaginalis* is considered normal vaginal flora and is only problematic if it exceeds normal levels. A semi-quantitative result indicates the severity of the infection and provides evidence that *Gardnerella vaginalis* is the causative agent of the symptoms.

Sexually transmitted diseases treatment guidelines, 2010. *MMWR*, December 17, 2010/Vol. 59/No. RR-12, 44-55.

<http://www.cdc.gov/std/trichomonas/STDFact-Trichomoniasis.htm>.

### **Genetic Assays, Inc.**

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