GENETIC ASSAYS
A Molecular Diagnostics Laboratory

BVP Bacterial Vaginosis Panel by PCR - Qual/Quant

GA Test Code	**824**
Method	Multiplex Real-Time Polymerase Chain Reaction (rPCR) – Qualitative/ Quantitative
Specimens	**eSwab®** 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). **ThinPrep**: 4.0 mL (2.0 mL), store and ship ambient (up to 3 months). **SurePath**: 1.0 mL (0.5 mL), store and ship ambient (14 days). **BD Affirm™VPIII Ambient Temperature Transport System (ATTS):** 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). *Note*: 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.
Causes for Rejection	Quantity not sufficient (QNS) for analysis; time and/or temperature instructions not followed. ATTS specimens held longer than 7 days may cause false results.
Reference Range	**All targets except *G. vaginalis*** Not Detected ***Gardnerella vaginalis*** Normal *Note:* The detection range for *G. vaginalis* is **>2 x 10^5 CFU**. Abnormally high levels of the bacteria are deemed clinically significant and will be reported as ELEVATED at a semi-quantitative level (e.g. **ELEVATED 10X Normal Level**).
Turnaround Time	24-72 hours
CPT Codes	***Candida* species** 87481 ***Candida albicans*** 87481 ***Gardnerella vaginalis*** 87512 ***Mycoplasma genitalium*** 87563 ***Mycoplasma hominis*** 87798 ***Trichomonas vaginalis*** 87661 ***Ureaplasma urealyticum*** 87798

Description

This test was developed and its performance characteristics determined by Genetic Assays. It has not been cleared nor approved by the U.S. FDA. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. Genetic Assays is certified under CLIA as qualified to perform high-complexity testing.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.

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