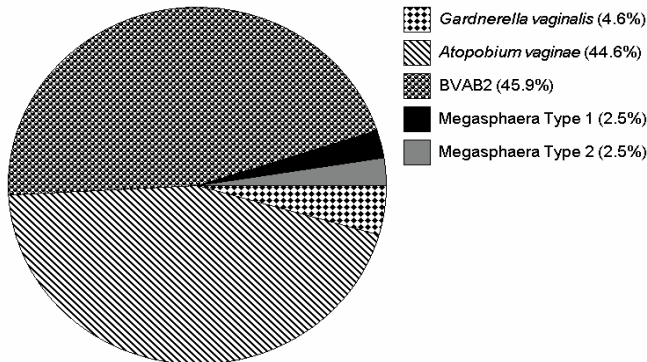


MEDICAL DIAGNOSTIC LABORATORIES, L.L.C.

INTERPRETATION GUIDELINES



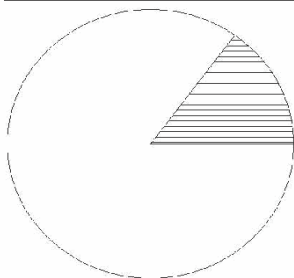
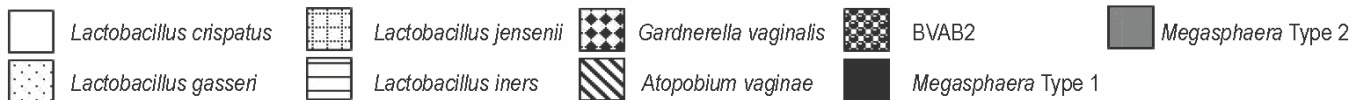
Bacterial Vaginosis Panel (with Lactobacillus Profiling) by Quantitative Real-Time PCR

MDL#: **3457157-1**

METHODOLOGY: Quantitative Real-Time PCR is used to measure the number of copies of various bacteria within a specimen.

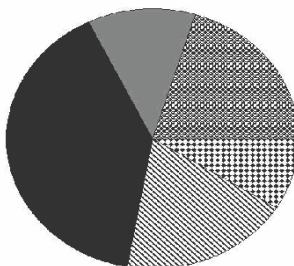
Patient's results: Relative concentrations of the following microbial DNAs indicated at left were identified by MDL's qPCR Bacterial Vaginosis Panel:

Indicative of Abnormal microflora.
Suggestive of Bacterial Vaginosis.



Normal vaginal microflora. Not Suggestive of Bacterial Vaginosis.

The healthy human vagina is dominated by lactobacilli. *L. crispatus*, *L. gasseri*, *L. jensenii*, and *L. iners* are four major vaginal *Lactobacillus* species. Usually the vaginal flora is dominated by one or, less frequently, two major *Lactobacillus* species. Lactobacilli support a healthy vaginal microenvironment by producing hydrogen peroxide, generating acidic pH, and protecting against colonization by other microbial pathogens. In general, *L. crispatus*, *L. gasseri*, and *L. jensenii* are described as members of the healthy vaginal microflora. Dominance of any of these three species suggests that vaginal microbial conditions are normal. Vaginal microflora might contain certain amounts of other bacteria such as *L. iners* and/or *Gardnerella vaginalis* which can be present in both normal and transitional microflora.



Abnormal vaginal microflora. Suggestive of Bacterial Vaginosis.

The composition of the vaginal microflora is not static but changes over time in response to various endogenous and exogenous influences. The most common alteration in vaginal microflora is a condition named Bacterial Vaginosis (BV). BV is a disorder characterized by a replacement of healthy lactobacilli by anaerobic bacteria in the vagina. Overgrowth of such bacterial species as *Gardnerella vaginalis*, *Atopobium vaginae*, *Megasphaera* spp., and BVAB2 is indicative of BV. The presence of these microorganisms along with a depletion of the protective *Lactobacillus* species (*L. crispatus*, *L. gasseri*, and *L. jensenii*) suggests that vaginal microbial conditions are abnormal. BV increases the risk of genital tract and sexually transmitted infections and can also cause serious pregnancy complications including miscarriage and preterm birth.

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This test was developed and its performance characteristics determined by this laboratory. It has not been cleared or approved by the Food and Drug Administration (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. The laboratory is regulated by the Clinical Laboratory Improvement Act of 1988.

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7/20/2011
Final