


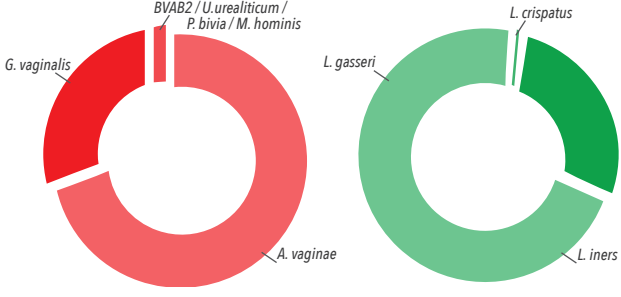


## A more objective comprehensive molecular diagnostic solution for symptoms relating to vaginal infections<sup>1</sup>

- Approximately 30% of women of childbearing age have bacterial vaginosis (BV)<sup>2</sup>
- 84% of women with BV report **no** symptoms<sup>2</sup>
- Detection of BV-associated organisms is associated with antimicrobial resistance and might be predictive of risk for subsequent treatment failure<sup>3,4</sup>

HEALTH RISKS OF BV AND RECURRENT BV	VAGINITIS SCREENING SPECIFICATIONS		
BV is linked to a wide variety of serious upper genital tract infections and pregnancy complications, including: <sup>5,6,7,8,9</sup>			
<p style="text-align: center;">Infertility</p> <p style="text-align: center;">Pelvic inflammatory disease</p> <p style="text-align: center;">Amniotic fluid infection</p> <p style="text-align: center;">Chorioamnionitis</p> <p style="text-align: center;">Preterm delivery</p> <p style="text-align: center;">Endometritis</p> <p style="text-align: center;">Post-Cesarean delivery wound infection</p> <p style="text-align: center;">Post-hysterectomy infection</p>	<b>Reliably detect BV status</b>	<b>Differentiates pathogens for optimal, personalized treatment</b>	<b>Interpret results easily</b>
	Molecular identification is a more reliable way to diagnose BV. Compared to Nugent score and Amsel criteria there is a 100% sensitivity and 93% specificity. <sup>10</sup>	Comprehensive panel allows for diagnosis the first time.	Simple diagnostic report offers treatment guidance recommended by the AMA.

TEST: BACTERIAL VAGINOSIS MOLECULAR ASSAY														
Results	Pathogenic Bacteria Detected													
Diagnosis	Positive for Bacterial Vaginosis													
Interpretation	The pattern of pathogenic and normal bacterial flora suggests bacterial vaginosis.													
Treatment Options*	<p style="text-align: center;">Bacterial Vaginosis:</p> <p style="text-align: center;">Metronidazole 250 mg orally three times daily for seven days OR</p> <p style="text-align: center;">Metronidazole 500 mg orally twice daily OR</p> <p style="text-align: center;">Clindamycin 300 mg orally twice daily for seven days.</p> <p style="text-align: center;">Note that the CDC states that "Although older studies indicated a possible link between use of vaginal clindamycin during pregnancy and adverse outcomes for the newborn, newer data demonstrate that this treatment approach is safe for pregnant women."</p> <p style="text-align: center;">Consider additional options if history of recurrent BV infection.</p>													
	M. hominis	Megasphaera type 2	P. bivia	M. curtisii	Megasphaera type 1	M. mulieris	BVAB2	U.urealiticum	G. vaginalis	A. vaginae	L. gasseri	L. crispatus	L. jensenii	L. iners
	+	-	+	-	-	-	+	+	+	+	+	+	-	+
	Pathogenic										Non-Pathogenic			
	<b>RELATIVE BACTERIA QUANTITIES</b>													
														

\* Treatment options are based on general recommendations from the AMA and are not intended to be prescriptive for this patient. Appropriate medical judgment should be exercised by the attending physician before prescribing a course of treatment.

### QUALITY & CONVENIENT TESTING

Our molecular assay identifies multiple pathogens from a single-swab sample, and our panels allow for tailored selection and subsequent treatment recommendations depending on results:

Panel	Indication	Pathogens tested	Comprehensive
Bacterial Vaginosis	For new clinical presentation or suspicion of bacterial vaginosis pathogens – the most common vaginal infection in women aged 15-44 <sup>11</sup> this panel tests the most commonly associated pathogens	<i>Atopobium vaginae</i> , BVAB2, <i>Gardnerella vaginalis</i> , <i>Lactobacillus</i> -4 species, <i>Megasphaera species 1</i> , <i>Megasphaera species 2</i> , <i>Mobiluncus curtisii</i> , <i>Mobiluncus mulieris</i> , <i>Mycoplasma hominis</i> , <i>Prevotella bivia</i> , <i>Ureaplasma urealyticum</i>	✓
BV recurrent	For recurrent BV cases, or in cases of failed BV treatment, this additional panel tests rare pathogens associated with aerobic vaginitis which is sparsely populated by one or two enteric commensal flora bacteria <sup>12</sup>	<i>Enterococcus faecalis</i> , <i>Escherichia coli</i> , <i>Staphylococcus aureus</i> , <i>Streptococcus agalactiae</i>	✓
Prenatal	Confirm vaginal health pre-conception and/or within first trimester to mitigate conditions associated with low birth weight, miscarriage, and pre-term birth <sup>13</sup>	<i>Atopobium vaginae</i> , <i>Bacteroides fragilis</i> , BVAB2, <i>Candida albicans</i> and species of non-albicans, <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> , <i>Gardnerella vaginalis</i> , <i>Lactobacillus</i> species, <i>Megasphaera species 1</i> , <i>Megasphaera species 2</i> , <i>Mobiluncus curtisii</i> , <i>Mobiluncus mulieris</i> , <i>Mycoplasma genitalium</i> , <i>Mycoplasma hominis</i> , <i>Prevotella bivia</i> , <i>Trichomonas vaginalis</i> , <i>Ureaplasma urealyticum</i>	
Yeast	For clinical presentation or suspicion of Candidiasis	<i>Candida albicans</i> and 6 species of non-albicans	✓
STI (à la carte)	For clinical presentation or suspicion of STI. The US has reached the highest level of STIs <sup>14</sup>	<i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> , <i>Trichomonas vaginalis</i> , <i>Mycoplasma genitalium</i>	✓

### TEST REQUIRING SEPARATE SWAB

Panel	Indication	Pathogens tested	Comprehensive
Genital ulcers	For clinical presentation of genital ulcers	<i>Haemophilus ducreyi</i> , <i>Herpes simplex 1</i> , <i>Herpes simplex 2</i> , <i>Treponema pallidum</i>	

### TURN AROUND TIME

24-48 hours






### RESULTS & GENETIC COUNSELOR SUPPORT FOR PROVIDERS

All positive results, and select negative results, may require additional testing due to patient history. These results will be reported to the provider by our dedicated Certified Genetic Counselor with maternal/fetal and infectious disease expertise, who can provide a comprehensive risk assessment and offer helpful resources.

**References:** 1. PMID: 26911864 2. PMID: 17621244 3. PMID: 16941351 4. PMID: 27431434 5. PMID: 19833694 6. PMID: 26671889 7. PMID: 15472851 8. PMID: 8906013 9. PMID: 1988895 10. PMID: 20814710 11. CDC fact sheet. <https://www.cdc.gov/std/bv/bv-fact-sheet-dec-2016.pdf>. Published December 02, 2016. Accessed February 03, 2017 12. PMID: 21668769 13. PMID: 25677078 14. CDC. 2015 STD surveillance reports press release <https://www.cdc.gov/nchhstp/newsroom/2016/std-surveillance-report-2015-press-release.html> Published October 19, 2016. Accessed February 05, 2017.

### ABOUT PREMIER GENOMICS

Premier Genomics is committed to advancing the field of personalized genetic medicine by offering cutting-edge genetic screening services to help practitioners and their patients in pursuit of tailored treatment and optimized, personalized health care. We work together with patients and their insurance providers to help ensure that access to these important genetic tests does not cause patients financial hardship.

 Specification	 Clinical Relevance	 Premier Genomics Vaginitis Panel	 NuSwab®	 Affirm™
DNA based	Reliably detect BV status	Yes	Yes	Yes
Only 1 swab needed	Ease of use	Yes	Yes	Yes
Yeast species tested	Greater number of species, increased sensitivity	7	6	1
BV pathogens tested	Increased pathogens indicate an increased ability to detect an imbalance	14	3	1
Trichomonas Detection	Sexually transmitted infection (parasite)	Yes	Yes	Yes
Mycoplasma profile pathogens	Causative agent of BV, harder to treat	3	3	0
Number of STIs tested	Sexually transmitted diseases	4 (plus 4 genital ulcers)	2 (plus 2 genital ulcers)	1
Total number of pathogens able to be detected using a single swab	All patients do not present with same pathogens	30	15	3
AMA Treatment options provided	This information will be available in the report	Yes	No	No

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If you have questions please call our infectious disease team at 1-888-416-8118