

GenviewDx Women's Reproductive Health

Bacterial or Candida-based vaginal infections are among the most common reasons for which women in the United States seek medical care—resulting: a) up to 75% of women face some kind of vaginal infection in their life-time, and b) in approximately 10 million visits to physician offices annually (references 1 to 4). However, 40% of women with vaginitis leave a first medical visit undiagnosed (reference 7). Vaginitis is caused by the imbalance of good Lactobacilli and vaginitis-causing pathogens (aerobic bacteria, bacterial vaginitis and candida-based infections).

Traditional microscopic diagnostic techniques tend to be subjective with variable sensitivity and specificity (references 2, 5 and 6) and lack the precision needed for accurate identification, especially in mixed infection scenarios. This lack of sensitivity potentially leads to continued symptoms, repeat visits, inappropriate treatment, poor antimicrobial stewardship and unnecessary associated healthcare system costs (references 1, 7 and 8). The GenviewDx women's health panel is a highly sensitive real-time polymerase chain reaction (PCR) assay that identifies the 3 most common infectious causes of vaginitis: Bacterial vaginosis (aerobic vaginitis caused by aerobic and enteric bacteria that show increased pH and redness, and general bacterial vaginitis is caused by the overgrowth of pathogenic bacteria over good bacteria), vulvovaginal candidiasis and trichomoniasis.

GenviewDx PCR test can maximize efficiency with one-collection/one-test for the 3 most common infectious causes of vaginitis (Bacterial vaginosis, vulvovaginal candidiasis and trichomoniasis) and supports antimicrobial resistance initiatives by reporting antibiotic resistance genes. GenviewDx also offers real-time PCR using a variety of specimen types including urine and female endocervical/vaginal swabs.



References:

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4. Workowski KA et al; Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2015. MMWR Recomm Rep. 2015;64(RR-03):1-137.
5. Gutman RE et al. Evaluation of clinical methods for diagnosing bacterial vaginosis. Obstet Gynecol. 2005;105(3):551-556.
6. Menard JP et al. Molecular quantification of Gardnerella vaginalis and Atopobium vaginae loads to predict bacterial vaginosis. Clin Infect Dis. 2008;47(1):33-43.
7. Carr PL et al. "Shotgun" versus sequential testing. Cost-effectiveness of diagnostic strategies for vaginitis. JGIM. 2005;793-799.
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GenviewDx - Women Health Panel

Atopobium vaginae

Bacteroides fragilis

Bacterial Vaginosis-Associated Bacterium 2

Chlamydia trachomatis

Enterococcus faecalis

Escherichia coli

Gardnerella vaginalis

Lactobacillus crispatus

Lactobacillus gasseri

Lactobacillus iners

Lactobacillus jensenii

Megasphaera 1

Megasphaera 2

Mobiluncus curtisii

Mobiluncus mulieris

Mycoplasma genitalium

Mycoplasma hominis

Neisseria gonorrhoeae

Prevotella bivia

Staphylococcus aureus

Streptococcus agalactiae

Treponema pallidum

Ureaplasma urealyticum

Candida albicans

Candida glabrata

Candida krusei

Candida lusitanae

Candida parapsilosis

Candida tropicalis

Trichomonas vaginalis

Herpes simplex virus 1

Herpes simplex virus 2

HPV 16, HPV 18

HPV 31, HPV 33, HPV 35, HPV 39

HPV 52, HPV 59, HPV 66, HPV 68

HPV 45, HPV 51, HPV 58, HPV 56

HPV 6 and HPV 11

GenviewDX

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The ABC's of Vaginal Health...



A

Aerobic Vaginitis (AV)

- Group B Streptococcus (GBS)
- *Staphylococcus aureus*
- *Escherichia coli*
- *Enterococcus faecalis*

B

Bacterial Vaginosis (BV)

- *Atopobium vaginae*
- Bacterial Vaginosis Associated Bacterium 2 (BVAB2)
- *Gardnerella vaginalis*
- *Megasphaera species* (Type 1 and Type 2)
- Lactobacillus Profiling by qPCR

Considered Medically Necessary by the CDC and Aetna for the Management of Vaginitis and the Diagnosis of Bacterial Vaginosis in Symptomatic Women^{1, 2}

C

Candida Vaginitis (CV)

- *Candida albicans*
- *Candida glabrata*
- *Candida krusei*
- *Candida parapsilosis*
- *Candida tropicalis*

**Fluconazole
Resistance
Testing Available**

Diagnostic Advantages...

- One vial, multiple pathogens
- DNA amplification via PCR technology
- Microbial drug resistance profiling
- High precision robotic accuracy
- High diagnostic sensitivity & specificity
- Specimen viability up to 5 days after collection
- Test additions available up to 30 days after collection
- No refrigeration required before or after collection
- Blood and excess mucus will not affect results



References:

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AV IS NOT BV

A Comparison of Bacterial Vaginosis and Aerobic Vaginitis

Clinical Characteristics	Bacterial Vaginosis	Aerobic Vaginitis (1)
Lactobacilli	Displaced	Displaced
Pathogen	<i>Gardnerella vaginalis</i> , <i>Atopobium vaginae</i> , <i>Megasphaera</i> species, BVAB2	<i>Escherichia coli</i> , Group B Streptococcus, <i>Staphylococcus aureus</i> , <i>Enterococcus faecalis</i>
Vaginal epithelial inflammation	None	Present
Elevation of pro-inflammatory cytokines (IL-1 β , IL-6, IL-8)	Moderate elevation	High elevation
Immune reaction (cytotoxic leukocyte)	Non-reactive	Reactive
pH [Normal = 3.8 – 4.2]	T= 4.2-4.5 BV \geq 4.5	> 4.5; usually >6
Shed vaginal epithelial cells	Clue cells	Parabasal cells
Vaginal discharge characteristic	White, homogenous	Yellowish
10% KOH Whiff Test (fishy amine odor)	Positive	Negative
Treatment	Metronidazole ^b Clindamycin ^b	Kanamycin ovule. (1) 2% clindamycin topical. (2) Fluoroquinolones are reported to have clinical success. (1) GBS is uniformly sensitive to penicillin, ampicillin, amoxicillin, amoxicillin/ clavulanic acid. (3) <i>E. faecalis</i> is traditionally treated with ampicillin. (4)

Fluoroquinolones, such as ciprofloxacin, ofloxacin, and levofloxacin, are contraindicated in pregnant women. Levofloxacin has improved efficacy against Streptococci compared to ciprofloxacin. T= Transitional.

References:

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2. Sobel JD, Reichman O, Misra D, Yoo W. 2011. Prognosis and Treatment of Desquamative Inflammatory Vaginitis. *Obstet Gynecol* 117: 850-855.
3. Tempera G, Bonfiglio G, Comparata E, Corsello S, Cianci A. 2004. Microbiological/clinical characteristics and validation of topical therapy with kanamycin in aerobic vaginitis: a pilot study. *Int J Antimicrob Agents* 24: 85-88.
4. Tempera G, Furneri PM. 2010. Management of Aerobic Vaginitis. *Gynecol Obstet Invest* 70: 244-249.

