

## Vaginitis Pathogens Molecular Testing Panel

The most common causes of infectious vaginitis are bacterial vaginosis (BV), candida vaginitis (CV), and trichomoniasis (TV). Vaginitis is one of the most frequent reasons women seek medical care, with an estimated 70% of patients diagnosed with bacterial vaginosis, CV/vulvovaginal candidiasis (VVC), or trichomoniasis (sexually transmitted).<sup>1</sup> Women with trichomoniasis or bacterial vaginosis are at a greater risk of acquiring HIV and other sexually transmitted infections such as chlamydia, gonorrhea, and herpes simplex virus (HSV). Premature deliveries and infants with low birth weight have been associated with symptomatic bacterial vaginosis and trichomoniasis in pregnant women. Diagnosis can be especially complicated due to the prevalence of coinfections.

### Disease Overview

#### Incidence

BV is the most common cause of vulvovaginitis in women ages 15-44, implicated in 40-50% of vaginitis cases. The prevalence in the United States is estimated to be 21.2 million (29.2%) among women ages 14-49.

CV or VVC accounts for 20% to 25% of cases in the United States, while TV accounts for 15% to 20%.<sup>2</sup>

#### Symptoms

Typical symptoms of infectious vaginitis include pruritus, vaginal soreness, dyspareunia, external dysuria, odor, and abnormal vaginal discharge. These symptoms may be nonspecific.

### Test Interpretation

Sensitivity and Specificity <sup>a</sup>		
Component	Sensitivity	Specificity
BV	95.0%	89.6%
<i>Candida</i> species group	91.7%	94.9%
<i>C. glabrata</i>	84.7%	99.1%
<i>T. vaginalis</i>	96.5%	95.1%

<sup>a</sup>Based on a multicenter trial study using clinician-collected samples.

Source: Hologic, Aptima BV assay<sup>3</sup>; Hologic, Aptima CV/TV assay<sup>4</sup>

### Tests to Consider

#### Bacterial Vaginosis by TMA 3002582

**Method:** Qualitative Transcription-Mediated Amplification

Aids in the diagnosis of bacterial vaginosis by detection of *Lactobacillus* (*L. gasseri*, *L. crispatus*, and *L. jensenii*), *Gardnerella vaginalis*, and *Atopobium vaginae*

#### Candida glabrata, Candida species, and Trichomonas vaginalis by TMA 3002583

**Method:** Qualitative Transcription-Mediated Amplification

Aids in the diagnosis of vulvovaginal candidiasis and trichomoniasis by detection of *Trichomonas vaginalis*, *Candida glabrata*, and other *Candida* species (*C. albicans*, *C. parapsilosis*, *C. dubliniensis*, and *C. tropicalis*)

#### Vaginitis Panel by TMA 3002581

**Method:** Qualitative Transcription-Mediated Amplification

- Aids in the diagnosis of bacterial vaginosis, vulvovaginal candidiasis, and trichomoniasis
- Components include *Lactobacillus* (*L. gasseri*, *L. crispatus*, and *L. jensenii*), *Gardnerella vaginalis*, *Atopobium vaginae*, *Trichomonas vaginalis*, *Candida glabrata*, and other *Candida* species (*C. albicans*, *C. parapsilosis*, *C. dubliniensis*, and *C. tropicalis*)

#### Related Tests

#### Trichomonas vaginalis by Transcription-Mediated Amplification (TMA) 2005506

**Method:** Qualitative Transcription-Mediated Amplification

Use to detect *T. vaginalis* in various specimens

Results <sup>a</sup>	
Component	Result(s)
BV	Positive
	Negative
<i>Candida</i> species group	Detected
	Not detected
<i>C. glabrata</i>	Detected
	Not detected
<i>T. vaginalis</i>	Detected
	Not detected

<sup>a</sup>Vaginitis panel includes results for each test component.

## Limitations

- Bacterial species and *Candida* species targeted by the vaginitis assay may comprise part of the normal microbiome for a significant number of women; a positive result should be interpreted in conjunction with other clinical data available to the clinician.<sup>3,4</sup>
- A positive result is indicative of the presence of target RNA and does not necessarily indicate the presence of viable organisms.<sup>3,4</sup>
- A negative result does not preclude a possible infection.<sup>3,4</sup>
- Collection and testing of patient-collected vaginal swab specimens with the vaginitis assay is not intended to replace clinical examination.<sup>3,4</sup>
- Performance of the assay has not been evaluated in women younger than 14 years of age.<sup>3,4</sup>

## References

1. Mills BB. [Vaginitis: beyond the basics](#). *Obstet Gynecol Clin North Am.* 2017;44(2):159-177.
2. Paladine HL, Desai UA. [Vaginitis: diagnosis and treatment](#). *Am Fam Physician.* 2018;97(5):321-329.
3. Hologic. [Aptima BV assay package insert](#). [Accessed: May 2021]
4. Hologic. [Aptima CV/TV assay package insert](#). [Accessed: May 2021]

## Related Information

[Vaginitis - Bacterial Vaginosis, Vulvovaginal Candidiasis, and Trichomoniasis](#)  
[Sexually Transmitted Infections](#)  
[Herpes Simplex Virus - HSV](#)  
[Human Immunodeficiency Virus - HIV](#)

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