

HOLOGIC®

THE

Right

DETECTION.
THE FIRST TIME.

Get her back to everyday life by accurately detecting vaginitis from an objective and comprehensive method.



Aptima® BV
Assay

Aptima® CV/TV
Assay

Vaginitis is a Leading Reason for OBGYN Visits¹⁻²

Most women will experience an episode of vaginitis at least once in their lifetime.³



90% of vaginitis is caused by **Bacterial vaginosis (BV)**, ***Candida vaginitis (CV)*** and ***Trichomonas vaginalis (TV)*** infections, either individually or in combination.⁴



When symptomatic, many women resort to self-treating before visiting an HCP; however, self-diagnosis of vaginitis is not recommended.⁵

- Mixed infections and overlapping symptoms make clinical diagnosis a challenge.⁶
- 30% of symptomatic women will remain undiagnosed after clinical evaluation.⁶⁻⁷

Traditional Diagnostic Methods Lead to Misdiagnosis⁸



Bacterial Vaginosis
(Amsel Criteria)



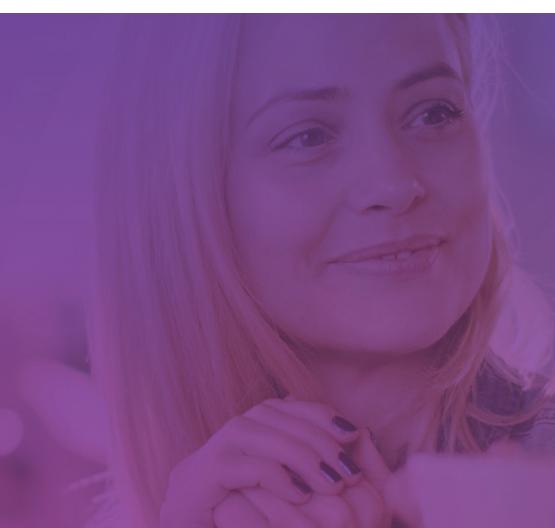
Bacterial Vaginosis
(Physical Exam)



Mixed Infection
(Microscopy)



- **37%** of women with BV are also infected with TV and/or *Candida* species.⁹
- **More than 50%** of women diagnosed with BV experience recurrent symptoms within 12 months.⁹



The Risks of Delayed Diagnosis or Misdiagnosis

Untreated BV and TV infections can lead to increased risk for complications associated with¹¹:



Acquisition of Sexually Transmitted infections (STIs) including chlamydia, gonorrhea, *Mycoplasma genitalium*, HPV and HIV.



Pelvic inflammatory Disease (PID) and cervicitis.



Pregnancy-related concerns such as premature delivery and low birth weight.

The DNA Probe Method Is Less Comprehensive, Less Sensitive, and Lacks Specificity

	BV	TV	CV
DNA Probe Method	<ul style="list-style-type: none">BV is 90.1% sensitive and only 67% specific resulting in a high number of false positives.¹²The detection of only <i>G. vaginalis</i> is not a specific marker for BV thus it cannot be used to diagnose BV.¹³ACOG does not currently support DNA probe method for diagnosis of BV.¹⁴	<ul style="list-style-type: none">TV sensitivity is 46% resulting in underdiagnosis of TV.¹²CDC and ACOG do not currently support DNA probe method for diagnosis of TV.^{11,14}	<ul style="list-style-type: none">Does not speciate <i>Candida</i>.¹⁴Only 58% sensitive for <i>Candida</i>.¹²
Aptima® BV, CV/TV Assays	<ul style="list-style-type: none">Aptima BV assay targets three indicators of the vaginal microbiome: <i>Lactobacillus</i>, <i>G. vaginalis</i>, and <i>A. vaginae</i>.¹⁵Aptima BV assay provides a clear diagnosis for BV with a high sensitivity of 95-97% and specificity of 86-90%.¹⁵	<ul style="list-style-type: none">Aptima TV assay has been shown to be 97% sensitive for the detection of <i>Trichomonas vaginalis</i>. As part of the Aptima CV/TV assay, the specificity range is 95-99% by collection device.^{16,17}CDC and ACOG recommend NAAT testing for diagnosis of TV.^{11,14}	<ul style="list-style-type: none">Aptima CV/TV assay qualitatively reports <i>Candida</i> species group (<i>C. albicans</i>, <i>C. tropicalis</i>, <i>C. parapsilosis</i>, and <i>C. dubliniensis</i>), <i>Candida glabrata</i>, and TV.¹⁶The Aptima CV/TV assay delivers a total of 3 positive or negative results. The CV portion of the CV/TV assay has a sensitivity of 85-93% and specificity of 91-99%.¹⁶<i>C. glabrata</i> is important to identify because it could be azole resistant, thus may require alternative treatment.¹⁴

Aptima® NAAT Assays Are More Accurate in Identifying Vaginitis Pathogens than Traditional Diagnostic Methods

Detect Up to

3X
More Infections

- Detects 3 times more mixed infection cases** than clinical diagnosis with wet mount, culture, and Amsel's criteria.¹⁸
- Detects mixed infections more frequently** than either clinical evaluation or probe testing.¹⁸
- Detects 3 times more TV infections** than wet-mount microscopy.^{11,19}

Test together. Treat differently.

	BV	TV	Candidiasis
Treatment^{*10}	<ul style="list-style-type: none"> ▶ Metronidazole ▶ Clindamycin 	<ul style="list-style-type: none"> ▶ Metronidazole 	<ul style="list-style-type: none"> ▶ Clotrimazole ▶ Miconazole ▶ Tioconazole ▶ Butoconazole ▶ Terconazole ▶ Fluconazole
Clinical Management	<ul style="list-style-type: none"> ▶ Recommend additional STI testing 	<ul style="list-style-type: none"> ▶ Recommend additional STI testing, EPT, and retest less than 3 months after initial treatment. 	<ul style="list-style-type: none"> ▶ Recommend follow-up for persistent or recurrent symptoms after treatment ▶ Consider azole resistance with <i>C. glabrata</i> call out

*Please refer to the CDC Treatment Guidelines for dosing and alternatives.

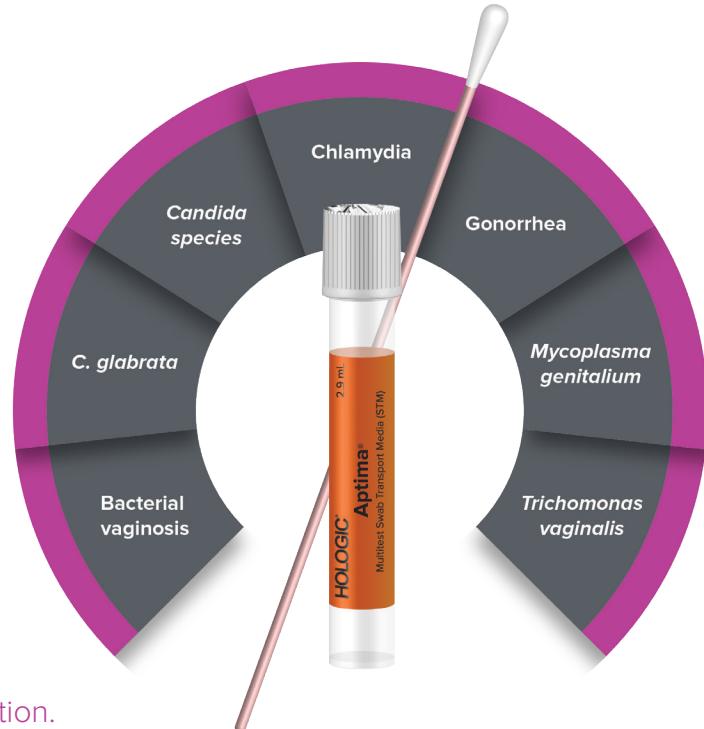
Aptima® Multitest Swab Collection Kit

**One sample. Multiple results.
Maximum efficiency.**

Detect up to **7 infections** and disease states from just one vaginal swab sample:

- ▶ Bacterial vaginosis
- ▶ *Candida* species
- ▶ *Candida glabrata*
- ▶ *Trichomonas vaginalis*
- ▶ Chlamydia
- ▶ Gonorrhea
- ▶ *Mycoplasma genitalium*

Visit HologicWomensHealth.com for more information.



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