



HOLOGIC®

The right diagnosis. The first time.

Get her back to everyday life by accurately diagnosing vaginitis with an objective and comprehensive method.

Aptima® BV
Assay

Aptima® CV/TV
Assay

Vaginitis is the Leading Reason for OBGYN Visits^{1,2}

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



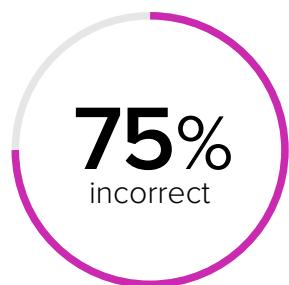
90% of vaginitis is caused by BV, *Candida* vaginitis (CV) and *Trichomonas vaginalis* (TV) infections, either individually or in combination.⁴



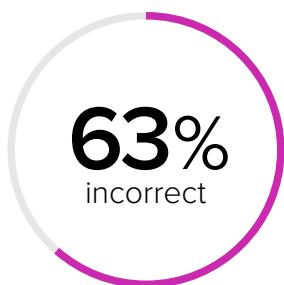
When symptomatic, many women resort to self-treating before visiting an HCP; however, self-diagnosis of common vaginitis is not recommended.

- Mixed infections and overlapping symptoms make clinical diagnosis a challenge.⁶
- 30% of symptomatic women will remain undiagnosed after clinical evaluation.^{5,6}

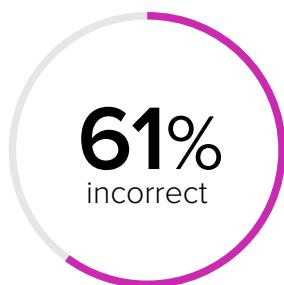
Correctness of Diagnosis in Recurrent Vaginitis⁷



Mixed Infection
(Microscopy)



Bacterial Vaginosis
(Amsel Criteria)



Bacterial Vaginosis
(Physical Exam)



- **37%** of women with BV are also infected with TV and/or *Candida* species.⁸
- **51%** of women diagnosed with BV experience recurrent symptoms within 12 months.⁹



The Risks of Delayed or Misdiagnosis

Untreated BV and TV infections can lead to increased risk for complications such as¹⁰:



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">▶ Lacks specificity resulting in overdiagnosis of BV.¹¹▶ The detection of only <i>G. vaginalis</i> is not a specific marker for BV thus it cannot be used to diagnose BV.¹²▶ ACOG does not currently support DNA probe method for diagnosis of BV.¹³	<ul style="list-style-type: none">▶ TV sensitivity is 46% resulting in underdiagnosis of TV.¹¹▶ CDC and ACOG do not currently support DNA probe method for diagnosis of TV.^{10,13}	<ul style="list-style-type: none">▶ Does not speciate <i>Candida</i>.¹³▶ <i>C. glabrata</i> is important to identify because it is azole resistant, thus requires alternative treatment.¹³▶ Only 58% specific for <i>Candida</i>.¹¹
Aptima® BV, CV/TV Assays	<ul style="list-style-type: none">▶ Aptima BV assay reports a single qualitative result for <i>Lactobacillus</i> spp., <i>G. vaginalis</i>, and <i>A. vaginalae</i>.¹⁴▶ Aptima BV assay provides a clear diagnosis for BV.	<ul style="list-style-type: none">▶ Aptima TV assay sensitivity is 100% and TV using CV/TV is 96-97%.^{15,16}▶ CDC and ACOG recommend NAAT testing for diagnosis of TV.^{10,13}	<ul style="list-style-type: none">▶ Aptima CV/TV assay speciates <i>Candida</i> spp.¹⁵▶ The Aptima CV/TV assay delivers a total of 3 positive or negative results for <i>Candida</i> species, <i>C. glabrata</i>, and TV.¹⁵

Aptima® NAAT Assays More Accurately Identify Vaginitis Pathogens than Traditional Diagnostic Methods

Detect Up to

5X
More Infections

- ▶ **Detects 3 times more mixed infection cases** than clinical diagnosis with wet mount, culture, and Amsel's criteria.¹⁷
- ▶ **Detects mixed infections more frequently** than either clinical evaluation or probe testing.¹⁷
- ▶ **Detects 3 to 5 times more TV infections** than wet-mount microscopy.¹⁰

Test together. Treat differently.

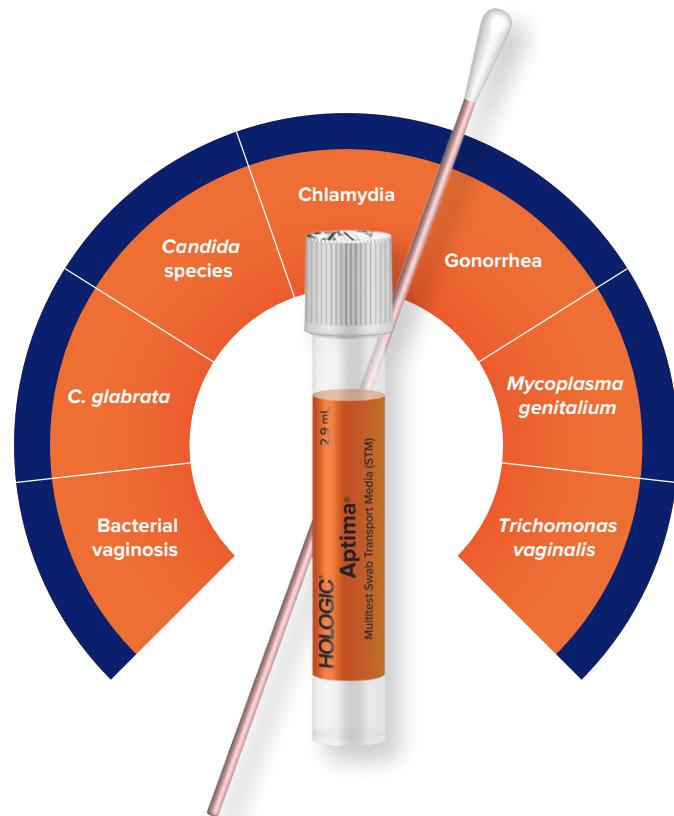
	BV	TV	Candidiasis
Treatment¹⁰	<ul style="list-style-type: none"> ▶ Metronidazole ▶ Clindamycin ▶ Secnidazole ▶ Tinidazole 	<ul style="list-style-type: none"> ▶ Metronidazole ▶ Tinidazole 	<ul style="list-style-type: none"> ▶ Clotrimazole ▶ Miconazole ▶ Tioconazole ▶ Butoconazole
Clinical Management¹⁰	<ul style="list-style-type: none"> ▶ Recommend additional STI testing 	<ul style="list-style-type: none"> ▶ Recommend additional STI testing, EPT, and retest at 3 months 	<ul style="list-style-type: none"> ▶ Consider azole resistance with <i>C. glabrata</i> call out

Aptima® Multitest Swab Collection Kit

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

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

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



Hologic.ca | Canada2@Hologic.com

References: **1.** CDC. Division of STD Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention. Bacterial Vaginosis (BV) Statistics. **2.** Schwebke JR, Taylor SN, Ackerman R, et al. Clinical Validation of the Aptima Bacterial Vaginosis and Aptima Candida/Trichomonas Vaginitis Assays: Results from a Prospective Multicenter Clinical Study. *J Clin Microbiol.* 2020 Jan;28:58(2):e01643-19. doi: 10.1128/JCM.01643-19. PMID: 31748322; PMCID: PMC6989072. **3.** Paladine HL, Desai UA. Vaginitis: Diagnosis and Treatment. *Am Fam Physician.* 2018 Mar 1;97(5):321-329. PMID: 29671516. **4.** Sobel JD. Vulvovaginitis in healthy women. *Compr Ther.* 1999 Jun-Jul;25(6-7):335-46. doi: 10.1007/BF02944280. PMID: 10470518. **5.** Hainer BL, Gibson MV. Vaginitis. *Am Fam Physician.* 2011 Apr 1;83(7):807-15. PMID: 21524046. **6.** Anderson MR, Klink K, Cohnsson A. Evaluation of vaginal complaints. *JAMA.* 2004 Mar 17;291(11):1368-79. doi: 10.1001/jama.29111368. PMID: 15026404. **7.** Schwietz A, Taras D, Rusch K, et al. Throwing the dice for the diagnosis of vaginal complaints? *Ann Clin Microbiol Antimicrob.* 2006 Feb 17;5:4. doi: 10.1186/1476-0711-5-4. PMID: 16503990; PMCID: PMC1395331. **8.** Belley-Montfort L, Lebed J, Smith B, et al. Sensitivity of the Amsel's Criteria compared to the Nugent Score in absence and in presence of *Trichomonas vaginalis* (TV) and/or *Candida* spp among women with symptomatic vaginitis/vaginosis. *Sex Transm Infect.* first published as 10.1136/sextrans-2015-052126.290 on 18 May 2015. **9.** Bradshaw CS, Morton AN, Hocking J, et al. High recurrence rates of bacterial vaginosis over the course of 12 months after oral metronidazole therapy and factors associated with recurrence. *J Infect Dis.* 2006 Jun 1;193(11):1478-86. doi: 10.1086/503780. *Epub* 2006 Apr 26. PMID: 16652274. **10.** Workowski KA, Bachmann LH, Chan PA, et al. Sexually Transmitted Infections Treatment Guidelines, 2022. *MMWR Recomm Rep.* 2021 Jul 23;70(4):1-187. doi: 10.15585/mmwr.mm7004a1. PMID: 34292926; PMCID: PMC8344968. **11.** Cartwright CP, Lemke BD, Ramachandran K, et al. Comparison of nucleic acid amplification assays with BD affirm VP III for diagnosis of vaginitis in symptomatic women. *J Clin Microbiol.* 2013 Nov;51(11):3694-9. doi: 10.1128/JCM.01537-13. *Epub* 2013 Aug 28. PMID: 23985917; PMCID: PMC3889753. **12.** Redelinghuys MJ, Geldenhuys J, Jung H, et al. Bacterial Vaginosis: Current Diagnostic Avenues and Future Opportunities. *Front Cell Infect Microbiol.* 2020 Aug 11:0354. doi: 10.3389/fcimb.2020.00354. PMID: 32850469; PMCID: PMC7431474. **13.** Vaginitis in Nonpregnant Patients: ACOG Practice Bulletin, Number 215. *Obstet Gynecol.* 2020 Jan;135(1):e1-e17. doi: 10.1097/AOG.0000000000003604. PMID: 31856123. **14.** Aptima BV Assay [package insert] #AW-1881-001_003_01, San Diego, CA; Hologic, Inc., 2020. **15.** Aptima CV/TV Assay [package insert] #AW-1881-001_004_01, San Diego, CA; Hologic, Inc., 2021. **16.** Aptima Trichomonas Assay [package insert] 503797-IFU-PI_004_01, San Diego, CA; Hologic, Inc., 2021. **17.** Schwebke JR, Gaydos CA, Nyirjesy P, et al. Performance of a Molecular Test versus Clinician Assessment of Vaginitis. *J Clin Microbiol.* 2018 May 25;56(6):e00252-18. doi: 10.1128/JCM.00252-18. PMID: 29643195; PMCID: PMC5971525.

PB-00917-CAN-EN REV.001 © 2022 Hologic, Inc. All rights reserved. Hologic, Aptima and associated logos are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries. This information is intended for medical professionals in the U.S. and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshows, it is not always possible to control where such materials appear. For specific information on what products are available for sale in a particular country, please contact your local Hologic representative.

**Aptima® BV
Assay**

**Aptima® CV/TV
Assay**