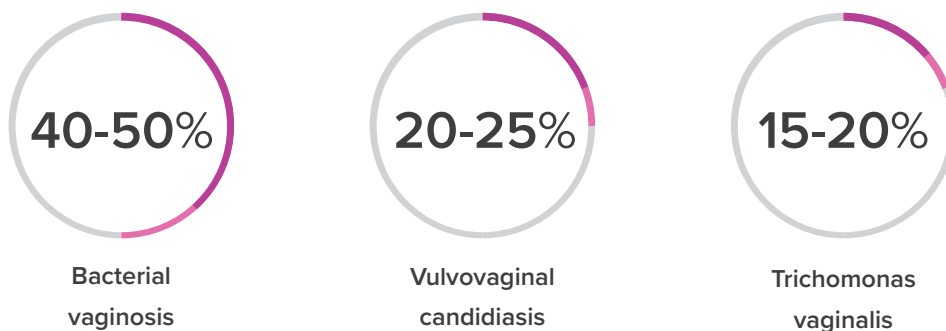


Better Understanding Vaginitis in Women

- ▶ Vaginitis is one of the most common reasons women visit their healthcare providers.¹
- ▶ Vaginitis is a general term for disorders of the vagina caused by infection, inflammation or changes in the normal vaginal flora.²
- ▶ Approximately 90% of vaginitis cases are caused by bacterial vaginosis (BV), *vulvovaginal candidiasis* (VVC) and *Trichomonas vaginalis* (TV).²

The most common causes of vaginitis²



Symptoms of the three major causes of vaginitis can vary but may include any combination of the following amongst others:³

- ▶ Increased vaginal pH
- ▶ Abnormal vaginal discharge, odour, itching or burning
- ▶ Pain during urination or sexual intercourse
- ▶ Spotting or bleeding

Vaginitis can have a significant impact on a woman's health. BV is known to recur in up to **60%** of women and has a severe impact on lifestyle, in both self-esteem and sex-life.⁴

Vaginitis is associated with STI's and other infections of the female genital tract including HIV as well as adverse reproductive outcomes in pregnant and non-pregnant women.³

Many women feel embarrassed and self-conscious of their symptoms and are often confused about why they experience recurrent vaginitis. They may become frustrated at their lack of control over their health.⁴

Bacterial vaginosis

- ▶ BV is a polymicrobial infection marked by a lack of lactic acid and hydrogen peroxide producing lactobacilli and an overgrowth of facultative anaerobic organisms.³
- ▶ Diagnostic methods include clinical criteria such as Amsel's and gram staining such as Nugent's.^{3,5,6} However, the complex microbiome makes diagnosis challenging and frequently subjective.
- ▶ The depletion of lactobacillus species combined with the presence of *Gardnerella vaginalis* or *Atopobium vaginae* at diagnostic levels are highly accurate BV predictors.⁷

Vulvovaginal candidiasis

- ▶ VVC is usually caused by *Candida albicans* but can be caused by other *Candida* species or yeasts. An estimated 75% of women will have one episode of VVC in their lifetime.⁸
- ▶ The traditional diagnostic methods for *Candida* include microscopy and culture.

Trichomoniasis vaginalis

- ▶ TV is a sexually transmitted infection caused by a single-cell protozoan parasite called *Trichomonas vaginalis*.
- ▶ It is the most common global non-viral STI being prevalent in women across a wide range of ages, peak prevalence is among women aged **46 to 55 years**.⁹
- ▶ Nucleic acid amplification testing is a highly sensitive diagnostic method detecting 3 to 5 times more infections than traditional culture and microscopy methods.¹⁰

The value of an HCP diagnosis and laboratory testing

Women frequently try to self-diagnose and self-treat vaginitis before they visit their healthcare provider assuming that the abnormal vaginal discharge, itching or irritation is due to a simple yeast infection that can be treated with over-the-counter medications.¹¹

Misidentifying infections and enabling the wrong treatment increases the potential for recurrent and persistent infections.¹² Diagnosis can be especially complicated due to the prevalence of co-infections, approximately **20-30%** of women with BV are co-infected with *Candida* species.¹³

A careful clinical history, examination and laboratory testing to determine the aetiology of the vaginal symptoms are warranted. Treatment recommendations vary between BV, *Candida* infections and TV, reinforcing the need for an accurate and objective diagnosis.¹⁴

Treatment recommendations

Infection	Treatment
Bacterial vaginosis	Treatment may include antibiotic regimens including metronidazole and clindamycin. ¹⁰
<i>Vulvovaginal candidiasis</i>	Short course topical formulations effectively treat most uncomplicated yeast infections. Antifungals such as fluconazole and clotrimazole are frequently used but <i>Candida</i> speciation is necessary for a targeted treatment as, for example, <i>C. glabrata</i> is commonly resistant to azole antifungals. ^{10,11}
<i>Trichomonas vaginalis</i>	Treatment with antibiotic regimens including metronidazole and tinidazole, as well as therapy for all sexual partners. ¹⁰

The current standard of care for BV relies on microscopic evaluation of vaginal swabs and an empiric diagnosis. This approach has shown to rely heavily on the clinicians level of training and it can often result in incorrect diagnosis and treatment.¹⁵ Given the low predictive value of current clinical practice, many women are misdiagnosed and require multiple medical appointments before reaching a resolution of their symptoms. Traditional microscopy methods for the causes of BV are labour-intensive and are subjective in nature resulting in inconsistent results.¹⁶

Testing with molecular diagnostic assays such as the Aptima® BV and Aptima CV/TV assays provide an objective, comprehensive and accurate method for diagnosing the causes of vaginitis.^{17,18} An example of the high performance of the Aptima vaginitis assays a recent study by Schwebke^{17,18} and co-workers demonstrated that the assays have a significantly higher sensitivity than clinician's diagnoses and in-clinic assessments, indicating that the molecular methods outperformed the traditional diagnostic methods.¹⁹

Clinician or patient collected vaginal swab samples collected with the Aptima Multitest Swab* Transport media can be tested directly onto the fully automated Panther® system allowing laboratories to deliver accurate results sooner and tests for several infections from a single patient sample.²⁰



Aptima[®] BV Assay Aptima[®] CV/TV Assay



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Hologic BV, Da Vincilaan 5, 1930 Zaventem, Belgium. NB number wherever applicable. EC REP details wherever applicable.

References: **1.** Kent HL. Epidemiology of Vaginitis Am J Obstet Gynecol. 1991 Oct;165(4 Pt 2):1168-76. doi: 10.1016/s0002-9378(12)90722-x. **2.** Paladine HL, Desai UA. Vaginitis: Diagnosis and Treatment. Am Fam Physician. 2018 Mar 1;97(5):321-329. **3.** Vaginitis. ACOG Practice Bulletin No. 72. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2006;107:195-206. **4.** Bilardi, JE, Walker S, Temple-Smith M, et al. The burden of bacterial vaginosis: women's experience of the physical, emotional, sexual and social impact of living with recurrent bacterial vaginosis PLoS One. 2013 Sep 11;8(9):e74378. Doi 10.1371/journal.pone.0074378. eCollection 2013. **5.** Amsel R, Totten PA, Spiegel CA et al. Nonspecific vaginitis. Diagnostic criteria and microbial and epidemiologic associations Am J Med. 1983 Jan;74(1):14-22. doi: 10.1016/0002-9343(83)91112-9. **6.** Nugent RP, Krohn MA, Hillier SL. Reliability of diagnosing bacterial vaginosis is improved by a standardized method of gram stain interpretation J Clin Microbiol. 1991 Feb;29(2):297-301. **7.** Shipitsyna E, Roos A, Datscu R et al. Composition of the vaginal microbiota in women of reproductive age—sensitive and specific molecular diagnosis of bacterial vaginosis is possible? PLoS One. 2013;8(4):e60670. **8.** Vulvovaginal Candidiasis Centers for Disease Control and Prevention. Available at <https://www.cdc.gov/std/treatment-guidelines/candidiasis.htm> Accessed February 10, 2023. **9.** Rowley J, Vander Hoorn S, Korenromp E et al. Chlamydia gonorrhoea, trichomoniasis and syphilis: global prevalence and incidence rates 2016. Bull World Health Organ 2019;97:548-562P. **10.** Sexually Transmitted Diseases Treatment Guidelines, 2015. Centers for Disease Control and Prevention. 2015;64(3). <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6403a1.htm>. Published June 5, 2015. Accessed March 14, 2023. **11.** Yano J, Sobel JD, Nyirjesy P et al. Current Patient perspectives of vulvovaginal candidiasis: incidence, symptoms, management and post-treatment outcomes. BMC women's Health 2019;19:48 **12.** 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;193(11):1478-1486. **13.** Sobel JD, Subramanian C, Foxman B, et al. Mixed vaginitis—more than coinfection and with therapeutic implications. Curr Infect Dis Rep. 2013 Apr;15(2):104-8. doi: 10.1007/s11908-013-0325-5 **14.** Sherrard J, Wilson J, Donders G et al. 2018 European (IUSTI/WHO) International Union against sexually transmitted infections (IUSTI) World Health Organisation (WHO) guideline on the management of vaginal discharge. Int J STD AIDS. 2018 Nov;29(13):1258-1272. doi: 10.1177/0956462418785451. Epub 2018 Jul 27. **15.** Schwabke JR, Gaydos CA, Nyirjesy P et al. Diagnostic Performance of a Molecular Test Versus Clinician Assessment of Vaginitis. J Clin Microbiol. 2018; 56(6). doi:10.1128/JCM.00252-18. **16.** Richter S, Otiso J, Oluwatosisin J, et al. Prospective Evaluation of Molecular Assays for Diagnosis of Vaginitis. J Clin Microbiol. 2020 Jan; 58(1): e01264-19. **17.** Aptima CV/TV assay [package insert]. AW-23713-001 Rev.001, San Diego, CA; Hologic, Inc., 2022. **18.** Aptima BV assay [package insert]. AW-23712-001 Rev.001, San Diego, CA; Hologic, Inc., 2022. **19.** Schwabke 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. J Clin Microbiol. 2020 Jan 28;58(2):e01643-19. doi: 10.1128/jcm.01643-19 Clinical Study. **20.** Panther / Panther Fusion System Operator's Manual AW-26055-001 Rev 001 San Diego, CA; Hologic, Inc., 2022.

* The Aptima Multitest Swab is from Legal Manufacturer Puritan. Hologic is not responsible for the performance of this product please refer to Puritan for any further details.

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