

Excellent Clinical Performance^{7,8}

Reported result	Sensitivity (%)	Specificity (%)
BV (clinician collected)	95.0	89.6
BV (patient collected)	97.3	85.8
Candida species (clinician collected)	91.7	94.9
Candida species (patient collected)	92.9	91.0
Candida glabrata (clinician collected)	84.7	99.1
Candida glabrata (patient collected)	86.2	98.7
TV (clinician collected)	96.5	95.1
TV (patient collected)	97.1	98.9

Reference methods: Bacterial vaginosis: Nugent score and Amsel criteria. *Candida* species & *Candida glabrata*: culture and bi-directional sequencing. *Trichomonas vaginalis*: FDA-cleared NAAT and InPouch culture

One Sample. Multiple Results. Maximum Efficiency.

Detect up to **SEVEN** infections and disease states with just one vaginal swab sample: BV, *C. species*, *C. glabrata*, TV, chlamydia, gonorrhea, and *Mycoplasma genitalium*.

Aptima®
Multitest Swab
Collection Kit



Set Your New Standard

Deliver objective, accurate vaginitis results.
Contact your Hologic representative for more information.

A New Standard
of Care
for Vaginitis Patients

References: **1.** Data on file. Vaginitis Patient Survey. Hologic, Inc., June 2019. **2.** Bradshaw CS, 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. doi.org/10.1086/503780. **3.** Anderson MR, Klink K and Cohrssen A. Evaluation of Vaginal Complaints. *JAMA.* 2004;291(11):1368–1379. doi:10.1001/jama.291.11.1368. **4.** Kent HL. Epidemiology of Vaginitis. *Am J Obstet Gynecol.* 1991;165(4, part 2):1168–1176. doi.org/10.1016/S0002-9378(12)90722-X. **5.** Sobel JD, et al. Mixed Vaginitis — More Than Coinfection and With Therapeutic Implications. *Curr Infect Dis Rep.* 2013; 15(2):104–108. **6.** Achkar J and Fries B. Candida Infections of the Genitourinary Tract. *Clin Microbiol Rev.* 2010;23(2):253–273. doi:10.1128/CMR.00076-09. **7.** Aptima BV Assay [package insert] #AW-18811, San Diego, CA; Hologic, Inc., 2019. **8.** Aptima CV/TV Assay [package insert] #AW-18812, San Diego, CA; Hologic, Inc., 2019. **9.** Schwebke JR, et al. Diagnostic Performance of a Molecular Test Versus Clinician Assessment of Vaginitis. *J Clin Microbiol.* 2018; 56. doi:10.1128/JCM.00252-18. **10.** CDC. 2015 Sexually Transmitted Diseases Treatment Guidelines. <https://www.cdc.gov/std/tg2015/trichomoniasis.htm>. Updated June 4, 2015. Accessed August 5, 2019. **11.** Shipitsyna E, 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. doi:10.1371/journal.pone.0060670. **12.** Workowski. Sexually Transmitted Diseases Treatment Guidelines, 2015. *MMWR Recomm Rep* 2015;64:70-76.

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Aptima® BV
Assay
Aptima® CV/TV
Assay

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Aptima® BV
Assay

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Assay



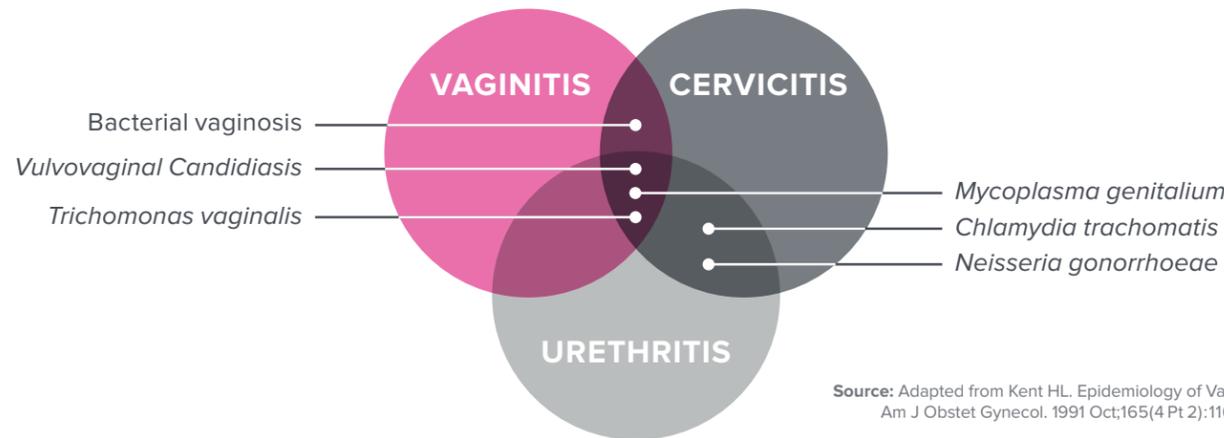
Vaginitis Is a Complex Problem With High Recurrence Rates

Over **70%** of women surveyed said that vaginitis had a significant impact on their lives—reporting high stress, discomfort and self-consciousness in their sex lives¹

More than **50%** of women diagnosed with BV experience recurrent symptoms within 12 months²

Traditional Methodologies Are Not Comprehensive, Often Missing Co-infections

Overlapping symptoms and co-infections make clinical diagnosis a challenge.³



- ▶ Up to 30% diagnosed with a BV co-infection are also co-infected with *Candida* species⁵
- ▶ Clinical diagnosis does not differentiate the common *C. albicans* from *C. glabrata*, which is present in 7-16% of yeast infections and is azole resistant⁶

Untreated BV and TV Infections Can Lead to an Increased Risk of Complications, Including:

- ▶ Sexually transmitted infections (STIs) such as **chlamydia**, **gonorrhea**, **HSV** and **HIV**^{7,8}
- ▶ **Pelvic inflammatory disease** and **cervicitis**^{7,8}
- ▶ Pregnancy-related concerns such as **premature delivery**, **low birth weight** and **pregnancy loss**^{7,8}

The Aptima FDA-Cleared Vaginitis Assays Deliver Objective, Comprehensive, Accurate Results

Aptima vaginitis NAAT (nucleic acid amplification test) assays identify bacterial vaginosis (BV), vulvovaginal candidiasis (Candida vaginitis, CV) and trichomoniasis (*Trichomonas vaginalis*, TV) in symptomatic women from one vaginal sample.^{7,8}

NAAT molecular tests detect 3x more co-infection cases than clinical diagnosis with wet mount, culture, and Amsel's criteria.⁹

3x more
Candidiasis + BV
co-infections⁹

3x more
Candidiasis + TV
co-infections⁹

4x more
BV + TV
co-infections⁹

- ▶ The Aptima BV assay reports a **single qualitative result** based on an algorithm targeting *Lactobacillus* species, *Gardnerella vaginalis*, and *Atopobium vaginae*⁷
- ▶ The Aptima CV/TV assay delivers **three positive or negative results** for *Candida* species, *C. glabrata* and Trichomoniasis. Differentiating *C. glabrata* allows appropriate selection of antifungal therapy⁸
- ▶ The CDC recommends NAAT testing for detecting *T. vaginalis* (TV)¹⁰
- ▶ NAAT testing is highly sensitive often detecting 3-5x more TV infections than wet-mount microscopy¹⁰

Test Together. Treat Differently.

	TV	Candidiasis	BV
Treatment ¹²	Metronidazole	Butoconazole Clotrimazole Miconazole Ticonazole	Metronidazole Clindamycin Tinidazole
Clinical management*	Consider additional STI testing, EPT, and retest at 3 months	Consider azole resistance with <i>C. glabrata</i> call out	Consider co-infection with <i>Candida</i> which may require different treatment

*The content in this piece is for information purposes only and is not intended to be medical advice. It is the responsibility of the treating provider to determine the appropriate course of action.

Aptima[®] BV
Assay

Aptima[®] CV/TV
Assay

“The depletion of *Lactobacillus* species combined with the presence of either *G. vaginalis* or *A. vaginae* at diagnostic levels was a highly accurate BV predictor.”

— E. SHIPITSYNA, ET AL.¹¹