



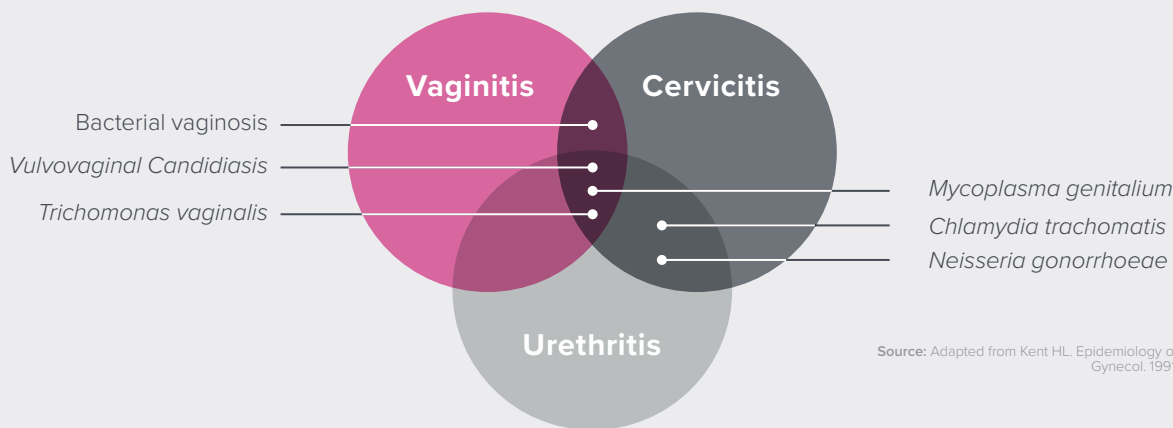
Aptima® BV and CV/TV Assays

Objective, comprehensive and accurate results for vaginitis testing.

Bacterial vaginosis (BV) is the commonest cause of abnormal vaginal discharge in woman of childbearing age.¹ More than 50% of women diagnosed with BV experience recurrent symptoms within 12 months.²

Traditional methodologies are subjective and can impact treatment pathways

- Clinical diagnosis that determines only a single pathogen is likely underdiagnosing infections that require different clinical management.³
- Clinical diagnosis does not differentiate the common *Candida albicans* from *Candida glabrata*, which is present in 7–16% of yeast infections and is azole resistant.⁴
- Additionally, overlapping symptoms and co-infections make clinical diagnosis a challenge.^{5,6}



Source: Adapted from Kent HL. Epidemiology of Vaginitis. Am J Obstet Gynecol. 1991 Oct;165(4 Pt 2):1168-76

Up to **30%** of women diagnosed with BV were co-infected with *Candida* species.⁷

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.^{8,9}
- Pelvic inflammatory disease and cervicitis.^{8,9}
- Pregnancy-related concerns such as premature delivery, low birth weight and pregnancy loss.^{8,9}

Excellent clinical performance.^{8,9}

Reported result	Sensitivity	Specificity
BV (clinician collected)	95.0%	89.6%
BV (patient collected)	97.3%	85.8%
<i>Candida species</i> (clinician collected)	91.7%	94.9%
<i>Candida species</i> (patient collected)	92.9%	91.0%
<i>Candida glabrata</i> (clinician collected)	84.7%	99.1%
<i>Candida glabrata</i> (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.

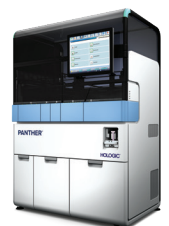
Aptima[®] assays can support any lab's growth capabilities, by offering:

- Detection of up to **SEVEN** infections and disease states with just one vaginal swab sample: BV, *Candida species*, *Candida glabrata*, TV, chlamydia, gonorrhea and *Mycoplasma genitalium*.
- Up to **FOUR** aliquots from the orange Aptima Multitest Swab Specimen Collection Kit.
- Sample-to-result workflow of the Panther[®] system.
- Platform consolidation and laboratory efficiencies on the automated and scalable Panther system.



Assay product description	Catalogue number	Kit quantity	Additional notes
Aptima BV Assay Kit	PRD-05186	100 tests	Includes 2 assay boxes, 1 calibrator kit, 1 controls kit
Aptima BV Assay Controls Kit	PRD-05187	10 tubes	Order separately as needed
Aptima BV Assay Calibrator Kit	PRD-05188	5 tubes	Order separately as needed
Aptima CV/TV Assay Kit	PRD-05189	100 tests	Includes 2 assay boxes, 1 calibrator kit, 1 controls kit
Aptima CV/TV Assay Controls Kit	PRD-05190	10 tubes	Order separately as needed
Aptima CV/TV Assay Calibrator Kit	PRD-05191	5 tubes	Order separately as needed

RUN ON
PANTHER[®]



References: 1. J.S.Jensen 2018 European (IUSTI/WHO) Guideline on the Management of Vaginal Discharge <https://www.iusti.org/regions/Europe/pdf/2018/IUSTIvaginalDischargeGuidelines2018.pdf>. Accessed Nov, 2019. 2. Bradshaw C, Morton A, 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. *Journal of Infectious Disease*. 2006 June; Volume 193, Issue 11: 1478–1486. 3. Van der pol B, Daniel G, Kodsí S, et al. Molecular-based Testing for Sexually Transmitted Infections Using Samples Previously Collected for Vaginitis Diagnosis. *Clin Infect Dis*. 2019 Feb 1; 68(3): 375-381. 4. Achkar J, and Fries B. *Clinical Microbiology Reviews*. 23(2):253-273, Fidel *Clinical Microbiology Reviews*. Jan. 1999; Vol 12. No.1. 5. Anderson MR, Klink K, Cohrssen A. Evaluation of vaginal complaints. *JAMA*. 2004;291(11):1368–79. 6. Adapted from Kent H. *Epidemiology of Vaginitis*. *Am J Obstet Gynecol*. 1991 Oct;165(4 Pt 2):1168-76 7. Sobel J, Subramanian C, Foxman B et al. Mixed Vaginitis—More Than Coinfection and With Therapeutic Implications. *Current Infectious Disease Reports*. 2013; 15:104–108. 8. Aptima BV Assay [package insert] #AW-18811, San Diego, CA; Hologic, Inc., 2019. 9. Aptima CV/TV Assay [package insert] #AW-18812, San Diego, CA; Hologic, Inc., 2019.

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