

Better diagnostics for your patients presenting with vaginitis symptoms

Comparing **advanced vaginitis NAAT testing** to DNA probe for the 3 common causes of vaginitis: bacterial vaginosis (BV), *Candida vaginitis* (CV), and *Trichomonas vaginalis* (TV).

Bacterial vaginosis

Advanced Molecular Testing

The Aptima® BV assay uses an algorithm to report a qualitative result for BV based on detection of the following organisms:

- *Lactobacillus* spp
- *Gardnerella vaginalis*
- *Atopobium vaginae*



Accurate results

with high sensitivity (95%-97%)
and specificity (86%-90%)¹

DNA probe

False positives on the order of

23%-32%

as a result of DNA probe only targeting:

- *Gardnerella vaginalis* ^{2,3}



The American College of Obstetrics and Gynecology (ACOG) has stated that, "... because a single sentinel organism has not been found that accurately identifies patients with bacterial vaginosis, the diagnostic utility of a test that identifies only a single organism (eg, *G vaginalis*)...is not currently supported."⁴

Candida vaginitis

Advanced Molecular Testing

Aptima CV assay qualitatively reports *Candida* species group (*C albicans*, *C tropicalis*, *C parapsilosis*, and *C dubliniensis*), and *Candida glabrata*⁵



Accurate results

with high sensitivity (93%-98%)
and specificity (83%-92%)⁵

DNA probe



NO separate callout for *C glabrata*⁴

58% Low sensitivity

when compared to diagnostic assays featuring nucleic acid amplification technologies (NAAT)⁶

Trichomonas vaginalis

Advanced Molecular Testing

97% Aptima TV Assay has high sensitivity and specificity (95%-99%), ensuring the provider and patient always receive an accurate result.⁷



CDC and ACOG recommend NAATs to detect TV^{4,8}

DNA probe

46% Low sensitivity

means TV is often missed or undercalled leading to false negatives⁶

Advanced diagnostic insights and flexibility for enhanced patient care

Our collection of clinically proven vaginitis assays gives you the flexibility to order the right advanced vaginitis testing for your patients.

Test Code	Test Name	Indicated Tests	CPT	Collection Device for Advanced Molecular Testing
904765	Bacterial Vaginosis (BV), TMA	Bacterial vaginosis (<i>Lactobacillus</i> spp, <i>G vaginalis</i> , <i>A vaginae</i>)	81513	 <p>Aptima Multi-Test Collection Kit Supply# 34893</p>
904766	<i>Candida</i> Vaginitis (CV), TMA	<i>Candida</i> vaginitis • <i>Candida</i> species (<i>C albicans</i> , <i>C tropicalis</i> , <i>C parapsilosis</i> , and <i>C dubliniensis</i>) • <i>Candida Glabrata</i>	87481*2	
907303	<i>Candida</i> Vaginitis (CV)/ <i>Trichomonas vaginalis</i> (TV), TMA	<i>Candida</i> vaginitis <i>Trichomonas vaginalis</i>	87481*2 87661	
804207	Bacterial Vaginosis (BV), CT/NG, TMA	Bacterial vaginosis Chlamydia Gonorrhea	81513 87491 87591	
803083	Vaginitis, TMA	Bacterial vaginosis <i>Candida</i> vaginitis <i>Trichomonas vaginalis</i>	81513 87481*2 87661	
704763	Vaginitis Plus, TMA	Bacterial vaginosis <i>Candida</i> vaginitis <i>Trichomonas vaginalis</i> Chlamydia Gonorrhea	81513 87481*2 87661 87491 87591	



Sonora Quest Laboratories Advanced Women's Health

Delivering care for all stages of a woman's life requires testing that you can rely on for the insights you need to make informed health decisions. Sonora Quest's Advanced Women's Health makes testing more actionable and accessible to support you, your patients, and your patients' families.

All components of tests can be ordered separately.

Trichomonas vaginalis RNA, Qualitative, TMA (test code 904768); Chlamydia trachomatis, Aptima, w/Reflex Conf <14 Years (test code 903150); *C. trachomatis*/N. gonorrhoeae, Aptima, w/Reflex Conf <14 Years (test code 904767); Chlamydia (CT)/N. gonorrhoeae (GC)/*Trichomonas* (TV), Aptima (test code 804211)

The CPT® codes provided are based on American Medical Association guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

References

1. Aptima BV Assay package insert #AW-18811. Hologic, Inc., 2021.
2. Richter SS, Otiso J, Goje OJ, et al. Prospective evaluation of molecular assays for diagnosis of vaginitis. *J Clin Microbiol.* 2020;58(1):e01264-19.
3. Muzny CA, et al. An Updated Conceptual Model on the Pathogenesis of Bacterial Vaginosis. *J Infect Dis.* 2019 Sep 26;220(9):1399-1405. doi: 10.1093/infdis/jiz342. PMID: 31369673; PMCID: PMC6761952.
4. Committee on Practice Bulletins—Gynecology. Vaginitis in Nonpregnant Patients: ACOG Practice Bulletin, Number 215. *Obstet Gynecol.* 2020;135(1):e1-s17.
5. Aptima CV/TV Assay package insert #AW-18812. Hologic, Inc., 2021.
6. Cartwright CP, Lembke BD, Ramachandran K, et al. Comparison of nucleic acid amplification assays with BD affirm VPIII for diagnosis of vaginitis in symptomatic women. *J Clin Microbiol.* 2013;51(11):3694-3699.
7. Aptima *Trichomonas vaginalis* Assay package insert. #503684. Hologic, Inc.; 2017.
8. CDC. 2015 Sexually transmitted diseases treatment guidelines. Updated June 4, 2015. <https://www.cdc.gov/std/tg2015/trichomoniasis.htm>. Accessed April 30, 2021

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