

# Aptima<sup>®</sup> Trichomonas Vaginalis Assay

Sense what can't be seen, test both symptomatic and asymptomatic patients - delivering up to 100% sensitivity.

In some regions, trichomoniasis is more prevalent than chlamydia and gonorrhea combined.<sup>1</sup> Because up to 80% of patients are asymptomatic, a highly sensitive assay is crucial to diagnosing and treating infections.<sup>2</sup>

## Untreated *Trichomonas vaginalis* infections can have serious health consequences<sup>3</sup>

- Adverse pregnancy outcomes, including preterm delivery and low birth weight.
- Prolonged HPV infection.
- Pelvic inflammatory disease and infertility.
- Increased risk for transmission and acquisition of HIV.

Choose the Aptima Trichomonas vaginalis assay for up to 100% detection and improved patient care.<sup>4</sup>

## Sensitivity and specificity by sample type<sup>4</sup>

Aptima Trichomonas vaginalis assay		
Specimen type	Sensitivity (95% CI) <sup>1*</sup>	Specificity (95% CI) <sup>1*</sup>
Vaginal swab	100% (96.7-100)	99.0% (97.9-99.5)
Endocervical swab	100% (96.7-100)	99.4% (98.6-99.7)
ThinPrep <sup>®</sup> Solution	100% (96.0-100)	99.6% (98.8-99.9)
Female urine	95.2% (88.4-98.1)	98.9% (97.8-99.5)

\*Score confidence interval.



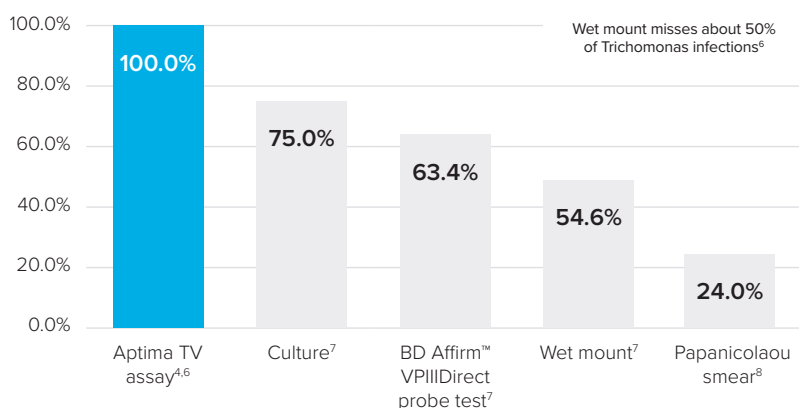
Nucleic acid amplification tests (NAATs) offer the highest sensitivity for the detection of *Trichomonas vaginalis* (TV). They should be the test of choice where resources allow and are becoming the current "gold standard." In-house PCRs have shown increased sensitivity in comparison to both microscopy and culture,<sup>31, 32, 40-51</sup> which has been found to be even greater using the commercial FDA approved platform which can detect TV DNA in vaginal or endocervical swabs and in urine samples from women and men with sensitivities of 88%-97% and specificities of 98%-99%, depending on the specimen and reference standard (Aptima TV, Hologic).<sup>28, 53-57</sup> In-house PCRs need validation before use on clinical specimens and are unlikely to be offered by many laboratories. However, the Aptima TV uses the same technology as testing for chlamydia and gonorrhoea, so that additional hardware will not be necessary and is becoming more widely available. – UK National Guideline on the Management of TV, 2014.<sup>5</sup>

## A sensitive assay for improved patient care.

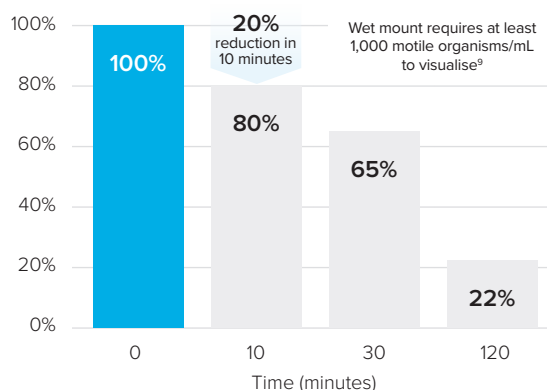
The Aptima® *Trichomonas vaginalis* assay overcomes the challenges associated with traditional, less sensitive methodologies, making it a highly reliable test to diagnose *Trichomonas* infections.<sup>4,6,7,8</sup>

- Targets rRNA with up to 100% sensitivity.<sup>4-6</sup>
- Detects as little as a fraction of 1 organism, whereas wet mount requires at least 1,000 motile organisms/mL to visualise.<sup>4,9</sup>
- Performs with an up to 47.6% improved sensitivity compared to wet mount, the most commonly used diagnostic method.<sup>10</sup>

Diagnostic sensitivity<sup>4,6,7,8</sup>



Motile organisms decrease rapidly<sup>11</sup>



*“Use of sensitive NAATS such as Aptima TV will identify additional cases and is likely to be cost effective in symptomatic patients.” – Nicholls et al. 2018<sup>12</sup>*

## One sample, multiple STI results

Multiple sample types make the Aptima *Trichomonas vaginalis* assay easy to order as a stand alone test, along with the Aptima Combo 2® assay for CT/NG, the Aptima *Mycoplasma genitalium* assay or with the ThinPrep® Pap test.\*



Aptima Multitest Swab Kit



Aptima Urine Kit



Aptima Unisex Swab Kit



ThinPrep Pap Test Vial

\*Refer to individual assay package inserts for cleared specimen types and performance claims.

RUN ON PANTHER®



**References:** 1. Centers for Disease Control and Prevention. CDC Fact Sheet: Incidence, Prevalence, and Cost of Sexually Transmitted Infections in the United States. CDC website. <http://www.cdc.gov/std/stats/sti-estimates-fact-sheet-feb-2013.pdf>. Published February 2013. Accessed January 28, 2020. 2. Kourmans E, Sternberg M, Bruce C, et al. The prevalence of bacterial vaginosis in the United States, 2001-2004; associations with symptoms, sexual behaviors, and reproductive health. *Sex Transm Dis.* 2007;34(11):864-869. 3. Chapin K, Andrea S. APTIMA *Trichomonas vaginalis*, a transcription-mediated amplification assay for detection of *Trichomonas vaginalis* in urogenital specimens. *Expert Rev Mol Diagn.* 2011;11(7):679-688. 4. Aptima *Trichomonas vaginalis* Assay package insert # 502536EN Rev. A. San Diego, CA: Hologic, Inc., 2013. 5. Sherrard J, Ison C, Moody J, et al. United Kingdom National Guideline on the Management of *Trichomonas vaginalis* 2014. *Int J STD AIDS.* 2014;25(8):541-49. 6. Andrea S, Chapin K. Comparison of Aptima *Trichomonas vaginalis* transcription-mediated amplification assay and BD Affirm VPlll for detection of *T. vaginalis* in symptomatic women: performance parameters and epidemiological implications. *J Clin Microbiol.* 2011;49(3):866-869. 7. Nye M, Schwabke J, Body B. Comparison of APTIMA *Trichomonas vaginalis* transcription-mediated amplification to wet mount microscopy, culture, and polymerase chain reaction for diagnosis of trichomoniasis in men and women. *Am J Obstet Gynecol.* 2009;200(2):188.e1-188.e7. 8. Wendel K, Erbeling E, Gaydos C, et al. *Trichomonas vaginalis* polymerase chain reaction compared with standard diagnostic and therapeutic protocols for detection and treatment of vaginal trichomoniasis. *Clin Infect Dis.* 2002;35(5):576-580. 9. Lee J, Moon H, Lee T, et al. PCR for diagnosis of male *Trichomonas vaginalis* infection with chronic prostatitis and urethritis. *Korean J Parasitol.* 2012;50(2):157-159. 10. Huppert J, Mortensen J, Reed J, et al. Rapid antigen testing compares favorably with transcription-mediated amplification assay for the detection of *Trichomonas vaginalis* in young women. *Clin Infect Dis.* 2007;45(2):194-198. 11. Kingston MA, Bansal D, Carlin EM. “Shelf life” of *Trichomonas vaginalis*. *Int J STD AIDS.* 2003;14(1):28-29. 12. Nicholls J, Turner K, North P, et al. Cross-sectional study to evaluate *Trichomonas vaginalis* positivity in women tested for *Neisseria gonorrhoea* and *Chlamydia trachomatis*, attending genitourinary medicine and primary care clinics in Bristol, South West England. *Sex Transm Infect.* 2018;94:93-99.