HOLOGIC
The Science of Sure

Sense what can't be seen.

The Aptima® Trichomonas vaginalis assay is the first nucleic acid amplification test (NAAT) cleared by the FDA and CE marked to test both symptomatic and asymptomatic patients—delivering up to 100% sensitivity, detecting infections missed by traditional methods and improving patients' care.

In some regions, trichomoniasis is more prevalent than chlamydia and gonorrhea combined[1]

Because up to 80% of patients are asymptomatic, a highly sensitive assay is crucial to diagnosing and treating infections.[2]

Untreated *Trichomonas vaginalis* infections can have serious health consequences[3]

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

Choose the Aptima Trichomonas vaginalis assay for up to 100% detection and improved patient care[4]

Sensitivity and Specificity by Sample Type[4]

Aptima *Trichomonas vaginalis* Assay

Specimen Type	Sensitivity (95% CI)[1,*]	Specificity (95% CI)[1,*]
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® 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.

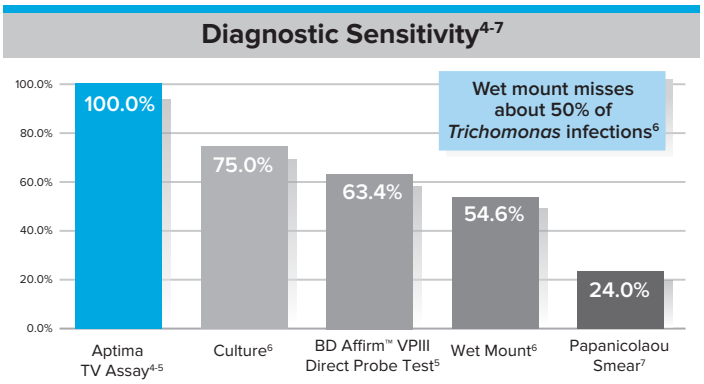
Nucleic acid amplification tests (NAATs) offer the highest sensitivity for the detection of Trichomonas vaginalis (TV). They should be the test of choice where resources allow and are becoming the current "gold standard." In-house PCRs have shown increased sensitivity in comparison to both microscopy and culture[31, 32, 40-51], 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)[28, 53-57]. 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.

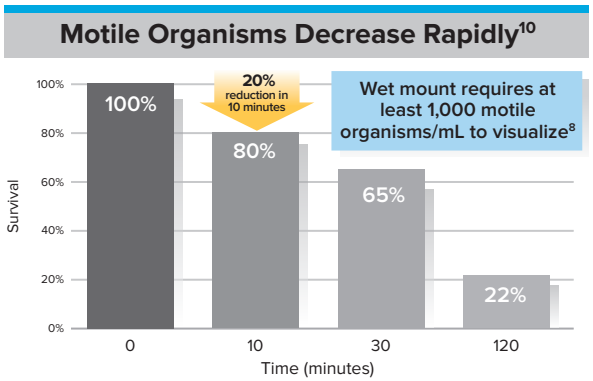
UK National Guideline on the Management of TV, 2014

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.[4-7]

- Targets rRNA with up to 100% sensitivity.[4-5]
- Detects as little as a fraction of 1 organism, whereas wet mount requires at least 1,000 motile organisms/mL to visualize.[4,8]
- Performs with an up to 47.6% improved sensitivity compared to wet mount, the most commonly used diagnostic method.[9]





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.

Diagnostic Solutions | Hologic.ca | info-canada@hologic.com

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 March 24, 2015. **2.** Koumans EH, 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 Trichonomas 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.** Andrea SB, Chapin KC. Comparison of Aptima Trichonomas vaginalis transcription-mediated amplification assay and BD Affirm VPIII for detection of T. vaginalis in symptomatic women: performance parameters and epidemiological implications. *J Clin Microbiol.* 2011;49(3):866-869. **6.** Nye MB, Schwebke JR, Body BA. Comparison of APTIMA Trichonomas 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. **7.** Wendel KA, Erbelding EJ, Gaydos CA, Rompalo AM. *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. **8.** Lee JJ, Moon HS, Lee TY, Hwang HS, Ahn MH, Ryu JS. PCR for diagnosis of male *Trichomonas vaginalis* infection with chronic prostatitis and urethritis. *Korean J Parasitol.* 2012;50(2):157-159. **9.** Huppert JS, Mortensen JE, Reed JL, et al. Rapid antigen testing compares favorably with transcription-mediated amplification assay for the detection of Trichonomas vaginalis in young women. *Clin Infect Dis.* 2007;45(2):194-198. **10.** Kingston MA, Bansal D, Carlin EM. "Shelf life" of *Trichomonas vaginalis*. *Int J STD AIDS.* 2003;14(1):28-29.

Aptima® Trichomonas vaginalis Assay