



Women's Health

Sexually Transmitted Infection Testing

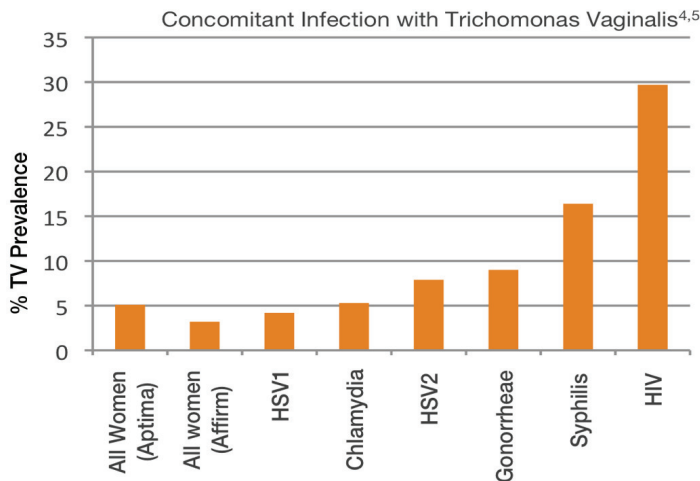
Accurate and Complete Diagnosis of Vaginitis

With increasing rates of infections, timely treatment is essential to minimize disease spread and eliminate symptoms. Trichomonas Vaginalis (TV) is associated with adverse pregnancy outcome and facilitates the sexual transmission of HIV infection.

Pregnant women with a sexually transmitted infection (STI), including TV infection, may result in premature or low birth weight. Symptoms and final diagnosis do not always correlate and treatment may not resolve symptoms.³

Trichomonas Vaginalis is Underestimated

- Available methodologies to date indicate a 3.2% prevalence rate.⁵
- Vaginitis symptoms or suggestive history of STI and the Gen-Probe APTIMA® assay for Trichomoniasis detected a prevalence of 5.1% in a current study of 766 patients.⁴
- Trichomonas vaginalis is primarily asymptomatic and associated with concurrent STIs in the general population.⁵



More Options for HPV and Cervical Cancer

With the availability of HPV Genotyping, disease progression is better predicted, options for follow up and colposcopy are assessed earlier and unnecessary procedures can ultimately be minimized.

MPLN has a Complete Menu for STI

HPV, Cervical Cancer	
Human papillomavirus Hybrid Capture II high risk assay (HPV HR) HPV Genotyping 16/18 (HPV G)	
STI Testing	
Tri-Screen Leukorrhea Profile	Chlamydia trachomatis (CT) Neisseria gonorrhoeae (NG) Trichomonas vaginalis (TV)
Herpes Simplex Virus Type 1 and 2 (HSV)	
Blood Based Infectious Disease Assays	
Human Immunodeficiency Virus Quantitative (HIV) Hepatitis C Virus RNA Quantitative (HCV Q) Hepatitis C Virus Genotyping (HCV G)	

Molecular Diagnostic Experts in STI Testing

MPLN has been offering a molecular diagnostic approach to HPV, CT, NG and HSV testing for more than two decades. In addition, because MPLN is involved in new platforms and assays for in vitro diagnostic approval, the laboratory has access to the latest advances and can share innovative technologies with clients.

A Partner Program To Support Your Business

MPLN is a leader in molecular diagnostics (MDx) and STI testing and understands complex technologies and the performance demands of clinicians.

Our Partner Program offers academic, clinical and business expertise in MDx referral testing, consulting and management services as well as regional partnerships to help grow your business.

Stay Ahead of Diagnostic Advances

Staying one step ahead of ever-changing diagnostic advances can be time consuming and complex. Let MPLN do it for you. We have the knowledge, experience and talent to help you better serve your clients and your business by expanding your portfolio of specialized tests.

For more information contact a technical service representative at 800.932.2943.



Trichomonas Vaginalis Aptima – Gen-Probe

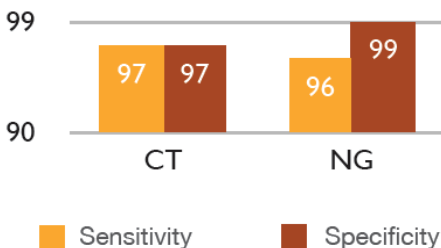
100% sensitivity

- FDA cleared to detect Trichomonas vaginalis in asymptomatic women, and/or to aid in the diagnosis of trichomoniasis in women symptomatic for vaginitis, cervicitis or urethritis
- The Gen-Probe TMA assay identifies a third more patients than current methodology. With up to 80% of patients being asymptomatic^{1,2} a sensitive assay is crucial to assessing diagnosis and treatment

CTNG Aptima Combo 2[®] Assay - Gen-Probe

Higher Sensitivity, Greater Specificity

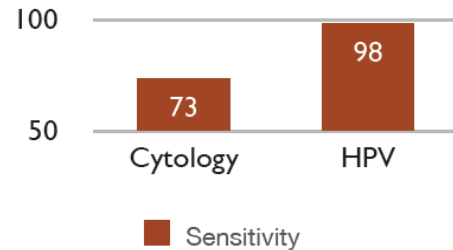
- FDA-cleared the test detects CT and NG
- Second generation test eliminates inhibition and cross reactivity issues, while minimizing equivocal results
- Three technologies: Target capture, transcription-mediated amplification, and dual kinetic assay delivers highest sensitivity and specificity



HPV HR Rapid Capture[®] II – Qiagen

Higher sensitivity for CIN2

- FDA-cleared for HPV screening as a primary adjunctive screen for women 30 and older with a Pap test
- CIN2 clinical threshold for treatment
- High sensitivity CIN2 = 95.9%
- High negative predictive value for CIN 2/3 of 99-100%
- ASC-US triage to colposcopy



Cervista[®] HPV 16/18 Genotyping - Hologic

CIN3 Risk

- Increases early detection of women at greatest risk for development of CIN3+ cervical cancer
- Cytology negative HPV HR positive women 30 years and older with HPV 16/18 can be referred to colposcopy sooner

Note: Cervical Specimens collected in BD SurePath™ liquid cytology and tested for CTNG, HPV HR and HPV 16/18 have been validated by MPLN as an off label laboratory determined test (LDT) under MPLN's high complexity CLIA license.

References

1. Koumans EH, Sternberg M, Bruce C, McQuillan G, Kendrick J, Sutton M, Markowitz LE. (2007)The prevalence of bacterial vaginosis in the United States, 2001-2004; associations with symptoms, sexual behaviors, and reproductive health. Sex Transm Dis. Nov;34(11):864-9.
2. Sutton M, Sternberg M, Koumans EH, McQuillan G, Berman S, Markowitz L. (2007).The prevalence of Trichomonas vaginalis infection among reproductive-age women in the United States, 2001-2004. Clin Infect Dis. Nov 15;45(10):1319-26
3. Owen MK, Clenney TL. (2004). Management of vaginitis. Am. Fam. Phys. 70: 2125-2132
4. Andrea SB, Chapin KC. J. (2011). Comparison of Aptima Trichomonas vaginalis Transcription-Mediated Amplification Assay and BD Affirm VPIII for Detection of T. vaginalis in Symptomatic Women: Performance Parameters and Epidemiological Implications. Clin Microbiol.49(3):866-9. Epub 2011 Jan 19.
5. Allsworth J et al.(2009). Trichomoniasis and other Sexually Transmitted Infections: Results from the 2001-2004 National Health and Nutrition Examination Surveys. Sexually transmitted diseases 36: 7238-744

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