

FDA cleared



Expand your test menu. Sense for HSV 1 and 2.

The Aptima® Herpes Simplex Virus (HSV) 1 & 2 assay is an ideal complement to your existing laboratory testing menu, enabling new opportunities for platform consolidation. This assay is used for the qualitative detection and differentiation of HSV types 1 and 2.

Identify a Common Viral Threat

The Aptima HSV 1 & 2 assay on the Panther® system incorporates testing for herpes types 1 and 2 into your current testing portfolio and joins the growing list of nucleic acid amplification tests (NAATs) on the fully automated Panther system. NAAT is the preferred testing method for genital herpes diagnosis.^{1,2} **The Aptima HSV 1 & 2 assay distinguishes between HSV 1 and 2, which is recommended in all patients with first-episode genital herpes.³**

An Important Distinction

Genital herpes infection is common, with an estimated 24 million people in the U.S. infected with HSV-2.³ Each herpes virus type has a unique presentation that requires targeted treatment.⁴ Diagnosing and distinguishing between HSV 1 and 2 is important because:



Patients can prevent transmission to neonates and among sex partners.⁴



Providers can guide patient treatment and daily management.⁵



Co-infection with other STIs is common in HSV-2 seropositive individuals.⁵

HIV Coinfection

A key distinction between the two HSV types is that HSV-2 is more commonly associated with HIV-1 coinfection.⁴ Persons infected with HSV-2 are **2-4 times higher risk of HIV-1 acquisition.**⁶⁻⁹

Molecular Testing Matters

Although HSV is commonly diagnosed on clinical grounds, a visual examination alone can lead to false positive and false negative diagnoses.¹⁰ Clinical diagnoses should be confirmed with laboratory tests.¹⁰ Culture is another diagnostic option, but it lacks the sensitivity and efficiency of NAAT testing^{1,5}:

Sensitivity Molecular NAAT testing is 3-5 times more sensitive than culture.⁵

Speed Time to first result: approximately 2.7 hours on the Panther system vs. 2 to 10 days for culture.¹

Molecular vs. Culture Testing Method¹¹

Specimen Category	Molecular	Culture
Sensitivity	3-5 times greater than culture	Fair
Specificity	Very high	Very high
Subtyping	Incorporated in initial procedure	2 nd step often required

Seamless Testing Integration

With the Aptima HSV 1 & 2 assay on the Panther system, experience:

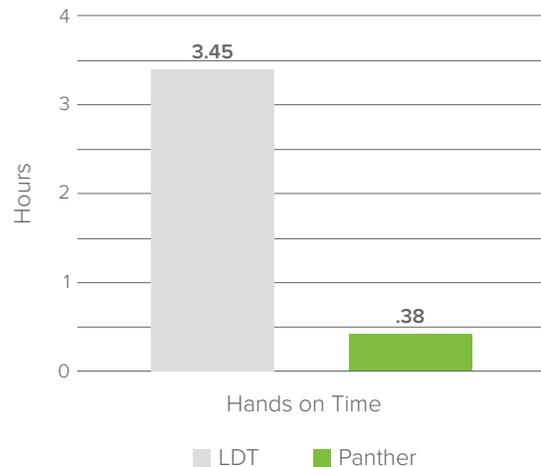
- ▶ Panther menu expansion, adding to Aptima assays for chlamydia, gonorrhea, trichomoniasis, and HPV.
- ▶ Superior workflow and benefits of the fully automated Panther system.
- ▶ Aptima Multitest Swab for specimen collection.
- ▶ Reduced hands-on time.



Improved Workflow

Workflow comparison for 96 samples demonstrates a significant reduction in hands on time for the Aptima HSV 1 & 2 assay compared to the LDT 96-well format used.¹¹

Note: First 5 results on the Panther system at 2.7 hours.



Strong Proven Performance¹

HSV 1

Anogenital Lesions

Sample Type	Sensitivity %	Specificity %
VTM	93.4%	99.8%
Aptima Swab	94.7%	99.6%

HSV 2

Anogenital Lesions

Sample Type	Sensitivity %	Specificity %
VTM	96.9%	97.5%
Aptima Swab	98.4%	92.8%

**The Aptima HSV 1 & 2 assay helps you offer more comprehensive viral testing in your laboratory.
Contact your Hologic representative for more information.**

References: **1.** Aptima HSV 1 & 2 assay [package insert]. AW-15346-001. San Diego, CA: Hologic, Inc., 2017. **2.** Radcliffe K. Molecular diagnosis of sexually transmitted infections (STI). IUSTI Europe. <http://md2010.org/files/presents/sp1/sp1-5.pdf>. Accessed June 21, 2017. **3.** Hook EW. A new look at genital herpes: the critical role of the laboratory in diagnosis and management. *Medical Laboratory Observer*. <http://www2.mlo-online.com/features/201207/cover-story/a-new-look-at-genital-herpes-the-critical-role-of-the-laboratory-in-diagnosis-and-management.aspx>. Published July 2012. Accessed June 21, 2017. **4.** World Health Organization. Herpes simplex virus. <http://www.who.int/mediacentre/factsheets/fs400/en/>. Published January 2016. Accessed October 5, 2016. **5.** Hook EW. A new look at genital herpes: the critical role of the laboratory in diagnosis and management. *Medical Laboratory Observer*. <http://www2.mlo-online.com/features/201207/cover-story/a-new-look-at-genital-herpes-the-critical-role-of-the-laboratory-in-diagnosis-and-management.aspx>. Published July 2012. Accessed June 21, 2017. **6.** Freeman EE, et al. Herpes simplex virus 2 infection increases HIV acquisition in men and women: systematic review and meta-analysis of longitudinal studies. *AIDS*. 2006;20(1):73-83. **7.** Sobngwi-Tambekou J, et al. Effect of HSV-2 serostatus on acquisition of HIV by young men: results of a longitudinal study in Orange Farm, South Africa. *J Infect Dis*. 2009;199(7):958-64. **8.** Glynn JR, et al. Why do young women have a much higher prevalence of HIV than young men? A study in Kisumu, Kenya and Ndola, Zambia. *AIDS*. 2001 Aug;15(Suppl 4):S51-60. **9.** Ward H, et al. The contribution of STIs to the sexual transmission of HIV. *Curr Opin HIV AIDS*. 2010;5(4):305-10. doi:10.1097/COH.0b013e32833a884. **10.** LeGoff J, et al. Diagnosis of genital herpes simplex virus infection in the clinical laboratory. *Virology*. 2014;11:83. doi:10.1186/1743-422X-11-83. **11.** Hook EW. A new look at genital herpes: the critical role of the laboratory in diagnosis and management. *MLO Med Lab Obs*. 2012;44(7):8. **12.** A. Jassem, Comparative Evaluation of the Aptima HSV 1&2 Assay and a Lab Developed Real-time PCR Test for Detection of HSV-1 and HSV-2 Viruses, presented at ESCV 2016 Poster No. PP20.

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Aptima[®] HSV 1 & 2
Assay