

CE-IVD Certified



Expand your testing capability with a sense for HSV 1 and 2.

The Aptima® HSV 1 & 2 assay (herpes simplex virus) is an ideal complement to your existing laboratory testing menu, providing new opportunities for platform consolidation. This assay is used for the qualitative detection and differentiation of HSV 1 and 2. It joins the ever-growing menu offering on the Panther® system.

Identify a Common Viral Threat

The Aptima® HSV 1 & 2 assay on the Panther® system incorporates testing for HSV 1 and 2 into your current testing portfolio.¹

The Aptima HSV 1 & 2 assay 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

More than 3.7 billion people globally are infected with HSV 1 or HSV 2.⁴ Each type has 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



Patients with HSV 2 are at higher risk for HIV-1 transmission and acquisition.⁶⁻⁹

HIV-1 Coinfection

A key distinction between the two HSV types is that HSV 2 is more commonly associated with HIV-1 coinfection.⁴ Multiple studies show a **2-3 times higher risk of HIV-1 acquisition with an HSV 2 infection** and an increased transmission of HIV-1.⁶⁻⁹

Molecular HSV 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, although 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

Aptima® HSV 1 & 2
Assay

Seamless Testing Integration

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

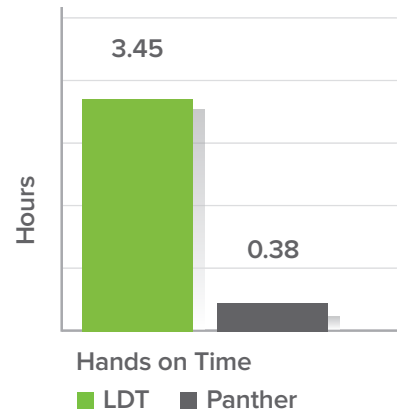
- ▶ Superior workflow and benefits of the fully automated Panther system.
- ▶ Aptima Multitest Swab and lesion samples in viral transport media.
- ▶ Reduced hands-on time.
- ▶ Sample volume scalability.



Improved Workflow

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

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



Strong Proven Performance¹

HSV 1

Anogenital Lesions.

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

Oral Lesions

Sample Type	Sensitivity %	Specificity %
VTM	81.5%	99.2%
Aptima Swab	97.5%	88.7%

HSV 2

Anogenital Lesions

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

Oral Lesions

Sample Type	Sensitivity %	Specificity %
VTM	100%	100%
Aptima Swab	66.7%	100%

The Aptima HSV 1 & 2 assay helps you offer more comprehensive molecular 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., 2016. **2.** Radcliffe K. Molecular diagnosis of sexually transmitted infections (STI). IUSTI Europe. <http://md2010.org/files/presents/sp1/sp1-5.pdf>. Accessed October 5, 2016. **3.** Patel, et al. 2010 European guideline for the management of genital herpes. IUSTI/WHO European STD guidelines Editorial Board. Published 2010. Accessed October 5, 2016. **4.** Patel R, et al. 2010 European Guideline for the Management of Genital Herpes. IUSTI/WHO European STD Guidelines Editorial Board. http://www.iusti.org/regions/europe/pdf/2010/Euro_Guideline_2010_herpes.pdf. Published 2010. Accessed October 5, 2016. **5.** World Health Organization. Herpes simplex virus. <http://www.who.int/mediacentre/factsheets/fs400/en/>. Published January 2016. Accessed October 5, 2016. **6.** 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 October 5, 2016. **7.** 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. **8.** 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. **9.** 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. **10.** 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. **11.** LeGoff J, et al. Diagnosis of genital herpes simplex virus infection in the clinical laboratory. *Viral J*. 2014;11:83. doi:10.1186/1743-422X-11-83. **11.** 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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The Aptima HSV 1 & 2 assay is not available for sale in the U.S.

Aptima® HSV 1 & 2 Assay