

Aptima[®] HSV 1 & 2 Assay

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

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:¹⁵

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:

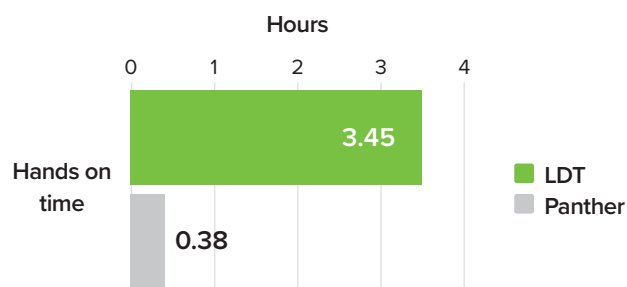
- Superior workflow and benefits of the fully automated Panther system.
- Aptima Multitest Swab and lesion samples in viral transport media.
- Reduced hands-on time.
- Sample volume scalability.



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%

Strong proven performance¹

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.

RUN ON
PANTHER®



References: 1. Aptima HSV 1 & 2 assay [package insert]. AW-15346-001. San Diego, CA: Hologic, Inc., 2016. 2. WHO Global Health Sector Strategy on Sexually Transmitted Infections 2016–2021. Accessed January 28, 2020. <https://apps.who.int/iris/bitstream/handle/10665/246296/WHO-RHR-16.09-eng.pdf?sequence=1>. 3. Patel R, Kennedy O, Clarke E, et al. 2017 European guidelines for the management of genital herpes. International Journal of STI & AIDS. <https://www.iusti.org/regions/Europe/pdf/2017/Herpes.pdf>. Accessed January 28, 2020. 4. World Health Organization. Herpes simplex virus. <http://www.who.int/mediacentre/factsheets/fs400/en/>. Reviewed January 2017. Accessed January 28, 2020. 5. Hook EW. A new look at genital herpes: the critical role of the laboratory in diagnosis and management. MLO Med Lab Obs. 2012 Jul;44(7):8, 10, 12. 6. Freeman E, Weiss H, Glynn J, 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(11):73-83. 7. Sobngwi-Tambekou J, Taljaard D, Lissouba P, 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 J, Carael M, Auvert B, 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, and Rönn M. 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, Pére H, Bélec L. Diagnosis of genital herpes simplex virus infection in the clinical laboratory. Virol 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.