

Simplexa™ HSV 1/2 & VZV Universal Direct Kit

A Comprehensive HSV 1/2 & VZV Molecular Test for Cutaneous and Mucocutaneous Swab Specimens

Direct detection and differentiation of HSV-1, HSV-2, & VZV



The quality of treatment starts with diagnosis.

Comprehensive, Fast and Accurate Molecular HSV & VZV Testing

Direct detection and differentiation of HSV-1, HSV-2, & VZV in cutaneous and mucocutaneous lesion swab specimens

HSV & VZV cause a wide spectrum of clinical manifestations

Herpes simplex viruses (HSV) and varicella-zoster virus (VZV) are members of the herpesviridae family of DNA viruses. A herpes simplex virus infection can cause cutaneous or mucosal lesions that are usually self-limited, but severe disease can occur in immunocompromised patients, pregnant woman and infants.^{1,2} HSV-1 is typically characterized by oral lesions, infectious keratitis, and eczema herpeticum, with a recent increase in genital lesions.³ HSV-2 infection is one of the most common sexually transmitted diseases causing vesicular genital lesions.⁴ Worldwide, approximately 90% of people are infected with HSV, 60-80% of whom have HSV-1 and 16-25% have HSV-2.^{5,6}

Varicella-zoster virus infection causes two clinically distinct forms of disease. The primary varicella disease, following initial infection of an individual, is commonly known as chickenpox, and is characterized by vesicular lesions in different stages of development on the face, trunk, and extremities.⁷ Secondary infection from the reactivation of endogenous latent VZV infection can result in Herpes zoster (also known as "shingles"). VZV reactivation may occur in multiple dermatomes resulting in a more widespread distribution. This condition is known as disseminated herpes zoster and is usually observed in immunocompromised individuals.⁸

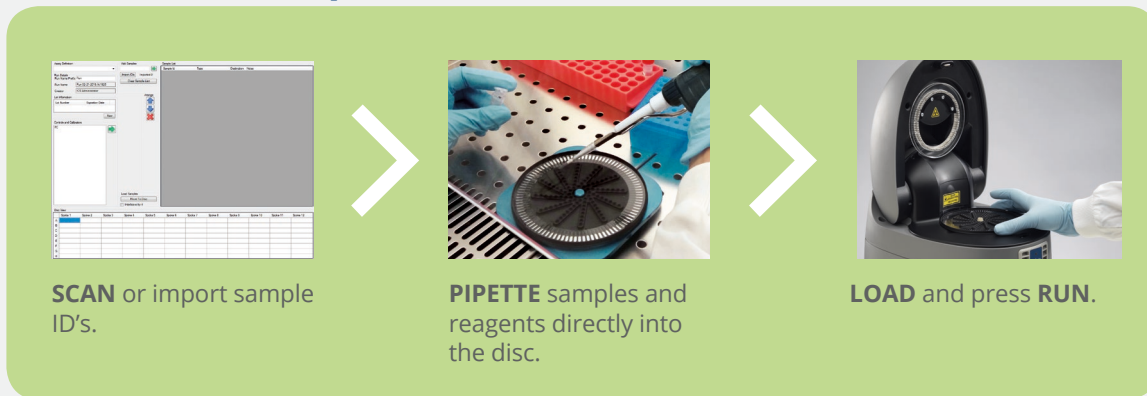
HSV-1, HSV-2 and VZV are human herpes viruses that can cause genital vesicular lesions. Although a majority of genital lesions are caused by HSV-1 and/or HSV-2, up to 2.9% of genital lesions are associated with VZV⁹. For many individuals, VZV at the genital site is associated with childhood chickenpox, rather than sexual transmission. Inclusion of VZV along with HSV-1 and HSV-2 testing may enable clinicians to provide improved therapeutic decisions and advice.

Comprehensive coverage for HSV & VZV testing needs

- **Sample types:**
Cutaneous & mucocutaneous lesion swabs.
- **High throughput:**
Up to 96 triplex reactions per run.
- **Fast and easy workflow:**
Streamlined workflow with results in about an hour.
- **Direct sample-to-answer workflow:**
No DNA extraction needed.
- **Includes positive control.**



Streamlined, simple workflow



The Simplexa™ HSV 1/2 & VZV Universal Direct assay on the LIAISON® MDX provides results in about an hour bypassing conventional DNA extraction procedures.

Accurate performance for confidence when testing multiple sample types

The Simplexa™ HSV 1/2 & VZV Universal Direct assay demonstrated greater than 98% positive percent agreement and greater than or equal to 99.0% negative percent agreement compared to another CE marked NAAT during clinical studies with over 380 retrospective samples.

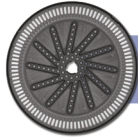
Simplexa™ HSV 1/2 & VZV Universal Direct Clinical Agreement¹⁰

	HSV-1		HSV-2		VZV	
	Positive % Agreement	Negative % Agreement	Positive % Agreement	Negative % Agreement	Positive % Agreement	Negative % Agreement
Retrospective Samples	100.0% (108/108) 95% CI: 96.6% to 100.0%	99.3% (276/278) ^{ab} 95% CI: 97.4% to 99.8%	100.0% (98/98) 95% CI: 96.2% to 100.0%	99.0% (285/288) ^c 95% CI: 97.0% to 99.6%	98.4% (60/61) ^d 95% CI: 91.3% to 99.7%	99.1% (322/325) ^e 95% CI: 97.3% to 99.7%

^a Confirmation of HSV-1 was determined in one (1) discordant upon discrepant analysis evaluation by PCR/bi-directional sequencing.
^b The presence of HSV-1 was unable to be determined in one (1) discordant upon discrepant analysis evaluation by PCR/bi-directional sequencing.
^c Confirmation of HSV-2 was determined for all three (3) discordants upon discrepant analysis evaluation by PCR/bi-directional sequencing.
^d Confirmation of VZV was determined for all three (3) discordants upon discrepant analysis evaluation by PCR/bi-directional sequencing.
^e The discordant was negative for VZV upon discrepant analysis evaluation by PCR/bi-directional sequencing.

REFERENCES: 1. Corey Lawrence, (2004) Herpes Simplex virus, In: Madell G.L., Bennett, J.E. and Dolin R., eds., Principles and Practice of Infectious Diseases, 6th edition, Philadelphia, PA Elsevier, Churchill and Livingstone: pp 1762-80. 2. Adelson, Martin E., et al. (2005) Simultaneous detection of herpes simplex virus types 1 and 2 by real-time PCR and Pyrosequencing. *J. Clin. Virol.* 33:25-34. 3. Shipley, M. M., Renner, D. W., Ott, M., Bloom, D. C., Koelle, D. M., Johnston, C., & Szpara, M. L. (2018). Genome-Wide Surveillance of Genital Herpes Simplex Virus Type 1 From Multiple Anatomic Sites Over Time. *The Journal of infectious diseases*, 218(4), 595-605. 4. LeGoff, J., Péré, H., & Bélec, L. (2014). Diagnosis of genital herpes simplex virus infection in the clinical laboratory. *Virology journal*, 11, 83. doi:10.1186/1743-422X-11-83 5. Selma Emre and Ayse Akkus (September 6th 2017). Genital Herpes, Fundamentals of Sexually Transmitted Infections, Server Serdaroglu and Zekayi Kutlubay, IntechOpen, DOI: 10.5772/intechopen.70105. 6. Wald A, Corey L. Persistence in the population: epidemiology, transmission. In: Arvin A, Campadelli-Fiume G, Mocarski E, et al., editors. Human Herpesviruses: Biology, Therapy, and Immunoprophylaxis. Cambridge: Cambridge University Press; 2007. Chapter 36. 7. Albrecht MA. (2017, May 31). Diagnosis of varicella-zoster virus infection. UpToDate. Retrieved on 06/27/2018 from <https://www.uptodate.com/contents/diagnosis-of-varicella-zoster-virus-infection>. 8. Lewis DJ, Schlichte MJ, Dao H Jr. Atypical disseminated herpes zoster: management guidelines in immunocompromised patients. *Cutis*. 2017; 100(5): 321; 324-330. 9. Birch, C. J., Druce, J. D., Catton, M. C, MacGregor L., & Read, T. Detection of varicella zoster virus in general specimens using multiplex polymerase chain reaction. *Sex Transm Infect.* 2003; 79: 298-300. 10. MOL2175 and MOL2185, Simplexa™ HSV 1/2 & VZV Universal Direct instructions for use.

Everything you need for molecular HSV & VZV testing



Ordering information – Simplexa™ HSV 1/2 & VZV Universal Direct

CATALOG NUMBER	DESCRIPTION	REACTIONS/KIT
MOL2185	Simplexa™ HSV 1/2 & VZV Universal Direct Kit*	100
MOL2175	Simplexa™ HSV 1/2 & VZV Universal Direct Kit*	1000

*Positive Control included with kit.



Ordering information – Simplexa™ Direct Kits

CATALOG NUMBER	DESCRIPTION	REACTIONS/KIT
MOL2150	Simplexa™ HSV 1 & 2 Direct Kit**	24
MOL3650	Simplexa™ VZV Direct Kit**	24

**To be used with Direct Amplification Discs (3 discs, MOL1455).

Other Simplexa™ Direct Products



Ordering information – Simplexa™ Direct Kits

CATALOG NUMBER	DESCRIPTION	REACTIONS/KIT
MOL2750	Simplexa™ Bordetella Direct Kit**	24
MOL2950	Simplexa™ <i>C. difficile</i> Direct Kit**	24
MOL2650	Simplexa™ Flu A/B & RSV Direct Kit**	24
MOL2850	Simplexa™ Group A Strep Direct Kit**	24
MOL3550	Simplexa™ GBS Direct Kit**	24

**To be used with Direct Amplification Discs (3 discs, MOL1455).



The Diagnostic Specialist



p: +39 0161 487526

p: +1 (562) 240-6500

e: cs.molecular@diasorin.com

w: www.molecular.diasorin.com

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