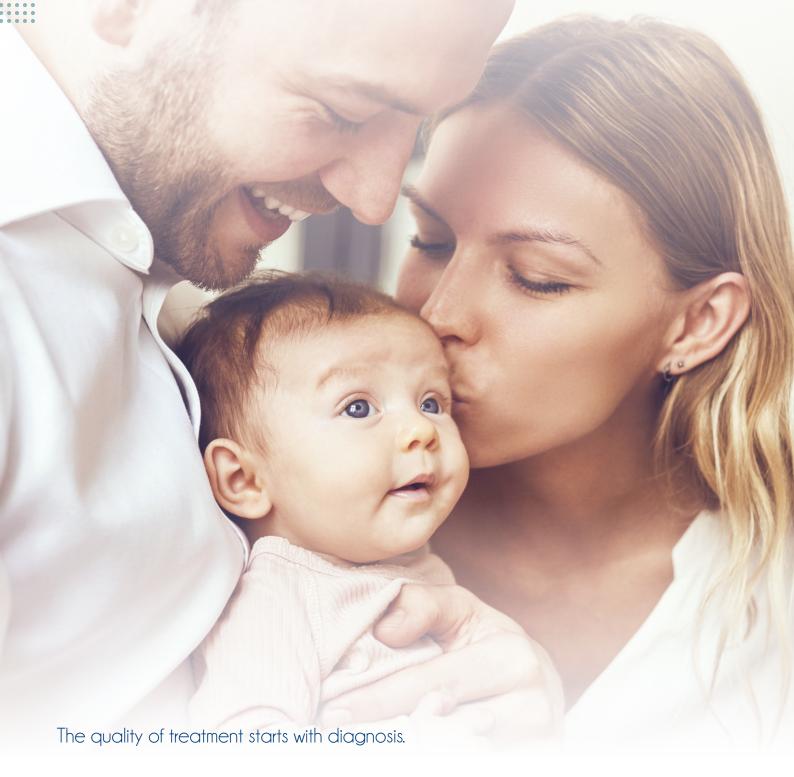




Simplexa™ HSV 1 & 2 Direct Kit

A Comprehensive HSV 1 & 2 Molecular Test for CSF, Cutaneous and Mucocutaneous Swab Samples

Direct detection and differentiation of HSV 1 & HSV 2



Simplexa™ HSV 1 & 2 Direct Kit

Comprehensive, Fast and Accurate Molecular HSV Testing

Direct detection and differentiation of HSV 1 & HSV 2 in CSF **and** cutaneous/mucocutaneous lesion swabs

HSV causes a wide spectrum of clinical manifestations

Herpes Simplex Virus (HSV 1 & 2) can cause a variety of diseases with multiple presentations, ranging from mucocutaneous oral and genital lesions to fulminate encephalitis.

HSV is a common cause of meningitis and encephalitis. Encephalitis occurs in all ages, from neonates to adults, and during all seasons. HSV encephalitis may have devastating results. Untreated HSV central nervous system (CNS) infection can reach mortality rates as high as 70% and for those who survive, only a minority will achieve full recovery.

HSV is also one of the most common causes of sexually transmitted disease. An estimated 3.7 billion have HSV 1 infection globally and an estimated 417 million have HSV 2 infection. Recognition of genital herpes is important to prevent transmission and provide counseling.

First of its kind coverage for HSV testing needs

- Comprehensive sample types:
 For use with CSF and cutaneous/mucocutaneous lesion swabs.
- The smallest sample volume: Only requires 50 µL of precious CSF sample.
- Fast and easy workflow:
 CLIA moderate complexity with results in about an hour.
- **Direct sample-to-answer workflow:** No DNA extraction needed.







Streamlined, simple workflow



The Simplexa[™] HSV 1 & 2 Direct assay is a CLIA moderate complexity assay. The LIAISON MDX[®] provides results in about an hour bypassing conventional DNA extraction procedures.

Accurate performance for confidence when testing multiple different sample types

Consolidate your CSF, cutaneous and mucocutaneous lesion swab testing.

CSF Clinical Agreement² HSV₁ HSV₂ Agreement with Agreement with Agreement with Agreement with Population Positives Negatives **Positives** Negatives **Encephalitis** 98.8% (159/161) 99.4% (156/157) 100.0% (3/3) 85.7% (6/7) Patients 95% CI: 43.8% to 100.0% 95% CI: 95.6% to 99.7% 95% CI: 48.7% to 99.9% 95% CI: 96.5% to 99.9% **HSV Molecular** 100.0% (13/13) 100.0% (42/42) N/A N/A **Positive Patients** 95% CI: 77.2% to 100.0% 95% CI: 91.6% to 100.0%

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	HSV 1		HSV 2				
Retrospective	Agreement with	Agreement with	Agreement with	Agreement with			
Population	Positives	Negatives	Positives	Negatives			
Cutaneous	100.0% (63/63)	100.0% (119/119)	100.0% (60/60)	100.0% (122/122)			
Lesion Swabs	95% CI: 94.3% to 100.0%	95% CI: 96.9% to 100.0%	95% CI: 94.0% to 100.0%	95% CI: 96.9% to 100.0%			
Mucocutaneous	100.0% (58/58)	100.0% (119/119)	100.0% (59/59)	100.0% (118/118)			
Lesion Swabs	95% Cl: 93.8% to 100.0%	95% CI: 96.9% to 100.0%	95% Cl: 93.9% to 100.0%	95% CI: 96.8% to 100.0%			

Cutaneous & Mucocutaneous Clinical Agreemen



Everything you need for molecular HSV testing



Ordering information – Simplexa™ HSV 1 & 2 Direct

CATALOG NUMBER	DESCRIPTION	REACTIONS/KIT
MOL2150	Simplexa™ HSV 1 & 2 Direct Kit*	24
MOL2160	Simplexa™ HSV 1 & 2 Positive Control Pack	10 x 100 μL

^{*}To be used with Direct Amplification discs (3 DAD discs, MOL1455).

Products for VZV testing



Ordering information – Simplexa™ VZV Direct

	CATALOG NUMBER	DESCRIPTION	REACTIONS/KIT
	MOL3650	Simplexa™ VZV Direct Kit*	24
•	MOL3660	Simplexa™ VZV Positive Control Pack	10

^{*}To be used with Direct Amplification discs (3 DAD discs, MOL1455).





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Product availability subject to required regulatory approvals.

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