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Simplexa™ HSV 1 & 2 Direct Assay

COMPREHENSIVE HSV 1 & 2 TESTING.

Direct detection and differentiation
of HSV-1 & HSV-2 in genital swabs
and CSF.



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REFERENCES: 1. <http://www.cdc.gov/std/herpes/stdfact-herpes.htm>. 2. http://www.idsociety.org/uploadedFiles/IDSA/Guidelines-Patient_Care/PDF_Library/Encephalitis.pdf
3. MOL2150, Simplexa HSV 1 & 2 Direct Kit, Package Insert, CSF - Rev. E, Genital Swab - Rev. D.



Simplexa™ HSV 1 & 2 Direct Assay

Herpes simplex viruses (HSV) are one of the most common causes of sexually transmitted infections and encephalitis. Nearly 1 in 6 individuals between the ages of 14 and 49 has a genital HSV infection.¹ 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. Infectious disease experts recommend HSV polymerase chain reaction testing on cerebrospinal fluid (CSF) from patients exhibiting signs of encephalitis infection.² Obstetrics experts have recognized that HSV PCR is 1.5 to 4 times more sensitive than viral culture, samples are easier to maintain, and PCR is the test of choice for diagnosis of infections of the CNS.

Our Simplexa HSV 1 & 2 Direct assay is the first of its kind—an HSV PCR test for both genital swabs and CSF without extraction. Results are available in about an hour and laboratories can test up to 8 samples per run to support their workflow needs.

Eliminate the constraints of costly extraction instrumentation with the Direct Amplification Disc.

- HSV-1 and HSV-2 differentiation
- No extraction required
- Results in about an hour
- Test up to 8 samples per run
- Sample type: genital swab or CSF
- 50 µL sample volume



Performance Summary.

Our Simplexa HSV 1 & 2 Direct assay features the high agreement results to culture that your laboratory is seeking.

You can have confidence in your results, without the constraints of sample extraction.

Swab Performance – Simplexa HSV 1 & 2 Direct ³				
	HSV-1		HSV-2	
Population	Agreement with Positives	Agreement with Negatives	Agreement with Positives	Agreement with Negatives
Genital Swabs	97.4% (114/117) 95% CI: 92.7% to 99.1%	98.0% (546/557) 95% CI: 96.5% to 98.9%	98.3% (174/177) 95% CI: 95.1% to 99.4%	97.8% (486/497) 95% CI: 96.1% to 98.8%

CSF Performance – Simplexa HSV 1 & 2 Direct ³				
	HSV-1		HSV-2	
Population	Agreement with Positives	Agreement with Negatives	Agreement with Positives	Agreement with Negatives
Encephalitis Patients	100.0% (3/3) 95% CI: 43.8% to 100%	98.8% (159/161) 95% CI: 95.6% to 99.7%	85.7% (6/7) 95% CI: 48.7% to 97.4%	99.4% (156/157) 95% CI: 96.5% to 99.9%
HSV Molecular Positive Patients	100.0% (13/13) 95% CI: 77.2% to 100.0%	N/A	100.0% (42/42) 95% CI: 91.6% to 100.0%	N/A

Prospective encephalitis patient samples were collected sequentially and compared against two bidirectional sequencing assays. HSV molecular positives were encephalitis patient samples that were positive with another PCR, confirmed with the two bidirectional PCRs and then tested with the Simplexa assay.

The complete solution for HSV-1 & HSV-2 testing.

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

*Direct Amplification Discs are provided with kit.