

Overview

Useful For

Aiding in the rapid diagnosis of disseminated disease due to herpes simplex virus (HSV)

Qualitative detection of HSV DNA

This test **should not be used** to screen asymptomatic patients.

Method Name

Real-Time Polymerase Chain Reaction (PCR)/DNA Probe Hybridization

NY State Available

No

Specimen

Specimen Type

Whole Blood EDTA

Ordering Guidance

If herpes simplex virus (HSV) is suspected in sources other than blood, order LHSV / Herpes Simplex Virus (HSV), Molecular Detection, PCR, Varies.

If HSV is suspected in cerebrospinal fluid, order HSVC / Herpes Simplex Virus (HSV), Molecular Detection, PCR, Spinal Fluid.

Specimen Required

Container/Tube: Lavender top (EDTA)

Specimen Volume: 1 mL

Collection Instructions: Send whole blood specimen in original tube. **Do not aliquot.**

Specimen Minimum Volume

0.4 mL

Reject Due To

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Whole Blood EDTA	Refrigerated (preferred)	7 days	
	Frozen	7 days	

Clinical & Interpretive

Clinical Information

Herpes simplex virus (HSV) types 1 and 2 cause a variety of clinical syndromes. Anatomic sites infected include the skin, lips, oral cavity, eyes, genital tract, and central nervous system. Systemic disease may also occur, in which the virus may be detectable in the bloodstream. The detection of HSV-1 or HSV-2 DNA from blood specimens may help support the diagnosis of disseminated disease associated with this virus.

Reference Values

HERPES SIMPLEX VIRUS (HSV)-1

Negative

HERPES SIMPLEX VIRUS (HSV)-2

Negative

Reference values apply to all ages.

Interpretation

This is a qualitative assay; results are reported either as negative or positive for herpes simplex virus (HSV) type 1 or HSV type 2.

An Indeterminate result means that HSV DNA was detected, but the assay was unable to differentiate between HSV type 1 and HSV type 2. If typing is required, it is recommended that a new sample be collected and tested by an alternate method.

Detection of HSV DNA in clinical specimens supports the clinical diagnosis of infection due to the virus.

Cautions

This test is intended for patients with evidence of disseminated disease due to herpes simplex virus (HSV). For patients with localized (eg, skin, genital) disease, a swab of suspect lesions should be collected and submitted for real-time [polymerase chain reaction](#) (PCR) analysis; LHSV / Herpes Simplex Virus (HSV), Molecular Detection, PCR, Varies).

A negative result does not eliminate the possibility of HSV infection.

Although the reference value is typically "negative" for this assay, viral shedding may be detected in asymptomatic individuals. This assay is only to be used for patients with a clinical history and symptoms consistent with HSV infection and must be interpreted in the context of the clinical picture.

Supportive Data

Accuracy:

Thirty (30) negative EDTA whole blood specimens were spiked with herpes simplex virus (HSV) 1 and HSV 2 plasmid control at the limit of detection (LOD; 10 copies DNA target/microliter). The spiked specimens were run in a blinded fashion along with approximately 30 negative (non-spiked) specimens; 100% of the spiked specimens were positive and 100% of the non-spiked specimens were negative.

Analytical Sensitivity/ LOD:

The lower LOD of this assay is 10 DNA target copies per microliter. This was established in anogenital swabs and confirmed in the matrix of EDTA whole blood.

Analytical Specificity:

No polymerase chain reaction signal was obtained from extracts of 30 bacterial, viral, and fungal isolates that could be found as normal flora in sites normally tested for this organism or that could cause similar symptoms.

Clinical Reference

1. Schiffer JT, Corey L: New concepts in understanding genital herpes. *Curr Infect Dis Rep.* Nov 2009 Nov;11(6):457-464
2. Espy MJ, Uhl JR, Sviens KA, et al: Laboratory diagnosis of herpes simplex virus infections in the clinical laboratory by LightCycler PCR. *J Clin Microbiol.* 2000 Feb;38(2):795-799
3. Espy MJ, Ross TK, Teo R, et al: Evaluation of LightCycler PCR for implementation of laboratory diagnosis of herpes simplex virus infections. *J Clin Microbiol.* 2000 Aug;38(8):3116-3118
4. Sauerbrei A, Eichhorn U, Hottenrott G, Wutzler P: Virological diagnosis of herpes simplex encephalitis. *J Clin Virol.* 2000 Jun;17(1):31-36
5. Mitchell PS, Espy MJ, Smith TF, et al: Laboratory diagnosis of central nervous system infections with herpes simplex virus by PCR performed with cerebrospinal fluid specimens. *J Clin Microbiol.* 1997 Nov;35(11):2873-2877
6. Yi-Wei T, Mitchell PS, Espy MJ, Smith TF, Persing DH: Molecular diagnosis of herpes simplex virus infections in the central nervous system. *J Clin Microbiol.* 1999 Jul;37(7):2127-2136
7. Schiffer JT, Corey L: Herpes simplex virus. In: Bennett JE, Dolin R, Blaser MJ, eds. *Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases.* 9th ed. Elsevier; 2020:1828-1848

Performance**Method Description**

Viral nucleic acid is extracted by the MagNA Pure or MagNA Pure 96 automated instrument (Roche Applied Science) from blood specimens. Primers directed to the DNA polymerase of herpes simplex virus (HSV) produce a 215-base pair amplicon. The LightCycler or LightCycler 480 instrument (Roche Applied Science), amplifies and monitors by fluorescence the development of target nucleic acid sequences after the annealing step during polymerase chain reaction (PCR) cycling. This is an automated PCR system that can rapidly detect (30-40 minutes) amplicon development through stringent air-controlled temperature cycling and capillary cuvettes or 96 well plate. The detection of amplified products is based on the fluorescence resonance energy transfer (FRET) principle. For FRET product detection, a hybridization probe with a donor fluorophore, fluorescein, on the 3'-end is excited by an external light source and emits light that is absorbed by a second hybridization probe with an acceptor fluorophore, LC-Red 640, at the 5'-end. The acceptor fluorophore then emits a light of a different wavelength that can be measured with a signal that is proportional

to the amount of specific PCR product. LightCycler hybridization probes are designed for HSV-type 2 and sequence differences between HSV-type 2- and HSV-type 1 are detected by melting curve analysis. Melting curve analysis is performed following PCR amplification. Sequence differences between the PCR amplification and probe melting curves are accomplished through the use of LightCycler software.(Binnicker MJ, Espy MJ, Duresko B, Irish C, Mandrekar J: Automated processing, extraction and detection of herpes simplex virus types 1 and 2: A comparative evaluation of three commercial platforms using clinical specimens. *J Clin Virol.* 2017 Apr;89:30-33)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

Same day/1 to 3 days

Specimen Retention Time

1 week

Performing Laboratory Location

Mayo Clinic Jacksonville Clinical Lab

Fees & Codes**Fees**

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact [Customer Service](#).

Test Classification

This test was developed using an analyte specific reagent. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

87529 x 2

87529 (if appropriate for government payers)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
LHSVb	Herpes Simplex Virus PCR, B	93440-6

Result ID	Test Result Name	Result LOINC® Value
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36367	HSV 1 PCR, B	93439-8
36368	HSV 2 PCR, B	93438-0