Test Definition: LHSV

Herpes Simplex Virus (HSV), Molecular Detection, PCR, Varies

Overview

Useful For

Aiding in the rapid diagnosis of herpes simplex virus (HSV) infections, including qualitative detection of HSV DNA in nonblood clinical specimens

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

Varies

Ordering Guidance

If herpes simplex virus (HSV) is suspected in blood, order LHSVB / Herpes Simplex Virus (HSV), Molecular Detection, PCR, Blood.

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

If varicella-zoster virus is suspected, order LVZV / Varicella-Zoster Virus, Molecular Detection, PCR, Varies.

Necessary Information

Specimen source is required.

Specimen Required

Submit only 1 of the following specimens:

Specimen Type: Body fluid
Sources: Pleural, peritoneal, ascites, pericardial, amniotic, or ocular
Container/Tube: Sterile container
Specimen Volume: 0.5 mL
Collection Instructions: Do not centrifuge.

Specimen Type: Swab
Sources: Genital, dermal, ocular, nasal, throat, or oral
Supplies: M4-RT (T605)
Container/Tube: Multimicrobe media (M4-RT)
Specimen Volume: Entire collection
Collection Instructions: Place swab back into multimicrobe media (M4-RT)
Additional Information: Source information should include main anatomical site of collection.

Specimen Type: Respiratory
Sources: Bronchial washing, bronchoalveolar lavage, nasopharyngeal aspirate or washing, sputum, or tracheal aspirate
Container/Tube: Sterile container
Specimen Volume: 1.5 mL

Specimen Type: Tissue
Sources: Brain, colon, kidney, liver, lung, etc.
Supplies: M4-RT (T605)
Container/Tube: Sterile container containing 1 mL to 2 mL of sterile saline or multimicrobe medium (M4-RT)
Specimen Volume: Entire collection
Collection Instructions: Submit only fresh tissue.
Additional Information: Source information should include main anatomical site of collection.

Specimen Type: Urine (<1-month old infant)
Container/Tube: Sterile container
Specimen Volume: 0.5 mL

Specimen Minimum Volume

Body or Ocular Fluid: 0.4 mL
Respiratory Specimen: 1 mL

Reject Due To

Calcium alginate-tipped swab Wood swab Transport swab containing gel Formalin-fixed and/or paraffin-embedded tissues	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Refrigerated (preferred)	7 days	
	Frozen	7 days	

Clinical & Interpretive

Clinical Information

Herpes simplex virus (HSV) types 1 and 2 are members of the *Herpesviridae* family and produce infections that may range from mild stomatitis to disseminated and fatal disease. Clinical conditions associated with HSV infection include gingivostomatitis, keratitis, encephalitis, vesicular skin eruptions, aseptic meningitis, neonatal herpes, genital tract infections, and disseminated primary infection.

Infections with HSV types 1 and 2 can differ significantly in their clinical manifestations and severity. HSV type 2 primarily causes urogenital infections and is found almost exclusively in adults. HSV type 1 is closely associated with orolabial infection, although genital infection with this virus can be common in certain populations.

The diagnosis of HSV infections is routinely made based on clinical findings and supported by laboratory testing using polymerase chain reaction or viral culture.

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, HSV type 2, or HSV type indeterminate.

An Indeterminate result indicates that HSV DNA was detected, but the assay is unable to differentiate between HSV-1 and HSV-2. If typing is required, it is suggested that a new sample be collected for testing by an alternate method.

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

Cautions

A negative result does not eliminate the possibility of herpes simplex virus infection.

Although the reference range is typically "negative" for this assay, this assay may detect viral nucleic acid shedding in asymptomatic individuals. This may be especially relevant when dermal or genital sites are tested since intermittent shedding without noticeable lesions has been described.(1) 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/Diagnostic Sensitivity and Specificity:
To assess the accuracy of the Roche herpes simplex virus (HSV)-1/2 analyte specific reagents, clinical specimens (n=50) were tested, and the results compared to those of a laboratory-developed reference polymerase chain reaction (PCR) method.

Roche HSV-1/2 ASR		**HSV-1/2 LDT**	
		Positive	Negative
	Positive	20	0
	Negative	0	30
	Total	20	30

Sensitivity (95% CI): 100% (81-100)
Specificity (95% CI): 100% (86-100)

Analytical Sensitivity/Limit of Detection:
The lower limit of detection of the HSV assay is 10 DNA target copies per microliter. This was established in anogenital swabs and confirmed in each specimen type accepted for this assay.

Analytical Specificity:
No PCR signal was obtained from extracts of 27 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.

Precision:
Interassay and intra-assay precision were 100% and 100%, respectively.

Clinical Reference

1. Schiffer JT, Corye L. New concepts in understanding genital herpes. Curr Infect Dis Rep. 2009;11(6):457-464
2. Espy MJ, Uhl JR, Mitchell PS, et al. Diagnosis of herpes simplex virus infections in the clinical laboratory by LightCycler PCR. J Clin Microbiol. 2000;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;38(8):3116-3118
4. Sauerbrei A, Eichhorn U, Hottenrott G, Wutzler P. Virological diagnosis of herpes simplex encephalitis. J Clin Virol. 2000;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;35(11):2873-2877
6. Tang YW, Mitchell PS, Espy MJ, Smith TF, Persing DH. Molecular diagnosis of herpes simplex virus infections in the central nervous system. J Clin Microbiol. 1999;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 automated instrument (Roche Applied Science) from genital, dermal, tissue, or body fluid specimens. Primers directed to the DNA polymerase of herpes simplex virus (HSV) produce a 215-base pair amplicon. The LightCycler instrument (Roche Applied Science) amplifies and monitors by fluorescence the development of target nucleic acid sequences after the annealing step during PCR cycling. This is an automated polymerase chain reaction (PCR) system that can rapidly detect (30-40 minutes) amplicon development through stringent air-controlled temperature cycling and capillary cuvettes. 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. Starting at 45 degrees C, the temperature in the thermal chamber is slowly raised to 80 degrees C, and the fluorescence is measured at frequent intervals. Sequence differences between the PCR amplification and probe melting curves are accomplished through the use of LightCycler software.(Espy MJ, Uhl JR, Mitchell PS, 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; 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 Sunday

Report Available

Same day/1 to 3 days

Specimen Retention Time

14 days

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 and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It 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
LHSV	Herpes Simplex Virus PCR	94580-8

Result ID	Test Result Name	Result LOINC® Value
SS001	Specimen Source	39111-0
34797	HSV 1, PCR	94581-6
34798	HSV 2, PCR	94582-4