MAYO CLINIC LABORATORIES

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

Yes

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 (CSF), 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
Supplies:
M4-RT (T605)
Bartels FlexTrans VTM-3 mL (T892)
Jiangsu VTM-3 mL (T891)
Sources: Genital, dermal, ocular, nasal, throat, or oral
Container/Tube: Multimicrobe media (M4-RT)
Specimen Volume: Entire collection
Collection Instructions: Place swab back into multimicrobe media (M4-RT, Bartels FlexTrans, or Jaingsu)
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
Supplies:
M4-RT (T605)
Bartels FlexTrans VTM-3 mL (T892)
Jiangsu VTM-3 mL (T891)
Sources: Brain, colon, kidney, liver, lung, etc.
Container/Tube: Sterile container containing 1 mL to 2 mL of sterile saline or multimicrobe medium (M4-RT, Bartels FlexTrans, or Jiangsu)
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

Forms

If not ordering electronically, complete, print, and send a Microbiology Test Request (T244) with the specimen.

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	Reject

Formalin-fixed and/or paraffin-embedded tissues	

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

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 (HSV) 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:
Of 200 specimens processed by both shell vial assay and LightCycler, herpes simplex virus (HSV) was detected in 88 specimens (44%). All 88 positive specimens were detected by LightCycler compared with 69 by the shell vial assay. The 19 discrepant results (LightCycler positive, shell vial assay negative) were resolved as true-positive results by using a polymerase chain reaction (PCR) assay directed to another gene target (thymidine kinase) of the virus.

Supplemental Data (Spiking Studies):
To supplement the above data, approximately 30 negative specimens each of various types were spiked with HSV 1 and HSV 2 plasmid control at the limit of detection (10 copies DNA target/microliter). The spiked specimens were run in a blinded fashion along with approximately 30 negative (nonspiked) specimens each of various specimen types; among the spiked specimen types, the assay was positive in 92% to 100% of the replicates tested. Furthermore, 100% of the nonspiked specimens were negative.

Analytical Sensitivity/Limit of Detection:
The lower limit of detection of this 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 was 100% and 100%, respectively.

Clinical Reference

1. Schiffer JT, Corye L: New concepts in understanding genital herpes. Curr Infect Dis Rep. Nov 2009;11(6):457-464
2. Espy MJ, Uhl JR, Svien 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. 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 Jul;37(7):2127-2136

Performance

Method Description

Viral nucleic acid is extracted by the MagNA Pure or MagNA Pure 96 automated instrument (Roche Applied Science) from genital, dermal, or tissue. 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 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; Varies

Report Available

Same day/1 to 3 days

Specimen Retention Time

1 week

Performing Laboratory Location

Rochester

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 Regional Manager. 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. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

87529 x 2

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