Test Definition: HSVPV

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 HSVPB / 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 VZVPV / Varicella-Zoster Virus, Molecular Detection, PCR, Varies.

Necessary Information

1. Specimen source is required.

2. Source information must include main anatomical site of collection.

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:
-Culturette (BBL Culture Swab) (T092)
-BD E-Swab (T853)
-M4-RT (T605),
Container/Tube: Multimicrobe media (M4-RT, M4, M5, Bartels, or Jiangsu) and E-Swab or Culturette
Specimen Volume: Entire collection
Collection Instructions: Place swab back into multimicrobe media.

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: Fresh tissue
Supplies: M4-RT (T605)
Container/Tube: Sterile container containing 1 mL to 2 mL of sterile saline or multimicrobe medium (M4-RT, M4, M5, Bartels, or Jiangsu)
Specimen Volume: Entire collection
Collection Instructions: Submit only fresh tissue. Fixed tissue is **not** acceptable.

Specimen Type: Urine (newborns < or =35 days old)
Container/Tube: Sterile container
Specimen Volume: 0.5 mL

Forms

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

Specimen Minimum Volume

Amniotic or ocular fluid: 0.4 mL; Sterile body fluid (Pleural, peritoneal, ascites, pericardial): 0.5 mL; Respiratory Specimen: 1 mL; Swab, tissue, or urine: See Specimen Required

Reject Due To

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

paraffin-embedded tissues	
Heat-inactivated specimens	Reject
Dry-flocked ESwab	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

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. Results can also be reported as invalid.
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 specimen be collected for testing by an alternate method.

An invalid result points to the inability to determine presence or absence of HSV-1 or HSV-2 DNA in the sample.

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 (non-spiked) 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 non-spiked 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. 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;89:30-33
2. Schiffer JT, Corye L. New concepts in understanding genital herpes. Curr Infect Dis Rep. 2009;11(6):457-464
3. 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;38(2):795-799
4. 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
5. Sauerbrei A, Eichhorn U, Hottenrott G, Wutzler P. Virological diagnosis of herpes simplex encephalitis. J Clin Virol. 2000;17(1):31-36
6. 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
7. 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

Performance

Method Description

Viral nucleic acid is extracted by the MagNA Pure 96 automated instrument (Roche Applied Science) from genital, dermal, or tissue 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 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;89:30-33)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

Same day/1 to 4 days

Specimen Retention Time

1 week

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Main Campus

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
HSVPV	Herpes Simplex Virus, PCR, Varies	94580-8

Result ID	Test Result Name	Result LOINC® Value
HSVS	Specimen Source	31208-2
618328	HSV 1, PCR	94581-6
618329	HSV 2, PCR	94582-4