

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

1. Specimen source is required.
2. Source information must include main anatomical site of collection.

Specimen Required

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) or Universal Transport Medium (UTM) and E-Swab or Culturette

Specimen Volume: Entire collection

Collection Instructions: Place swab back into multimicrobe media (M4-RT, M4, or M5) or Universal Transport Medium (UTM).

Specimen Minimum Volume

See Specimen Required

Reject Due To

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

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Refrigerated (preferred)	7 days	
	Frozen	30 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

A positive result suggests the presence of herpes simplex virus (HSV)-1 and/or HSV-2 DNA in the sample.

A negative result suggests that HSV-1 and HSV-2 DNA are not present in the sample.

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

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.

Clinical Reference

1. 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
2. Szpara ML, Parsons L, Enquist LW. Sequence variability in clinical and laboratory isolates of herpes simplex virus 1 reveals new mutations. J Virol. 2010;84(10):5303-531
3. Workowski KA. Centers for Disease Control and Prevention Sexually Transmitted Diseases Treatment Guidelines. Clin Infect Dis. 2015;61 Suppl 8:S759-S762
4. Omarova S, Cannon A, Weiss W, Bruccoleri A, Puccio J. Genital Herpes Simplex Virus-An Updated Review. Adv Pediatr. 2022;69(1):149-162
5. Gitman MR, Ferguson D, Landry ML. Comparison of Simplexa HSV 1 & 2 PCR with culture, immunofluorescence, and laboratory-developed TaqMan PCR for detection of herpes simplex virus in swab specimens. J Clin Microbiol. 2013;51(11):3765-3769

Performance**Method Description**

The Simplexa HSV (herpes simplex virus)-1 and -2 Direct assay system is a real-time polymerase chain reaction (PCR) that enables the direct amplification, detection, and differentiation of HSV-1 and HSV-2 DNA from unprocessed specimens

without nucleic acid extraction.

In this assay, bifunctional fluorescent probe primers are used together with corresponding reverse primers to amplify HSV-1, HSV-2, and internal control targets. Well-conserved regions of the HSV-1 and HSV-2 DNA polymerase genes are targeted to identify HSV-1 and HSV-2 DNA, respectively, in the specimen. An internal control is used to detect PCR failure or inhibition.(Binnicker MJ, Espy MJ, Irish CL. Rapid and direct detection of herpes simplex virus in cerebrospinal fluid by use of a commercial real-time PCR assay. J Clin Microbiol. 2014;52(12):4361-4362; Package insert: Simplexa HSV 1 and 2 Direct, Diasorin; 07/2014)

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 has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

87529 x 2

87529 (if appropriate for government payers)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
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Test Definition: HSVSW

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

HSVSW	Herpes Simplex Virus, PCR, Varies	94580-8
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Result ID	Test Result Name	Result LOINC® Value
HSVS1	Specimen Source	39111-0
623131	HSV 1 PCR	94581-6
623132	HSV 2 PCR	94582-4