# Test Definition: HERPV

Herpes Simplex Virus PCR, Varies

## Overview

### Useful For

Direct detection and differentiation of HSV-1 and HSV-2 DNA in various specimen types from symptomatic patients

Aids in diagnosis of HSV infection in symptomatic patients

This test is **not intended** to be used for prenatal screening.

### Highlights

This test is intended for symptomatic patients with evidence of disseminated herpes simplex virus (HSV) infection. It should not be used to determine if a patient has been exposed to HSV at some point in the past; rather, it should be ordered when there is a suspicion for active infection.

### Method Name

Real-Time Polymerase Chain Reaction (RT-PCR)

### NY State Available

Yes

## Specimen

### Specimen Type

Varies

### Advisory Information

If HSV is suspected in blood, order HERPB / Herpes Simplex Virus 1 and 2, Qualitative 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.

### Additional Testing Requirements

If both HERPV / Herpes Simples Virus 1 and 2, Qualitative PCR, Varies and LVZV / Varicella-Zoster Virus, Molecular Detection, PCR will be ordered, 2 swabs should be submitted, each in a separate transport media.

### Necessary Information

**Specimen source is required.** Swabs and tissue specimens must include the main anatomical site of collection.

### Specimen Required

It is recommended that HERPV be collected separately from other PCR tests.

**Submit only 1 of the following specimens:**

**Specimen Type:** 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:** Respiratory

**Sources:** Bronchial washing, bronchoalveolar lavage, nasopharyngeal aspirate or washing, sputum, or tracheal aspirate

**Container/Tube:** Sterile container

**Specimen Volume:** 1 mL

**Specimen Type:** Swab

**Sources:** Genital, cervical, rectal, dermal, ocular, nasal, throat, or oral

**Supplies:**

Culturette (BBL Culture Swab) (T092)

M4 media, M4-RT (T605)

**Specimen Volume:** Entire collection

**Collection Instructions:** Place swab into multimicrobe media (M4-RT [T605], M4, or M5 media).

**Specimen Type:** Tissue

**Sources:** Brain, colon, kidney, liver, lung, etc.

**Supplies:** M4-RT (T605) or M4 media

**Container/Tube:** Sterile container containing 1-2 mL of sterile saline or multi-microbe medium (M4-RT [T605], M4 media, or M5 media)

**Specimen Volume:** Entire collection

**Collection Instructions:** Submit only fresh tissue.

**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 1 of the following forms with the specimen:

-General Request (T239)

-Microbiology Test Request (T244)

### Specimen Minimum Volume

Fluids, Respiratory, and Urine: 0.3 mL
Swabs and Tissue: Entire collection

### Reject Due To

| | |
|---|---|
| Tissues/Swabs | Calcium alginate-tipped swab, wood swab, or transport swab containing gel Formalin-fixed and/or paraffin-embedded tissues |

### Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---|---|---|---|
| Varies | Refrigerated | 7 days | |

## Clinical and Interpretive

### Clinical Information

Herpes simplex virus types 1 and 2 (HSV-1/2) 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-1 and -2 can differ significantly in their clinical manifestations and severity. HSV-2 primarily causes urogenital infections and is found most often in adults. HSV-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 (PCR) or viral culture.

### Reference Values

Negative

### 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 nucleic acid.

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. There is a risk of a false-negative result due to improperly collected, transported, or handled swab samples.

There is a risk of a false-positive result due to contamination by target organisms or their nucleic acids, which may be introduced at the point of sample collection or testing. Every effort to minimize the risk of contamination should be taken.

The ARIES HSV 1 and 2 assay may not detect a coinfection of HSV-1 and -2 in specimens where the 2 virus types are not equally represented in clinical specimens.

The ARIES HSV 1 and 2 assay detects and differentiates between HSV-1 and HSV-2 only. It does not detect or differentiate any other herpes viruses (eg, cytomegalovirus [CMV], Epstein-Barr virus [EBV]). This assay does not distinguish between infectious HSV-1 or -2 and the presence of nucleic acid (ie, noninfectious viral particles).

Results should be interpreted in conjunction with other clinical and laboratory findings.

## Supportive Data

The following validation data supports the use of this assay for clinical testing.

Accuracy/Diagnostic Sensitivity and Specificity:

At least 60-positive (30 each for herpes simplex virus [HSV-1] and HSV-2) and 10-negative specimens from each of the following sample groupings were tested by the ARIES HSV-1/2 assay and Roche HSV-1/2 analyte specific reagents (ASR): dermal/genital swab specimens, sterile body fluids (peritoneal/ascites, pericardial, pleural/thoracentesis, amniotic), eye swabs, ocular fluids, upper respiratory, lower respiratory, fresh tissues, blood and urine. Concordance was 99.2% between these methods.

Analytical Sensitivity/Limit of Detection (LoD):

The limit of detection (LoD) was established by spiking analyte-negative specimens with known concentrations of HSV-1 and HSV-2 using whole virus controls from ZeptoMetrix.

| Sample Grouping | HSV-1 LoD (copies/mL) | HSV-2 LoD (copies/mL) |
|---|---|---|
| Genital/dermal swabs (in viral transport media ) | 312 | 78 |
| Sterile body fluids | 312 | 39 |
| Eye Swabs | 625 | 156 |
| Ocular Fluid/CSF | 625 | 156 |
| Upper respiratory | 312 | 39 |
| Lower respiratory | 1250 | 78 |
| Tissue | 312 | 39 |
| Urine | 312 | 78 |

Analytical Specificity:

No cross-reactivity was observed with the Luminex ARIES HSV 1 and -2 assay when tested against the comprehensive specificity panel. This included testing of 5 replicates each of HSV-1 and HSV-2 near the assay's LoD, as well as negative replicates spiked with 61 potential cross-reacting organisms. The reactivity of microbes should not be altered by the specimen source they are present in; therefore, the manufacturer's specificity data that was generated for cutaneous and mucocutaneous lesion specimens are determined to be sufficient for off-label clinical sources.

Precision:

Intra-assay precision was 100% (9/9 replicates positive) for both HSV-1 and HSV-2. Cp values for all replicates were within plus or minus 2 cycles of the mean.

Reference Range:

The reference value for this assay is negative.

Reportable Range:

This is a qualitative test and will be reported as "Positive for HSV-1," "Positive for HSV-2," "Negative," or "Invalid."

## Clinical Reference

1. Filen F, Strand A, Allard A, et al: Duplex real-time polymerase chain reaction assay for detection and quantification of herpes simplex virus type 1 and herpes simplex virus type 2 in genital and cutaneous lesions. Sex Transm Dis 2004;31(6):331-336

2. Jerome KR, Morrow RA: Herpes Simplex Viruses and Herpes B Virus. In Manual of Clinical Microbiology. Tenth edition. Edited by J Versalovic, KC Carroll, G Funke, et al. Washington, DC, ASM Press, 2011, pp 1530-1544

3. Modi S, Van L, Gerwirtzman A, et al: Single day treatment of orolabial and genital herpes: a brief review of pathogenesis and pharmacology. Ther Clin Risk Manag 2008;4:409-417

4. Nadelman CM, Newcomer VD: Herpes simplex virus infections. New treatment approaches make early diagnosis even more important. Postgrad Med 2000;107:189-200

5. Slomka MJ: Current diagnostic techniques in genital herpes; their role in controlling the epidemic. Clin Lab 2000;46:591-607

6. Superti F, Ammendolia MG, Marchetti M: New advances in anti-HSV chemotherapy. Curr Med Chem 2008;15:900-911

7. Tronstein E, Johnston C, Huang ML, et al: Genital shedding of herpes simplex virus among symptomatic and asymptomatic persons with HSV-2 infection. JAMA 2011;305:1441-1449

## Performance

## Method Description

The Luminex ARIES system utilizes PCR chemistry for the detection and differentiation of herpes simplex virus-1 (HSV-1) and HSV-2. In brief, primary specimen is added to the sample chamber of an ARIES HSV-1 and-2 assay cassette. The cassette is then placed into an ARIES system magazine. A magazine can hold up to 6 cassettes. The magazine is inserted into an ARIES system, which can process 2 magazines simultaneously. A barcode on top of the HSV-1 and -2 assay cassette is automatically scanned by the ARIES system, associating a preloaded ARIES HSV-1 and -2 assay protocol file with the cassette. The HSV-1 and -2 assay protocol file contains the necessary parameters to run the cassette, analyze data, and generate reports.

Once a run is started, the Sample Processing Control (SPC) is automatically added to the sample chamber of the cassette to control for sample lysis, recovery of extracted nucleic acid, detection of inhibitory substances, and

confirmation of PCR reagent integrity. Sample and SPC lysis, as well as isolation and purification of nucleic acids, are automated within the ARIES system and the ARIES HSV 1 and 2 assay cassette. Purified nucleic acids are automatically transferred to the cassette's PCR tube that contains the lyophilized HSV-1 and -2 master mix for the PCR amplification step.(Binnicker MJ, Espy MJ, Duresko B, et al. 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) and Time(s) Test Performed

Monday through Saturday; Varies

### Analytic Time

Same day/1 day

### Maximum Laboratory Time

3 days

### Specimen Retention Time

1 week

### Performing Laboratory Location

Rochester

## Fees and 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 has been modified from the manufacturer's instructions. 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 U.S. Food and Drug Administration.

### CPT Code Information

87529 x 2

### LOINC® Information

| Test ID | Test Order Name | Order LOINC Value |
|---|---|---|
| HERPV | Herpes Simplex Virus PCR, Varies | 87431-3 |

| Result ID | Test Result Name | Result LOINC Value |
|---|---|---|
| SSHSV | Herpes Source | 31208-2 |
| 601902 | HSV 1 PCR, Varies | 16130-7 |

# Test Definition: HERPV

Herpes Simplex Virus PCR, Varies

| Result ID | Test Result Name | Result LOINC Value |
|---|---|---|
| 601903 | HSV 2 PCR, Varies | 16131-5 |