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 Simplex 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
**Test Definition: HERPV**
Herpes Simplex Virus PCR, Varies

**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:
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

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varies</td>
<td>Refrigerated</td>
<td>7 days</td>
<td></td>
</tr>
</tbody>
</table>

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.

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

**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.
Test Definition: HERPV
Herpes Simplex Virus PCR, Varies

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


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

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<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>HERPV</td>
<td>Herpes Simplex Virus PCR, Varies</td>
<td>87431-3</td>
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<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
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<tbody>
<tr>
<td>SSHSV</td>
<td>Herpes Source</td>
<td>31208-2</td>
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<tr>
<td>601902</td>
<td>HSV 1 PCR, Varies</td>
<td>16130-7</td>
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<tr>
<td>Result ID</td>
<td>Test Result Name</td>
<td>Result LOINC Value</td>
</tr>
<tr>
<td>-----------</td>
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</tr>
<tr>
<td>601903</td>
<td>HSV 2 PCR, Varies</td>
<td>16131-5</td>
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