Test Definition: LEBV
Epstein-Barr Virus PCR

### Overview

### Useful For
Rapid qualitative detection of Epstein-Barr virus (EBV) DNA in specimens for laboratory diagnosis of disease due to this virus

### Method Name
Real-Time Polymerase Chain Reaction (PCR)/DNA Probe Hybridization

### NY State Available
Yes

### Specimen

#### Specimen Type
Varies

#### Necessary Information
Specimen source is required.

#### Specimen Required

**Supplies:** Aliquot Tube, 5 mL (T465)

**Specimen Type:** Fluid

**Sources:** Spinal fluid, sterile body fluids (peritoneal fluid/ascites, pericardial fluid, pleural fluid/thoracentesis, amniotic, or ocular

**Preferred:** Sterile screw-cap 5-mL aliquot tube

**Acceptable:** Sterile container

**Specimen Volume:** 0.5 mL

**Collection Instructions:** Do not centrifuge.

**Supplies:** Aliquot Tube, 5 mL (T465)

**Specimen Type:** Fluid

**Sources:** Respiratory; bronchial washing, bronchoalveolar lavage, nasopharyngeal aspirate or washing, sputum, or tracheal aspirate

**Container/Tube:**

**Preferred:** Sterile screw-cap 5-mL aliquot tube

**Acceptable:** Sterile container
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Specimen Volume: 1.5 mL

Supplies:
Culturette (BBL Culture Swab) (T092)
M4-RT (T605)

Specimen Type: Swab

Sources: Eye swabs and upper respiratory swabs (nasal, throat)

Container/Tube: Multimicrobe media (M4-RT) and Eswabs

Collection Instructions: Place swab back into multimicrobe media (M4-RT, M4 or M5)

Specimen Volume: 0.5 mL

Additional Information: Clotted specimens will be rejected.

Supplies: M4-RT (T605)

Specimen Type: Tissue

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

Preferred: Multimicrobe medium (M4-RT)

Acceptable: Sterile container containing 1 mL to 2 mL of sterile saline or multimicrobe medium (M4-RT, M4 or M5)

Specimen Volume: Entire collection

Collection Instructions: Submit only fresh tissue.

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

Specimen Minimum Volume
Body Fluid, Ocular Fluid, Spinal Fluid: 0.3 mL
Respiratory Specimens: 1 mL
Tissue: 2 x 2-mm biopsy

Reject Due To

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

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Specimen Stability Information

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<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Varies</td>
<td>Refrigerated (preferred)</td>
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<tr>
<td></td>
<td>Frozen</td>
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Clinical and Interpretive

Clinical Information
Epstein-Barr virus (EBV) is the causative agent of infectious mononucleosis, Burkitt lymphoma, and in Southern China, nasopharyngeal carcinoma. EBV-associated central nervous system (CNS) disease is most commonly associated with primary CNS lymphoma in patients with AIDS. In addition, CNS infection associated with the detection of EBV DNA can be seen in immunocompetent patients.

Reference Values
Negative

Interpretation
Detection of Epstein-Barr virus (EBV) DNA in cerebrospinal fluid (CSF) supports the clinical diagnosis of central nervous system (CNS) disease due to the virus. EBV DNA is not detected in CSF from patients without CNS disease caused by this virus.

Cautions
A negative result does not eliminate the possibility of Epstein-Barr virus (EBV) infection of the central nervous system.

This assay may detect viremia or viral shedding in asymptomatic individuals. However, this assay is only to be used for patients with a clinical history and symptoms consistent with EBV infection, and must be interpreted in the context of the clinical picture. This test should not be used to screen asymptomatic patients.

Supportive Data
Thirty negative specimens of each matrix accepted for this assay were spiked with Epstein-Barr positive control plasmid at the approximate limit of detection (10-20 targets/mcL). The 30 spiked specimens of each type were run in a blinded manner along with 30 negative (nonspiked) specimens; 93% to 100% of the spiked specimens were positive and 100% of the nonspiked specimens were negative.

Analytical Sensitivity/Limit of Detection (LoD):
The 95% LoD for this assay is less than 10 targets per microliter using plasmid and whole virus spiked into matrix. The LoD was confirmed in each matrix type that is accepted for testing with this assay.

Analytical Specificity:
No PCR signal was obtained from extracts of 40 bacterial and viral isolates that could cause similar symptoms including herpes simplex virus (HSV) 1 and 2; cytomegalovirus (CMV); varicella zoster virus (VZV); and human herpesvirus (HHV) 6, HHV 7, and HHV 8.
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Precision:
Interassay precision was 100% and intraassay precision was 100%.

Reportable Range:
This is a qualitative assay and results are reported as either negative or positive for targeted Epstein-Barr virus (EBV) DNA.

Clinical Reference

Performance

Method Description
Viral nucleic acid is extracted by the MagNA Pure automated instrument (Roche Applied Science) from clinical specimens. Primers are directed to the target gene (latent membrane protein). The LightCycler instrument amplifies and monitors by fluorescence the development of target nucleic acid sequences after the annealing step during PCR cycling. This is an automated PCR system that can rapidly detect (30-40 minutes) amplicon development through stringent air-controlled temperature cycling in capillary cuvettes. 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, LC-Red 640, 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. Melting curve analysis is performed following PCR amplification. Starting at 45 degrees C, the temperature in the thermal chamber is slowly raised to 80 degrees C and the fluorescence is measured at frequent intervals. Analysis of the PCR amplification and probe melting curves is accomplished through the use of LightCycler software.(Espy MJ, Patel R, Paya C, Smith TF: Quantification of Epstein-Barr virus viral load in transplant patients by LightCycler PCR. Abstr Gen Meet Am Soc Microbiol 2001;May:20-24)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday; 6 a.m.

**Analytic Time**
Monday through Friday: 2 days; Saturday, Sunday: 3 days

**Maximum Laboratory Time**
5 days

**Specimen Retention Time**
1 week

**Performing Laboratory Location**
Rochester

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**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 was developed using an analyte specific reagent. 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**
87798

**LOINC® Information**

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<th>Order LOINC Value</th>
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<td>LEBV</td>
<td>Epstein-Barr Virus PCR</td>
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