Overview

Useful For
Diagnosis of EBV-associated infectious mononucleosis in individuals with equivocal or discordant Epstein-Barr virus (EBV) serologic marker test results

Diagnosis of posttransplant lymphoproliferative disorders (PTLD), especially in EBV-seronegative organ transplant recipients receiving antilymphocyte globulin for induction immunosuppression and OKT-3 treatment for early organ rejection

Monitoring progression of EBV-associated PTLD in organ transplant recipients

Method Name
Real-Time Polymerase Chain Reaction (PCR) Followed by Minor Groove-Binding (MGB) Probe Hybridization

NY State Available
Yes

Specimen

Specimen Type
Plasma EDTA

Shipping Instructions
1. Freeze plasma specimen immediately, and ship specimen frozen on dry ice.

2. If shipment will be delayed for more than 7 days, freeze plasma specimen at -20 degrees C (up to 30 days) until shipment on dry ice.

Specimen Required
Collection Container/Tube: Lavender top (EDTA)

Submission Container/Tube: Plastic vial

Specimen Volume: 1.5 mL

Collection Instructions:
1. Centrifuge blood collection tube per collection tube manufacturer's instructions.

2. Pour off plasma into aliquot tube.

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
0.8 mL

Reject Due To

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<table>
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<tr>
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<tbody>
<tr>
<td>Hemolysis</td>
<td>Mild OK; Gross OK</td>
</tr>
<tr>
<td>Lipemia</td>
<td>Mild OK; Gross OK</td>
</tr>
<tr>
<td>Icterus</td>
<td>NA</td>
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<td>Other</td>
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Specimen Stability Information

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<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
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<tbody>
<tr>
<td>Plasma EDTA</td>
<td>Frozen (preferred)</td>
<td>30 days</td>
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<tr>
<td></td>
<td>Refrigerated</td>
<td>7 days</td>
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Clinical and Interpretive

Clinical Information
Primary infection with Epstein-Barr virus (EBV), a DNA virus in the Herpesviridae family, may cause infectious mononucleosis resulting in a benign lymphoproliferative condition characterized by fever, fatigue, sore throat, and lymphadenopathy. Infection occurs early in life, and by 10 years of age, 70% to 90% of children have been infected with this virus. Usually, infection in children is asymptomatic or mild and may be associated with minor illnesses such as upper respiratory tract infection, pharyngitis, tonsillitis, bronchitis, and otitis media.

The target cell for EBV infection is the B-lymphocyte. Immunocompromised individuals lacking antibody to EBV are at risk for acute EBV infection that may cause lymphoproliferative disorders in organ transplant recipients (posttransplant lymphoproliferative disorders [PTLD]) and AIDS-related lymphoma. The incidence of PTLD ranges from 1% for renal transplant recipients to as high as 9% for heart/lung transplants and 12% for pancreas transplant patients.

EBV DNA can be detected in the blood of patients with this viral infection, and increasing serial levels of EBV DNA in plasma have been shown to correlate highly with subsequent (in 3-4 months) development of PTLD in susceptible patients. Organ transplant recipients who are sero-negative (at risk for primary EBV infection) for EBV (most often children) who receive antilymphocyte globulin for induction immunosuppression and OKT-3 treatment for early organ rejection are at highest risk for developing PTLD when compared to immunologically normal individuals with prior EBV infection.

Reference Values
Undetected

Interpretation
The quantification range of this assay is 100 to 5,000,000 IU/mL (or 2.00-6.70 log IU/mL), with a limit of detection (based on a 95% detection rate) at 45 IU/mL (1.65 log IU/mL).

Increasing levels of Epstein-Barr virus (EBV) DNA in serial plasma specimens of a given organ transplant recipient
may indicate possible development of posttransplant lymphoproliferative disorder (PTLD).

An "Undetected" result indicates that EBV DNA is not detected in the plasma specimen (see Cautions). If clinically indicated, repeat testing in 1 to 2 months is recommended.

A result of "<100 IU/mL" indicates that the EBV DNA level present in the plasma specimen is below 100 IU/mL (or 2.00 log IU/mL), and the assay cannot accurately quantify the EBV DNA present below this level.

A quantitative value (reported in IU/mL and log IU/mL) indicates the EBV DNA level (ie, viral load) present in the plasma specimen.

A result of ">5,000,000 IU/mL" indicates that the EBV DNA level present in the plasma specimen is above 5,000,000 IU/mL (6.70 log IU/mL), and this assay cannot accurately quantify the EBV DNA present above this level.

An "Inconclusive" result indicates that the presence or absence of EBV DNA in the plasma specimen could not be determined with certainty after repeat testing in the laboratory, possibly due to PCR inhibition or presence of interfering substance. Submission of a new specimen for testing is recommended if clinically indicated.

**Cautions**

Serial determination of plasma specimens from organ transplant recipients may be necessary to monitor increasing (risk of development of posttransplant lymphoproliferative disorders: PTLD) or decreasing (treatment efficacy) levels of Epstein-Barr virus (EBV) DNA.

Nonsymptomatic EBV viremia or viral shedding may occur occasionally in healthy individuals. Therefore, this test should be used only for patients with a clinical history and symptoms consistent with EBV infection, and must be interpreted in the context of patient’s clinical history, signs and symptoms. This test should not be used to screen asymptomatic patients.

Only plasma specimens are acceptable for testing with this assay, and lipemic plasma specimens may result in reduced assay sensitivity or assay failure.

Due to potential differences in assay performance, serial monitoring of a patient's EBV viral load should be performed using the same exact assay.

**Clinical Reference**


Performance

Method Description
Testing is performed using a combination of MGB Alert EBV Primer and Probe ASRs (ELITechGroup Molecular Diagnostics, Inc.) and 2x MGB Alert PCR Master Mix with the Abbott m2000 RealTime System (Abbott Molecular, Inc.). The MGB Alert reagents are designed based on minor groove-binding Pleiades probe chemistry. This assay amplifies the p140 region of the BNRF1 gene of Epstein-Barr virus (EBV) for detection and quantification of EBV DNA in human plasma.

The Abbott mSample Preparation System kit is used with the automated Abbott m2000sp sample preparation system to extract and purify viral DNA from human plasma specimens, based on magnetic particle technology. An internal control template is introduced into each specimen during sample preparation to assess extraction failure or inhibition during the sample preparation and qPCR processes, respectively. Amplification and detection of target sequence is performed on the Abbott m2000rt instrument. The assay is calibrated to the First World Health Organization International Standard for EBV, NIBSC code: 09/260 by using commercially available EBV verification panels consisting of multiple panel members calibrated to the WHO standard and with EBV DNA levels ranging over 4 log IU/mL. (Unpublished Mayo method)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday; 7 a.m.-4 p.m.

Analytic Time
2 days

Maximum Laboratory Time
3 days

Specimen Retention Time
30 days

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 was developed and its performance characteristics 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
87799
## LOINC® Information

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<td>EBV DNA Detect / Quant, P</td>
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