Overview

Useful For
Aiding in the diagnosis of acute or past infection with cytomegalovirus (CMV)

Determination of prior exposure to CMV

Profile Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMVM</td>
<td>Cytomegalovirus Ab, IgM, S</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>CMVG</td>
<td>Cytomegalovirus Ab, IgG, S</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Method Name
Multiplex Flow Immunoassay (MFI)

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Aliquot tube

Specimen Volume: 1 mL

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

Specimen Minimum Volume
0.8 mL

Reject Due To

<table>
<thead>
<tr>
<th>Condition</th>
<th>Acceptance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemolysis</td>
<td>Mild OK; Gross reject</td>
</tr>
<tr>
<td>Lipemia</td>
<td>Mild OK; Gross reject</td>
</tr>
<tr>
<td>Icterus</td>
<td>Mild OK; Gross reject</td>
</tr>
</tbody>
</table>
Test Definition: CMVP
Cytomegalovirus Ab, IgM and IgG, S

<table>
<thead>
<tr>
<th>Other</th>
<th>Heat-inactivated specimen</th>
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</thead>
</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>14 days</td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>14 days</td>
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</tbody>
</table>

Clinical and Interpretive

Clinical Information

Cytomegalovirus (CMV) is a member of the Herpesviridae family of viruses and usually causes asymptomatic infection after which it remains latent in patients, primarily within bone marrow derived cells. Primary CMV infection in immunocompetent individuals may also manifest as a mononucleosis-type syndrome, similar to primary Epstein-Barr virus infection, with fever, malaise and lymphadenopathy.

CMV is a significant cause of morbidity and mortality among bone marrow or solid organ transplant recipients, individuals with AIDS and other immunosuppressed patients due to virus reactivation or from a newly acquired infection. Infection in these patient populations can affect almost any organ and lead to multiorgan failure. CMV is also responsible for congenital disease among newborns and is 1 of the TORCH infections (toxoplasmosis, other infections including syphilis, rubella, CMV, and herpes simplex virus).

CMV seroprevalence increases with age. In the United States the prevalence of CMV specific antibodies increases from approximately 36% to over 91% in adolescents between the ages of 6 to 11 and adults over 80 years old, respectively.

Reference Values

CMV IgM:
- Negative

CMV IgG:
- Negative

Reference values apply to all ages.

Interpretation

IgM:

A negative cytomegalovirus (CMV) IgM result suggests that the patient is not experiencing acute or active infection. However, a negative result does not rule-out primary CMV infection.

It has been reported that CMV-specific IgM antibodies were not detectable in 10% to 30% of cord blood sera from infants demonstrating infection in the first week of life. In addition, up to 23% (3/13) of pregnant women with primary CMV infection did not demonstrate detectable CMV IgM responses within 8 weeks postinfection. In cases of primary infection where the time of seroconversion is not well defined as high as 28% (10/36) of pregnant women did not
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Cytomegalovirus Ab, IgM and IgG, S

demonstrate CMV IgM antibody.

Positive CMV IgM results indicate a recent infection (primary, reactivation, or reinfection). IgM antibody responses in secondary (reactivation) CMV infections have been demonstrated in some CMV mononucleosis patients, in a few pregnant women, and in renal and cardiac transplant patients. Levels of antibody may be lower in transplant patients with secondary rather than primary infections.

IgG:

Positive CMV IgG results indicate past or recent CMV infection. These individuals may transmit CMV to susceptible individuals through blood and tissue products.

Individuals with negative CMV IgG results are presumed to not have had prior exposure or infection with CMV and are, therefore, considered susceptible to primary infection.

Equivocal CMV IgM or IgG results may occur during acute infection or may be due to nonspecific binding reactions. Submit an additional sample for testing if clinically indicated.

Cautions

Sera drawn very early during the acute stage of infection may have undetectable levels of cytomegalovirus (CMV) IgM or IgG.

Immunocompromised patients may have impaired immune responses and non-reactive IgM/IgG results may be due to delayed seroconversion and do not rule out current infection.

The CMV IgM and IgG results should not be used alone to diagnose CMV infection. Results should be considered in conjunction with clinical presentation, patient history and other laboratory findings. In cases of suspected disease, submit a second sample for testing in 10 to 14 days.

The performance characteristics of these assays have not been evaluated in immunosuppressed or organ transplant recipients and have not been established for cord blood or for testing of neonates. These assays should not be used for screening blood or plasma donors.

Immune complexes or other immunoglobulin aggregates present in patient samples may cause increased nonspecific binding and produce false-positive results.

Potential cross-reactivity for CMV IgM may occur with specimens positive for Epstein-Barr virus viral capsid antigen IgM and parvovirus B19 IgM.

Potential cross-reactivity for CMV IgG with human chorionic gonadotropin, HIV IgG, multiple myeloma IgG, rheumatoid factor IgM, and Toxoplasma gondii IgG have not be ruled out.

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Performance

Method Description
The BioPlex 2200 cytomegalovirus (CMV) IgM and IgG assay use multiplex flow immunoassay technology. Briefly, CMV antigen-coated fluorescent beads are mixed with an aliquot of patient sample and sample diluent and incubated at 37 degrees C. During this time IgM and IgG anti-CMV antibodies in the specimen will bind to the CMV antigen on the beads. After a wash cycle, a fluorescently labeled antihuman IgM- and IgG-antibody conjugate is added to the mixture and incubated at 37 degrees C. Following a wash step to remove unbound conjugate, the bead mixture is passed through a detector that identifies the bead based on dye fluorescence and determines the amount of antibody captured by the antigen based on fluorescence of the antihuman-IgG conjugate. Raw data is calculated in relative fluorescence intensity and is converted to an antibody index for interpretation. Antibody index (AI) values of 0.8 and lower are considered negative. AI values of 0.9 and 1.0 are equivocal. AI values of 1.1 and above are considered positive. Three additional dyed beads, an internal standard bead, a serum verification bead, and a reagent black bead are present in each reaction mixture to verify detector response, the addition of serum to the reaction vessel and the absence of significant nonspecific binding in serum, respectively. (Package inserts: BioPlex 2200 System, ToRC IgG and ToRC IgM, Bio-Rad Laboratories, Clinical Diagnostics Group, Hercules, CA 3/2012)

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
14 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 has been cleared or approved by the U.S. 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.
**Test Definition: CMVP**
Cytomegalovirus Ab, IgM and IgG, S

### CPT Code Information
- 86644-CMV, IgG
- 86645-CMV, IgM

### LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>CMVP</td>
<td>Cytomegalovirus Ab, IgM and IgG, S</td>
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<table>
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<th>Test Result Name</th>
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<tbody>
<tr>
<td>CMVG</td>
<td>Cytomegalovirus Ab, IgG, S</td>
<td>13949-3</td>
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<tr>
<td>CMVM</td>
<td>Cytomegalovirus Ab, IgM, S</td>
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