MAYO CLINIC LABORATORIES

Test Definition: CMVAB

Cytomegalovirus Antibody, IgM and IgG, Serum

Overview

Useful For

Aiding in determining the serological status to cytomegalovirus

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
CMVMS	CMV Ab, IgM, S	Yes	Yes
CMVGS	CMV Ab, IgG, S	Yes	Yes

Method Name

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Supplies: Sarstedt Aliquot Tube 5 mL (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.7 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial

Forms

If not ordering electronically, complete, print, and send an Infectious Disease Serology Test Request (T916) with the specimen.

Specimen Minimum Volume

0.7 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject
Additives (eg, biocides, antioxidants)	Reject
Heat inactivation	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	28 days	
	Ambient	7 days	
	Frozen	90 days	

Clinical & 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 manifest as a mononucleosis-type syndrome, similar to primary Epstein-Barr virus infection, with fever, malaise and lymphadenopathy.

Cytomegalovirus 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 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 one of the TORCH infections (toxoplasmosis, other infections including syphilis, rubella, CMV, and herpes simplex virus).

Cytomegalovirus seroprevalence increases with age. In the US, the prevalence of CMV-specific antibodies increases from approximately 36% in children aged 6 to 11 years to over 91% in adults older than 80 years.

A negative 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 demonstrate CMV-IgM antibody.

Reference Values

CYTOMEGALOVIRUS IgM
Negative

CYTOMEGALOVIRUS IgG
Negative

Reference values apply to all ages.

Interpretation

Negative:
Negative for cytomegalovirus (CMV) IgM and IgG. False-negative results may occur in immunocompromised patients.

Borderline:
Recommend follow-up testing in 10 to14 days if clinically indicated.

Positive IgG:
CMV IgG antibodies detected, which indicate recent or remote infection. These individuals may transmit CMV to susceptible individuals through blood and tissue products.

Positive IgM:
CMV IgM antibodies detected, which may indicate active or recent infection. Low level IgM antibodies may persist for more than 12 months following disease resolution.

Cautions

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

Performance characteristics have not been evaluated in immunocompromised or immunosuppressed individuals. Immunocompromised patients may have impaired immune responses and nonreactive IgM and IgG results may be due to delayed seroconversion and, therefore, 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.

The performance characteristics of these assays have not been evaluated or established for blood or plasma donors, cord blood, patients undergoing immunosuppressive therapy, patients with other disorders leading to immune suppression, or testing neonates.

Immune complexes or other immunoglobulin aggregates present in patient specimens 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. Potential cross-reactivity with autoimmune markers and antibodies against influenza vaccination could not be ruled out.

Potential cross-reactivity for CMV IgG with varicella-zoster virus IgG, measles IgG, mumps IgG and parvovirus B19 IgG and could not be ruled out. The potential cross-reactivity with *Escherichia coli* and autoimmune markers could not be ruled out.

Samples should not be taken from patients receiving therapy with high biotin doses (ie, >5 mg/day) until at least 8 hours following the last biotin administration.

The anti-CMV IgG results in a given specimen, as determined by assays from different manufacturers, can vary due to differences in assay and reagent methods. The results obtained with the Elecsys CMV IgG assay, a qualitative test indicates the absence or presence of CMV IgG antibodies in the sample. Specific cutoff index values, or changes thereof, are not related to specific antibody concentrations in a sample and cannot be compared to numeric assay results from assays of other manufacturers.

Clinical Reference

1. Fowler K, Mucha J, Neumann M, et al. A systematic literature review of the global seroprevalence of cytomegalovirus: possible implications for treatment, screening, and vaccine development. BMC Public Health. 2022;22(1):1659. Published 2022 Sep 1. doi:10.1186/s12889-022-13971-7
2. Limaye AP, Babu TM, Boeckh M. Progress and challenges in the prevention, diagnosis, and management of cytomegalovirus infection in transplantation. Clin Microbiol Rev. 2020;34(1):e00043-19. Published 2020 Oct 28. doi:10.1128/CMR.00043-19
3. Leber AL. Maternal and congenital human cytomegalovirus infection: laboratory testing for detection and diagnosis. J Clin Microbiol. 2024;62(4):e0031323. doi:10.1128/jcm.00313-23
4. Bruminhent J, Thongprayoon C, Dierkhising RA, Kremers WK, Theel ES, Razonable RR. Risk factors for cytomegalovirus reactivation after liver transplantation: can pre-transplant cytomegalovirus antibody titers predict outcome?. Liver Transpl. 2015;21(4):539-546. doi:10.1002/lt.2407
5. Dioverti MV, Razonable RR. Cytomegalovirus. In: Hayden RT, Wolk DM, Carroll KC, Tang YW, eds. Diagnostic Microbiology of the Immunocompromised Host; 2016:97-125

Performance

Method Description

Cytomegalovirus IgM:
The electrochemiluminescence immunoassay for the in vitro qualitative determination of IgM antibodies to cytomegalovirus (CMV) in human serum is a micro-capture test principle. During the first incubation, 6 mcL of sample are automatically prediluted 1:20 with Diluent Universal. Biotinylated monoclonal anti-h-IgM-specific antibodies are added. In the second incubation, CMV-specific recombinant antigen labeled with a ruthenium complex and streptavidin-coated microparticles are added. The complex becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell II M. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier. Results are determined automatically by the software by comparing the electrochemiluminescence signal obtained from the reaction product of the sample with the signal of the cutoff value previously obtained by calibration.(Package insert:

Elecsys CMV IgM, Roche Diagnostics GmbH, 11/2022)

Cytomegalovirus IgG:
The electrochemiluminescence immunoassay for the in vitro quantitative determination of IgG antibodies to CMV in human serum is a sandwich test principle. During the first incubation, 12 mcL of sample, biotinylated recombinant CMV-specific antigens, and CMV-specific recombinant antigens labeled with a ruthenium complex form a sandwich complex. In the second incubation, streptavidin-coated microparticles are added and the complex becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell II M. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier. Results are determined by a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the cobas link.(Package insert: Elecsys CMV IgG, Roche Diagnostics GmbH, 01/2023)

PDF Report
No

Day(s) Performed
Monday through Saturday

Report Available
Same day/1 to 3 days

Specimen Retention Time
14 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

Fees & 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 account representative. For assistance, contact Customer Service.

Test Classification
This test has been cleared, approved, or is exempt by the US 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.

CPT Code Information
86645-Cytomegalovirus IgM

86644-Cytomegalovirus IgG

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CMVAB	CMV Ab, IgM and IgG, S	87424-8

Result ID	Test Result Name	Result LOINC® Value
MCMV	CMV Ab, IgM, S	30325-5
GCMV	CMV Ab, IgG, S	22244-8