MAYO CLINIC LABORATORIES

Test Definition: CMVP

Cytomegalovirus (CMV) Antibodies, IgM and IgG, Serum

Overview

Useful For

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

Determining prior exposure to CMV

This test should **not be used for** screening blood or plasma donors.

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
CMVM	Cytomegalovirus Ab, IgM, S	Yes	Yes
CMVG	Cytomegalovirus Ab, IgG, S	Yes	Yes

Method Name

Multiplex Flow Immunoassay (MFI)

NY State Available

No

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: 1 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Specimen Minimum Volume

0.8 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject
Heat-inactivated specimen	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Frozen	14 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 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 one of the TORCH infections (toxoplasmosis, other infections including syphilis, rubella, CMV, and herpes simplex virus).

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

Reference Values

CYTOMEGALOVIRUS IgM:
Negative

CYTOMEGALOVIRUS 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 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, a few pregnant women, and kidney 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 specimen for testing if clinically indicated.

Cautions

Sera collected 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 nonreactive IgM/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. In cases of suspected disease, submit a second specimen for testing in 10 to 14 days.

The performance characteristics of these assays have not been evaluated in immunosuppressed patients or organ transplant recipients and have not been established for cord blood or for testing of 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 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.

Clinical Reference

1. Soderberg-Naucler C, Fish NK, Nelson JA. Reactivation of latent human cytomegalovirus by allogeneic stimulation of blood cells from healthy donors. Cell. 1997;91(1):119-126
2. 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
3. Dioverti MV, Razonable RR. Cytomegalovirus. Microbiol Spectr. 2016;4(4)
4. Staras SA, Dollard SC, Radford KW, Flanders WD, Pass RF, Cannon MJ. Seroprevalence of cytomegalovirus infection in the United States, 1998-1994. Clin Infect Dis. 2006;43(9):1143-1151

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 insert: BioPlex 2200 System, ToRC IgG ToRC IgM, Bio-Rad Laboratories, Clinical Diagnostics Group, Hercules, CA 3/2012)

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 Jacksonville Clinical Lab

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

86644-CMV, IgG
86645-CMV, IgM

LOINC® Information

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

Result ID	Test Result Name	Result LOINC® Value
CMVG	Cytomegalovirus Ab, IgG, S	13949-3
CMVM	Cytomegalovirus Ab, IgM, S	24119-0