MAYO CLINIC LABORATORIES

Test Definition: CMVG

Cytomegalovirus (CMV) Antibodies, IgG, Serum

Overview

Useful For

Determining whether a patient (especially transplant recipients and organ and blood donors) has had a recent infection or previous exposure to cytomegalovirus

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: Plastic vial

Specimen Volume: 0.5 mL

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

Forms

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

Specimen Minimum Volume

0.4 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.(1) 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.(2,3) 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).

CMV 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.(4)

Reference Values

Negative (reported as positive, negative, or equivocal)

Interpretation

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

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

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.

Cautions

Sera collected very early during the acute stage of infection may have undetectable levels of cytomegalovirus (CMV) IgG. The CMV IgG assay 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 this assay 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 with human chorionic gonadotropin, HIV IgG, multiple myeloma IgG, rheumatoid factor IgM, and *Toxoplasma gondii* IgG have not be ruled out.

Supportive Data

To evaluate the accuracy of the BioPlex cytomegalovirus (CMV) IgG multiplex flow immunoassay, 598 prospective serum samples submitted for routine CMV IgG testing by the VIDAS enzyme-linked fluorescence immunoassay (ELFA; bioMerieux) were also analyzed in a blinded fashion by the BioPlex assay within a 24-hour period. Samples with discordant results after initial testing were repeated by both assays during the same freeze/thaw cycle. Further resolution of discrepant results was performed by using the Diamedix CMV IgG enzyme immunoassay. The results are summarized in the table below:

Table. CMV IgG Comparison

		CMV IgG (VIDAS ELFA)		
BioPlex CMV IgG		Positive	Negative	Equivocal
	Positive	336	2(a)	0
	Negative	3(b)	254	3
	Equivocal	0	0	0

a) Both serum samples were negative by the Diamedix CMV IgG EIA
b) All three serum samples were negative by the Diamedix CMB IgG EIA
Sensitivity: 99.1% (336/339); 95% CI: 97.3%-99.8%
Specificity: 99.2% (254/256); 95% CI: 97.0%-100%)
Overall Percent Agreement: 98.7% (590/598); 95% CI: 97.3%-99.4%

Clinical Reference

1. Soderberg-Naucler C, Fish KN, Nelson JA: Reactivation of latent human cytomegalovirus by allogeneic stimulation of blood cells from healthy donors. 1997 Oct 3;91(1):119-126
2. Kusne S, Shapiro R, Fung J: Prevention and treatment of cytomegalovirus infection in organ transplant recipients. Transpl Infect Dis. 1999 Sep;1(3):187-203
3. Rubin RH: Importance of CMV in the transplant population. Transpl Infect Dis. 1999;1 Suppl 1:3-7
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 Nov 143(9):1143-1151
5. 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 Apr;21(4):539-546
6. Dioverti MV, Razonable RR: Cytomegalovirus. Microbiol Spectr. 2016;4(4). doi: 10.1128/microbiolspec.DMIH2-0022-2015

Performance

Method Description

The BioPlex 2200 cytomegalovirus (CMV) IgG assay uses 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 IgG anti-CMV antibodies in the specimen will bind to the CMV antigen on the beads. After a wash cycle, a fluorescently labeled antihuman 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 are calculated in relative fluorescence intensity and is converted to an antibody index for interpretation. Antibody index (AI) values 0.8 and lower are considered negative. AI values of 0.9 and 1.0 are equivocal. AI values 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, Bio-Rad Laboratories;03/2012)

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
Rochester

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

LOINC® Information

Test Definition: CMVG

Cytomegalovirus (CMV) Antibodies, IgG, Serum

Test ID	Test Order Name	Order LOINC® Value
CMVG	Cytomegalovirus Ab, IgG, S	13949-3

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