

Overview

Useful For

Determining whether a patient has had previous exposure to or recent infection with cytomegalovirus, including pregnant women.

This test is not useful for screening blood or plasma donors, or neonatal screening.

Highlights

Detection of IgG-class antibodies to cytomegalovirus (CMV) may be useful to assess the serological status of CMV.

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: 0.6 mL

Collection Instructions: Centrifuge and aliquot serum into plastic vial

Forms

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

Specimen Minimum Volume

0.6 mL

Reject Due To

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

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	28 days	
	Ambient	7 days	
	Frozen	180 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 also 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.(4)

Reference Values

Negative

Reference values apply to all ages.

Interpretation

Negative

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

Borderline

Recommend follow-up testing in 10 to 14 days if clinically indicated.

Positive

Cytomegalovirus IgG antibodies detected, which indicate recent or remote 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 detection of CMV-specific IgG antibodies in a single sample indicates a previous exposure to CMV but is not sufficient to distinguish between an acute or latent 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.

Performance characteristics have not been evaluated in immunosuppressed patients or organ transplant recipients and have not been established for cord blood or testing neonates. Immunocompromised patients may have impaired immune responses and nonreactive IgG results may be due to delayed seroconversion and, therefore, do not rule out current infection.

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 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
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
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. Brumihent 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):539-46. doi:10.1002/lt.2407
5. Dioverti MV, Razonable RR. Cytomegalovirus. *Diagnostic Microbiology of the Immunocompromised Host*. 2016 Aug 15:97-125

Performance

Method Description

The electrochemiluminescence immunoassay for the in vitro quantitative determination of IgG antibodies to cytomegalovirus (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

86644

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CMVGS	CMV Ab, IgG, S	22244-8

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