

Overview

Useful For

Aiding in the diagnosis of acute infection with cytomegalovirus

Highlights

Detection of IgM-class antibodies to cytomegalovirus may be useful to assess for recent infection with cytomegalovirus.

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 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

See Specimen Required

Reject Due To

| | |
|-----------------|--------|
| Gross hemolysis | Reject |
| Gross lipemia | Reject |
| Gross icterus | Reject |
| Additives (eg, | Reject |

| | |
|----------------------------|--------|
| biocides, antioxidants) | |
| Heat inactivated | 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 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 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 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

Negative

Reference values apply to all ages.

Interpretation

Negative:

No IgM to cytomegalovirus (CMV) detected. False negative results may occur in immunocompromised patients.

Borderline:

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

Positive:

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.

The CMV IgM 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 IgM antibodies in a single sample is not sufficient to prove an acute infection. In single cases elevated IgM antibody levels may persist even for years after initial infection.

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

Sera from patients with primary EBV infections can demonstrate positive results in the Elecsys CMV IgM assay. This is not unexpected as both viruses belong to the herpes virus family and this potential interference is known for the CMV IgM assays. Potential cross-reactivity with autoimmune markers and antibodies against influenza vaccination could not be ruled out. As with many micro-capture assays, an interference with unspecific IgM is observed. Increasing amounts of unspecific IgM may lead to a decrease in the recovery of positive samples with the Elecsys CMV IgM assay.

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.

Clinical Reference

1. 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.24078
2. Dioverti MV, Razonable RR. Cytomegalovirus. *Microbiol Spectr*. 2016;4(4):10.1128/microbiolspec.DMIH2-0022-2015. doi:10.1128/microbiolspec.DMIH2-0022-2015
3. 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
4. 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
5. Leber AL. Maternal and congenital human cytomegalovirus infection: laboratory testing for detection and diagnosis

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Performance

Method Description

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. 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)

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

LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---------|-----------------|--------------------|
| CMVMS | CMV Ab, IgM, S | 30325-5 |

| Result ID | Test Result Name | Result LOINC® Value |
|-----------|------------------|---------------------|
| MCMV | CMV Ab, IgM, S | 30325-5 |