Test Definition: CMVLR

Cytomegalovirus (CMV) Molecular Detection, PCR, Lower Respiratory

Overview

Useful For

Rapid qualitative detection of cytomegalovirus (CMV) DNA in lower respiratory specimens

This test is **not intended** for the monitoring of CMV disease progression or response to therapy.

Method Name

Real-Time Polymerase Chain Reaction (PCR)/DNA Probe Hybridization

NY State Available

No

Specimen

Specimen Type

Varies

Ordering Guidance

For plasma specimens, order CMVQN / Cytomegalovirus (CMV) DNA Detection and Quantification by Real-Time PCR, Plasma.

Necessary Information

Specimen source is required.

Specimen Required

Specimen Type: Lower respiratory
Source: Bronchial washing, bronchoalveolar lavage, fluid/washings from lung, sputum, tracheal secretions, tracheal aspirates
Container/Tube:
Preferred: Sterile, screwcap, 5-mL aliquot tube
Acceptable: Sterile container
Specimen Volume: 1 mL
Collection Instructions: Do not centrifuge.

Specimen Minimum Volume

0.5 mL

Reject Due To

Lower	Reject

respiratory swab Calcium alginate-tipped swab Wood swab Transport swab containing gel Feces Paraffin blocks Tissue specimens Tissue biopsy Bronchial brushings Heat-inactivated specimens Lower respiratory in transport media	

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Refrigerated (preferred)	7 days	
	Frozen	7 days	

Clinical & Interpretive

Clinical Information

Cytomegalovirus (CMV) is a double-stranded DNA virus of the Herpesviridae family. CMV is transmitted through infected body fluids, as well as through sexual contact, organ transplantation, and intrauterine transmission during pregnancy. CMV infection may be asymptomatic but can cause a wide range of symptoms in immunocompromised individuals. Detection of CMV DNA in lower respiratory specimens may support the clinical diagnosis of CMV pneumonitis. Infection with CMV is a significant cause of morbidity and mortality in transplant recipients and other immunocompromised hosts.

Reference Values

Negative

Reference values apply to all ages.

Interpretation

A positive result indicates the presence of cytomegalovirus (CMV) DNA in the patient specimen.

A negative result indicates the absence of CMV DNA in the patient specimen but does not rule out possible infection with CMV.

An invalid result indicates the inability to conclusively determine presence or absence of CMV DNA in the patient specimen.

Cautions

This test is not validated for lung tissue or biopsy specimens; it is only validated for the lower respiratory specimens indicated in Specimen Required.

Negative results do not preclude cytomegalovirus (CMV) infection and should not be used as the sole basis for treatment or other patient management decisions.

False-negative results may occur if the viral nucleic acid is present at a level below the analytical sensitivity of the assay, if the virus has genomic mutations, insertions, deletions, or rearrangements, or if the assay is performed very early in the course of illness.

The performance of this test has not been established for monitoring treatment of CMV infection.

Clinical Reference

1. Caliendo, AM. Approach to the diagnosis of cytomegalovirus infection. UpToDate; Updated May 16, 2024. Accessed November 1, 2024. Available at www.uptodate.com/contents/approach-to-the-diagnosis-of-cytomegalovirus-infection
2. Fernholz EC, Vidal-Folch N, Hasadsri L. Rapid and direct detection of congenital cytomegalovirus using a commercial real-time PCR assay. J Clin Microbiol. 2023;61(3):e0178122. doi:10.1128/jcm.01781-22
3. Saksirisampant G, Kawamatawong T, Promsombat K, et al. A prospective study of plasma and bronchoalveolar lavage fluid CMV DNA load quantification for the diagnosis and outcome of CMV pneumonitis in immunocompromised hosts. J Clin Virol. 2022;155:105243. doi:10.1016/j.jcv.2022.105243
4. Setiabudi D, Sukur RR, Nugraha HG, Nataprawira HM. Cytomegalovirus pneumonitis in infants: The challenge in diagnosis among pediatricians. IDCases. 2023;32:e01724. doi:10.1016/j.idcr.2023.e01724
5. Prokop K, Schmitt B. Performance evaluation of a new CMV Direct PCR assay using urine, CSF and Bronchoalveolar lavage specimen types.ASM Clinical Virology Symposium. 09/11/2023

Performance

Method Description

The Simplexa Congenital CMV (cytomegalovirus) Direct assay is a real-time polymerase chain reaction (PCR) system that enables the direct amplification and detection of CMV DNA from liquid lower respiratory specimens without nucleic acid extraction. The system consists of the Simplexa Congenital CMV Direct Reaction Mix, the LIAISON MDX (with LIAISON MDX Studio Software), the direct amplification disc, and associated accessories.

In the Simplexa Congenital CMV Direct assay, bifunctional fluorescent probe-primers are used together with corresponding reverse primers to amplify CMV DNA. A well-conserved region of the CMV UL83 gene is targeted to identify CMV DNA. An internal control is used to detect PCR failure or inhibition. (Package insert: Simplexa Congenital CMV Direct. Diasorin; REF MOL2255. Rev. 01, 11/2022)

PDF Report
No

Day(s) Performed
Monday through Saturday

Report Available
Same day/1 to 2 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 was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
87496

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CMVLR	Cytomegalovirus, PCR, Lower Resp	104760-4

Result ID	Test Result Name	Result LOINC® Value
CMVSS	Specimen Source	31208-2
621771	CMVLR, PCR	104760-4