# 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<br>Calcium alginate-tipped swab<br>Wood swab<br>Transport swab containing gel<br>Feces<br>Paraffin blocks<br>Tissue specimens<br>Tissue biopsy<br>Bronchial brushings<br>Heat-inactivated specimens<br>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 |