MAYO CLINIC LABORATORIES

# Test Definition: CMVQN

Cytomegalovirus (CMV) DNA Detection and Quantification by Real-Time PCR, Plasma

## Overview

### Useful For

Detection and quantification of cytomegalovirus (CMV) viremia

Monitoring CMV disease progression and response to antiviral therapy

### Method Name

Real-Time Polymerase Chain Reaction (PCR)

### NY State Available

Yes

## Specimen

### Specimen Type

Plasma EDTA

### Shipping Instructions

1. Ship specimen frozen on dry ice only.
2. If shipment will be delayed for more than 24 hours, freeze plasma at -20 to -80 degrees C (up to 84 days) before shipment and transport on on dry ice.

### Specimen Required

**Supplies:** Sarstedt Aliquot Tube, 5 mL (T914)
**Collection Container/Tube:** Lavender top (EDTA)
**Submission Container/Tube:** Plastic vial
**Specimen Volume:** 1.5 mL Plasma
**Collection Instructions:** Within 2 hours of collection, centrifuge and aliquot plasma into a plastic vial.

### Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:
-Microbiology Test Request (T244)
-General Test Request (T239)
-Kidney Transplant Test Request

### Specimen Minimum Volume

Plasma: 0.6 mL

### Reject Due To

| | |
|---|---|
| Gross hemolysis | Reject |
| Gross lipemia | OK |
| Gross icterus | OK |

### Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---|---|---|---|
| Plasma EDTA | Frozen (preferred) | 84 days | |
| | Refrigerated | 6 days | |

## Clinical & Interpretive

### Clinical Information

Cytomegalovirus (CMV) is a common and major cause of opportunistic infection in organ transplant recipients, causing significant morbidity and mortality. CMV infection and disease typically occur during the first year after organ transplantation after cessation of antiviral prophylaxis. Such infection usually manifests as fever, leukopenia, hepatitis, colitis, or retinitis. Other manifestations of CMV infection in this population may be more subtle and include allograft injury and loss, increased susceptibility to infections with other organisms, and decreased patient survival (ie, indirect effects). The risk of CMV disease is highest among organ recipients who are CMV seronegative prior to transplantation and receive allografts from CMV-seropositive donors (ie, CMV D+/R- mismatch). The infection is transmitted via latent CMV present in the transplanted organ donor and the virus subsequently reactivates, causing a primary CMV infection in the recipient. CMV disease may also occur from reactivation of the virus already present within the recipients. Factors, such as the type of organ transplanted, intensity of the antirejection immunosuppressive therapy, advanced age, and presence of comorbidities in the recipient, are also associated with increased risk for CMV disease after allograft transplantation. Lung, heart, small intestine, pancreas, and kidney-pancreas transplant recipients are at greater risk for CMV infection than kidney and liver transplant recipients.

Among the various clinical laboratory diagnostic tests currently available to detect CMV infection, nucleic acid amplification tests (eg, polymerase chain reaction) are the most sensitive and specific detection methods. In addition, quantification of CMV DNA level in peripheral blood (ie, CMV viral load) is used routinely to determine when to initiate preemptive antiviral therapy, diagnose active CMV disease, and monitor response to antiviral therapy. A number of factors can affect CMV viral load results, including the specimen type (whole blood versus plasma), biologic properties of CMV, performance characteristics of the quantitative assay (eg, limit of detection, limits of quantification, linearity, and reproducibility), degree of immunosuppression, and intensity of antiviral therapy.

In general, higher CMV viral loads are associated with tissue-invasive disease, while lower levels are associated with asymptomatic infection. However, the viral load in the peripheral blood compartment may be low or undetectable in some cases of tissue-invasive disease. Since a wide degree of overlap exists in CMV viral load and disease, a rise in viral load over time is more important in predicting CMV disease than a single viral load result at a given time point. Therefore, serial monitoring (eg, weekly intervals) of organ transplant recipients with quantitative CMV PCR is recommended in such patients at risk for CMV disease. Since changes in viral load may be delayed by several days in

response to antiviral therapy and immunosuppression, viral load should not be monitored more frequently than a weekly basis. Typically, CMV viral load changes of greater than 0.5 log IU/mL are considered biologically significant changes in viral replication. Patients with suppression of CMV replication (ie, viral load of <35 or <1.54 log IU/mL at days 7, 14, and 21 of treatment) had shorter times to resolution of clinical disease than those without viral suppression. No degree of relative viral load reduction from pretreatment level was associated with faster resolution of CMV disease.

### Reference Values

Undetected

### Interpretation

The quantification range of this assay is 35 to 10,000,000 IU/mL (1.54 log to 7.00 log IU/mL), with a 95% or higher limit of detection at 35 IU/mL.

A result of "Undetected" indicates the absence of cytomegalovirus (CMV) DNA in the plasma (see Cautions below).

A result of "<35 IU/mL (<1.54 log IU/mL)" indicates that CMV DNA is detected in the plasma, but the assay cannot accurately quantify the CMV DNA present below this level.

A quantitative value (reported in IU/mL and log IU/mL) indicates the level of CMV DNA (ie, viral load) present in the plasma.

A result of ">10,000,000 IU/mL (>7.00 log IU/mL)" indicates that CMV DNA level present in plasma is above 10,000,000 IU/mL (7.00 log IU/mL), and the assay cannot accurately quantify CMV DNA present above this level.

### Cautions

Cytomegalovirus (CMV) viral load results generated with this assay may be higher (up to 1.00 log IU/mL) than those from the previous cobas AmpliPrep/cobas TaqMan CMV test (Roche Molecular Systems Inc), due to differences in the sensitivity of both assays.

Variants within the highly conserved regions of the CMV DNA polymerase (UL54) gene covered by cobas CMV may affect primers or probe binding resulting in the under quantitation of virus or failure to detect the presence of virus. The cobas CMV assay mitigates this risk by using redundant CMV target sequence amplification primers.

### Clinical Reference

1. Kotton CN, Kumar D, Caliendo AM, et al. The third international consensus guidelines on the management of cytomegalovirus in solid-organ transplantation. Transplantation. 2018;102(6):900-931. doi:10.1097/TP.0000000000002191
2. Razonable RR, Humar A. Cytomegalovirus in solid organ transplant recipients-Guidelines of the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019;33(9):e13512. doi:10.1111/ctr.13512
3. Razonable RR, Inoue N, Pinninti SG, et al. Clinical diagnostic testing for human cytomegalovirus infections. J Infect Dis. 2020;221(Suppl 1):S74-S85. doi:10.1093/infdis/jiz601

## Performance

### Method Description

The cobas CMV (cytomegalovirus) assay is a US Food and Drug Administration-approved, in vitro nucleic acid amplification test for the quantification of CMV DNA in human EDTA-plasma using the cobas 5800/6800/8800 systems for fully automated viral nucleic acid extraction (generic silica-based capture technique) and automated amplification and detection of the viral nucleic acid sequence. This polymerase chain reaction (PCR) assay amplifies sequences within CMV DNA polymerase (UL54) gene region and generates amplification products that are detected and quantified in real-time with 2 sequence-specific TaqMan probes. A non-CMV armored DNA quantitation standard (DNA-QS) is introduced into each specimen during sample preparation to serve as internal control for nucleic acid extraction and PCR amplification and detection processes. Fluorescent reporter dye-labeled TaqMan probes hybridized to the complementary CMV target sequences and DNA-QS sequence undergo hydrolysis during PCR amplification step to generate fluorescent signal detected in 2 different dye channels. Concentration of the CMV DNA in a patient's plasma sample is determined by a ratio of the intensity of the fluorescent dye from the cleaved CMV target sequence probes and that from the DNA-QS target probe detected throughout the PCR process.(Package insert: cobas CMV-Quantitative nucleic acid test for use on the cobas 5800/6800/8800 Systems. Roche Molecular Systems, Inc; Rev 7.0, 11/2025)

### PDF Report

No

### Day(s) Performed

Monday through Saturday

### Report Available

1 to 5 days

### Specimen Retention Time

30 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

# Test Definition: CMVQN

Cytomegalovirus (CMV) DNA Detection and Quantification by Real-Time PCR, Plasma

87497

## LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---|---|---|
| CMVQN | CMV DNA Detect/Quant, P | 72493-0 |

| Result ID | Test Result Name | Result LOINC® Value |
|---|---|---|
| 601954 | CMV DNA Detect/Quant, P | 72493-0 |