

Cytomegalovirus (CMV), Quantitative, PCR

Test Code: QCMV1

Use: For detection of cytomegalovirus DNA; early detection and management of CMV infections. Quantitative CMV DNA PCR testing provides a “viral load” value useful for monitoring antiviral therapy and possible identifying patients at risk for CMV disease.

Clinical Significance: Human Cytomegalovirus (CMV) is a member of the Herpes Virus Family and may cause a wide variety of disease manifestations depending on the patient’s age and immune status. In an immunosuppressed adult, the lungs, gastrointestinal tract and /or the retina can be infected. Transplant patients are at a high risk for pulmonary infections (Pneumonitis) that can progress to full blown Adult Respiratory Distress Syndrome (ARDS), intestinal necrosis and ulceration leading to debilitating diarrhea.

Methodology: Extraction of CMV DNA from plasma is followed by amplification and detection using polymerase chain reaction (PCR). The assay detects the presence of CMV DNA in cell free plasma by amplifying viral genomic DNA. The amplified target DNA sequence, located within the CMV DNA polymerase gene, is specific for CMV and is not homologous to other members of the Herpesvirus family. The use of plasma avoids potential detection of latent virus in blood. An internal control is added to each sample to assure that the extraction was performed correctly and to insure that the PCR reaction was not inhibited. Results are expressed in CMV DNA IU/ml plasma.

Normal Range: CMV is usually undetectable in blood from healthy persons even if they were previously exposed to the virus. Immunosuppressed patients may have stable low viral loads in the absence of disease. Increasing viral load over time suggests progression of active disease.

Reportable Range:

300-3,000,000 CMV DNA IU/mL

Interpretative Data:

Result: No DNA detected.

A negative result does not rule out the presence of CMV DNA in concentrations below the level of detection of the assay.

Result: <300CMV DNA IU/mL

A value of <300 implies that, while present, the level of CMV DNA is below the linear threshold of 300 CMV DNA IU/mL plasma but above background levels. The clinical significance of CMV levels in this range is uncertain.

Result: Specific [300 to 3,000,000] CMV DNA IU/mL

The presence of specific [300 to 3,000,000] CMV DNA in a clinical specimen may suggest active infection, reactivated infection, or latent infection without disease.

Result: >3,000,000 CMV DNA IU/mL

Studies have shown that high viral load is associated with CMV disease.

Assay Availability: Monday-Friday

Results Reported: 72 hrs.

Specimen: Whole blood: 1 Pearl top (EDTA) tube

Specimens should be labeled with patient name, medical record number, date and time of collection, and then sent at room temperature to the laboratory. Specimens used for testing in other departments are unacceptable due to possible contamination.

Volume: 4mL (minimum volume: 1mL)

Storage: If not tested immediately, store whole blood refrigerated. If plasma has been separated, specimen may be frozen.

Causes for Rejection: Heparinized specimen; Quantity not sufficient for analysis; specimen grossly contaminated; specimen too old; frozen whole blood specimen; specimen leaky or tube broken.

Notes: Our facility recommends that patient's who have tested positive for CMV (>300 CMV IU/mL) have retesting performed every 48 hours until the result falls below detectable limits. Patient's having results that are considered positive but are below the threshold for quantification (<300 CMV IU/mL), should be retested every 3-4 days. Patients who are negative for CMV should be tested once a week. Requests that are obtained outside these guidelines will be cancelled as "Inappropriate testing interval; retest (*time interval based on previous results*); last tested (*date of last CMV test*)."

Laboratory Contact: For further information, please call the Molecular Diagnostics Laboratory at (501) 526-6439.