

CMV Quantitative Real-time DNA PCR

Test ID	5500 Cytomegalovirus (CMV) Real-time qPCR
Clinical Utility	CMV is an important pathogen in the transplant setting causing pneumonitis, colitis, hepatitis, CNS disease, neutropenia, and disseminated disease. Prior to the availability of rapid and sensitive DNA PCR, CMV was a leading cause of morbidity and mortality in the transplant population. Quantitative CMV DNA PCR can be used for early detection of CMV reactivation, primary infections, and monitoring response to treatment.
Procedure	ViraCor's assay design includes dual-gene targets to account for viral mutations, which dramatically reduces the chance of false negative results. Extraction of CMV DNA from plasma, CSF, urine, other biological fluids, or tissues followed by amplification and detection using real-time, quantitative PCR. An internal control is added to ensure the extraction was performed correctly and the PCR reaction was not inhibited.
Specimens	Whole Blood: 3-5 ml submitted in an EDTA tube; ship ambient. CSF: 1 ml fluid frozen; submitted in a sterile, leakproof tube; ship on dry ice. BAL: 1-4 ml submitted in a sterile, leakproof tube; ship ambient. Other: Please inquire.
Specificity	The primers and probes used in this assay are specific for known CMV strains based on similarity search algorithms. Additionally, no cross reactivity was detected when tested against adenoviruses, BKV, EBV, HSV-1, HSV-2, HHV-6 variant A, HHV-6 variant B, HHV-7, HHV-8, JCV, parvovirus B19, SV-40, and VZV.
Assay Range	100 copies/ml to 1×10^{10} copies/ml
Turnaround Time	Within 24 hours of receiving specimen

PCR tests are performed pursuant to a license agreement with Roche Molecular Systems, Inc.

This assay was developed and the performance characteristics were determined at ViraCor Laboratories. This test is performed in a CLIA certified laboratory. FDA approval is not required for the performance of this test.

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