GENETIC ASSAYS
A Molecular Diagnostics Laboratory

CMV Cytomegalovirus DNA by PCR - Quantitative

GA Test Code	**3702**
Method	Quantitative Real-Time Polymerase Chain Reaction (qPCR)
Specimens	**Urine**: 10.0 (min 5.0) mL, refrigerated (7 days). **CSF**: 1.0 (min 0.25) mL, refrigerated (7 days) or frozen. **Swab (e.g. newborn saliva, or from any other site):** Collect sample and place entire swab in 2.0 mL saline or viral transport media in a sterile screw top tube. Do not use calcium alginate or wood shafted swab. Ship ambient up to 14 days. **Whole Blood (ACD or EDTA)**: 5.0 (min 3.0) mL, ambient (4 days), refrigerated (7 days). **Plasma (ACD, EDTA, or PPT)**: 3.0 (min 1.0) mL, separated/centrifuged within 6 hours, refrigerated or frozen *(do not freeze in PPT).* If storing longer than 24 hours, store frozen. **Fluid (e.g. amniotic, peritoneal, pleural)**: 2.0 (min 1.0) mL, ambient (4 days). **Bronchial Washing**: 3.0 (min 1.0) mL, refrigerated (7 days). **Sputum**: 10.0 (min 5.0) mL, refrigerated (7 days). **Stool**: 4-8 g of feces, screw-cap container, refrigerated (7 days). Do **not** dilute the specimen or use preservatives. **Other Samples**: Please contact GA for questions about other specimens.
Causes for Rejection	Quantity not sufficient (QNS) for analysis; time and/or temperature instructions not followed; blood in heparin; plasma frozen in PPT; calcium alginate or wood shafted swab; no swab in tube and/or received ambient after 14 days.
Reference Range	Not Detected (< 500 IU/mL)
Quantitative Range	500 to 2.5 x 10^{10} CMV DNA IU/mL
Turnaround Time	Same or Next Day
CPT Code	87497

Description

This test was developed and its performance characteristics determined by Genetic Assays. It has not been cleared nor approved by the U.S. FDA. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. Genetic Assays is certified under CLIA as qualified to perform high-complexity testing. Cytomegalovirus (CMV) DNA is detected by a real-time PCR assay utilizing PCR primers directed against viral sequences found in the US17 region of the CMV genome. A patient value of less than 500 CMV DNA IU/mL indicates that the patient's viral load is below the quantitative limit of this assay, but does not indicate that the patient is not infected with CMV.

Clinical Utility

CMV is a commonly found virus that threatens immunocompromised patients including neonates, transplant recipients, oncology patients and patients with AIDS. Commonly seen manifestations of a CMV infection include: encephalitis, retinitis, colitis, hepatitis, adrenalitis, polyradiculopathy, and esophagitis. CMV is the major viral pathogen that causes death after renal transplantation. The use of PCR has been found to detect CMV infection at a much higher rate in renal allograft cases, thus resulting in improved patient management.

Every year, 1 in 150 children is born with congenital CMV infection, resulting in possible hearing loss. Studies have shown that using a real-time PCR assay to screen newborn saliva for CMV yielded at least 97.4% sensitivity and 99.9% specificity when compared to culture. CMV-infected babies can be monitored closely for hearing loss, with support services made available as necessary.

Boppana S, et al. Saliva polymerase-chain-reaction assay for cytomegalovirus screening in newborns. *N Engl J Med* 2011; 364: 2111-2118.

Liapis, et al. CMV infection of the renal allograft is much more common than pathology indicates: a retrospective analysis of qualitative and quantitative buffy coat CMV-PCR, renal biopsy pathology and tissue CMV-PCR. *Nephrol Dial Transplant* 2003; 18:397-402.

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