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

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.