Cytomegalovirus (CMV) Quantitative Real-time PCR
Test Code: 5500

Some specimen types for this assay are reported as qualitative results; please see our Specimen Information section below for more information.

Clinical and Procedure

Clinical Utility
Cytomegalovirus (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.

About Cytomegalovirus
Clinically significant Cytomegalovirus infection frequently develops in immunocompromised patient populations (e.g. hematopoietic stem cell transplantation, solid organ transplant and HIV). A frequent complication after transplantation, CMV infection may cause a series of direct and indirect effects that lead to increased incidence of graft rejection, opportunistic infections, and decreased allograft and patient survival.1,2 Symptomatic CMV disease in immunocompromised individuals can affect almost every organ of the body, resulting in fever, pneumonia, hepatitis, encephalitis, myelitis, colitis, uveitis, retinitis, and neuropathy.

Procedure
Extraction of CMV DNA from specimen 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. Viracor Eurofins’ assay design includes multiple targets to account for viral mutations, which significantly reduces the chance of false negative results. This test has not been cleared or approved for diagnostic use by the U.S. Food and Drug Administration.

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.

Turnaround Time
Same day (within 8 - 12 hours from receipt of specimen), Monday through Saturday.

Specimen Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Order Code</th>
<th>CPT Code</th>
<th>NY Approved</th>
<th>Volume</th>
<th>Assay Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>amniotic fluid</td>
<td>5507</td>
<td>87497</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>104 IU/mL to 1.88x10^8 IU/mL</td>
</tr>
<tr>
<td>aqueous fluid</td>
<td>5545</td>
<td>87497</td>
<td>Yes</td>
<td>1 mL (min. 0.05 mL)</td>
<td>1,423 IU/mL to 1.88x10^8 IU/mL</td>
</tr>
</tbody>
</table>

Special Instructions
- Collect 2 mL in sterile, screw top tube.
- Can be shipped at ambient or frozen temperature Monday through Friday.
- Specimens shipped ambient temperature must be received within 96 hours of collection.
<table>
<thead>
<tr>
<th>Specimen Type</th>
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<th>NY Approved</th>
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</tr>
</thead>
<tbody>
<tr>
<td>BAL</td>
<td>5509</td>
<td>87497</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>79 IU/mL to 1.88x10^8 IU/mL</td>
</tr>
</tbody>
</table>
| Special Instructions
- Transfer collected amount to sterile, screw top tube for shipment.
- Do not add water, saline or other fluid media to container.
- Do not ship specimen in syringe.
- Store frozen and ship on dry ice.

| bone marrow    | 5504       | 87497    | Yes         | 2 mL (min. 0.5 mL)      | 1,039 IU/mL to 1.88x10^8 IU/mL |
| Special Instructions
- Collect in a sterile, screw top tube.
- Can be shipped at ambient or frozen temperature Monday through Friday.
- Specimens shipped at ambient temperature must be received within 96 hrs. of collection.

| bronch wash    | 5526       | 87497    | Yes         | 2 mL (min. 0.5 mL)      | 79 IU/mL to 1.88x10^8 IU/mL |
| Special Instructions
- Collect in a sterile, screw top tube.
- Can be shipped at ambient or frozen temperature Monday through Friday.
- Specimens shipped at ambient temperature must be received within 96 hrs. of collection.

| CSF            | 5503       | 87497    | Yes         | 2 mL (min. 0.5 mL)      | 142 IU/mL to 1.88x10^8 IU/mL |
| Special Instructions
- Collect in a sterile, screw top tube.
- Store frozen and ship on dry ice for overnight delivery.

| eye swab       | 5527       | 87496    | Yes         | 2 mL                    | Detected/Not Detected       |
| Special Instructions
- Place sterile swab placed in 2 mL sterile saline, M4, or viral transport media in a sterile, screw top tube.
- Do not use calcium alginate swab or wood shafted swab.
- Can be shipped at ambient or frozen temperature Monday through Friday.
- Specimens shipped at ambient temperature must be received within 96 hrs. of collection.

| fecal          | 5508       | 87496    | Yes         | Size of pea, or 2 mL liquid stool | Detected/Not Detected       |
| Special Instructions
- Collect and place in a sterile, screw top tube.
- Store frozen and ship on dry ice for overnight delivery.

| pericardial fluid | 5512         | 87497 | Yes         | 2 mL (min. 0.5 mL)      | 104 IU/mL to 1.88x10^8 IU/mL |
| Special Instructions
- Collect in a sterile, screw top tube.
- Can be shipped at ambient or frozen temperature Monday through Friday.
- Specimens shipped at ambient temperature must be received within 96 hrs. of collection.

| plasma         | 5501       | 87497    | Yes         | 2 mL (min. 0.5 mL)      | 96 IU/mL to 1.88x10^8 IU/mL |
| Special Instructions
- Collect 4-5 mL whole blood in EDTA or ACD tube.
- Centrifuge and transfer 2 mL plasma to sterile, screw top tube.
- Can be shipped at ambient or frozen temperature Monday through Friday.
- Specimens shipped at ambient temperature must be received within 96 hrs. of collection.
<table>
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<th>Volume</th>
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</tr>
</thead>
<tbody>
<tr>
<td>pleural fluid</td>
<td>5511</td>
<td>87497</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>104 IU/mL to $1.88 \times 10^8$ IU/mL</td>
</tr>
<tr>
<td>Serum</td>
<td>5510</td>
<td>87497</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>$96$ IU/mL to $1.88 \times 10^8$ IU/mL</td>
</tr>
<tr>
<td>Tissue [Qual]</td>
<td>5506</td>
<td>87496</td>
<td>Yes</td>
<td>5 mg fresh tissue (approximately ½ of a pencil eraser size)</td>
<td>Detected/Not Detected</td>
</tr>
<tr>
<td>Tissue [Quant]</td>
<td>5505</td>
<td>87497</td>
<td>Yes</td>
<td>5 mg fresh tissue (approximately ½ of a pencil eraser size)</td>
<td>$37$ IU/mg to $1.88 \times 10^7$ IU/mg</td>
</tr>
<tr>
<td>Trach Asp</td>
<td>5519</td>
<td>87497</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>$79$ IU/mL to $1.88 \times 10^8$ IU/mL</td>
</tr>
<tr>
<td>Trach Wash</td>
<td>5548</td>
<td>87497</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>$79$ IU/mL to $1.88 \times 10^8$ IU/mL</td>
</tr>
<tr>
<td>Urine</td>
<td>5502</td>
<td>87497</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>$475$ IU/mL to $1.88 \times 10^8$ IU/mL</td>
</tr>
<tr>
<td>Vitreous Fluid</td>
<td>5514</td>
<td>87497</td>
<td>Yes</td>
<td>1 mL (min. 0.05 mL)</td>
<td>$1,423$ IU/mL to $1.88 \times 10^8$ IU/mL</td>
</tr>
</tbody>
</table>

**Special Instructions**
- Collect in a sterile, screw top tube.
- Can be shipped at ambient or frozen temperature Monday through Friday.
- Tissue shipped at ambient temperature must be received within 96 hrs. of collection.
- Do not add water, saline or other fluid media to container.
- Do not ship specimen in syringe.
**Specimen Type** | **Order Code** | **CPT Code** | **NY Approved** | **Volume** | **Assay Range**
--- | --- | --- | --- | --- | ---
*saliva*  | 5571  | 87496 | Yes | 1 mL | Detected/Not Detected

**Special Instructions**
- Store frozen and ship on dry ice for overnight delivery.
- Place swab in the mouth until saturated with saliva. Wait 90-120 minutes following breast feeding to collect the sample.
- Transfer swab to tube containing 1 to 3 mL of Universal Transport Media (UTM).
- Can be shipped at ambient or frozen temperature Monday through Friday.
- Specimens shipped at ambient temperature must be received within 48 hrs. of collection. (If a dry swab is shipped at ambient temperature, must be received within 24 hrs. of collection.)
- Samples are stable refrigerated or frozen for 7 days.
- Do not use calcium alginate swab or wood shafted swab.

**Shipping**
Ship Monday through Friday. Friday shipments must be labeled for Saturday delivery. All specimens must be labeled with patient’s name and collection date. A Viracor Eurofins test requisition form must accompany each specimen. Multiple tests can be run on one specimen. Ship specimens FedEx Priority Overnight® to: Viracor Eurofins, 1001 NW Technology Dr, Lee's Summit, MO 64086

**Causes for Rejection**
Whole blood frozen, specimens beyond their acceptable length of time from collection as listed in the specimen handling, specimens received in trap containers, or specimen types other than those listed.

**Disclaimer**
Specimens are approved for testing in New York only when indicated in the Specimen Information field above.

The CPT codes provided are based on Viracor Eurofins’ interpretation of the American Medical Association’s Current Procedural Terminology (CPT) codes and are provided for informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. Viracor Eurofins assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.

**References**