Cytomegalovirus (CMV) Saliva Real-Time PCR  
Test Code: 5571

Clinical and Procedure

Clinical Utility
For the detection of CMV in saliva. Congenital CMV infection can be diagnosed by testing a newborn baby’s saliva, urine, or blood by CMV PCR. However, of the three specimen types that are recommended, only saliva is simple, noninvasive and easy to collect. Specimens must be collected for testing within 21 days after the baby is born in order to confirm a diagnosis of congenital CMV infection. Specimen collection should be performed at least 90 minutes (and preferably 120 minutes) post-breastfeeding.

About Cytomegalovirus
CMV is a leading cause of permanent hearing loss in neonates (and/or of other important brain, vision and developmental problems). Early treatment with anti-viral medication like ganciclovir or valganciclovir (ideally within 1st month of life) improves outcomes and prevents further damage from hearing/vision loss.

Procedure
Extraction of CMV DNA from saliva followed by amplification and detection using real-time, PCR. An internal control is added to ensure the extraction was performed correctly and the PCR reaction was not inhibited. Viracor's 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 to 12 hours of receiving 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>saliva</td>
<td>5571</td>
<td>87496</td>
<td>Yes</td>
<td>1 mL</td>
<td>Detected/Not Detected</td>
</tr>
</tbody>
</table>

Special Instructions
- 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. Ship specimens FedEx Priority Overnight® to: Viracor Eurofins Laboratories, 1001 NW Technology Dr, Lee's Summit, MO 64086.

Causes for Rejection
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


