CMV T Cell Immunity Panel
Test Code: 30360

Clinical and Procedure

Clinical Utility
The CMV T Cell Immunity Panel measures the strength of T cell responses to Cytomegalovirus (CMV) specific antigens. It evaluates and reports the activity of CD4 and CD8 T cell responses independently. Effective T cell immunity against CMV is a factor in controlling CMV viral latency. CMV can affect patients with weakened immune systems and is a common risk factor in patients following solid organ or hematopoietic stem cell transplant.

About Cytomegalovirus

Cytomegalovirus, also known as human herpesvirus 5, is a highly ubiquitous, double-stranded DNA virus in the Betaherpesvirinae subfamily. Following primary infection, CMV establishes a lifelong latent infection, which may reactivate in both immunocompetent and immunocompromised individuals. Clinically significant CMV 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. CMV reactivations have also been reported to occur frequently in critically ill immunocompetent patients and are associated with prolonged hospitalization or death. T cell responses, both CD4+ and CD8+ T cells, are vital components of CMV immune control. The monitoring of CMV-specific T cell responses utilizing intracellular cytokine staining may aid in the detection of patients at increased risk of CMV disease after transplantation and may be useful in guiding prophylaxis and preemptive therapies.

Procedure

Whole blood is stimulated with SEB, CMV antigens, or left unstimulated as a negative control and incubated at 37°C. During the incubation Brefeldin A is added, causing the interferon (IFN)-gamma to be retained inside the cell. Following the stimulation phase, cells are recovered, stained for surface markers (CD45, CD3, CD4, CD8, CD69) and intracellular IFN-gamma, and analyzed by flow cytometry. This test has not been cleared or approved for diagnostic use by the U.S. Food and Drug Administration.

Turnaround Time

2-3 business days from receipt of specimen.

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>whole blood</td>
<td>30360</td>
<td>86352 x 4</td>
<td>No</td>
<td>10 mL</td>
<td>Quantitative. The percent of CD4 and CD8 cells that are activated after stimulation with either CMV antigens or mitogen are reported quantitatively.</td>
</tr>
</tbody>
</table>

Special Instructions
Specimen Collection and Shipment Information:

- Collect 10 mL whole blood in a sodium heparin tube.
- Tube must be at least ¾ full to maintain proper ratio of blood to anticoagulant.
- Blood must be drawn Monday through Friday after 7:00 AM CST.
- DO NOT SHIP on days when a holiday follows the shipping or set up day.
- Ship samples priority overnight Monday through Friday, at ambient temperature on the same day as collection.
<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>
</table>

Causes for Rejection:

- Whole blood received after stability (32 hours after collection)
- Whole blood received cold or frozen
- Tubes received less than ¾ full
- Specimens received in lithium heparin, ACD tubes or EDTA anticoagulants

Please contact Client Services at 1-800-305-5198 if any of the following apply:

- Is it your first time sending Viracor a live cell test? Client Services will assist in setting up live cell shippers with you, or your courier.
- Do you have volume concerns with high risk patients, like pediatric patients? Client Services has additional information regarding volume for high risk patients.

Shipping
Ship Monday through Friday. 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
Whole blood received after stability (32 hours after collection), whole blood received cold or frozen, specimens received on Saturday, and tubes received less than ¾ full are not accepted and are cause for rejection

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
