Tacrolimus LC-MS/MS
Test Code: 30406

Clinical and Procedure

Clinical Utility
Tacrolimus is a calcineurin inhibitor that inhibits the production of IL-2 thus discouraging proliferation of T cells. It is metabolized in the liver, mainly via CYP3A with a ~43 hour half-life in healthy individuals. Common interactions include grapefruit, antimicrobials and antifungals leading to increased tacrolimus levels. The Tacrolimus LC-MS/MS assay is used to quantify levels of Tacrolimus in the blood. Monitoring trough levels of tacrolimus is suggested in patients receiving the drug to prevent rejection of kidney, heart or liver transplants. Additionally, results may be clinically useful to determine if current dosing levels have achieved adequate therapeutic concentrations. Results may also be used when investigating if therapeutic failure was a result of suboptimal drug levels or for potential toxicity attributable to Tacrolimus.

About Immunosuppressive Drug Level Monitoring
The successful management of transplant rejection and graft vs. host disease (GVHD) continues to pose a difficult challenge for physicians treating solid organ and bone marrow transplant patients. Immunosuppressive drugs are commonly used to prevent rejection in these patient populations. Compliance with immunosuppressive therapy is essential to long term survival, however provides the additional risks of infection. Therapeutic drug monitoring of immunosuppressive medication is required due to variable metabolism, absorption and drug interactions. By using drug level monitoring with timely results, the physician is able to individualize drug dosage to improve efficacy and reduce toxicity.

Procedure
Tacrolimus is extracted from whole blood by simple protein precipitation with Zinc Sulfate Solution followed by centrifugation. Chromatographic separation and quantitative analysis of the drug containing supernatant is performed using reversed-phase UPLC-MS/MS method. This test has not been cleared or approved for diagnostic use by the U.S. Food and Drug Administration.

Specificity
Compound is identified by two mass transitions. The first mass transition is used to quantify the compound and the second is qualitative for confirmation. Test is specific for Tacrolimus and does not cross react with other immunosuppressants.

Turnaround Time
Same day (within 12-18 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>whole blood</td>
<td>30406</td>
<td>80197</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>1.6 ng/mL to 50 ng/mL</td>
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</tbody>
</table>

Special Instructions
- Collect in EDTA tube
- Specimens shipped at ambient temperature must be received within 7 days of collection
- Stability: 7 days ambient, 14 days refrigerated, 14 days frozen

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**
Specimens received outside stability, whole blood collected in serum or plasma gel tubes, or specimen types other than those listed are not accepted.

**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.