Overview

Useful For
Management of everolimus immunosuppression in solid organ transplant

Method Name
Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)

NY State Available
Yes

Specimen

Specimen Type
Whole Blood EDTA

Specimen Required
Container/Tube: Lavender top (EDTA)

Specimen Volume: 3 mL

Collection Instructions:
1. Draw blood immediately before next scheduled dose.
2. Do not centrifuge.
3. Send specimen in original tube.

Additional Information: Therapeutic range applies to trough specimens drawn immediately prior to a.m. dose.

Forms
If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:
- Renal Diagnostics Test Request (T830)
- Therapeutics Test Request (T831)

Reject Due To

| Gross hemolysis | OK |
| Gross lipemia   | OK |
| Gross icterus   | OK |

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Blood EDTA</td>
<td>Refrigerated (preferred)</td>
<td>28 days</td>
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</table>
Everolimus is an immunosuppressive agent derived from sirolimus (rapamycin). Both drugs function via inhibition of mTOR signaling and share similar pharmacokinetic and toxicity profiles. Everolimus has a shorter half-life than sirolimus, which allows for more rapid achievement of steady-state pharmacokinetics. Everolimus is extensively metabolized, primarily by cytochrome P450 (CYP) 3A4, thus its use with inducers or inhibitors of that enzyme may require dose adjustment. The most common adverse effects include hyperlipidemia, thrombocytopenia, and nephrotoxicity. Everolimus is useful as adjuvant therapy in renal cell carcinoma and other cancers. It recently gained FDA approval for prophylaxis of graft rejection in solid organ transplant, an application which has been accepted for years in Europe. The utility of therapeutic drug monitoring has not been established for everolimus as an oncology chemotherapy agent; however, measuring blood drug concentrations is common practice for its use in transplant. Therapeutic targets vary depending on the transplant site and institution protocol. Guidelines for heart and kidney transplants suggest that trough (immediately prior to the next scheduled dose) blood concentrations between 3 and 8 ng/mL provide optimal outcomes.

**Reference Values**

3-8 ng/mL

Target steady-state trough concentrations vary depending on the type of transplant, concomitant immunosuppression, clinical/institutional protocols, and time post-transplant. Results should be interpreted in conjunction with this clinical information and any physical signs/symptoms of rejection/toxicity.

**Interpretation**

Therapeutic targets vary by transplant site and institution protocol. Heart and kidney transplant guidelines suggest a therapeutic range of 3 to 8 ng/mL.

Measurement of drug concentrations in oncology chemotherapy is less common, thus no therapeutic range is established for this application.

**Cautions**

Therapeutic targets vary by transplant site and institution protocol. Established ranges refer to trough (predose) concentrations.

**Clinical Reference**


Performance

Method Description
Whole blood samples are mixed with methanolic zinc sulfate to lyse blood cells. The supernatant is removed and analyzed by liquid chromatography-tandem mass spectrometry method. (Unpublished Mayo method)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Sunday; 1 p.m.

Analytic Time
Same day/1 day

Maximum Laboratory Time
2 days

Specimen Retention Time
14 days

Performing Laboratory Location
Rochester

Fees and Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
80169

LOINC® Information

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<th>Test ID</th>
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<th>Order LOINC Value</th>
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<td>Everolimus, B</td>
<td>50544-6</td>
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<tr>
<td>Result ID</td>
<td>Test Result Name</td>
<td>Result LOINC Value</td>
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