Overview

Useful For
Monitoring serum concentrations of lacosamide to ensure compliance and appropriate dosing in specific clinical conditions (ie, severe renal impairment, mild-to-moderate hepatic impairment, and end-stage renal disease)

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

Portions of this test are covered by patent(s) held by Quest Diagnostics

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Container/Tube:

Preferred: Red top

Acceptable: Serum gel

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions:
1. Draw blood immediately before next scheduled dose.

2. For sustained-release formulations ONLY, draw blood a minimum of 12 hours after last dose.

3. Centrifuge and separate serum from cells or gel within 2 hours of draw.

Forms
If not ordering electronically, complete, print, and send a Neurology Specialty Testing Client Test Request (T732) with the specimen.

Specimen Minimum Volume
0.2 mL

Reject Due To

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>OK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross lipemia</td>
<td>OK</td>
</tr>
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</table>
Test Definition: LACO
Lacosamide, S

| Gross icterus | OK |

Specimen Stability Information

<table>
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<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Serum</td>
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<td></td>
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<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
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Clinical and Interpretive

Clinical Information

Lacosamide is approved for adjunctive therapy to treat partial-onset seizures in epileptic patients 17 years of age and older. In clinical trials, the most common side effects were dizziness, headache, nausea, and double vision. Lacosamide is completely absorbed after oral administration with negligible first-pass metabolism. Peak plasma concentrations occur 1 to 4 hours after oral dosing, and the elimination half-life is approximately 13 hours. Steady-state plasma concentrations are achieved after 3 days of twice daily repeated administration. About 40% of the administered dose is eliminated by the renal system unchanged and 30% is metabolized by hepatic isoenzymes (CYP2C9, CYP2C19, and CYP3A4) to the O-desmethyl inactive metabolite. The relationship between lacosamide plasma concentrations and its efficacy or adverse effects is not well established. However, central nervous system toxicity has been associated with higher drug concentrations in plasma.

Reference Values

Patients receiving therapeutic doses usually have lacosamide concentrations of 1.0-10.0 mcg/mL.

Interpretation

The serum concentration should be interpreted in the context of the patient's clinical response and may provide useful information in patients showing poor response or adverse effects, particularly when lacosamide is coadministered with other anticonvulsant drugs.

Toxic ranges have not been established.

Cautions

Abnormalities in liver function tests (alanine aminotransferase) have been observed in controlled trials in adult patients with partial-onset seizures who were taking 1 to 3 concomitant antiepileptic drugs.

Clinical Reference


4. Sattler A, Schaefer M, May TW, et al: Fluctuation of lacosamide serum concentrations during the day and


6. McMullin M, Dalrymple R: Analysis for lacosamide in human serum by LC/MS/MS and a summary of 8,000 patient values. Ther Drug Monit 2011;33(4):520-521

Performance

Method Description
Lacosamide and the internal standard are separated from other serum constituents by high-performance liquid chromatography with analysis on a tandem mass spectrometer equipped with an electrospray ion source using multiple reaction monitoring. (Unpublished Mayo method)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday; 9 a.m.
Saturday; 1 p.m.

Analytic Time
Same day/1 day

Maximum Laboratory Time
4 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
80235

LOINC® Information
## Test Definition: LACO
Lacosamide, S

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<td>Lacosamide, S</td>
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