Overview

Useful For
Evaluation of patients with liver disease of unknown etiology
Evaluation of patients with suspected autoimmune hepatitis

Method Name
Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required

Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Specimen Volume: 0.5 mL

Forms
If not ordering electronically, complete, print, and send a Gastroenterology and Hepatology Client Test Request (T728) with the specimen.

Specimen Minimum Volume
0.4 mL

Reject Due To

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>Reject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross lipemia</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross icterus</td>
<td>OK</td>
</tr>
</tbody>
</table>

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>Serum</td>
<td>Refrigerated (preferred)</td>
<td>21 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>21 days</td>
<td></td>
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</table>
Clinical and Interpretive

Clinical Information
Autoimmune liver disease (eg, autoimmune hepatitis and primary biliary cirrhosis) is characterized by the presence of autoantibodies including smooth muscle antibodies (SMA), antimitochondrial antibodies (AMA), and anti-liver/kidney microsomal antibodies type 1 (anti-LKM-1).(1) Subtypes of autoimmune hepatitis (AIH) are based on autoantibody reactivity patterns.

Anti-LKM-1 antibodies serve as a serologic marker for AIH type 2 and typically occur in the absence of SMA and antinuclear antibodies. These antibodies react with a short linear sequence of the recombinant antigen cytochrome monoxygenase P450 2D6.(2) Patients with AIH type 2 more often tend to be young, female, and have severe disease that responds well to immunosuppressive therapy.

Reference Values
< or =20.0 Units (negative)
20.1-24.9 Units (equivocal)
> or =25.0 Units (positive)

Reference values apply to all ages.

Interpretation
Seropositivity for anti-liver/kidney microsomal antibodies type 1 (anti-LKM-1) antibodies is consistent with a diagnosis of autoimmune hepatitis (AIH) type 2.

Cautions
Serologic tests for autoantibodies, including anti-liver/kidney microsomal antibodies type 1 (anti-LKM-1), should not be relied upon exclusively to determine the etiology or prognosis of patients with liver disease.

Anti-LKM-1 antibodies may occur in some patients with chronic hepatitis caused by hepatitis C virus infection. Although the epitopes recognized by anti-LKM-1 antibodies in hepatitis C virus infection are different than in patients with autoimmune hepatitis (AIH) type 2, physicians must use caution in interpreting the results of tests for anti-LKM-1 antibodies in such patients.

Clinical Reference

Performance

Method Description
Enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative detection of liver/kidney microsomal antibodies type 1 (LKM-1) antibodies in human serum.(Package insert: INOVA Diagnostics, Inc. San Diego, Revision 1, March 2000)

PDF Report
Test Definition: LKM
Liver/Kidney Microsome Type 1 Ab, S

Day(s) and Time(s) Test Performed
Monday, Wednesday, Friday

Analytic Time
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 has been cleared or approved by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
86376

LOINC® Information

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<tr>
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<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>LKM</td>
<td>Liver/Kidney Microsome Type 1 Ab, S</td>
<td>32220-6</td>
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<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
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<tbody>
<tr>
<td>LKM</td>
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