Overview

Useful For
Establishing the diagnosis of primary biliary cirrhosis

Method Name
Enzyme Immunoassay (EIA)

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 1 of the following forms with the specimen:

- General Request (T239)
- Gastroenterology and Hepatology Client Test Request (T728)

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>
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</table>
Clinical and Interpretive

Clinical Information
Antimitochondrial antibodies (AMA) are detectable by indirect immunofluorescence in more than 90% of patients with primary biliary cirrhosis (PBC), but this method also detects AMA of differing specificities in other diseases. The mitochondrial antigens recognized by AMA in patients’ sera have been classified numerically as M1 through M9, with the M2 antigen complex recognized by AMA in sera from patients with PBC. M2 antigen is comprised of enzyme proteins of the 2-oxoacid dehydrogenase complex that are located on inner mitochondrial membranes. Included in this group of autoantigens are the pyruvate dehydrogenase complex, and 2-oxoglutarate dehydrogenase complex.

Reference Values
Negative: <0.1 Units
Borderline: 0.1-0.3 Units
Weakly positive: 0.4-0.9 Units
Positive: > or =1.0 Units
Reference values apply to all ages.

Interpretation
Positive results for antimitochondrial antibody (AMA) of M2 specificity are highly specific for primary biliary cirrhosis (PBC), and false-negative results are rare.

A positive result for AMA of M2 specificity in a patient with clinical features of PBC is virtually diagnostic for this disease.

Cautions
The level of antimitochondrial antibody (AMA) is not useful to indicate the stage or prognosis of the disease or for monitoring the course of disease. Positive results are found (infrequently) in patients with CREST (calcinosis, Raynaud’s phenomenon, esophageal hypomotility, sclerodactyly, and telangiectasia) syndrome, relatives of patients with primary biliary cirrhosis and other autoimmune diseases.

Supportive Data
Testing performed in the Immunology Antibody Laboratory of the antimitochondrial antibody (AMA)-M2 by EIA revealed a false-positive rate of less than 2% in normals and overall concordance compared with indirect immunofluorescence of 90% on sera from the Mayo primary biliary cirrhosis (PBC) Serum Bank. Ten discordant results were obtained (negative by EIA and positive by immunofluorescence assay). Seven of the 10 patients had no histologic evidence of PBC on liver biopsy.

Clinical Reference

**Performance**

**Method Description**
Enzyme immunosorbent assay with purified M2 antigens. This method detects both IgG and IgM antibodies to M2 antigens. Testing is performed on the Agility instrument by Dynex.(Package insert: Bio-Rad, Kallestad Anti-Mitochondrial Kit, Distributed by Bio-Rad Laboratories, Inc., Hercules, CA 04/14)

**PDF Report**
No

**Day(s) and Time(s) Test Performed**
Monday through Saturday; 11 a.m.

**Analytic Time**
1 day

**Maximum Laboratory Time**
1 day

**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, approved or is exempt 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**
83516

**LOINC® Information**

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<th>Order LOINC Value</th>
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<td>51715-1</td>
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