Test Definition: ALDP
Autoimmune Liver Disease Panel, S

Overview

Useful For
Evaluation of patients with suspected autoimmune liver disease, specifically autoimmune hepatitis or primary biliary cirrhosis
Evaluation of patients with liver disease of unknown etiology

Profile Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMA</td>
<td>Mitochondrial Ab, M2, S</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>SMA</td>
<td>Anti-Smooth Muscle Ab</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>ANA2</td>
<td>Antinuclear Ab, S</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Method Name
AMA: Enzyme Immunoassay (EIA)
SMA: Indirect Immunofluorescence
ANA2: 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: 1.5 mL

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

Specimen Minimum Volume
1 mL
Test Definition: ALDP
Autoimmune Liver Disease Panel, S

Reject Due To

<table>
<thead>
<tr>
<th>Condition</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject</td>
</tr>
<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>14 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>14 days</td>
<td></td>
</tr>
</tbody>
</table>

Clinical and Interpretive

Clinical Information

Autoimmune liver diseases result from damage to hepatocytes or cholangiocytes caused by an inflammatory immune reaction. Included within this disease group are autoimmune hepatitis (AIH), primary biliary cirrhosis (PBC), and primary sclerosing cholangitis (PSC). In some cases, patients with these diseases may present asymptomatically, with increases in various liver enzymes being identified incidentally during an unrelated clinical evaluation. On the other end of the spectrum are patients who present with clinical evidence of liver disease, including fatigue, hepatomegaly, ascites, esophageal varices, and jaundice.

Diagnosis of an autoimmune liver disease first requires that other etiologies of liver injury, including viral, drug, and metabolic causes, be excluded. In some situations, a liver biopsy may be indicated. For those patients in whom an autoimmune liver disease is suspected, autoantibody serology testing may be considered. This assay includes markers that may support a diagnosis of an autoimmune liver disease, specifically AIH or PBC. Unfortunately, there are no known autoantibodies specific for PSC that are useful as diagnostic markers.

Patients with AIH may be positive for smooth muscle antibodies (SMA) and/or antinuclear antibodies (ANA). The SMA associated with AIH are generally specific for F-actin. SMA have a specificity of 80% to 90% for AIH, although the sensitivity is only in the range of 70% to 80%. In contrast, ANA, although relatively sensitive for AIH, lack specificity, being associated with a variety of autoimmune diseases. Both SMA and ANA, along with other lab markers and biopsy evaluation, are included in the international diagnostic criteria for AIH.

Antimitochondrial antibodies (AMA) are a diagnostic marker for PBC. AMA are found in more than 90% of patients with PBC, with a specificity of greater than 95%. AMA are included in the diagnostic criteria for PBC, which was developed through an international collaborative effort.

Reference Values

SMOOTH MUSCLE ANTIBODIES

Negative

If positive, results are titered.

Reference values apply to all ages.
MITOCHONDRIAL ANTIBODIES (M2)

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.

ANTINUCLEAR ANTIBODIES (ANA2)

Negative: < or =1.0 Units
Weakly positive: 1.1-2.9 Units
Positive: 3.0-5.9 Units
Strongly positive: > or =6.0 Units

Reference values apply to all ages.

**Interpretation**

The presence of smooth muscle antibodies (SMA) or antinuclear antibodies (ANA) is consistent with a diagnosis of chronic autoimmune hepatitis, in patients with clinical or laboratory evidence of hepatocellular damage.

The presence of antimitochondrial antibodies (AMA) is consistent with a diagnosis of primary biliary cirrhosis, in patients with clinical or laboratory evidence of hepatobiliary damage.

**Cautions**

Smooth muscle antibodies (SMA) may be found in patients with active hepatitis cause by alcohol or drug exposure.

Antinuclear antibodies (ANA) occur in patients with a variety of systemic autoimmune diseases, including systemic lupus erythematosus, rheumatoid arthritis, Sjogren syndrome, and systemic sclerosis.

The presence of smooth muscle antibodies (SMA), antinuclear antibodies (ANA), and antimitochondrial antibodies (AMA) should not be exclusively relied upon to diagnose an autoimmune liver disease. Correlation with clinical presentation and other laboratory parameters of liver disease is required.

**Clinical Reference**


Performance

Method Description

Smooth Muscle Antibody: The patient's serum in 1:20 and 1:40 dilutions is added to fresh tissue from mouse stomach/kidney and incubated; fluorescein-conjugated antiglobulin is then added. The slides are read with a fluorescence microscope. (Doniach D, Roitt IM, Walker JG, Sherlock S: Tissue antibodies in primary biliary cirrhosis, active chronic [lupoid] hepatitis, cryptogenic cirrhosis, and other liver diseases and their clinical implications. Clin Exp Immunol 1966;1:237-262)

Mitochondrial Antibodies: This method is an enzyme immunosorbent assay that detects both IgG and IgM antibodies to M2 antigens. A dilution of patient serum is added to the wells coated with M2 antigen and incubated. After incubation and washing, all unbound human antibodies are washed away and enzyme-conjugated IgG and IgM anti-human is added. The enzyme conjugate binds to the antibody complex. Excess enzyme-conjugate is washed away and substrate is added. After incubation, the enzyme substrate reaction is stopped. The complete assay is measured on a spectrophotometer plate reader. The intensity of the color generated is proportional to the amount of IgG and IgM specific antibody in the sample. Testing is performed on the PhD by Bio-Rad. (Package insert: Bio-Rad, Kallestad Anti-Mitochondrial Kit, Distributed by Bio-Rad Laboratories, Hercules, CA, October 2014)

Antinuclear Antibodies: The method used to detect antinuclear antibody (ANA) is enzyme-linked immunosorbent assay (ELISA). A HEP-2 lysate supplemented with various purified antigens (double-stranded deoxyribonucleic acid: dsDNA, histone, SS-A [Ro], SS-B [La], Smith, RNP, Scl-70, Jo-1, plus centromere antigen) are coated onto microtiter plate wells. A dilution of patient serum is added to the well and incubated. After washing to remove unbound serum protein, an enzyme conjugated antihuman-IgG antibody is added to detect human IgG bound to the microtiter plate well. After incubation and washing to remove unbound conjugate, a substrate to the enzyme is added to the well. After incubation, the enzyme substrate reaction is stopped. The complete assay is measured on a spectrophotometer plate reader. The optical density measured is proportional to the antibody present in the patient serum. Testing is performed on the PhD instrument by Bio-Rad. (Package insert: ELISA kits, Bio-Rad Laboratories, Hercules, CA, July 2014)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Saturday

Analytic Time

2 days

Maximum Laboratory Time

3 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

See Individual Test IDs

CPT Code Information

86255

83516

86038

86256-Smooth muscle antibodies titer (if appropriate)

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALDP</td>
<td>Autoimmune Liver Disease Panel, S</td>
<td>In Process</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMA</td>
<td>Mitochondrial Ab, M2, S</td>
<td>51715-1</td>
</tr>
<tr>
<td>ANA2</td>
<td>Antinuclear Ab, S</td>
<td>5047-6</td>
</tr>
<tr>
<td>6284</td>
<td>Anti-Smooth Muscle Ab</td>
<td>26971-2</td>
</tr>
</tbody>
</table>