Overview

Useful For
Detection of previous exposure or immunity to hepatitis A infection

Special Instructions
- [Viral Hepatitis Serologic Profiles]

Method Name
Chemiluminescent Microparticle Immunoassay (CMIA)

NY State Available
Yes

Specimen

Specimen Type
Serum

Necessary Information
Date of draw is required.

Specimen Required
Collection Container/Tube:
- Preferred: Serum gel
- Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions:
1. Centrifuge blood collection tube per collection tube manufacturer’s instructions.
2. Pour off serum into aliquot tube.

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>Reject</td>
</tr>
</tbody>
</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
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</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>8 days</td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>4 days</td>
</tr>
</tbody>
</table>

Clinical and Interpretive

Clinical Information

Hepatitis A virus (HAV) is endemic throughout the world, occurring most commonly, however, in areas of poor hygiene and low socioeconomic conditions. The virus is transmitted primarily by the fecal-oral route, and it is spread by close person-to-person contact and by food- and water-borne epidemics. Outbreaks frequently occur in overcrowded situations and in high-density institutions and centers, such as prisons and health care or day care centers. Viral spread by parenteral routes (eg, exposure to blood) is possible but rare, because infected individuals are viremic for a short period of time (usually <3 weeks). There is little or no evidence of transplacental transmission from mother to fetus or transmission to newborn during delivery.

In most cases, antibodies to HAV (anti-HAV) are detectable by the time that symptoms occur, usually 15 to 45 days after exposure. Initial antibodies consist almost entirely of the IgM subclass. HAV-specific IgM antibody level in serum usually falls to an undetectable level by 6 months after acute infection. HAV-specific IgG antibody level in serum rises quickly once the virus is cleared and may persist for many years.

Reference Values

Unvaccinated: negative

Vaccinated: positive

See Viral Hepatitis Serologic Profiles in Special Instructions.

Interpretation

This assay detects the presence of hepatitis A virus (HAV)-specific IgG antibody in serum.

A negative result indicates the absence of HAV-specific IgG antibody, implying no past exposure or immunity to HAV infection.

A positive result indicates the presence of HAV-specific IgG antibody from either vaccination or past exposure to hepatitis A virus.

Cautions

Passively acquired IgG antibody from recent immune globulin administration or transfusion may result in transiently
positive test results.

The presence of heterophilic antibodies, cytomegalovirus (CMV)-specific antibodies, or human antimouse antibodies (in patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy) in serum may interfere with the assay and cause erroneous results (false-positive or false-negative).

Performance characteristics have not been established for the following specimen characteristics:

- Grossly icteric (total bilirubin level of >20 mg/dL)
- Grossly hemolyzed (hemoglobin level of >500 mg/dL)
- Grossly lipemic (triolein level >3,000 mg/dL)
- Containing particulate matter
- Cadaveric specimens

Clinical Reference


Performance

Method Description

The ARCHITECT HAVAb-IgG assay is an automated immunoassay designed for the qualitative detection of hepatitis A virus (HAV)-specific IgG antibody in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) method. Patient’s sample, assay diluent, and HAV-coated paramagnetic microparticles are combined first in a reaction well. Anti-HAV IgG present in the patient sample binds to the HAV-coated microparticles. After washing, the acridinium-labeled antihuman IgG conjugate is added to bind to anti-HAV IgG. Following another wash cycle, pretrigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). The presence or absence of anti-HAV IgG in the patient sample is determined by comparing the chemiluminescent signal in the reaction to the cutoff signal determined from an ARCHITECT HAVAB-G calibration. Specimens with signal to cutoff (S/CO) values at or above 1.00 are considered positive for anti-HAV IgG. Specimens with S/CO values below 1.00 are considered negative. (Package insert: HAVAB-G; Abbott Laboratories, Abbott Park, IL. February 2016)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Saturday; Varies

Analytic Time

1 day
Test Definition: HAIGG
Hepatitis A IgG Ab, S

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 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
86708

LOINC® Information

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<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>HAIGG</td>
<td>Hepatitis A IgG Ab, S</td>
<td>40724-7</td>
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<table>
<thead>
<tr>
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