Test Definition: HAIGM

Hepatitis A IgM Ab, S

Overview

Useful For

Diagnosis of acute or recent 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 (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).

2. Aliquot serum into plastic vial.

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

Gross hemolysis	Reject

Gross lipemia	Reject
Gross icterus	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	7 days	
	Ambient	72 hours	

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.

Serological diagnosis of acute viral hepatitis A depends on the detection of specific anti-HAV IgM. Its presence in the patient's serum indicates a recent exposure to HAV. HAV-specific IgM antibody level becomes detectable in the blood by 4 weeks after infection, persisting at elevated levels for about 2 months before declining to undetectable levels by 6 months. They rarely persist beyond 12 months after infection.

Reference Values

Negative

See Viral Hepatitis Serologic Profiles in Special Instructions.

Interpretation

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

Negative results indicate either 1) inadequate or delayed anti-HAV IgM response after known exposure to HAV, or 2) absence of acute or recent hepatitis A.

Equivocal results may be seen in early acute hepatitis A associated with rising anti-HAV IgM levels or recent hepatitis A infection associated with declining anti-HAV IgM levels. Retesting for both anti-HAV IgM (HAIGM / Hepatitis A IgM Antibody, Serum) and anti-HAV IgG (HAIGG / Hepatitis A IgG Antibody, Serum) in 2 to 4 weeks is recommended to determine the definitive HAV infection status.

Positive results indicate acute or recent (<6 months) hepatitis A infection. As required by laws in almost all states, positive anti-HAV IgM test results must be urgently reported to state health departments for epidemiologic investigations of possible outbreak transmission.

Cautions

Testing too early (<2 weeks) after exposure to hepatitis A virus (HAV) may yield negative anti-HAV IgM results.

False-positive results may be due to presence of cross-reactive antibodies from other viral infection or underlying illnesses (such as non-Hodgkin lymphoma). Positive results should be correlated with patient's clinical history and epidemiologic exposure.

The presence of heterophilic antibodies and 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 >3,000 mg/dL)

-Containing particulate matter

-Heat-inactivated

-Cadaveric specimens

Clinical Reference

1. Centers for Disease Control and Prevention: Prevention of hepatitis A through active or passive immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Morb Mortal Wkly Rep. 2006;55(RR7):1-23

2. Nainan OV, Xia G, Vaughan G, Margolis HS: Diagnosis of hepatitis A infection: a molecular approach. Clin Microbiol. Rev 2006;19:63-79

3. de Paula VS: Laboratory diagnosis of hepatitis A. Future Virology. 2012;7(5):461-472

Performance

Method Description

The ARCHITECT HAVAB-M assay is a 2-step automated immunoassay designed for the qualitative detection of hepatitis A virus (HAV)-specific IgM antibody in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) method. Prediluted patient sample, assay diluent, and HAV-coated paramagnetic microparticles are combined first in a reaction well. Anti-HAV IgM present in the patient sample binds to the HAV-coated microparticles. After washing, acridinium-labeled antihuman IgM conjugate is added to bind to anti-HAV IgM. 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). A direct relationship exists between the amount of anti-HAV IgM present in the patient sample and the RLUs detected by the ARCHITECT System optics. The presence or absence of anti-HAV IgM in the patient sample is determined by comparing the chemiluminescent signal in the reaction to the cutoff signal determined from an active ARCHITECT HAVAB-M calibration. Specimens with signal to cutoff (S/Co) values at or above 1.21 are considered positive for anti-HAV IgM. Specimens with S/Co values of 0.80 to below 1.21 are considered equivocal. Specimens with S/Co values below 0.80 are considered negative.(Package insert: Architect HAVAB-M. Abbott Laboratories; G6-5290/R05 B6L210. 02/2016)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

1 to 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, approved, or is exempt by the US 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

86709

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
HAIGM	Hepatitis A IgM Ab, S	13950-1

Result ID	Test Result Name	Result LOINC Value
HAIGM	Hepatitis A IgM Ab, S	13950-1