MAYO CLINIC LABORATORIES

Test Definition: HAIGM

Hepatitis A Virus IgM Antibody, Serum

Overview

Useful For

Diagnosis of acute or recent hepatitis A infection

Special Instructions

- Viral Hepatitis Serologic Profiles

Method Name

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available

Yes

Specimen

Specimen Type

Serum SST

Necessary Information

Date of collection is required.

Specimen Required

Patient Preparation: For 24 hours before specimen collection, patient **should not** take multivitamins or dietary supplements (eg, hair, skin, and nail supplements) containing biotin (vitamin B7).
Collection Container/Tube: Serum gel (red-top tubes are **not acceptable**)
Submission Container/Tube: Plastic vial
Specimen Volume: 0.6 mL Serum
Collection Instructions:
1. Centrifuge blood collection tube per 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 1 of the following:
-Gastroenterology and Hepatology Test Request (T728)
-Infectious Disease Serology Test Request (T916)

Specimen Minimum Volume

Serum: 0.6 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject
Heat-inactivated specimen	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum SST	Frozen (preferred)	90 days	
	Ambient	72 hours	
	Refrigerated	6 days	

Clinical & Interpretive

Clinical Information

Hepatitis A virus (HAV) is endemic throughout the world, occurring most commonly in areas of poor hygiene and low socioeconomic conditions. The virus is transmitted primarily by the fecal-oral route and spread by close person-to-person contact and by food and waterborne epidemics. Outbreaks frequently occur in overcrowded situations and high-density institutions and centers, such as prisons and healthcare or daycare 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.

Interpretation

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

Negative results indicate either inadequate or delayed anti-HAV IgM response after known exposure to HAV or 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 Virus IgM

Antibody, Serum) and anti-HAV Total (HAVTA / Hepatitis A Virus Total Antibodies, 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

This assay has not been licensed by the US Food and Drug Administration for the screening of blood, plasma, and tissue donors.

For diagnostic purposes, the results should always be assessed in conjunction with the patient’s medical history, clinical examination, and other findings.

In rare cases, interference due to high titers of antibodies to immunological components, streptavidin or ruthenium can occur. As with many IgM antibody assays, interference with unspecific IgM antibodies can occur and may lead to false-positive results with the Elecsys Anti-HAV IgM assay.

False-positive results may also 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. A reactive anti-HAV IgM result does not necessarily rule out other hepatitis infections.

The presence of heterophilic antibodies and human anti-mouse 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).

Consumption of high-dose biotin supplement within 12 hours of blood collection for this test can cause false-negative test results. Individuals should cease taking these biotin-containing dietary supplements for minimum 12 hours before blood collection for this test. Testing too early (<2 weeks) after exposure to hepatitis A virus (HAV) may yield negative anti-HAV IgM results.

A negative test result does not exclude the possibility of exposure to hepatitis A virus. Levels of anti-HAV IgM may be below the cutoff in early infection and late after infection.

Assay performance characteristics have not been established for testing serum of immunosuppressed individuals.

Performance characteristics have not been established for the following specimen characteristics or specimen types:
-Grossly icteric (total bilirubin level of >50 mg/dL)
-Grossly hemolyzed (hemoglobin level of >1000 mg/dL)
-Grossly lipemic (intralipid >2000 mg/dL)
-Containing particulate matter
-Heat-inactivated specimens
-Cadaveric specimens
-Specimens stabilized with azide
-Specimen types other than serum

Clinical Reference

1. de Paula VS. Laboratory diagnosis of hepatitis A. Future Virology. 2012;7(5):461-472
2. Nelson NP, Weng MK, Hofmeister MG, et al. Prevention of hepatitis A infection in the United States: Recommendations of the Advisory Committee on Immunization Practices, 2020. MMWR Morb Mortal Wkly Rep. 2020;69(5):1-38. Erratum in MMWR Morb Mortal Wkly Rep. 2021;70(8):294
3. Webb GW, Kelly S, Dalton HR. Hepatitis A and hepatitis E: clinical and epidemiological features, diagnosis, treatment, and prevention. Clin Microbiol Newslett. 2020;42(21):171-179

Performance

Method Description

The Elecsys Anti-HAV (hepatitis A virus) IgM assay is based on the sandwich immunoassay principle and performed using an electrochemiluminescence immunoassay on the automated cobas e 801 immunochemistry analyzer. HAV-specific IgM antibody (anti-HAV IgM) in the patient's serum sample is pretreated with anti-Fdy reagent to block specific IgG in the presence of monoclonal anti-HAV antibodies labeled with ruthenium complex. After addition of biotinylated monoclonal human-IgM-specific antibodies, HAV antigen, and streptavidin-coated microparticles, patient's anti-HAV IgM form a sandwich complex with the HAV antigen and the ruthenium-labeled anti-HAV antibody which becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is then aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode, and unbound substances are washed away. Voltage is applied to the electrode then induces chemiluminescent emissions that are measured by a photomultiplier. Test result is determined automatically by the assay-specific software program by comparing the electrochemiluminescence signal generated from the patient's sample to the cutoff index value set from reagent lot-specific assay calibration.(Package insert: Elecsys Anti-HAV IgM. Roche Diagnostics; v5.0, 11/2022)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

1 to 2 days

Specimen Retention Time

14 days

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

Fees & 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 account representative. 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