

## Overview

### Useful For

Detection of recent or previous exposure or immunity to hepatitis A.

This test should not be used as a screening or confirmatory test for blood or solid or soft tissue donor specimens.

### 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).

**Supplies:** Sarstedt Aliquot Tube, 5 mL (T914)

**Collection Container/Tube:** Serum gel (red-top tubes are **not acceptable**)

**Submission Container/Tube:** Plastic vial

**Specimen Volume:** 0.6 mL

#### 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 forms with the specimen:

[Gastroenterology and Hepatology Test Request](#) (T728)

[Infectious Disease Serology Test Request](#) (T916)

Specimen Minimum Volume

0.6 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

Specimen Stability Information

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

Clinical & 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, HAV-specific antibodies (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. Anti-HAV IgM usually falls to an undetectable level by 6 months after HAV infection. Anti-HAV IgG levels rise quickly once the virus is cleared and may persist for many years. Currently, commercial diagnostic assays are available for detecting anti-HAV IgM alone (HAIGM / Hepatitis A IgM Antibody, Serum) or anti-HAV total (IgM and IgG) but not anti-HAV IgG alone.

Reference Values

Unvaccinated: Negative

Vaccinated: Positive

Interpretation

This assay detects the presence of hepatitis A virus (HAV)-specific total antibodies (both anti-HAV IgG and anti-HAV IgM combined). A positive result indicates that the patient had hepatitis A either recently or in the past or immunity to hepatitis A from vaccination. A reactive (positive) result by the Elecsys Anti-HAV II assay does not differentiate between acute or past HAV infection or immunity from vaccination, and it does not necessarily rule out other hepatitis infections.

If clinically indicated, specific testing for anti-HAV IgM is necessary to confirm the presence of acute or recent hepatitis A. A positive result for anti-HAV total with a negative anti-HAV IgM result indicates immunity to hepatitis A from either past HAV infection or vaccination against HAV.

A negative result indicates the absence of recent or past hepatitis A or a lack of immunity to HAV infection. A non-reactive (negative) test result does not exclude the possibility of early acute infection with HAV.

### Cautions

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 extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. Passively acquired antibody (eg, recent immune globulin administration, transfusion) may result in transiently positive test results.

Serum specimens from individuals taking biotin supplements at 20 mg or more per day may have false-positive anti-HAV (hepatitis A virus) total Ab test results due to interference of biotin with the assay. Such individuals should stop taking these biotin-containing dietary supplements for a minimum 12 hours before blood collection for this test.

Regardless of exposure history, testing for anti-HAV total antibodies alone is insufficient to confirm a diagnosis of acute hepatitis A.

Assay performance characteristics have not been established for immunosuppressed individuals or those under 2 years of age.

Assay performance characteristics have not been established for the following specimen characteristics or specimen types:

- Grossly icteric (total bilirubin level of >66 mg/dL)
- Grossly hemolyzed (hemoglobin level of >1000 mg/dL)
- Grossly lipemic (intralipid >2000 mg/dL)
- Containing particulate matter
- Cadaveric specimens
- Specimen types other than serum

### Clinical Reference

1. De Paula VS. Laboratory diagnosis of hepatitis A. *Future Virology*. 2012;7(5):461-472
2. Prasadhrathsint K, Stapleton JT. Laboratory Diagnosis and Monitoring of Viral Hepatitis. *Gastroenterol Clin North Am*. 2019;48(2):259-279. doi:10.1016/j.gtc.2019.02.007
3. Centers for Disease Control and Prevention. Prevention of hepatitis A virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices, 2020. *Mort Morbid Wkly Rpt*. 2020;69(5):1-38. doi:10.15585/mmwr.rr6905a1
4. Van Damme P, Pinto RM, Feng Z, Cui F, Gentile A, Shouval D. Hepatitis A virus infection. *Nature Rev Dis Primers*. 2023;9(1):51. doi:10.1038/s41572-023-00461-2

## Performance

### Method Description

The Elecsys Anti-HAV (hepatitis A virus) II assay is performed using an electrochemiluminescence immunoassay on the automated cobas e 801 immunochemistry analyzer. HAV-specific antibodies in the patient's serum binds with added HAV antigen in the reaction. After addition of biotinylated monoclonal anti-HAV and streptavidin-coated microparticles, patient's anti-HAV 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 which induces chemiluminescent emissions that are measured by a photomultiplier. Test result is determined automatically with the assay-specific software in comparing the electrochemiluminescence signal generated in the patient's sample to the signal cutoff index value set from reagent lot-specific assay calibration. (Package insert: Elecsys Anti-HAV II. Roche Diagnostics; v3.0, 11/2022)

### PDF Report

No

### Day(s) Performed

Monday through Saturday

### Report Available

Same day/1 to 3 days

### Specimen Retention Time

14 days

### Performing Laboratory Location

Rochester

## 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

86708

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HAVTA	Hepatitis A Virus Total Ab, S	13951-9

Result ID	Test Result Name	Result LOINC® Value
HAVT	Hepatitis A Virus Total Ab, S	13951-9