

## 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 collection 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 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**

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	8 days	
	Ambient	4 days	

**Clinical and 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 is spread by close person-to-person contact as well as 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 of acute hepatitis A, IgM antibodies to HAV (anti-HAV IgM) are detectable by the time symptoms occur, usually 15 to 45 days after exposure. HAV-specific IgM antibody level in serum usually falls to an undetectable level by 6 months after acute infection. HAV-specific IgG antibody (anti-HAV IgG) 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.Â

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 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).

Specimens from individuals with anti-*Escherichia coli*, anti-cytomegalovirus (CMV), or hemodialysis patients may cross-react with this assay.

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

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-IgG assay is an automated immunoassay designed for the qualitative detection of hepatitis A virus (HAV)-specific IgG antibody in human serum 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; 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 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**

Test ID	Test Order Name	Order LOINC Value
HAIGG	Hepatitis A IgG Ab, S	40724-7

Result ID	Test Result Name	Result LOINC Value
HAIGG	Hepatitis A IgG Ab, S	40724-7