

## Overview

### Useful For

Differential diagnosis of recent acute viral hepatitis

### Profile Information

Test ID	Reporting Name	Available Separately	Always Performed
HAIGM	Hepatitis A IgM Ab, S	Yes	Yes
HBAG	HBs Antigen, S	Yes	Yes
HBIM	HBc IgM Ab, S	Yes	Yes
HCVDX	HCV Ab w/Reflex to HCV PCR, S	Yes	Yes

### Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
HBGNT	HBs Antigen Confirmation, S	No	No
HCVQN	HCV RNA Detect/Quant, S	Yes	No

### Testing Algorithm

If hepatitis C virus (HCV) antibody is reactive, then HCV RNA detection and quantification by real-time reverse transcription-PCR will be performed at an additional charge.

If hepatitis Bs antigen is reactive, then confirmation will be performed at an additional charge.

The following algorithms are available in Special Instructions:

[-HBV Infection-Diagnostic Approach and Management Algorithm](#)

[-Hepatitis C: Testing Algorithm for Screening and Diagnosis](#)

[-Viral Hepatitis Serologic Profiles](#)

### Special Instructions

- [Viral Hepatitis Serologic Profiles](#)
- [HBV Infection-Diagnostic Approach and Management Algorithm](#)
- [Hepatitis C: Testing Algorithm for Screening and Diagnosis](#)

### Method Name

HAIGM: Chemiluminescent Microparticle Immunoassay (CMIA)

HBAG, HBIM, HCVDX, HBGNT: Chemiluminescence Immunoassay (CIA)

**NY State Available**

Yes

**Specimen****Specimen Type**Serum  
Serum SST**Necessary Information****Date of draw is required.****Specimen Required****Both 0.5 mL of refrigerated serum and 2.5 mL of frozen serum are preferred** for this test.**Patient Preparation:** For 24 hours before this test, do not take multivitamins or dietary supplements containing biotin (vitamin B7), which is commonly found in hair, skin, and nail supplements and multivitamins.**Collection Container/Tube:** Serum gel**Submission Container/Tube:** Plastic vial**Specimen Volume:** 3 mL**Collection Instructions:**

1. Centrifuge blood collection tube per collection tube manufacturer's instructions.
2. Transfer 0.5 mL serum into an aliquot tube labeled as HAIGM, and ship refrigerate (required).
3. Transfer remaining 2.5 mL serum into a second aliquot tube labeled as SST Serum, and ship frozen (preferred).

**Forms**If not ordering electronically, complete, print, and send a [Gastroenterology and Hepatology Client Test Request \(T728\)](#) with the specimen.**Specimen Minimum Volume**

2 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	Refrigerated	5 days	
Serum SST	Frozen (preferred)	30 days	
	Refrigerated	5 days	

## Clinical and Interpretive

### Clinical Information

#### Hepatitis A:

Hepatitis A virus (HAV) is an RNA virus that accounts for 20% to 25% of the viral hepatitis in United States adults. HAV infection is spread by the oral/fecal route and produces acute hepatitis that follows a benign, self-limited course. Spread of the disease is usually associated with contaminated food or water caused by poor sanitary conditions. Outbreaks frequently occur in overcrowded situations and in institutions or high-density centers such as prisons and health care centers. Epidemics may occur following floods or other disaster situations. Chronic carriers of HAV have never been observed.

#### Hepatitis B:

Hepatitis B virus (HBV) is a DNA virus that is endemic throughout the world. The infection is spread primarily through percutaneous contact with infected blood products (eg, blood transfusion, sharing of needles by drug addicts). The virus is also found in virtually every type of human body fluid and is known to be spread through oral and genital contact. HBV can be transmitted from mother to child during delivery through contact with blood and vaginal secretions; it is not commonly transmitted transplacentally. After a course of acute illness, HBV persists in approximately 10% of patients. Some of these chronic carriers are asymptomatic others develop chronic liver disease, including cirrhosis and hepatocellular carcinoma.

#### Hepatitis C:

Hepatitis C virus (HCV) is an RNA virus that is a significant cause of morbidity and mortality worldwide. HCV is transmitted through contaminated blood or blood products or through other close, personal contacts. It is recognized as the cause of most cases of posttransfusion hepatitis. HCV shows a high rate of progression (>50%) to chronic disease. In the United States, HCV infection is quite common, with an estimated 3.5 to 4 million chronic HCV carriers. Cirrhosis and hepatocellular carcinoma are sequelae of chronic HCV.

The following algorithms are available in Special Instructions:

[-HBV Infection-Diagnostic Approach and Management Algorithm](#)

[-Hepatitis C: Testing Algorithm for Screening and Diagnosis](#)

[-Viral Hepatitis Serologic Profiles](#)

### Reference Values

HEPATITIS B SURFACE ANTIGEN

Negative

## HEPATITIS B SURFACE ANTIGEN CONFIRMATION

Negative

## HEPATITIS B CORE IgM ANTIBODY

Negative

## HEPATITIS A IgM ANTIBODY

Negative

## HEPATITIS C ANTIBODY

Negative

## HEPATITIS C VIRUS RNA DETECTION and QUANTIFICATION by REAL-TIME RT-PCR

Undetected

Interpretation depends on clinical setting. See [Viral Hepatitis Serologic Profiles](#) in Special Instructions.

**Interpretation**

## Hepatitis A:

Antibody against hepatitis A antigen is usually detectable by the onset of symptoms (usually 15-45 days after exposure). The initial antibody consists almost entirely of IgM subclass antibody. Antibody to hepatitis A virus (anti-HAV) IgM usually falls to undetectable levels 3 to 6 months after infection.

## Hepatitis B:

Hepatitis B surface antigen (HBsAg) is the first serologic marker appearing in the serum 6 to 16 weeks following hepatitis B virus (HBV) infection. In acute cases, HBsAg usually disappears 1 to 2 months after the onset of symptoms. Hepatitis B surface antibody (anti-HBs) appears with the resolution of HBV infection after the disappearance of HBsAg. Anti-HBs also appears as the immune response following a course of inoculation with the hepatitis B vaccine.

Initially, hepatitis B core antibody (anti-HBc) consists almost entirely of the IgM subclass. Anti-HBc, IgM can be detected shortly after the onset of symptoms and is usually present for 6 months. Anti-HBc may be the only marker of a recent HBV infection detectable following the disappearance of HBsAg, and prior to the appearance of anti-HBs, ie, window period.

## Hepatitis C:

Hepatitis C antibody is usually not detectable during the early months following infection and is almost always detectable by the late convalescent stage of infection. Hepatitis C antibody is not neutralizing and does not provide immunity.

If HBsAg, anti-HAV (IgM), and anti-HCV are negative and patient's condition warrants, consider testing for Epstein-Barr virus or cytomegalovirus.

The following algorithms are available in Special Instructions:

---

[-HBV Infection-Diagnostic Approach and Management Algorithm](#)

[-Hepatitis C: Testing Algorithm for Screening and Diagnosis](#)

### Cautions

Consider administration of immune globulin to individuals exposed to patients with hepatitis A.

Â

Consider administration of hepatitis B immune globulin and/or hepatitis B vaccine to individuals exposed to hepatitis B patient's blood or body fluids.

Â

Positive hepatitis B surface antigen or positive antibody to hepatitis A virus IgM test results should be reported by the attending physician to the State Department of Health, as required by law in some states.

Â

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

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

### Clinical Reference

1. Roque-Afonso AM, Desbois D, Dussaix E: Hepatitis A virus: serology and molecular diagnostics. *Future Virology* 2010;5(2):233-242
2. de Paula VS: Laboratory diagnosis of hepatitis A. *Future Virology* 2012;7(5):461-472
3. Bonino F, Piratvisuth T, Brunetto MR, et al: Diagnostic markers of chronic hepatitis B infection and disease. *Antiviral Therapy* 2010;15(Suppl. 3):35-44
4. Wasley A, Fiore A, Bell BP: Hepatitis A in the era of vaccination. *Epidemiol Rev* 2006;28:101-111
5. American Association for the Study of Liver Diseases/Infectious Diseases Society of America/International Antiviral Society-USA: Recommendations for Testing, Managing, and Treating Hepatitis C. Accessed on January 27, 2015. Available at [www.hcvguidelines.org](http://www.hcvguidelines.org)

### Performance

### Method Description

Hepatitis B Surface Antigen (HBsAg):

---

Specimens are first tested by the VITROS HBsAg assay. With modification to the assay manufacturer's instructions for use, specimens yielding S/CO at or above 1.00 but less than or equal to 100.0 will be confirmed by the VITROS HBsAg Confirmatory assay. Specimens that are strongly positive (ie, S/CO >100.0) do not require this confirmation.

This immunometric technique involves the simultaneous reaction of HBsAg in the sample with mouse monoclonal hepatitis B surface antibody (anti-HBs) coated onto the wells and a horseradish peroxidase (HRP)-labeled mouse monoclonal anti-HBs antibody in the conjugate. Unbound conjugate is removed by washing. A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent, is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent increases the level and duration of the light produced. The light signals are read by the VITROS Immunodiagnostic System. The amount of HRP conjugate bound is indicative of the level of HBsAg present in the sample. (Package insert: VITROS HBsAg assay, no. GEM1201\_US\_EN, version 12.0; Ortho-Clinical Diagnostics, Inc. Rochester, NY 6-22-2017)

#### HBs Antigen Confirmation:

The VITROS HBsAg Confirmatory Kit uses the principle of specific antibody neutralization to confirm the presence of HBsAg. The sample is tested twice: 1 aliquot is incubated with a neutralizing reagent containing high titer anti-HBs (the confirmatory antibody); the second aliquot is incubated with a nonneutralizing control reagent (the sample diluent). The confirmatory antibody binds to HBsAg in the sample inhibiting its reaction in the VITROS HBsAg assay. This leads to a reduced result compared to that for the nonneutralized control sample. (Package insert: VITROS HBsAg Confirmation assay, no. GEM4201\_US\_EN, version 12.0; Ortho-Clinical Diagnostics, Inc. Rochester, NY 6-22-2017)

#### Hepatitis A IgM Antibody:

The ARCHITECT HAVAb-IgM assay is an 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. Patient's sample, assay diluent, and HAV-coated paramagnetic microparticles are combined first in a reaction well. Anti-aHAV IgM present in the patient sample binds to the HAV-coated microparticles. After washing, the 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). 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 ARCHITECT HAVAB-M calibration. Specimens with signal to cutoff (S/CO) values at or above 1.00 are considered positive for anti-HAV IgM. Specimens with S/CO values below 1.00 are considered negative. (Package insert: HAVAB-M; Abbott Laboratories, Abbott Park, IL. February 2016)

#### Hepatitis B Core (HBc) IgM Antibody:

An antibody class capture technique is used. This involves the dilution of the sample and the simultaneous reaction of IgM in the diluted sample with biotinylated mouse monoclonal antihuman IgM antibody. The immune complex is captured by streptavidin on the wells. Unbound materials are removed by washing. Horseradish peroxidase (HRP)-labeled mouse monoclonal anti-hepatitis B core (anti-HBc) IgM antibody, which has been complexed with recombinant HBc antigen (conjugate), is then captured by anti-HBc specific IgM bound to the wells. Unbound material is removed by washing. The bound HRP conjugate is measured by a luminescent reaction. A reagent containing luminogenic substrates (a luminal derivative and a peracid salt) and an electron transfer agent is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminal derivative, producing light. The electron transfer agent increases the level and duration of the light produced. The light signals are read by the VITROS Immunodiagnostic System. The amount of HRP conjugate bound is indicative of the concentration of anti-HBc IgM present in the sample. (Package insert: VITROS Anti-HBc IgM assay, GEM0216\_US\_EN, version 13.0;

---

Ortho-Clinical Diagnostics, Inc. Rochester, NY 14626-5101 2-14-2017)

Hepatitis C Virus (HCV) Antibody:

The VITROS anti-HCV assay is performed using the VITROS Anti-HCV Reagent Pack and VITROS Immunodiagnostic Products Anti-HCV Calibrator on the VITROS 3600 Immunodiagnostic System (Ortho-Clinical Diagnostics, Inc., Raritan, NJ). An immunometric technique is used, involving a 2-stage reaction. In the first stage, HCV antibody present in the sample binds to HCV recombinant antigens coated on the reaction wells, and unbound sample is removed by washing. In the second stage, horseradish peroxidase (HRP)-labeled antibody conjugate (mouse monoclonal antihuman IgG) binds to human IgG captured on the well in the first stage. Unbound conjugate is removed by washing. A reagent containing luminogenic substrates (a luminal derivative and a peracid salt) and an electron transfer agent is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminal derivative, producing light. The electron transfer agent increases the level and duration of the light produced. The emitted light signals are detected and measured by the VITROS 3600 Immunodiagnostic System. The amount of HRP conjugate bound is directly proportional to the level of anti-HCV antibodies present in a given sample. (Package insert: VITROS Anti-HCV assay, GEM1243\_US\_EN, version 13.0; Ortho-Clinical Diagnostics, Inc. Rochester, NY 14626-5101 03-08-2017)

### PDF Report

No

### Day(s) and Time(s) Test Performed

Monday through Saturday; Varies

### Analytic Time

1 day

### 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, 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

80074 (if all 4 initial tests are performed)

---

86709 (if all 4 are not performed)

86705 (if all 4 are not performed)

87340 (if all 4 are not performed)

86803 (if all 4 are not performed)

87522 (if appropriate)

87341 (if appropriate)

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
AHEP	Acute Hepatitis Profile	24363-4

Result ID	Test Result Name	Result LOINC Value
HCVA4	HCV Ab, S	13955-0
HBIM	HBc IgM Ab, S	24113-3
H_BAG	HBs Antigen, S	5196-1
HAIGM	Hepatitis A IgM Ab, S	13950-1