

Overview

Useful For

Determining if an individual has been infected following exposure to an unknown type of hepatitis

Obtaining baseline serologic markers of an individual exposed to a source with an unknown type of hepatitis

Determining immunity to hepatitis A and B viral infections

Profile Information

Test ID	Reporting Name	Available Separately	Always Performed
HAIGG	Hepatitis A IgG Ab, S	Yes	Yes
HBAG	HBs Antigen, S	Yes	Yes
HBAB	HBs Antibody, S	Yes	Yes
HBC	HBc Total 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 B surface antigen (HBsAg) is reactive, then HBsAg confirmation will be performed at an additional charge.

See the following 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

HAIGG: Chemiluminescent Microparticle Immunoassay (CMIA)

HBAG, HBAB, HBC, 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 12 hours before specimen collection 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 HAIGG, and ship refrigerate (required)
3. Transfer remaining 2.5 mL serum into a second aliquot tube labeled as SST Serum, and ship frozen (preferred).

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

2.5 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

Red-top serum Heat-inactivated specimen	Reject
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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.

See the following 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 SURFACE ANTIBODY, QUALITATIVE/QUANTITATIVE

Hepatitis B Surface Antibody

Unvaccinated: negative

Vaccinated: positive

Hepatitis B Surface Antibody, Quantitative

Unvaccinated: <5.0 mIU/mL

Vaccinated: > or =12.0 mIU/mL

HEPATITIS B CORE TOTAL ANTIBODIES

Negative

HEPATITIS A IgG ANTIBODY

Unvaccinated: negative

Vaccinated: positive

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 (anti-HAV) is almost always detectable by the onset of symptoms (usually 15-45 days after exposure). The initial antibody consists almost entirely of the IgM subclass of antibody. Anti-HAV IgM usually falls to undetectable levels 3 to 6 months after infection. Anti-HAV IgG levels rise quickly once the virus is cleared and persist for many years.

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.

Hepatitis B core antibody (anti-HBc) appears shortly after the onset of symptoms of HBV infection and may be the only serologic marker remaining years after exposure to hepatitis B.

Hepatitis C:

Hepatitis C virus antibody (anti-HCV) is usually not detectable during the early months following infection, but is almost always detectable by the late convalescent stage of infection. Anti-HCV is not neutralizing and does not provide immunity.

Cautions

Consider administration of immune globulin to the individual exposed to hepatitis A.

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Consider administration of hepatitis B immune globulin and/or hepatitis B vaccine to the individual exposed to hepatitis B.

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

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Type-specific tests should be used to evaluate individuals who have been exposed to a source with a known type of hepatitis (eg, hepatitis A, hepatitis B, hepatitis C).

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

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

Performance

Method Description

Hepatitis A IgG Antibody:

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 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-HAV IgG present in the patient sample binds to the hepatitis A virus-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, Abbott Park, IL. February 2016)

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_EN_US, version 12.0; Ortho-Clinical Diagnostics, Inc. Rochester, NY 6-22-2017)

Hepatitis Bs 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_EN_US, version 12.0; Ortho-Clinical Diagnostics, Inc., Rochester, NY 6-22-2017)

Hepatitis Bs Antibody:

VITROS anti-HBs quantitative assay is performed using the VITROS Anti-HBs Quantitative Reagent Pack and VITROS Immunodiagnostic Products Anti-HBs Calibrators on the automated VITROS Immunodiagnostic System.

This chemiluminescent immunoassay is based on an immunometric technique in which the anti-HBs present in the clinical serum sample reacts with HBsAg (ad and ay subtypes) coated onto the assay reaction wells. A horseradish peroxidase (HRP)-labeled HBsAg conjugate (ad and ay subtypes) then complexes with the bound anti-HBs forming an "antigen sandwich." Unbound materials are 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. HRP in the bound conjugate catalyzes the oxidation of the luminol derivative to produce light. The electron transfer agent increases the level and duration of the light produced. The light signals are detected by the VITROS Immunodiagnostic System. The amount of HRP conjugate bound is directly proportional to the concentration of anti-HBs antibody present. (Package insert: VITROS Anti-HBs Quantitative Assay, Ortho-Clinical Diagnostics, Inc., Rochester, NY, publication no. GEM1208 EN, v 12.0 6-22-2017)

Hepatitis B Core Total Antibody:

The VITROS anti-hepatitis B core (anti-HBc) assay is a competitive immunoassay method based on the reaction of anti-HBc in the sample with hepatitis B core antigen (HBcAg)-coated wells. Unbound sample is removed by washing. HRP-labeled antibody conjugate (mouse monoclonal anti-HBc) is then allowed to react with the remaining exposed HBcAg on the well surface. Unbound conjugate is removed by washing.

The bound HRP conjugate is measured by a luminescent reaction. 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 concentration of anti-HBc present in the sample. (Package insert: VITROS Anti-HBc Assay, no. GEM1208_EN_US, version 12.0; 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, 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, no. GEM1243_EN_US, 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

86704

86706

86708

86803

87340

87341 (if appropriate)

87522 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
PHEP	Previous Hepatitis Profile	92890-3

Result ID	Test Result Name	Result LOINC Value
HCVA4	HCV Ab, S	13955-0
HBC	HBc Total Ab, S	13952-7
HB_AB	HBs Antibody, S	10900-9
H_BAG	HBs Antigen, S	5196-1
HAIGG	Hepatitis A IgG Ab, S	40724-7
HBSQN	HBs Antibody, Quantitative, S	5193-8