

## Overview

### Useful For

[Diagnosis and evaluation of patients with symptoms of hepatitis with a duration more than 6 months](#)

Distinguishing between chronic hepatitis B and chronic hepatitis C

### Profile Information

Test ID	Reporting Name	Available Separately	Always Performed
HBC	HBc Total Ab, S	Yes	Yes
HBAB	HBs Antibody, S	Yes	Yes
HBAG	HBs Antigen, S	Yes	Yes
HCVDX	HCV Ab w/Reflex to HCV PCR, S	Yes	Yes

### Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
HCVQN	HCV RNA Detect/Quant, S	Yes	No
HBGNT	HBs Antigen Confirmation, S	No	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 is reactive, then confirmation will be performed at an additional charge.

The following algorithms are available in Special Instructions:

[-Chronic Hepatitis C Treatment and Monitoring Algorithm: Direct Antiviral Antigen \(DAA\) Combination](#)

[-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](#)
- [Chronic Hepatitis C Treatment and Monitoring Algorithm: Direct Antiviral Agent \(DAA\) Combination](#)

**Method Name**

Chemiluminescence Immunoassay (CIA)

**NY State Available**

Yes

**Specimen**
**Specimen Type**

Serum SST

**Necessary Information**

Date of draw is required.

**Specimen Required**
**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. Aliquot serum into plastic vial.

**Forms**

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

**Specimen Minimum Volume**

2.75 mL

**Reject Due To**

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

**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Serum SST	Frozen (preferred)	30 days	
	Refrigerated	5 days	

---

## Clinical and Interpretive

### Clinical Information

#### 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 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 post-transfusion 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:

[-Chronic Hepatitis C Treatment and Monitoring Algorithm: Direct Antiviral Antigen \(DAA\) Combination](#)

[-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 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 C ANTIBODY**

Negative

Interpretation depends on clinical setting.

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

Hepatitis B surface antigen (HBsAg) is the first serologic marker appearing in the serum 6 to 16 weeks following hepatitis B viral (HBV) infection. In acute cases, HBsAg usually disappears 1 to 2 months after the onset of symptoms. Persistence of HBsAg for more than 6 months indicates development of either a chronic carrier state or chronic HBV infection.

Hepatitis B core antibodies (anti-HBc Ab) appear shortly after the onset of symptoms of HBV infection and soon after the appearance of HBsAg. The IgM subclass usually falls to undetectable levels within 6 months, and the IgG subclass may remain for many years.

Hepatitis B surface antibody (anti-HBs) usually appears with the resolution of hepatitis B virus infection after the disappearance of HBsAg.

If HBsAg and anti-HBc (total antibody) are positive and patient's condition warrants, consider testing for hepatitis Be antigen (HBeAg), anti-HBe, hepatitis B virus DNA (HBV-DNA) or anti-hepatitis D virus (anti-HDV).

**Chronic Hepatitis C:**

Anti-HCV is almost always detectable by the late convalescent and chronic stage of infection.

The serologic tests currently available do not differentiate between acute and chronic hepatitis C infections.

**Cautions**

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

Consider administration of hepatitis B immune globulin (HBIG) and hepatitis B vaccine to HBsAg antibody negative individuals exposed to the HBsAg-positive patient's blood or body fluids.

Neonates (<1 month old) with positive hepatitis B core (anti-HBc) total antibody results from this assay method should be tested for anti-HBc IgM antibody to rule-out possible maternal anti-HBc total antibody causing false-positive results. Repeat testing for anti-HBc total antibody within 1 month is also recommended in these anti-HBc total antibody-positive neonates.

[Assay performance characteristics have not been established for:](#)

-Individuals under 10 years of age (HCVDX)

- 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)
- Cadaveric specimens
- Those that contain particulate matter

### Clinical Reference

1. Wietzke P, Schott P, Braun F, et al: Clearance of HCV RNA in a chronic hepatitis C virus-infected patient during acute hepatitis B virus superinfection. *Liver* 1999;19:348-353
2. Villari D, Pernice M, Spinella S, et al: Chronic hepatitis in patients with active hepatitis B virus and hepatitis C virus combined infections: A histological study. *Am J Gastroenter* 1995;90:955-958
3. Bonino F, Piratvisuth T, Brunetto MR, et al: Diagnostic markers of chronic hepatitis B infection and disease. *Antiviral Therapy* 2010;15(3):35-44
4. American Association for the Study of Liver Diseases and Infectious Diseases Society of America: HCV guidance: Recommendations for testing, managing, and treating hepatitis C. Accessed July 14, 2017 Available at: [www.hcvguidelines.org/full-report-view](http://www.hcvguidelines.org/full-report-view)
5. Badur S, Akgun A: Diagnosis of hepatitis B infections and monitoring of treatment. *J Clin Virol* 2001;21:229-237

### 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 signal-to-cutoff (S/CO) of 1.00 or greater but 100.0 or less 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 13.0; Ortho-Clinical Diagnostics, Inc. Rochester, NY 09-06-2019)

HBsAg 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 non-neutralized control sample. (Package insert: VITROS

---

HBsAg Confirmation assay, no. GEM4201\_US\_EN, version 13.1; Ortho-Clinical Diagnostics, Inc., Rochester, NY 10-05-2017)

**Hepatitis B Surface Antibody (anti-HBs):**

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, publication no. GEM1208\_US\_EN, v 13.1 Ortho-Clinical Diagnostics, Inc., Rochester, NY; 09-06-2019)

**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. GEM1211\_US\_EN, version 13.1; Ortho-Clinical Diagnostics, Inc. Rochester, NY 14626-5101 09-06-2019)

**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 automated VITROS Immunodiagnostic System. 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 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\_US\_EN, version 14.0; Ortho-Clinical Diagnostics, Inc. Rochester, NY 14626-5101 10-03-2017)

**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 or approved 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

86803

87340

87341 (if appropriate)

87522 (if appropriate)

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
CRHEP	Chronic Hepatitis Profile	92889-5

Result ID	Test Result Name	Result LOINC Value
HCVA4	HCV Ab, S	13955-0

---

Result ID	Test Result Name	Result LOINC Value
H_BAG	HBs Antigen, S	5196-1
HBC	HBc Total Ab, S	13952-7
HB_AB	HBs Antibody, S	10900-9
HBSQN	HBs Antibody, Quantitative, S	5193-8