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## Overview

### Useful For

Identifying previous exposure to hepatitis B virus

Determining adequate immunity from hepatitis B vaccination

### Testing Algorithm

For more information see [Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management](#)

### Special Instructions

- [Viral Hepatitis Serologic Profiles](#)
- [Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management](#)

### Highlights

This assay provides both qualitative and quantitative results.

This diagnostic test should be used for testing individuals to evaluate post-vaccination immunity status or post-acute infection status of hepatitis B virus.

### Method Name

Electrochemiluminescence Immunoassay (ECLIA)

### NY State Available

No

## Specimen

### Specimen Type

Serum SST

### Ordering Guidance

If patient is being monitored for hepatitis B immune globulin (HBIG) therapy after organ transplantation, order HBABT / Hepatitis B Virus Surface Antibody Monitor, Post-Transplant, Serum.

This test should **not** be used for screening **asymptomatic, nonpregnant** individuals with or without risk factors for hepatitis B virus (HBV) infection. For screening such patients, order HBBSN / Hepatitis B Virus Surface Antibody Screen, Qualitative/Quantitative, Serum.

This test should **not** be used for prenatal screening of **pregnant** individuals with or without risk factors for HBV infection.

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For screening such patients, order HBABP / Hepatitis B Virus Surface Antibody Prenatal, Qualitative/Quantitative, Serum.

**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:** 0.7 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 a plastic vial.

**Forms**

If not ordering electronically, complete, print, and send 1 of the following:

[-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	Frozen (preferred)	90 days	
	Refrigerated	6 days	
	Ambient	7 hours	

**Clinical & Interpretive****Clinical Information**

Hepatitis B virus (HBV) is a DNA virus that is endemic throughout the world. The infection is spread primarily through

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blood transfusion or percutaneous contact with infected blood products, such as sharing of needles among injection drug users. The virus is found in virtually every type of human body fluid and has been 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, but it is not commonly transmitted via the transplacental route.

The incubation period for HBV infection averages 60 to 90 days (range of 45-180 days). Common symptoms include malaise, fever, gastroenteritis, and jaundice (icterus). After acute infection, HBV infection becomes chronic in 30% to 90% of infected children younger than 5 years and in 5% to 10% of infected individuals 5 years or older. Some of these chronic carriers are asymptomatic, while others progress to chronic liver disease, including cirrhosis and hepatocellular carcinoma.

Hepatitis B surface antigen (HBsAg) is the first serologic marker, appearing in the serum 6 to 8 weeks following HBV infection. In acute cases, HBsAg usually disappears 1 to 2 months after the onset of symptoms with the appearance of HBs antibody (anti-HBs). Anti-HBs also appears as the immune response following hepatitis B vaccination.

**Reference Values**

## HEPATITIS B SURFACE ANTIBODY

Unvaccinated: Negative

Vaccinated: Positive

## HEPATITIS B SURFACE ANTIBODY, QUANTITATIVE

Unvaccinated: &lt;8.5 mIU/mL

Vaccinated: &gt; or =11.5 mIU/mL

See [Viral Hepatitis Serologic Profiles](#).**Interpretation**

A positive result indicates recovery from acute or chronic hepatitis B virus (HBV) infection or acquired immunity from HBV vaccination. This assay does not differentiate between a vaccine-induced immune response and an immune response induced by HBV. A positive hepatitis B core (anti-HBc) total antibody result would indicate that the hepatitis B surface antibody (anti-HBs) response is due to past HBV infection.

Per assay manufacturer's instructions for use, positive results, defined as anti-HBs levels of 11.5 mIU/mL or greater, indicate adequate immunity to HBV from past hepatitis B or HBV vaccination. However, per current Centers for Disease Control and Prevention guidance,<sup>(1)</sup> individuals with anti-HBs levels greater than 10 mIU/mL after completing an HBV vaccination series are considered protected from hepatitis B infection.

Negative results, defined as anti-HBs levels of less than 8.5 mIU/mL, indicate a lack of recovery from acute or chronic hepatitis B or inadequate immune response to HBV vaccination. The US Advisory Committee on Immunization Practices does not recommend more than 2 HBV vaccine series in vaccine nonresponders.

Indeterminate results, defined as anti-HBs levels in the range from 8.5 to less than 11.5 mIU/mL, indicate inability to determine if anti-HBs is present at levels consistent with recovery or immunity. Repeat testing is recommended in 1 to 2 months to determine definitive anti-HBs status.

For more information see [Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management](#).

### Cautions

Individuals who have received blood component therapies (eg, whole blood, plasma, or intravenous immunoglobulin infusion) in the previous 3 to 6 months may have false-positive hepatitis B surface antibody (anti-HBs) results due to passive transfer of anti-HBs present in these products.

Anti-HBs levels from past hepatitis B or hepatitis B virus vaccination may fall below detectable levels over time.

A positive anti-HBs result does not exclude infection by another hepatitis virus.

[Serum specimens from individuals taking biotin supplements of 20 mg or more per day may have false-negative HBs Ab test results due to interference of biotin with the assay. Such individuals should stop taking these biotin-containing dietary supplements for a minimum of 12 hours before blood collection for this test.](#)

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

- Grossly icteric (total bilirubin level of >30 mg/dL)
- Grossly lipemic (intralipid level of >1500 mg/dL)
- Grossly hemolyzed (hemoglobin level of >1600 mg/dL)
- Containing particulate matter
- Heat-inactivated samples
- Cadaveric specimens
- Body fluids other than serum (eg, saliva, urine, CSF, amniotic, peritoneal, or pleural fluids)

### Clinical Reference

1. Advisory Committee on Immunization Practices; Centers for Disease Control and Prevention: Immunization of health-care personnel: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep. 2011 Nov 25;60(RR-7):1-45
2. LeFevre ML. Screening for hepatitis B virus infection in nonpregnant adolescents and adults: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2014;161(1):58-66. doi:10.7326/M14-1018
3. Jackson K, Locarnini S, Gish R. Diagnostics of hepatitis B virus: Standard of care and investigational. Clin Liver Dis. 2018; 12(1):5-11. doi:10.1002/cld.729
4. Coffin CS, Zhou K, Terrault NA. New and old biomarkers for diagnosis and management of chronic hepatitis B virus infection. Gastroenterology. 2019;156(2):355-368. doi:10.1053/j.gastro.2018.11.037
5. WHO guidelines on hepatitis B and C testing. World Health Organization, 2017. Accessed December 21, 2023. Available at [www.who.int/publications/i/item/9789241549981](http://www.who.int/publications/i/item/9789241549981)
6. [Conners EE, Panagiotakopoulos L, Hofmeister MG, et al. Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations - United States, 2023. MMWR Recomm Rep. 2023;72\(1\):1-25. doi:10.15585/mmwr.rr7201a1](#)

### Performance

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**Method Description**

Elecsys hepatitis B virus core antibodies (anti-HBs) assay is based on the sandwich immunoassay principle and performed using an electrochemiluminescent immunoassay on the automated cobas e 801 immunochemistry analyzer. Anti-HBs present in patient's serum sample reacts with the biotinylated HBs antigen (*ad* and *ay* subtypes) and HBs antigen (*ad/ay*) labeled with a ruthenium complex to form a sandwich complex. After the addition of streptavidin-coated microparticles (solid phase), the complexes bind to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then washed away, and voltage is applied to the electrode, which induces chemiluminescent emissions that is measured by a photomultiplier. The emission signal generated is directly proportional to the concentration of anti-HBs present in the patient's sample. (Package insert: Elecsys Anti-HBs. Roche Diagnostics; v3.0, 03/2024)

**PDF Report**

No

**Day(s) Performed**

Monday through Friday, Sunday

**Report Available**

Same day/1 to 3 days

**Specimen Retention Time**

14 days

**Performing Laboratory Location**

Jacksonville

**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**

86706

**LOINC® Information**

## Test Definition: HBAB

Hepatitis B Virus Surface Antibody,  
Qualitative/Quantitative, Serum

Test ID	Test Order Name	Order LOINC® Value
HBAB	HBs Antibody, S	5193-8

Result ID	Test Result Name	Result LOINC® Value
HB_AB	HBs Antibody, S	10900-9
HBSQN	HBs Antibody, Quantitative, S	5193-8