MAYO CLINIC LABORATORIES

Test Definition: HBABP

Hepatitis B Virus Surface Antibody Prenatal, Qualitative/Quantitative, Serum

Overview

Useful For

Identifying previous exposure to hepatitis B virus in pregnant individuals

Determining adequate immunity from hepatitis B vaccination during pregnancy

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 testing should be used for prenatal screening of **pregnant** individuals with or without risk factors for hepatitis B virus infection.

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 infection. For screening such patients, order HBBSN / Hepatitis B Virus Surface Antibody Screen, Qualitative/Quantitative, Serum.

This test should **not** be used for diagnostic testing **symptomatic** individuals to evaluate post-vaccination immunity status

or post-acute infection status of hepatitis B. For diagnostic testing such patients, order HBAB / Hepatitis B Virus Surface Antibody, 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 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
Heat-inactivated specimen	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum SST	Ambient	7 hours	
	Refrigerated	6 days	
	Frozen (preferred)	90 days	

Clinical & Interpretive

Clinical Information

Hepatitis B virus (HBV) is a DNA virus that is endemic throughout the world. The infection is spread primarily through 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 hepatitis B surface 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: <8.5 mIU/mL
Vaccinated: > or =11.5 mIU/mL

See Viral Hepatitis Serologic Profiles.

Interpretation

A positive result indicates recovery from acute or chronic hepatitis B or acquired immunity from hepatitis B virus (HBV) vaccination. This assay does not differentiate between a vaccine-induced immune response and an immune response induced by HBV. A positive total hepatitis B core 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 hepatitis B from past hepatitis B or HBV vaccination. However, per current Centers for Disease Control and Prevention guidance,(1) individuals with anti-HBs levels greater than 10 mIU/mL after completing an HBV vaccination series are considered protected from hepatitis B.

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 in 1 to 2 months is recommended to determine definitive anti-HBs status.

For more information see Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management

Cautions

This assay has not been licensed by the US Food and Drug Administration for the screening of blood, plasma, and tissue donors.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination, and other findings.

Assay performance characteristics have not been established for the use of the Elecsys Anti-HBs assay as an aid in determining susceptibility to hepatitis B virus infection prior to or following vaccination in infants, children, or adolescents.

A positive hepatitis B surface antibody (anti-HBs) result does not exclude infection by another hepatitis virus.

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 (anti-HBs) results due to passive transfer of anti-HBs present in these products. In rare cases, interference due to high titers of antibodies to immunological components, streptavidin or ruthenium can occur, causing false-positive anti-HBs results.

Serum specimens from individuals taking biotin supplements of 20 mg or more per day may have negative anti-HBs 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.

Anti-HBs levels from past hepatitis B or hepatitis B virus vaccination may fall below detectable levels over time. Negative anti-HBs test results from immunosuppressed individuals should be interpreted with caution.

Results obtained with the Elecsys Anti-HBs immunoassay may not be used interchangeably with values obtained with different manufacturers' assay methods.

Assay performance characteristics have not been established for the following specimen characteristics or specimen types:
-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
-Specimen types other than serum

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; U.S. Preventive Services Task Force. 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. Geneva: World Health Organization; February 2017. Accessed December 19, 2023. Available at 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

Method Description

The Elecsys hepatitis B surface antibody (anti-HBs) quantitative assay is performed using an electrochemiluminescent immunoassay on the automated cobas e 801 immunochemistry analyzer. Anti-HBs present in patient's 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, the complexes bind to a 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, and unbound substances are washed away. Voltage is applied to the electrode, which induces chemiluminescent emissions that are 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

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

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