MAYO CLINIC LABORATORIES

Test Definition: HBABY

Hepatitis B Virus Perinatal Exposure Follow-up Panel, Serum

Overview

Useful For

Determining hepatitis B virus infection and immunity status (with or without perinatal prophylaxis) in infants born to mothers with chronic hepatitis B

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
HBAG	HBs Antigen, S	Yes	Yes
HBC	HBc Total Ab, S	Yes	Yes
HBAB	HBs Antibody, S	Yes	Yes

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
HBGNT	HBs Antigen Confirmation, S	No	No

Testing Algorithm

If hepatitis B surface antigen (HBsAg) is reactive, then HBsAg confirmation will be performed at an additional charge.

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 test should be ordered for infants born to mothers with chronic hepatitis B only.

Method Name

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available

Yes

Specimen

Specimen Type

Serum SST

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 containing biotin (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: 1.2 mL
Collection Instructions:
1. Centrifuge blood collection tube per collection tube 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

0.9 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	
	Ambient	7 hours	
	Refrigerated	6 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 percutaneous contact with infected blood products (eg, blood transfusion, sharing of needles among injection drug users). The virus is found in virtually every type of human body fluid and is also 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. Infection of the infant can occur if the mother is a chronic hepatitis B surface antigen (HBsAg) carrier or has an acute HBV infection at the time of delivery. Transmission is rare if an acute infection occurs in either the first or second trimester of pregnancy.

After a course of acute illness, HBV persists in about 10% of patients who were infected during adulthood. Some chronic carriers are asymptomatic while others may develop chronic liver disease, including cirrhosis and hepatocellular carcinoma.

Without postexposure prophylaxis (a combination of HBV vaccination and hepatitis B immune globulin), the risk of an infant acquiring HBV from an infected mother as a result of perinatal exposure is 70% to 90% for infants born to mothers who are positive for HBsAg and HBeAg. The risk is 5% to 20% for infants born to HBsAg-positive but HBeAg-negative mothers.

Reference Values

Negative
See Viral Hepatitis Serologic Profiles.

Interpretation

Hepatitis B surface antigen (HBsAg) is the first serologic marker appearing in blood 6 to 8 weeks after exposure to hepatitis B virus (HBV). A confirmed positive HBsAg result is indicative of acute or chronic hepatitis B. In acute cases, HBsAg usually disappears 1 to 2 months after the onset of symptoms. Persistence of HBsAg for more than 6-months duration indicates development of either a chronic carrier state or chronic hepatitis B.

Hepatitis B surface antibody (anti-HBs) appears with the resolution of HBV infection and disappearance of HBsAg. A positive result indicates recovery from acute or chronic hepatitis B or acquired immunity from HBV vaccination. This assay does not differentiate between a vaccine-induced immune response and recovery from HBV infection. Per assay manufacturer's instructions for use, positive results are defined as anti-HBs levels of 11.5 mIU/mL or greater, with adequate immunity to hepatitis B after recovery from past infection or HBV vaccination. Per current Centers for Disease Control and Prevention guidance, individuals with anti-HBs levels of 10 mIU/mL or greater after completing an HBV vaccination series are considered protected from hepatitis B infection.(1)

Negative ant-HBs 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.

Indeterminate anti-HBs 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 3 months is recommended to determine definitive anti-HBs status.

Hepatitis B virus core (HBc) total and IgM antibodies appear shortly after the onset of symptoms of HBV infection and may be the only serologic marker remaining years after exposure to HBV. A positive result indicates exposure to HBV

infection. A positive anti-HBs result along with a positive HBc total antibody result is indicative of recovery from HBV infection. A positive anti-HBs result with a negative HBc total antibody result is consistent with immunity to hepatitis B from HBV vaccination.

For more information see:
-Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management
-Viral Hepatitis Serologic Profiles

Cautions

Assay performance characteristics have not been established for the following specimen characteristics:
-Grossly icteric (total bilirubin level of >25 mg/dL)
-Grossly lipemic (intralipid level of >1000 mg/dL)
-Grossly hemolyzed (hemoglobin level of >500 mg/dL)
-Contain particulate matter
-Cadaveric specimens
-Heat inactivated specimens

Clinical Reference

1. 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
2. Terrault NA, Lok ASF, McMahon BJ, et al. Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 hepatitis B guidance. Hepatology. 2018;67(4):1560-1599. Available at https://journals.lww.com/hep/fulltext/2018/04000/update_on_prevention,_diagnosis,_and_treatment_of.34.aspx
3. Centers for Disease Control and Prevention: Prevention of hepatitis B virus infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. MMWR Recomm Rep. 2018;67(1):1-31. Available at www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.PDF
4. Centers for Disease Control and Prevention (CDC), Division of Viral Hepatitis: Interpretation of hepatitis B serologic test results. CDC; Accessed December 21, 2023. Available at www.cdc.gov/hepatitis/hbv/interpretationOfHepBSerologicResults.htm
5. Centers for Disease Control and Prevention: Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations-United States, 2023. CDC; Updated August 10, 2023. Accessed December 21, 2023. Available at www.cdc.gov/mmwr/volumes/72/rr/rr7201a1.htm?s_cid=rr7201a1_w

Performance

Method Description

Hepatitis B surface Antigen screen:
The Elecsys HBsAG (hepatitis B surface antigen) II assay is based on the sandwich immunoassay principle and performed using an electrochemiluminescence immunoassay on the automated cobas e 801 immunochemistry analyzer. HBsAg present in the patient's sample reacts with two biotinylated monoclonal anti-hepatitis B surface (anti-HBs), and a mixture of monoclonal anti-HBs and polyclonal anti-HBs labeled with a ruthenium complex react to form a sandwich

complex. After 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 the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then washed away, and voltage is applied to the electrode that induces chemiluminescent emissions, which are measured by a photomultiplier. Test result is determined by comparing the electrochemiluminescence signal generated from the reaction product in the patient's sample to the cutoff index (COI) value set from reagent lot-specific assay calibration.(Package insert: Elecsys HBsAG II. Roche Diagnostics; v3.0, 02/2022)

HBsAg confirmation:
The Elecsys HBsAg II Auto Confirm assay is based on the sandwich immunoassay principle and performed using an electrochemiluminescence immunoassay on the automated cobas e 801 immunochemistry analyzer. This test is based on 2 parallel measurements. For the first measurement, the sample is treated with the control pretreatment reagent (PT2) prior to immunoreaction. This measurement serves as a reference. For the second measurement the sample is treated with the confirmatory pretreatment reagent (PT1) prior to immunoreaction. During incubation with confirmatory pretreatment, unlabeled polyclonal anti-HBs are bound to the sample HBsAg and thereby block the binding sites for the labeled antibodies used in the following immunoreaction. The confirmation result (%) is automatically assessed by determining the ratio of both measurements.

During testing, the auto-diluted sample is incubated with control pretreatment and confirmatory pretreatment, followed by formation of sandwich complexes of biotinylated monoclonal anti-HBs and a mixture of monoclonal anti-HBs and polyclonal anti-HBs labeled with a ruthenium complex. After addition of streptavidin-coated microparticles (solid phase), the complexes bind to the solid phase via interaction of biotin and streptavidin. The reaction mixture is then aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. After the unbound substances are washed away, a voltage is applied to the electrode that induces chemiluminescent emissions, which are measured by a photomultiplier. Results are determined by comparing the electrochemiluminescence signal generated from the reaction product to the COI value set from reagent lot-specific assay calibration. The confirmation result (%) is calculated from the ratio of the COI obtained for the measurement with confirmatory pretreatment to the COI obtained for the measurement of control pretreatment reaction.(Package insert: Elecsys HBsAg II Auto Confirm. Roche Diagnostics; v1.0, 12/2020)

Hepatitis B surface Antibody:
The Elecsys Anti-HBs (hepatitis B surface antibody) 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 sample reacts with the biotinylated HBsAg (ad and ay subtypes) and HBsAg (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 that induces chemiluminescent emissions, which 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)

Hepatitis B core Total Antibodies:
The Elecsys Anti-HBc (hepatitis B core) II assay is based on the competitive immunoassay principle and performed using an electrochemiluminescence immunoassay on the automated cobas e 801 immunochemistry analyzer. Patient's sample

is pretreated first with a reducing reagent, and after the addition of hepatitis B virus core antigen (HBcAg), complexes are formed with HBc antibodies present in the sample. The remaining unbound sites on the HBcAg become occupied with the added biotinylated antibodies and ruthenium complex-labeled antibodies specific for HBcAg. The entire complex binds to the streptavidin-coated microparticles (solid phase) via interaction of biotin and streptavidin. The reaction mixture is then aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. After unbound substances are washed away, voltage is applied to the electrode that induces chemiluminescent emissions, which are measured by a photomultiplier. Test result is determined by comparing the electrochemiluminescence signal generated from the reaction product in the sample to the COI value set from assay reagent lot-specific assay calibration.(Package insert: Elecsys Anti-HBc II. Roche Diagnostics; v1.0, 04/2022)

PDF Report
No

Day(s) Performed
Monday through Saturday

Report Available
Same day/1 to 3 days

Specimen Retention Time
14 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

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
86704
87340
87341 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HBABY	Hepatitis B Perinatal Exposure, S	77190-7

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