MAYO CLINIC LABORATORIES

Test Definition: HBPES

Hepatitis B Virus Past Exposure Panel, Serum

Overview

Useful For

Screening for past exposure to hepatitis B virus (HBV)

Determining HBV infection and immunity status prior to initiating chemotherapy or other immunosuppressive agents

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
HBGSN	HBs Antigen Scrn, S	Yes	Yes
HBCSN	HBc Total Ab Scrn, S	Yes	Yes
HBBSN	HBs Antibody Scrn, S	Yes	Yes

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
HBGSC	HBs Antigen Screen 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 panel is intended to screen for presence of past or active hepatitis B viral infection in individuals who will be receiving chemotherapy, immunosuppressive therapy, or organ transplantation.

Method Name

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available

No

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 (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 manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).
2. Aliquot serum into plastic vial.

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	72 hours	
	Refrigerated	6 days	

Clinical & Interpretive

Clinical Information

Hepatitis B virus (HBV) is a DNA virus that is endemic throughout the world. HBV is transmitted parenterally or percutaneously from exposure to contaminated blood, blood products, or injection needles, sexually from exposure to body fluids from infected individuals, or perinatally from mother to child during birth delivery by contact with infected mother's blood and vaginal secretions. Transplacental transmission from mother to fetus is uncommon.

Hepatitis B virus persists and causes chronic infection (defined as being positive for hepatitis B virus surface antigen

[HBsAg] in serum or plasma for minimum 6 months) in about 10% of individuals who had acute infection during childhood. These individuals may become asymptomatic HBV carriers (ie, inactive chronic hepatitis B), while others may develop chronic liver diseases including cirrhosis and hepatocellular carcinoma. Asymptomatic HBV carriers are at risk (up to 50%) for decompensation of liver function with acute HBV replication (ie, HBV reactivation) during immunosuppression from chemotherapy, immunosuppressive therapy, or organ transplantation.

Individuals who recovered from acute hepatitis B (defined as being negative for HBsAg, positive for HBc total antibodies, negative or positive for HBs antibody) are at lower risk (up to 20%) of HBV reactivation than those with inactive chronic hepatitis B during immunosuppressive therapy or organ transplantation.

For individuals born in regions of the world where HBV prevalence is moderate to high, universal HBV serologic screening before initiation of immunosuppressive therapy is recommended. In the absence of systematic, risk-based testing, universal HBV serologic screening is an option to reduce the risk of missing individuals with HBV infection prior to initiation of immunosuppressive treatment.

Reference Values

Negative
See Viral Hepatitis Serologic Profiles.

Interpretation

Hepatitis B virus 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 a 6-month duration indicates development of either a chronic carrier state or chronic hepatitis B.

Hepatitis B virus 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 10.0 mIU/mL or greater, with adequate immunity to hepatitis B after recovery from past infection or HBV vaccination. This anti-HBs level to achieve immunity is in accordance with 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.

Negative anti-HBs results, defined as anti-HBs levels of less than 10.0 mIU/mL, indicate a lack of recovery from acute or chronic hepatitis B or inadequate immune response to HBV vaccination.

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.

Table. Summary of interpretation of the various HBV serologic test result profiles

HBV serologic test results			Interpretation
HBsAg	HBc total Ab	HBsAb	

+	+	-	Chronic hepatitis B
-	+	+	Past HBV infection
-	+	-	Past HBV infection or possible false-positive test result
-	-	+	Immunity from HBV vaccination
-	-	-	No previous exposure to hepatitis B virus (not immune)

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, et al. 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/M14-10182
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. doi:10.1002/hep.29800
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. Accessed July 17, 2025. 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: Clinical Testing and Diagnosis for Hepatitis B. CDC; Updated January 31, 2025. Accessed July 17, 2025. Available at www.cdc.gov/hepatitis-b/hcp/diagnosis-testing/
5. 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. Published 2023 Mar 10. doi:10.15585/mmwr.rr7201a1

Performance

Method Description

Hepatitis B Surface Antigen Screen:
The Elecsys HBsAg (hepatitis B surface antigen) II assay is 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 hepatitis B surface antibody (anti-HBs) and a mixture of monoclonal anti-HBs and polyclonal anti-HBsAg antibodies labeled with a ruthenium complex react to form a sandwich complex. After addition of streptavidin-coated microparticles, the complexes become bound 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, and unbound substances are washed away. Voltage is applied to the

electrode that induces chemiluminescent emissions, which are measured by a photomultiplier. Test results for each patient's sample are determined by comparing the electrochemiluminescence signal generated from the reaction product to the cutoff index (COI) value set from reagent lot-specific assay calibrations.(Package insert: Elecsys HBsAG II. Roche Diagnostics; v3.0, 02/2022)

Hepatitis B Surface Antigen Confirmation:
The Elecsys HBsAg II Auto Confirm assay is 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-HBsAg antibodies 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-HBsAg antibodies and a mixture of monoclonal anti-HBsAg antibody and polyclonal anti-HBsAg antibodies labeled with a ruthenium complex. After addition of streptavidin-coated microparticles, the complexes become bound 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, and unbound substances are then washed away. 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 cutoff index 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 with control pretreatment.(Package insert: Elecsys HBsAg II Auto Confirm. Roche Diagnostics; v1.0, 12/2020)

Hepatitis B Surface Antibody:
The Elecsys Anti-HBs (hepatitis B surface) quantitative assay is 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 HBsAg (ad and ay subtypes) and HBsAg (ad/ay) labeled with a ruthenium complex to form a sandwich complex. After 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 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 serum sample.(Package insert: Elecsys Anti-HBs II. Roche Diagnostics; v1.0, 09/2024)

Hepatitis B Core Total Antibodies:
The Elecsys Anti-HBc (hepatitis B core) II assay is performed using an electrochemiluminescence immunoassay on the automated cobas e 801 analyzer. Anti-HBc present in the 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 anti-HBc in the sample. The remaining unbound sites on the HBcAg become occupied after addition of biotinylated antibodies and ruthenium complex-labeled antibodies specific for HBcAg, together with streptavidin-coated microparticles. The entire complex becomes bound 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 unbound substances are washed away, 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 of 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 Friday, Sunday

Report Available
Same day/1 to 3 days

Specimen Retention Time
14 days

Performing Laboratory Location
Mayo Clinic Jacksonville Clinical Lab

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)
G0499 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HBPES	Hepatitis B Past Exposure, S	77190-7

Test Definition: HBPES

Hepatitis B Virus Past Exposure Panel, Serum

Result ID	Test Result Name	Result LOINC® Value
HBCSN	HBc Total Ab Scrn, S	13952-7
HBAGS	HBs Antigen Scrn, S	5196-1
HBSQN	HBs Antibody, Quantitative, S	5193-8
HBASN	HBs Antibody Scrn, S	10900-9