

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

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 (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 | |
| | Refrigerated | 6 days | |
| | Ambient | 7 hours | |

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.

HBV 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 persons 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 6-months 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 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.

Negative anti-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 of 8.5 to 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.

Summary of interpretation of the various HBV serologic test result profiles is provided in the table below:

| 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 December 21. 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, 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 hepatitis B surface antibody (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 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)

Hepatitis B Surface Antigen 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. Unbound substances are then washed away, and 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 of control pretreatment reaction. (Package insert: Elecsys HBsAg II Auto Confirm. Roche Diagnostics; v1.0, 12/2020)

Hepatitis B Surface Antibody:

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 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 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 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 serum sample. (Package insert: Elecsys Anti-HBs. Roche Diagnostics; v3.0, 03/2024)

Hepatitis B core Total Antibodies:

Elecsys Anti-HBc (hepatitis B core antibody) 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 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 cutoff index (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

Rochester

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 |

| 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 |