MAYO CLINIC LABORATORIES

Test Definition: CHBVS

Chronic Hepatitis B Screen, Serum

Overview

Useful For

Diagnosis and evaluation of patients at risk for or suspected of having chronic hepatitis B

This test is **not offered** as a screening or confirmatory test for blood donor specimens.

This test is **not useful** during the "window period" of acute hepatitis B virus infection (ie, after disappearance of hepatitis B surface antigen [HBsAg] and prior to appearance of hepatitis B surface antibody).

This test is **not useful** as a stand-alone prenatal screening test of HBsAg status in pregnant women.

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
HBGSN	HBs Antigen Scrn, S	Yes	Yes

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
EAG	Hepatitis Be Ag, S	Yes	No
HBGSC	HBs Antigen Screen Confirmation, S	No	No
HEAB	HBe Antibody, S	Yes	No

Testing Algorithm

If the hepatitis B surface antigen (HBsAg) result is reactive, then HBsAg confirmation testing will be performed at an additional charge. If the HBsAg confirmation result is positive, then hepatitis B e antigen (HBeAg) and hepatitis B e antibody (anti-HBe) tests will be performed at an additional charge.

The following algorithms are available:
-Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management
-HBV Infection-Monitoring Before and After Liver Transplantation
-Viral Hepatitis Serologic Profiles

Special Instructions

- Viral Hepatitis Serologic Profiles
- HBV Infection-Monitoring Before and After Liver Transplantation
- Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management

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 Serum
Collection Instructions:
1. Centrifuge blood collection tube per manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).

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

Serum: 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. 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 also found in various human body fluids and is 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 transplacentally.

Hepatitis B surface antigen (HBsAg) is the first serologic marker appearing in the serum at 6 to 8 weeks following exposure to HBV. In acute infection, HBsAg usually disappears in 1 to 2 months after the onset of symptoms. Persistence of HBsAg for more than 6 months in duration indicates development of either a chronic carrier state or chronic HBV infection.

Serum levels of both hepatitis B e antigen (HBeAg) and HBsAg rise rapidly during the period of viral replication. The presence of HBeAg in serum correlates with viral infectivity, the number of infectious virions, and the presence of HBV core antigen in the infected hepatocytes.

During recovery from acute hepatitis B, HBeAg level declines and becomes undetectable in the serum, while HBe antibody (anti-HBe) appears and becomes detectable in the serum. Anti-HBe usually remains detectable for many years after recovery from acute HBV infection.

In HBV carriers and patients with chronic hepatitis B, positive HBeAg results usually indicate presence of active HBV replication and high infectivity, while a negative HBeAg result indicates very minimal or no HBV replication. Positive anti-HBe results usually indicate inactivity of the virus and low infectivity, and such positive results in the presence of detectable HBV DNA in serum also indicate active viral replication in these patients.

The following algorithms are available:
-Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management
-HBV Infection-Monitoring Before and After Liver Transplantation
-Viral Hepatitis Serologic Profiles

Reference Values

Negative
See Viral Hepatitis Serologic Profiles

Interpretation

A reactive screen result (cutoff index value of 1.00 or above) confirmed as positive by hepatitis B surface antigen (HBsAg) confirmatory test (see Method Description) is indicative of acute or chronic hepatitis B or chronic hepatitis B virus (HBV) carrier state.

Specimens with reactive screen results but negative (ie, not confirmed) HBsAg confirmatory test results are likely to contain cross-reactive antibodies from other infectious or immunologic disorders. Repeat testing at a later date is recommended if clinically indicated.

Confirmed presence of HBsAg is frequently associated with HBV replication and infectivity, especially when accompanied by the presence of HBe antigen or detectable HBV DNA.

The following algorithms are available:
-Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management
-HBV Infection-Monitoring Before and After Liver Transplantation
-Viral Hepatitis Serologic Profiles

Cautions

Positive hepatitis B surface antigen (HBsAg) results will need to be reported by the healthcare providers to their communicable disease surveillance units of state department of health, as required by law in various states.

Individuals, especially neonates and children, who recently received hepatitis B vaccination may have transient positive HBsAg test results because of the large dose of HBsAg used in the vaccine relative to the individual's body mass.

Disappearance of hepatitis B e antigen (HBeAg) or appearance of anti-HBe in serum does not completely rule-out chronic hepatitis B virus carrier state or infectivity.

Serum specimens from individuals taking multivitamins containing biotin or biotin supplements of 20 mg or more per day may have false-negative HBeAg and false-positive HBe antibody results due to interference of biotin with the assays. 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:
-Assay performance characteristics have not been established in pregnant women or in populations of immunocompromised or immunosuppressed patients.
-Grossly icteric (total bilirubin level of >25 mg/dL)
-Grossly lipemic (Intralipid level of >1500 mg/dL)
-Grossly hemolyzed (hemoglobin level of >1600 mg/dL)
-Containing particulate matter
-Cadaveric 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. Jackson K, Locarnini S, Gish R. Diagnostics of hepatitis B virus: standard of care and investigational. Clin Liver Dis (Hoboken). 2018;12(1):5-11. doi:10.1002/cld.729
3. 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.e3. doi:10.1053/j.gastro.2018.11.037
4. WHO guidelines on hepatitis B and C testing. World Health Organization; 2017. Accessed December 22, 2025. Available at www.who.int/publications/i/item/9789241549981
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. doi:10.15585/mmwr.rr7201a1

Performance

Method Description

Hepatitis B Surface Antigen:
The Elecsys HBsAg (hepatitis B surface antigen) II assay is performed using an electrochemiluminescence immunoassay on the automated cobas e 801 immunochemistry analzyer. HBsAg present in the patient's sample reacts with 2 biotinylated monoclonal 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, which induces chemiluminescent emission that is measured by a photomultiplier. Test results for each patient’s sample is 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)

HBsAg 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 which induces chemiluminescent emission that is 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)

PDF Report

No

Day(s) Performed

Monday through Friday, Sunday

Report Available

Same day/1 to 4 days

Specimen Retention Time

7 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

87340
G0499-(if appropriate)
87350 (if appropriate)
87341 (if appropriate)
86707 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CHBVS	Chronic Hepatitis B Screen, S	5196-1

Result ID	Test Result Name	Result LOINC® Value
HBAGS	HBs Antigen Scrn, S	5196-1