MAYO CLINIC LABORATORIES

Test Definition: CHSBP

Chronic Hepatitis B Monitoring Profile, Serum

Overview

Useful For

Evaluating and monitoring individuals with known chronic hepatitis B

Monitoring hepatitis B viral infectivity after resolution of acute hepatitis B

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
HBAG	HBs Antigen, S	Yes	Yes
EAG	Hepatitis Be Ag, S	Yes	Yes
HEAB	HBe Antibody, S	Yes	Yes

Reflex Tests

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

Testing Algorithm

If the hepatitis B surface antigen (HBsAg) result 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

Method Name

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available

No

Specimen

Specimen Type

Serum SST

Necessary Information

1. Date of collection is required.

2. Indicate "Type B"

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. Transfer serum into a 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	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 and sharing of needles among injection drug users) and body fluids (eg, sexual contact). The virus is found in virtually every type of human body fluid 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; it is not commonly transmitted transplacentally.

After a course of acute illness, HBV persists in approximately 10% of exposed individuals (ie, chronic hepatitis B). Some of these carriers or chronically infected individuals remain asymptomatic, while others develop chronic liver disease, including cirrhosis and hepatocellular carcinoma.

Serum levels of both hepatitis B e antigen (HBeAg) and hepatitis B surface antigen 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.

Reference Values

HEPATITIS B SURFACE ANTIGEN:
Negative

HEPATITIS Be ANTIGEN:
Negative

HEPATITIS Be ANTIBODY:
Negative

Interpretation depends on clinical setting. See Viral Hepatitis Serologic Profiles.

Interpretation

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

HBs antibody appears with the resolution of acute hepatitis B after the disappearance of HBsAg. Anti-HBs also appears as the immune response following a course of inoculation with the hepatitis B vaccine.

Hepatitis B core (HBc) IgM and total antibodies appears shortly after the onset of symptoms of HBV infection, and HBc total antibodies may be the only serologic marker remaining years after exposure to hepatitis B.

The presence of hepatitis B e antigen correlates with infectivity, the number of viral Dane particles, the presence of core antigen in the nucleus of the hepatocyte, and the presence of viral DNA polymerase in serum. HBe antibody-positivity in a carrier is often associated with chronic asymptomatic infection.

If the patient has a sudden exacerbation of disease, testing for anti-hepatitis C and anti-hepatitis D virus (HDV) total is recommended.

If HBsAg converts to negative and patient's condition warrants, consider testing for HBs antibody.

If HBsAg is confirmed positive, testing for anti-HDV total is recommended.

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

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 assay. Such individuals should stop taking these biotin-containing dietary supplements for a minimum of 12 hours before blood collection for this test.

Performance characteristics of these assays have not been established in patients younger than 2 years, pregnant women, or in populations of immunocompromised or immunosuppressed patients. These assays are not licensed by the US Food and Drug Administration for testing cord blood samples or screening donors of blood, plasma, human cell, or tissue products.

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 >1500 mg/dL)
-Grossly hemolyzed (hemoglobin level of >1600 mg/dL)
-Containing particulate matter
-Cadaveric specimen

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. 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. doi:10.1053/j.gastro.2018.11.037
4. WHO guidelines on hepatitis B and C testing. World Health Organization; 2017. Accessed December 19, 2023. 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 analyzer. 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 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 with control pretreatment.(Package insert: Elecsys HBsAg II Auto Confirm. Roche Diagnostics; v1.0, 12/2020)

Hepatitis Be Antigen:
The Elecsys HBeAg (hepatitis B e antigen) assay is performed using an electrochemiluminescence immunoassay on the automated cobas e 801 immunochemistry analyzer. HBeAg present in patient's sample reacts with 2 biotinylated

monoclonal anti-HBeAg antibodies and a mixture of monoclonal anti-HBeAg antibody and polyclonal anti-HBeAg antibodies labeled with a ruthenium complex react 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 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 result for each patient's sample is determined automatically by the assay-specific software program by comparing the electrochemiluminescence signal generated from the patient's sample to the COI value set from reagent lot-specific assay calibrations.(Package insert: Elecsys HBeAg. Roche Diagnostics; v1.0, 10/2020)

HBe Antibody:
The Elecsys Anti-HBe (hepatitis B e antibody) assay will be performed on the fully automated cobas e 801 electrochemiluminescence immunoassay analyzer. During the first incubation, anti-HBe present in the patient's sample binds to the added HBeAg. In the second incubation, the still-free binding sites on the HBeAg become occupied after addition of biotinylated antibodies and ruthenium complex-labeled antibodies specific for HBeAg, 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. Unbound substances are then washed away, and application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier. Test result for each patient's sample is determined automatically by the assay-specific software program by comparing the electrochemiluminescence signal obtained from the sample with the COI value set from reagent lot-specific assay calibrations.(Package insert: Elecsys Anti-HBe. Roche Diagnostics; v1.0, 12/2021)

PDF Report
No

Day(s) Performed
Monday through Friday, Sunday

Report Available
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 Definition: CHSBP

Chronic Hepatitis B Monitoring Profile, Serum

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

86707
87340
87350
87341 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CHSBP	Chronic Hepatitis B Profile, S	95148-3

Result ID	Test Result Name	Result LOINC® Value
EAG	Hepatitis Be Ag, S	13954-3
HEAB	HBe Antibody, S	33463-1
H_BAG	HBs Antigen, S	5196-1