MAYO CLINIC LABORATORIES

Test Definition: HBAG

Hepatitis B Virus Surface Antigen, Serum

Overview

Useful For

Diagnosis of acute, recent, or chronic hepatitis B

Determination of chronic hepatitis B status

This test **should not be used** as a screening or confirmatory test for blood donor specimens.

Reflex Tests

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

Testing Algorithm

If the hepatitis B virus surface antigen (HBsAg) result is reactive with cutoff index value greater than 1.00, then HBsAg confirmation testing will be performed at an additional charge.

For more information see:
-Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management
-HBV Infection-Monitoring Before and After Liver Transplantation

Special Instructions

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

Highlights

This test should be used to test **symptomatic** individuals who may or may not have risk factors for hepatitis B virus infection.

Method Name

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available

No

Specimen

Specimen Type

Serum SST

Ordering Guidance

This test **should not** be used to test or screen for chronic hepatitis B in pregnant women. For testing such patients, order HBAGP / Hepatitis B Virus Surface Antigen Prenatal, Serum.

This test **should not** be used to screen or test asymptomatic, nonpregnant individuals with or without risk factors for hepatitis B virus (HBV) infection. For testing such patients, order HBGSN / Hepatitis B Virus Surface Antigen Screen, Serum.

This test is **not intended for** testing cadaver or grossly hemolyzed specimens. For testing such patients, order HBGCD / Hepatitis B Surface Antigen for Cadaveric or Hemolyzed Specimens, Serum, which is US Food and Drug Administration-approved for testing on these sources.

Additional Testing Requirements

Testing for acute hepatitis B virus infection should also include HBIM / Hepatitis B Virus IgM Core Antibody Serum, as during the acute hepatitis B virus infection "window period," hepatitis B virus surface (HBs) antigen and HBs antibody may not be detected.

Necessary Information

1. Date of collection is required.

2. Indicate if specimens are from autopsy/cadaver or hemolyzed sources so that the proper US Food and Drug Administration-approved assay can be performed.

Specimen Required

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: 0.9 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 a plastic vial.

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:
-Kidney Transplant Test Request
-Gastroenterology and Hepatology Test Request (T728)

Specimen Minimum Volume

0.7 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 it 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.

HBV 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.

Reference Values

Negative

See Viral Hepatitis Serologic Profiles

Interpretation

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

Specimens with initially reactive screen results, but negative (not confirmed) by HBsAg confirmatory test results, are likely to contain cross-reactive antibodies from other infectious or immunologic disorders. These unconfirmed HBsAg-reactive screening test results should be interpreted in conjunction with test results of other HBV serologic markers (eg, HBs antibody; hepatitis B core [HBc] total antibody, and HBc IgM antibody). If clinically indicated, repeat testing at a later date is recommended.

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

For more information see:
-Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management
-HBV Infection-Monitoring Before and After Liver Transplantation

-Viral Hepatitis Serologic Profiles

Cautions

This assay has not been licensed by the US Food and Drug Administration for the screening of blood, plasma, and tissue donors.

For diagnostic purposes, results should always be assessed in conjunction with the patient's medical history, clinical examination, and other findings.

Individuals, especially neonates and children, who recently received hepatitis B vaccination may have transient positive hepatitis B virus surface antigen (HBsAg) test results because of the large dose of HBsAg used in the vaccine relative to the individual's body mass. In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur, causing false-positive results.

Positive HBsAg test results will need to be reported by the healthcare professionals to the communicable disease surveillance units of state departments of health, as required by law in various states.

Current methods for the detection of HBsAg may not detect all infected individuals.
A negative test result does not exclude with certainty a possible exposure to or on infection with the hepatitis B virus. Negative test results obtained for persons with a past exposure may be caused by an antigen concentration below the detection limit of this assay or the lack of reactivity of the antigens to the antibodies used in this assay.

Performance characteristics of the Elecsys HBsAg II assay have not been established for testing of newborns or when used in conjunction with other manufacturers' assays for specific hepatitis B virus serological markers.

Assay performance characteristics have not been established for the following specimen characteristics or specimen types:
-Grossly icteric (total bilirubin level of >40 mg/dL)
-Grossly lipemic (intralipid level of >2200 mg/dL)
-Grossly hemolyzed (hemoglobin level of >2200 mg/dL)
-Containing particulate matter
-Cadaveric specimens
-Specimen types other than serum

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. Geneva: World Health Organization; February 2017. Accessed December 23, 2024. Available at www.who.int/publications/i/item/9789241549981
5. Centers for Disease Control and Prevention: Testing and public health management of persons with chronic hepatitis B virus infection. CDC; Updated March 6, 2024. Accessed December 23, 2024. Available at

www.cdc.gov/hepatitis-b/hcp/diagnosis-testing/
6. 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

Specimens are first tested with the Elecsys HBsAg (hepatitis B surface antigen) II assay. Specimens yielding cutoff index (COI) values of greater than or equal to 1.00 will be confirmed with the Elecsys HBsAg II Auto Confirm assay.

HBsAg Screen:
The Elecsys HBsAg 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 that induces chemiluminescent emissions, which are measured by a photomultiplier. The 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)

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 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 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 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
87340
87341 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HBAG	HBs Antigen, S	5196-1

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