MAYO CLINIC LABORATORIES

Test Definition: HBAGP

Hepatitis B Virus Surface Antigen Prenatal, Serum

Overview

Useful For

Diagnosis of acute, recent, or chronic hepatitis B

Determination of chronic hepatitis B status

Screening pregnant women for evidence of chronic hepatitis B (or hepatitis B carrier state) to identify neonates who are at high risk of acquiring hepatitis B at birth

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

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

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
HBNTP	HBs Ag Confirmation Prenatal, 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.

Special Instructions

- Viral Hepatitis Serologic Profiles

Highlights

This test should be used to test or screen for chronic hepatitis B in **pregnant** individuals.

Method Name

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available

Yes

Specimen

Specimen Type

Serum SST

Ordering Guidance

This test should **not** be used to test **symptomatic** individuals who may or may not have risk factors for hepatitis B virus (HBV) infection. For testing such individuals, order HBAG / Hepatitis B Virus Surface Antigen, Serum.

This test should **not** be used to screen or test **asymptomatic, nonpregnant** individuals with or without risk factors for 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 (HBV) infection should also include HBIM / Hepatitis B Virus Core IgM Antibody, Serum, as during the acute HBV 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-licensed 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 with the specimen:
-Infectious Disease Serology Test Request (T916)
-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 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.

Infection of the infant can occur if the mother is a chronic hepatitis B surface antigen carrier or has an acute HBV infection at the time of delivery. Transmission is rare if an acute infection occurs in either the first or second trimester of pregnancy.

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 test results but negative (not confirmed) by HBsAg confirmatory testing 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 the presence of HBe antigen or detectable HBV DNA.

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 results will need to be reported by the healthcare professionals to their 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 21, 2023. 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 28, 2022. Accessed December 21, 2023. Available at www.cdc.gov/hepatitis/hbv/testingchronic.htm
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

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 2 biotinylated monoclonal 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 then washed away, and voltage is applied to the electrode that induces chemiluminescent emissions, which are measured by a photomultiplier. The 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)

HBsAg Confirmation:
The Elecsys HBsAg (hepatitis B virus surface antigen) 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. Patient's sample is treated first 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. The result is determined by comparing the electrochemiluminescence signal generated from the reaction product in the patient's samples to the cutoff index (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 of control pretreatment reaction.(Package insert: Elecsys HBsAg II Auto Confirm. Roche Diagnostics; v1.0, 12/2020)

PDF Report

No

Day(s) Performed
Monday through Sunday

Report Available
Same day/1 to 3 days

Specimen Retention Time
14 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

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
HBAGP	HBs Antigen Prenatal, S	5196-1

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