MAYO CLINIC LABORATORIES

Test Definition: HBNTP

Hepatitis B Virus Surface Antigen Confirmation, Prenatal, Serum (Non-Orderable)

Overview

Useful For

Only orderable as a reflex. For more information see HBAGP / Hepatitis B Virus Surface Antigen Prenatal, Serum.

Diagnosis of acute, recent, or chronic hepatitis B in prenatal patients

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

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

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

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

Only orderable as a reflex. For more information see HBAGP / Hepatitis B Virus Surface Antigen Prenatal, Serum.

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available

Yes

Specimen

Specimen Type

Serum SST

Specimen Required

Only orderable as a reflex. For more information see HBAGP / Hepatitis B Virus Surface Antigen Prenatal, Serum.

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: 0.8 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).
2. Aliquot serum into a plastic vial.

Specimen Minimum Volume
Serum: 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.

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.

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

Reference Values

Only orderable as a reflex. For more information see HBAGP / Hepatitis B Virus Surface Antigen Prenatal, Serum.

Negative

Interpretation

A reactive screen result (cutoff index values > or =1.00) confirmed as positive by a 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 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. 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.

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 surface antigen (HBsAg) test results because of the large dose of HBsAg used in the vaccine relative to the individual's body mass.

Positive HBsAg test results will need to be reported by the healthcare provider to their state department of health surveillance units, as required by law in some 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 (HBV). 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 this assay have not been established for testing of newborns or when used in conjunction with other manufacturers' assays for specific HBV 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 26, 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

The Elecsys HBsAg (hepatitis B virus surface antigen) 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. 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)

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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
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
87341

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HBNTP	HBs Ag Confirmation Prenatal, S	7905-3

Result ID	Test Result Name	Result LOINC® Value
HBNTP	HBs Ag Confirmation Prenatal, S	7905-3