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

Yes

## 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

Hepatitis B Surface Antigen Screen:
The Elecsys HBsAg (hepatitis B surface antigen) II assay is based on the sandwich 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-HBsAg antibodies 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. 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 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. Result is determined by comparing the electrochemiluminescence signal generated from the reaction product in the patient's samples 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 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 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
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 |