MAYO CLINIC LABORATORIES

# Test Definition: HBABT

Hepatitis B Virus Surface Antibody Monitor, Post-Transplant, Serum

## Overview

### Useful For

Monitoring serum hepatitis B virus surface antibody levels during intravenous or intramuscular hepatitis B immune globulin therapy to prevent hepatitis B virus reinfection in liver transplant recipients with known previous chronic hepatitis B

### Testing Algorithm

For information see HBV Infection-Monitoring Before and After Liver Transplantation.

### Special Instructions

- HBV Infection-Monitoring Before and After Liver Transplantation

### Highlights

This test provides quantitative results only; this test does not provide interpretation of the hepatitis B surface antibody level detected.

### Method Name

Electrochemiluminescence Immunoassay (ECLIA)

### NY State Available

No

## Specimen

### Specimen Type

Serum SST

### Necessary Information

**Date of collection is required.**

### 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:** 0.7 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:
-Gastroenterology and Hepatology Test Request (T728)
-Infectious Disease Serology Test Request (T916)

### Specimen Minimum Volume

0.6 mL

### Reject Due To

| | |
|---|---|
| Gross hemolysis | Reject |
| Gross lipemia | Reject |
| Gross icterus | Reject |
| Heat-inactivated specimen | 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

For patients with chronic hepatitis B, the outcome following liver transplantation for end-stage liver disease is poor. Recurrent hepatitis B is common and associated with decreased liver graft and patient survival (approximately 50% at 5 years). Studies have shown administration of hepatitis B immune globulin (HBIG) in the perioperative and early posttransplant periods could delay or prevent recurrent hepatitis B virus (HBV) infection in these transplant recipients.

Since mid-1990, intravenous or intramuscular administration of HBIG has become the standard of care for these liver transplant recipients in most liver transplant programs in the United States. Most therapy protocols administer HBIG in high doses (10,000 IU) during the perioperative period and first week after transplantation with the goal of achieving serum hepatitis B virus surface antibody (anti-HBs) levels of above 500 mIU/mL. Serial levels of anti-HBs are obtained to determine the pharmacokinetics of HBIG in each patient to guide frequency of HBIG dosing.

During the first few weeks to months after transplantation, there is a high degree of variability in HBIG dosage required to achieve desirable serum anti-HBs levels among transplant recipients. Patients who were hepatitis B e antigen positive

before transplantation usually require more HBIG to achieve the target anti-HBs levels, especially in the first week after transplantation.

Duration of HBIG therapy varies from 6 months to indefinite among different US liver transplant programs. Protocols providing less than 12 months of therapy usually combine HBIG with another effective anti-HBV agent, such as lamivudine.

### Reference Values

Not applicable

### Interpretation

Refer to the healthcare professional's institutional hepatitis B immune globulin (HBIG) therapy protocol for desirable hepatitis B virus surface antibody (anti-HBs) levels.

Studies indicated that serum anti-HBs levels needed to prevent hepatitis B virus reinfection were greater than 500 mIU/mL during the first week after transplantation, greater than 250 mIU/mL during weeks 2 to 12, and greater than 100 mIU/mL after week 12.

For more information see HBV Infection-Monitoring Before and After Liver Transplantation.

### Cautions

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

Results obtained with the Elecsys Anti-HBs (hepatitis B surface antibody) immunoassay may not be used interchangeably with values obtained with different manufacturers' assay methods.

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

Individuals who have received blood component therapies (eg, whole blood), plasma, or intravenous immunoglobulin infusion in the previous 3 to 6 months may have false-positive anti-HBs results due to passive transfer of anti-HBs present in these products. In rare cases, interference due to high titers of antibodies to immunological components, streptavidin, or ruthenium can occur causing false-positive anti-HBs results.

Serum specimens from individuals taking biotin supplements of more than 300 mg per day may have negative anti-HBs test 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.

Results obtained with the Elecsys Anti-HBs immunoassay may not be used interchangeably with values obtained with different manufacturers' assay methods.

Assay performance characteristics have not been established for the following specimen characteristics or specimen types:
-Grossly icteric (total bilirubin level of >30 mg/dL)

-Grossly lipemic (intralipid level of >1500 mg/dL)
-Grossly hemolyzed (hemoglobin level of >1600 mg/dL)
-Containing particulate matter
-Heat-inactivated specimens
-Cadaveric specimens
-Specimen types other than serum

### Clinical Reference

1. Nasir M, Wu GY. Prevention of HBV recurrence after liver transplant: a review. J Clin Translat Hepatol. 2020;8(2):150-160
2. Te H, Doucette K. Viral hepatitis: guidelines by the American Society of Transplantation Infectious Disease Community of Practice. Clin Transplant. 2019;33(9):e13514. doi:10.1111/ctr.13514
3. 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 Anti-HBs (hepatitis B surface antibody) quantitative assay is performed using an electrochemiluminescent immunoassay on the automated cobas e 801 immunochemistry analyzer. Anti-HBs present in patient's sample reacts with the biotinylated HBs antigen (*ad* and *ay* subtypes) and HBs antigen (*ad/ay*) labeled with a ruthenium complex 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 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 emissions that are measured by a photomultiplier. The emission signal generated is directly proportional to the concentration of anti-HBs present in the patient's sample.(Package insert: Elecsys Anti-HBs II. Roche Diagnostics; v1.0, 09/2024)

### 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

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## 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

86317

### LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---|---|---|
| HBABT | HBs Ab Monitor, Post-transplant, S | 5193-8 |

| Result ID | Test Result Name | Result LOINC® Value |
|---|---|---|
| HBABT | HBs Ab Monitor, Post-transplant, S | 5193-8 |