Test Definition: HBABT

HBs Ab Monitor, Post-transplant, S

Overview

Useful For

Monitoring serum anti-hepatitis B surface (anti-HBs) levels during intravenous or intramuscular hepatitis B immune globulin (HBIG) therapy to prevent hepatitis B virus (HBV) reinfection in liver transplant recipients with known previous chronic HBV

Highlights

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

Testing Algorithm

See HBV Infection-Monitoring Before and After Liver Transplantation in Special Instructions.

Special Instructions

- HBV Infection-Monitoring Before and After Liver Transplantation

Method Name

Chemiluminescent Immunoassay (CIA)

NY State Available

Yes

Specimen

Specimen Type

Serum SST

Ordering Guidance

This test is not useful for determining past hepatitis B or immune status after hepatitis B virus (HBV) vaccination and it does not provide interpretation of the anti-hepatitis B surface (anti-HBs) level detected; order HBAB / Hepatitis B Surface Antibody, Qualitative/Quantitative, Serum for those situations.

Necessary Information

Date of collection is required.

Specimen Required

Collection Container/Tube: Serum gel

Submission Container/Tube: Plastic vial

Specimen Volume:1 mL

Collection Instructions:

1. Centrifuge blood collection tube per collection tube manufacturer's instructions.

2. Aliquot serum into plastic vial.

Forms

If not ordering electronically, complete, print, and send a Gastroenterology and Hepatology Client Test Request (T728) with the specimen.

Specimen Minimum Volume

0.5 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)	28 days	
	Refrigerated	7 days	
	Ambient	24 hours	

Clinical and Interpretive

Clinical Information

For patients with chronic hepatitis B virus (HBV) infection (hepatitis B surface antigen-positive), outcomes following liver transplantation for end-stage liver disease are poor. Recurrent HBV disease 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 HBV infection in these transplant recipients.

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 since mid-1990. 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 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.

There is a high degree of variability in HBIG dosage required to achieve desirable serum anti-HBs levels among transplant recipients during the first few weeks to months after transplantation. Patients who were hepatitis B e (HBe) 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.

See HBV Infection-Monitoring Before and After Liver Transplantation in Special Instructions.

Reference Values

Not applicable

Interpretation

Please refer to health care provider's institutional hepatitis B immune globulin (HBIG) therapy protocol for desirable hepatitis B surface antibody (anti-HBs) levels.

Studies indicated that serum anti-HBs levels needed to prevent hepatitis B virus (HBV) 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.

See HBV Infection-Monitoring Before and After Liver Transplantation in Special Instructions.

Cautions

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.

Performance characteristics have not been established for the following specimen characteristics:

-Grossly icteric (total bilirubin level of >20 mg/dL)

-Grossly lipemic (triolein level of >3000 mg/dL)

-Grossly hemolyzed (hemoglobin level of >500 mg/dL)

-Containing particulate matter

-Cadaveric specimens

-Body fluids other than serum (eg, saliva, urine, CSF, amniotic, peritoneal, or pleural fluids)

Clinical Reference

1. Samuel D: Management of hepatitis B in liver transplant patients. Semin Liver Dis. 2004;24(suppl 1):55-62

2. Terrault NA, Vyas G: Hepatitis B immune globulin preparations and use in liver transplantation. Clin Liver Dis. 2003 Aug;7(3):537-550

3. Lok AS: Prevention of recurrent hepatitis B post-liver transplantation. Liver Transpl. 2002;8:S67-S73

4. Levitsky J, Doucette K, AST Infectious Diseases Community of Practice: Viral hepatitis in solid organ transplant recipients. Am J Transplant. 2009 Dec;9(Suppl 4):S116-S130

5. LeFebre 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 Jul 1;161(1):58-66. doi:10.7326/M14-1018

6. Jackson K, Locarnini S, Gish R: Diagnostics of hepatitis B virus: Standard of care and investigational. Clin Liver Dis. 2018 Jul;12(1):5-11. doi: 10.1002/cld.729

7. Coffin CS, Zhou K, Terrault NA: New and old biomarkers for diagnosis and management of chronic hepatitis B

virus infection. Gastroenterology. 2019 Jan;156(2):355-368. doi: 10.1053/j.gastro.2018.11.037

8. WHO Guidelines Development Group: World Health Organization: Guidelines on hepatitis B and C testing. World Health Organization; 2017. Accessed September 29, 2020. Available at www.who.int/hepatitis/publications/guidelines-hepatitis-c-b-testing/en/

9. Centers for Disease Control and Prevention: Testing and public health management of persons with chronic hepatitis B virus infection. Accessed April 8, 2020. Available at www.cdc.gov/hepatitis/hbv/testingchronic.html

Performance

Method Description

The VITROS hepatitis B surface antibody (anti-HBs) quantitative assay is performed using an immunometric technique in which the anti-HBs present in the clinical serum sample reacts with hepatitis B surface antigen (HBsAg) (ad and ay subtypes) coated onto the assay reaction wells. A horseradish peroxidase (HRP)-labeled HBsAg conjugate (ad and ay subtypes) then complexes with the bound anti-HBs forming an "antigen sandwich." Unbound materials are removed by washing.

A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent is added to the wells. HRP in the bound conjugate catalyzes the oxidation of the luminol derivative to produce light. The electron transfer agent increases the level and duration of the light produced. The light signals are detected by the system. The amount of HRP conjugate bound is directly proportional to the concentration of anti-HBs antibody present.(Package insert: VITROS Anti-HBs Quantitative Assay, no. GEM1208_US_EN, Version 13.1. Ortho-Clinical Diagnostics, Inc; 09/06/2019)

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

Rochester

Fees and 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 Regional Manager. 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