Test Definition: HBAB

HBs Antibody, S

Overview

Useful For

Identifying previous exposure to hepatitis B virus

Determining adequate immunity from hepatitis B vaccination

Testing Algorithm

See Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management

Special Instructions

- Viral Hepatitis Serologic Profiles
- Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management

Highlights

This assay provides both qualitative and quantitative results.

This diagnostic test should be used for testing individuals to evaluate post-vaccination immunity status or post-acute infection status of hepatitis B virus.

Method Name

Chemiluminescent Immunoassay (CIA)

NY State Available

Yes

Specimen

Specimen Type

Serum SST

Ordering Guidance

If patient is being monitored for hepatitis B immune globulin (HBIG) therapy after organ transplantation, order HBABT / Hepatitis B Surface Antibody Monitor, Post-Transplant, Serum.

This test should **not** be used for screening **asymptomatic, nonpregnant** individuals with or without risk factors for hepatitis B virus (HBV) infection. For screening such patients, order HBBSN / Hepatitis B Surface Antibody Screen, Qualitative/Quantitative, Serum.

This test should **not** be used for prenatal screening of **pregnant** individuals with or without risk factors for HBV infection. For screening such patients, order HBABP / Hepatitis B Surface Antibody Prenatal, Qualitative/Quantitative, Serum.

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 (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).

2. Aliquot serum into plastic vial.

Forms

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

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

Specimen Minimum Volume

0.5 mL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum SST	Frozen (preferred)	28 days	

	Refrigerated	7 days	
	Ambient		

Clinical & Interpretive

Clinical Information

Hepatitis B virus (HBV) infection, also known as serum hepatitis, is endemic throughout the world. The infection is spread primarily through blood transfusion or percutaneous contact with infected blood products, such as sharing of needles among injection drug users. The virus is also found in virtually every type of human body fluid and has been 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 via the transplacental route.

The incubation period for HBV infection averages 60 to 90 days (range of 45-180 days). Common symptoms include malaise, fever, gastroenteritis, and jaundice (icterus). After acute infection, HBV infection becomes chronic in 30% to 90% of infected children younger than 5 years of age and in 5% to 10% of infected individuals age 5 years or older. Some of these chronic carriers are asymptomatic, while others progress to chronic liver disease, including cirrhosis and hepatocellular carcinoma.

Hepatitis B surface antigen (HBsAg) is the first serologic marker, appearing in the serum 6 to 16 weeks following HBV infection. In acute cases, HBsAg usually disappears 1 to 2 months after the onset of symptoms with the appearance of hepatitis B surface antibody (anti-HBs). Anti-HBs also appears as the immune response following hepatitis B vaccination.

See Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management

Reference Values

HEPATITIS B SURFACE ANTIBODY

Unvaccinated: negative

Vaccinated: positive

HEPATITIS B SURFACE ANTIBODY, QUANTITATIVE

Unvaccinated: <5.0 mIU/mL

Vaccinated: > or =12.0 mIU/mL

See Viral Hepatitis Serologic Profiles in Special Instructions.

Interpretation

A positive result indicates recovery from acute or chronic hepatitis B virus (HBV) infection or acquired immunity from HBV vaccination. This assay does not differentiate between a vaccine-induced immune response and an immune response induced by infection with HBV. A positive total antihepatitis B core (anti-HBc) result would indicate that the hepatitis B surface antibody (anti-HBs) response is due to past HBV infection.

Per assay manufacturer's instructions for use, positive results, defined as anti-HBs levels of 12.0 mIU/mL or greater, indicate adequate immunity to HBV from past hepatitis B viral infection or HBV vaccination. However, per current CDC guidance,(1) individuals with anti-HBs levels greater than 10 mIU/mL after completing an HBV vaccination series are considered protected from hepatitis B.

Negative results, defined as anti-HBs levels of less than 5.0 mIU/mL, indicate a lack of recovery from acute or chronic hepatitis B or inadequate immune response to HBV vaccination. The US Advisory Committee on Immunization Practices does not recommend more than 2 HBV vaccine series in nonresponders.

Indeterminate results, defined as anti-HBs levels in the range from 5 to 11.9 mIU/mL, indicate inability to determine if anti-HBs is present at levels consistent with recovery or immunity. Repeat testing is recommended in 1 to 3 months.

See Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management

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 hepatitis B surface antibody (anti-HBs) results due to passive transfer of anti-HBs present in these products.

Individuals possessing IgM anti-rubella virus may have falsely high results with the VITROS Anti-HBs quantitative test.

Anti-HBs levels from past hepatitis B or hepatitis B virus (HBV) vaccination may fall below detectable levels over time.

A positive anti-HBs result does not exclude infection by another hepatitis virus.

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

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

-Grossly lipemic (triglyceride 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. Advisory Committee on Immunization Practices; Centers for Disease Control and Prevention: Immunization of health-care personnel: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep. 2011 Nov 25;60(RR-7):1-45

2. Badur S, Akgun A: Diagnosis of hepatitis B infections and monitoring of treatment. J Clin Virol. 2001 Jun;21(3):229-237

3. Servoss JC, Friedman LS: Serologic and molecular diagnosis of hepatitis B virus. Clin Liver Dis. 2004 May;8(2):267-281

4. 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

5. 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

6. 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

7. WHO Guidelines Development Group: WHO guidelines on hepatitis B and C testing. World Health Organization; 2017. Accessed July 8, 2021. Available at www.who.int/publications/i/item/9789241549981

8. Centers for Disease Control and Prevention: Testing and public health management of persons with chronic hepatitis B virus infection. CDC; Updated October 8, 2019. Accessed April 8, 2020. Available at www.cdc.gov/hepatitis/hbv/testingchronic.html

Performance

Method Description

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

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees & Codes

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

86706

Test Definition: HBAB

HBs Antibody, S

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
HBAB	HBs Antibody, S	5193-8

Result ID	Reporting Name	LOINC®
HB_AB	HBs Antibody, S	10900-9
HBSQN	HBs Antibody, Quantitative, S	5193-8