Test Definition: HBAG

HBs Antigen, S

Overview

Useful For

Diagnosis of acute, recent, or chronic hepatitis B infection

Determination of chronic hepatitis B infection status

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

This test, by itself, is not useful during the "window period" of acute hepatitis B virus (HBV) infection (ie, after disappearance of hepatitis B surface antigen and prior to appearance of hepatitis B surface antibody). Testing for acute HBV infection should also include hepatitis B core IgM antibody (anti-HBc IgM).

Testing Algorithm

If hepatitis B surface antigen (HBsAg) screen is reactive with signal-to-cutoff ratio in the range of 1.00 to 100.0 then HBsAg confirmation will be performed at an additional charge.

The following algorithms are available:

-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.

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
HBGNT	HBs Antigen Confirmation,	No	No

	S		

Method Name

Chemiluminescence Immunoassay (CIA)

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 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 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 FDA-approved for testing on these sources.

Additional Testing Requirements

Testing for acute hepatitis B virus infection should also include HBIM / Hepatitis B Core Antibody, IgM, Serum, as during the acute HBV infection "window period," Hepatitis B 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 FDA-licensed assay can be performed.

Specimen Required

Collection Container/Tube: Serum gel

Submission Container/Tube: Plastic vial

Specimen Volume: 2 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

0.6 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) is endemic throughout the world. The infection is spread primarily through percutaneous contact with infected blood products (eg, blood transfusion, sharing of needles by intravenous drug addicts). The virus is also found in various human body fluids, and it is known to be spread through oral and genital contacts. 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 16 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.

See the following in Special Instructions:

-HBV Infection-Monitoring Before and After Liver Transplantation

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

Reference Values

Negative

See Viral Hepatitis Serologic Profiles in Special Instructions.

Interpretation

A reactive screen result (signal-to-cutoff ratio [S/Co]: > or =1.00 but < or =100.0) confirmed as positive by hepatitis B surface antigen (HBsAg) confirmatory test (see Method Description) or a positive screen result (S/Co >100.0) is indicative of acute or chronic hepatitis B virus (HBV) infection, or chronic 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, hepatitis B surface antibody; hepatitis B core antibody, total and IgM). Repeat testing is recommended at a later date if clinically indicated.

Confirmed presence of HBsAg is frequently associated with HBV replication and infectivity, especially when accompanied by presence of hepatitis B e antigen and/or detectable HBV DNA.

See the following in Special Instructions:

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

-HBV Infection-Monitoring Before and After Liver Transplantation

-Viral Hepatitis Serologic Profiles

Cautions

Positive screen results (ie, signal-to-cutoff ratio >100.0) without need for confirmation testing should be interpreted in

conjunction with test results of other hepatitis B virus (HBV) serologic markers (eg, hepatitis B surface antibody [anti-HBs], hepatitis B core antibody [anti-HBc] total, and anti-HBc IgM).

Positive hepatitis B surface antigen (HBsAg) test results should be reported by the health care provider to the State Department of Health, as required by law in some states.

Individuals, especially neonates and children, who recently received hepatitis B vaccination may have transient positive HBsAg test results because of the large dose of HBsAg used in the vaccine relative to the individual's body mass.

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

Clinical Reference

1. Bonino F, Piratvisuth T, Brunetto MR, Liaw YF: Diagnostic markers of chronic hepatitis B infection and disease. Antivir Ther. 2010;15(3):35-44

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

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

4. 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 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 Aug 22;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.htm

Performance

Method Description

Specimens are first tested by the VITROS hepatitis B surface antigen (HBsAg) assay. With modification to the assay manufacturer's instructions for use, specimens yielding signal-to-cutoff (S/Co) of 1.00 or greater but 100.0 or less will be confirmed by the VITROS HBsAg confirmatory assay. Specimens that are strongly positive (ie, S/Co >100.0) do not require this confirmation.

Chemiluminescence Immunoassay:

This immunometric technique involves the simultaneous reaction of HBsAg in the sample with mouse monoclonal anti-hepatitis B surface (anti-HBs) antibody coated onto the wells and a horseradish peroxidase (HRP)-labeled mouse monoclonal anti-HBs antibody in the conjugate. Unbound conjugate is 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. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent increases the level and duration of the light produced. The light signals are read by the system. The amount of HRP conjugate bound is indicative of the level of HBsAg present in the sample.(Package insert: VITROS HBsAg assay, no. GEM1201, version 13.1. Ortho-Clinical Diagnostics, Inc; 09/06/2019)

Confirmation:

The VITROS HBsAg Confirmatory kit uses the principle of specific antibody neutralization to confirm the presence of HBsAg. The sample is tested twice: the first aliquot is incubated with a neutralizing reagent containing high titer anti-HBs (the confirmatory antibody); the second aliquot is incubated with a non-neutralizing control reagent (the sample diluent). The confirmatory antibody binds to HBsAg in the sample inhibiting its reaction in the VITROS HBsAg assay. This leads to a reduced result compared to that for the non-neutralized control sample.(Package insert: VITROS HBsAg Confirmation assay, no. GEM4201, 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

87340

87341 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
HBAG	HBs Antigen, S	5196-1

Result ID	Reporting Name	LOINC®
H_BAG	HBs Antigen, S	5196-1