MAYO CLINIC LABORATORIES

Test Definition: CHBVS

Chronic Hepatitis B Screen, Serum

Overview

Useful For

Diagnosis and evaluation of patients at risk for or suspected of having chronic hepatitis B

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

This test is **not useful** during the "window period" of acute hepatitis B virus infection (ie, after disappearance of hepatitis B surface antigen [HBsAg] and prior to appearance of hepatitis B surface antibody).

This test is **not useful** as a stand-alone prenatal screening test of HBsAg status in pregnant women.

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
HBGSN	HBs Antigen Scrn, S	Yes	Yes

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
EAG	Hepatitis Be Ag, S	Yes	No
HBGSC	HBs Antigen Screen Confirmation, S	No	No
HEAB	HBe Antibody, S	Yes	No

Testing Algorithm

If hepatitis B surface antigen (HBsAg) is reactive, then HBsAg confirmation will be performed at an additional charge. If HBsAg confirmation is positive, then hepatitis B e antigen (HBeAg) and hepatitis B e antibody (anti-HBe) tests 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
-Viral Hepatitis Serologic Profiles

Special Instructions

- Viral Hepatitis Serologic Profiles
- HBV Infection-Monitoring Before and After Liver Transplantation
- Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management

Method Name

Chemiluminescence Immunoassay (CIA)

NY State Available

Yes

Specimen

Specimen Type

Serum SST

Necessary Information

Date of collection is required.

Specimen Required

Patient Preparation: For 24 hours before specimen collection do not take multivitamins or dietary supplements containing biotin (vitamin B7), which is commonly found in hair, skin, and nail supplements and multivitamins.
Supplies: Sarstedt 5 mL Aliquot Tube (T914)
Collection Container/Tube: Serum gel
Submission Container/Tube: Plastic vial
Specimen Volume: 3.5 mL
Collection Instructions:
1. Centrifuge per collection tube manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).
2. Transfer serum into plastic vial.

Forms

If not ordering electronically, complete, print, and send 1 of the following:
-Gastroenterology and Hepatology Client Test Request (T728)
-Infectious Disease Serology Test Request (T916)

Specimen Minimum Volume

1.5 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 & 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 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.

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.

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Reference Values

Negative
See Viral Hepatitis Serologic Profiles

Interpretation

A reactive screen result (signal to cutoff ratio; S/Co ratio > or =1.0 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 ratio >100.0) is indicative of acute or chronic hepatitis B virus (HBV) infection, or chronic HBV carrier state.

Specimens with reactive screen results but negative (ie, not confirmed) HBsAg confirmatory test results are likely to contain cross-reactive antibodies from other infectious or immunologic disorders. Repeat testing at a later date is recommended if clinically indicated.

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

The following algorithms are available:
-Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management
-HBV Infection-Monitoring Before and After Liver Transplantation
-Viral Hepatitis Serologic Profiles

Cautions

Positive hepatitis B surface antigen (HBsAg) 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, hepatitis B core antibody [anti-HBc] total, and anti-HBc IgM).

Positive 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 >61 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. doi: 10.3851/IMP1622
2. Servoss JC, Friedman LS: Serologic and molecular diagnosis of hepatitis B virus. Clin Liver Dis. 2004 May;8(2):267-281. doi: 10.1016/j.cld.2004.02.001
3. Badur S, Akgun A: Diagnosis of hepatitis B infections and monitoring of treatment. J Clin Virol. 2001 Jun;21(3):229-237. doi: 10.1016/s1386-6532(01)00147-0
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 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 ratio (S/Co) > or =1.0 but < or =100.0 will be confirmed by the VITROS HBsAg Confirmatory assay. Specimens that are strongly positive (ie, S/Co ratio >100.0) do not require this confirmation.

HBsAg:
This immunometric technique involves the simultaneous reaction of HBsAg in the sample with mouse monoclonal HBs antibody (anti-HBs) coated onto the wells and a horseradish peroxidase (HRP)-labeled mouse monoclonal anti-HBs 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 VITROS Immunodiagnostic System. The amount of HRP conjugate bound is indicative of the level of HBsAg present in the sample.(Package insert: VITROS HBsAg assay, GEM1201, version 13.1. Ortho-Clinical Diagnostics, Inc; 09/06/2019)

HBsAg Confirmation:
The VITROS HBsAg Confirmatory Kit uses the principle of specific antibody neutralization to confirm the presence of HBsAg. The sample is tested twice: one 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, GEM4201, 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 4 days

Specimen Retention Time
14 days

Performing Laboratory Location
Rochester

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 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

87340

G0499-(if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CHBVS	Chronic Hept Scrn B, S	5196-1

Result ID	Test Result Name	Result LOINC® Value
HBAGS	HBs Antigen Scrn, S	5196-1