MAYO CLINIC LABORATORIES

Test Definition: HBPES

Hepatitis B Virus Past Exposure Panel, Serum

Overview

Useful For

Screening for past exposure to hepatitis B virus (HBV)

Determining HBV infection status prior to initiating chemotherapy or other immunosuppressive therapies

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
HBGSN	HBs Antigen Scrn, S	Yes	Yes
HBCSN	HBc Total Ab Scrn, S	Yes	Yes
HBBSN	HBs Antibody Scrn, S	Yes	Yes

Testing Algorithm

If hepatitis B surface antigen (HBsAg) is reactive, then HBsAg confirmation will be performed at an additional charge.

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 test panel is intended to screen for presence of past or active hepatitis B viral infection in individuals who will be receiving chemotherapy, immunosuppressive therapy, or organ transplantation.

Method Name

Chemiluminescence Immunoassay (CIA)

NY State Available

Yes

Specimen

Specimen Type

Serum SST

Necessary Information

Date of collection is required.

Specimen Required

Collection Container/Tube: Serum gel
Submission Container/Tube: Plastic vial
Specimen Volume: 1.5 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.

Specimen Minimum Volume

1 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 is a DNA viral infection that is endemic throughout the world. The hepatitis B virus (HBV) is transmitted parenterally or percutaneously from exposure to contaminated blood, blood products, or injection needles, sexually from exposure to body fluids from infected individuals, or perinatally from mother to child during birth delivery by contact with infected mother's blood and vaginal secretions. Transplacental transmission from mother to fetus is uncommon.

HBV persists and causes chronic infection (defined as being positive for hepatitis B virus surface antigen [HBsAg] in serum or plasma for minimum 6 months) in about 10% of individuals who had acute infection during childhood. These individuals may become asymptomatic HBV carriers (ie, inactive chronic hepatitis B), while others may develop chronic liver diseases including cirrhosis and hepatocellular carcinoma. Asymptomatic HBV carriers are at risk (up to 50%) for decompensation of liver function with acute HBV replication (ie, HBV reactivation) during immunosuppression from chemotherapy, immunosuppressive therapy, or organ transplantation.

Individuals who recovered from acute hepatitis B (defined as being negative for HBsAg, positive for total HBV core antibodies, negative or positive for HBV surface antibody) are lower risk (up to 20%) of HBV reactivation than those with

inactive chronic hepatitis B during immunosuppressive therapy or organ transplantation.

For individuals born in regions of the world where HBV prevalence is moderate to high, universal HBV serologic screening before initiation of immunosuppressive therapy is recommended. In the absence of systematic, risk-based testing, universal HBV serologic screening is an option to reduce the risk of missing persons with HBV infection prior to initiation of immunosuppressive treatment.

Reference Values

Negative

See Viral Hepatitis Serologic Profiles in Special Instructions.

Interpretation

Hepatitis B virus surface antigen (HBsAg) is the first serologic marker appearing in blood 6 to 16 weeks after exposure to hepatitis B virus (HBV). A confirmed positive HBsAg result is indicative of acute or chronic hepatitis B. In acute cases, HBsAg usually disappears 1 to 2 months after the onset of symptoms. Persistence of HBsAg for more than 6-months duration indicates development of either a chronic carrier state or chronic hepatitis B.

Hepatitis B virus surface antibody (HBsAb) appears with the resolution of HBV infection and disappearance of HBsAg. A positive result indicates recovery from acute or chronic hepatitis B or acquired immunity from HBV vaccination. This assay does not differentiate between a vaccine-induced immune response and recovery from HBV infection. Per assay manufacturer's instructions for use, positive results are defined as HBsAb levels of 12.0 mIU/mL or greater, with adequate immunity to hepatitis B after recovery from past infection or HBV vaccination. Per current CDC guidance, individuals with HBsAb levels of 10 mIU/mL or greater after completing an HBV vaccination series are considered protected from hepatitis B.

Negative HBsAb results (levels of < 5.0 mIU/mL) indicate a lack of recovery from acute or chronic hepatitis B or inadequate immune response to HBV vaccination.

Indeterminate results (HBsAb levels in the range of 5.0 to 11.9 mIU/mL) indicate inability to determine if HBsAb is present at levels consistent with recovery or immunity. Repeat testing is recommended in 1 to 3 months.

Hepatitis B virus core (HBc) total antibodies (combined IgG and IgM) appear shortly after the onset of symptoms of HBV infection and may be the only serologic marker remaining years after exposure to HBV. A positive result indicates exposure to HBV infection. A positive HBsAb result along with a positive HBc total Ab result is indicative of recovery from HBV infection. A positive HBsAb result with a negative HBc total Ab result is consistent with immunity to hepatitis B from HBV vaccination.

Summary of interpretation of the various HBV serologic test result profiles is provided in the table below:

HBV serologic test results			Interpretation
HBsAg	**HBc total Ab**	**HBsAb**	
+	+	-	Chronic hepatitis B
-	+	+	Past HBV infection (resolved)
-	+	-	Past HBV infection, resolved or false-positive
-	-	+	Immune (from HBV vaccination)

-	-	-	Uninfected (not immune)

Cautions

Assay 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)
-Contain particulate matter
-Cadaveric specimens
-Heat inactivated specimens

Clinical Reference

1. Schillie S, Vellozzi C, Reingold A, et al: Prevention of hepatitis B virus infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. MMWR Recomm Rep. 2018 Jan 12;67(1):1-31. doi: 10.15585/mmwr.rr6701a1
2. Centers for Disease Control and Prevention (CDC), Division of Viral Hepatitis: Interpretation of hepatitis B serologic test results. CDC; Accessed January 4, 2021. Available at www.cdc.gov/hepatitis/HBV/PDFs/SerologicChartv8.pdf
3. Terrault NA, Lok ASF, McMahon BJ, et al: Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 hepatitis B guidance. Hepatology. 2018 Apr;67(4):1560-1599

Performance

Method Description

Hepatitis B Surface Antigen Screen:
This immunometric technique involves the simultaneous reaction of hepatitis B surface antigen (HBsAg) in the sample with mouse monoclonal anti-hepatitis B surface (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 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)

Hepatitis B Surface Antigen 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 nonneutralizing 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 nonneutralized control sample.(Package insert: VITROS HBsAg Confirmation assay. No GEM4201, version 13.1. Ortho-Clinical Diagnostics, Inc; 09/06/2019)

Hepatitis B Surface Antibody:

This chemiluminescent immunoassay is based on an immunometric technique in which the anti-HBs present in the clinical serum sample reacts with HBsAg (ad and ay subtypes) coated onto the assay reaction wells. 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, version 14.0. Ortho-Clinical Diagnostics, Inc; 04/08/2020)

Hepatitis B core Total Antibodies:
The VITROS anti-hepatitis B core (anti-HBc) assay is a competitive immunoassay method based on the reaction of anti-HBc in the sample with hepatitis B core antigen (HBcAg)-coated wells. Unbound sample is removed by washing. HRP-labeled antibody conjugate (mouse monoclonal anti-HBc) is then allowed to react with the remaining exposed HBcAg on the well surface. Unbound conjugate is removed by washing. The bound HRP conjugate is measured by a luminescent reaction. A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent are 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 concentration of anti-HBc present in the sample.(Package insert: VITROS Anti-HBc Assay. No GEM1211, 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 & 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 Definition: HBPES

Hepatitis B Virus Past Exposure Panel, Serum

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
86704
87340
G0499 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HBPES	Hepatitis B Past Exposure, S	77190-7

Result ID	Test Result Name	Result LOINC® Value
HBCSN	HBc Total Ab Scrn, S	13952-7
HBAGS	HBs Antigen Scrn, S	5196-1
HBSQN	HBs Antibody, Quantitative, S	5193-8
HBASN	HBs Antibody Scrn, S	10900-9