MAYO CLINIC LABORATORIES

Test Definition: HBGCD

HBsAg Cadaver/Hemolyzed, S

Overview

Useful For

Testing cadaveric and hemolyzed blood specimens for hepatitis B surface antigen (HBsAG); FDA-licensed for use with hemolyzed specimens

Diagnosis of acute, recent (<6 month duration), or chronic hepatitis B infection; determination of chronic hepatitis B carrier status

This test is **not useful** during the "window period" of acute hepatitis B virus (HBV) infection, (ie, after disappearance of HBsAg and prior to appearance of anti-HBs antibody).

Testing Algorithm

All reactive results are confirmed by a neutralization procedure at an additional charge.

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
BNTCD	HBsAg Confirm Cadav/Hemol, S	No	No

Method Name

Enzyme Immunoassay (EIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Additional Testing Requirements

Testing for acute hepatitis B virus (HBV) infection should also include HBIM / Hepatitis B Core Antibody, IgM, Serum as during the acute HBV infection "window period," HB surface (HBs) antigen and HBs antibody may not be detected.

Necessary Information

Date of collection is required.

Specimen Required

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 2 mL

Collection instructions:

1. Centrifuge blood collection tube per collection tube manufacturer's instructions (eg, centrifuge within 2 hours of collection for BD Vacutainer tubes).

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.

Reject Due To

Gross hemolysis	OK
Gross lipemia	Reject
Gross icterus	Reject

Specimen Minimum Volume

1.5 mL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	30 days	
	Ambient	7 days	
	Refrigerated	7 days	

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 HBV infection. In acute infection, HBsAg usually disappears in 1 to 2 months after the onset of symptoms. Persistence of HBsAg for greater than 6 months indicates development of either a chronic carrier or chronic HBV infection.

Reference Values

Negative

Interpretation

A positive result (reactive screening and confirmed positive by neutralization test) is indicative of acute or chronic hepatitis B virus (HBV) infection, or chronic HBV carrier state.

A positive confirmatory test result is considered the definitive test result for hepatitis B surface antigen (HBsAg). Specimens that are reactive by the screening test but negative (not confirmed) by the confirmatory test are likely to contain cross-reactive antibodies from other infectious or immunologic disorders. These unconfirmed HBsAg screening test results should be interpreted in conjunction with test results of other HBV serological markers (eg, anti-hepatitis B surface antibody, anti-hepatitis B core total antibody).

The presence of HBsAg is frequently associated with HBV infectivity, especially when accompanied by the presence of hepatitis Be antigen or HBV DNA.

Cautions

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:

-Icteric cadavers

-Lipemic cadavers

-Containing particulate matter

Clinical Reference

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

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

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

4. Terrault NA, Bzowej NH, Chang K-M, et al: AASLD guidelines for treatment of chronic hepatitis B. Hepatology. 2016;63:261-283

Performance

Method Description

Specimens are first screened by the Genetic Systems hepatitis B surface antigen (HBsAg) 3.0 EIA. All reactive results are confirmed by the Genetic Systems HBsAg Confirmatory Assay 3.0 (HBsAg Neutralization) at an additional charge.

HBsAg:

The Bio-Rad GS HBsAg EIA 3.0 is a qualitative third generation enzyme immunoassay which uses mouse monoclonal antibodies to detect anti-HBsAg in human serum or in cadaveric serum specimens. Wells of a microwell strip plate are coated with mouse monoclonal antibody to HBsAg (anti-HBs). Patient serum and appropriate controls are added to the wells and incubated with bound antibody. If HBsAg is present it will bind to the antibody and not be removed by washing. The strips are washed to remove any unbound material. Washing is followed by the addition of conjugate solution (peroxidase-conjugated mouse monoclonal antibodies directed against HBsAg). The conjugate solution will bind to the antibody-HBsAg complex, if present. Unbound conjugate is removed by a wash step. Next, working 3,3',5,5'-tetramethylbenzidine (TMB) solution is added to the plate and allowed to incubate. A blue or blue-green color develops in proportion to the amount of HBsAg present in the sample. The enzyme reaction is stopped by the addition of acid, which changes the blue-green color to yellow. The absorbance values of controls and specimens are determined using a spectrophotometer with wavelength set at 450 nm.(Package insert: Genetic Systems HBsAg 3.0 EIA. Bio-Rad Laboratories; 02/2019)

HBsAg Confirmation:

The repeatedly reactive specimen is incubated with HBsAg confirmatory reagent (human antibody to HBsAg). If HBsAg is present in the specimen, it will be neutralized by the HBsAg confirmatory reagent. The treated specimen is re-assayed using the Genetic Systems HBsAg 3.0 EIA assay. The neutralized HBsAg is prevented from binding to the HBsAg antibody-coated microwells, which results in a reduction of signal. A non-neutralized control of the specimen (treated with HBsAg-negative control [human] in place of the HBsAg confirmatory reagent) is tested in parallel to the neutralized specimen for comparison of signal. Genetic Systems HBsAg EIA 3.0 repeatedly reactive specimens are confirmed as positive by the Genetic Systems HBsAg Confirmatory Assay 3.0 if the reduction in signal of the neutralized specimen is greater than or equal to 50% of the corresponding non-neutralized specimen and the non-neutralized specimen signal is greater than or equal to the assay cutoff.(Package insert: Genetic Systems HBsAg Confirmatory Assay 3.0. Bio-Rad Laboratories; January 2009)

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
HBGCD	HBsAg Cadaver/Hemolyzed, S	In Process

Result ID	Reporting Name	LOINC®
83626	HBsAg Cadaver/Hemolyzed, S	5196-1