Test Definition: CHSBP

Chronic Hepatitis Profile (Type B)

Overview

Useful For

Evaluating patients with suspected or confirmed chronic hepatitis B

Monitoring hepatitis B viral infectivity

Profile Information

Test ID	Reporting Name	Available Separately	Always Performed
HBAG	HBs Antigen, S	Yes	Yes
EAG	Hepatitis Be Ag, S	Yes	Yes
HEAB	HBe Antibody, S	Yes	Yes

Reflex Tests

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

Testing Algorithm

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

See HBV Infection-Diagnostic Approach and Management Algorithm in Special Instructions.

Special Instructions

- Viral Hepatitis Serologic Profiles
- HBV Infection-Diagnostic Approach and Management Algorithm

Method Name

Chemiluminescence Immunoassay

NY State Available

Yes

Specimen

Specimen Type

Serum SST

Necessary Information

1. Date of collection is required.

2. Indicate "Type B"

Specimen Required

Patient Preparation: For 24 hours before this test do not take multivitamins or dietary supplements containing biotin (vitamin B7), which is commonly found in hair, skin, and nail supplements and multivitamins.

Collection Container/Tube: Serum gel

Submission Container/Tube: Plastic vial

Specimen Volume: 2.5 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 aliquot tube.

Forms

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

Specimen Minimum Volume

2 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)		
	Refrigerated	7 days	
	Ambient	24 hours	

Clinical and Interpretive

Clinical Information

Hepatitis B virus (HBV) is a DNA virus that is endemic throughout the world. The infection is spread primarily through percutaneous contact with infected blood products (eg, blood transfusion and sharing of needles by drug addicts). The virus is also found in virtually every type of human body fluid and 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; it is not commonly transmitted transplacentally.

After a course of acute illness, HBV persists in approximately 10% of patients. Some of these carriers are asymptomatic; others develop chronic liver disease including cirrhosis and hepatocellular carcinoma.

The following algorithms are available in Special Instructions:

-HBV Infection-Diagnostic Approach and Management Algorithm

-Viral Hepatitis Serologic Profiles

Reference Values

HEPATITIS B SURFACE ANTIGEN

Negative

HEPATITIS Be ANTIGEN

Negative

HEPATITIS Be ANTIBODY
Negative

Interpretation depends on clinical setting. See Viral Hepatitis Serologic Profiles in Special Instructions.

Interpretation

Hepatitis B surface antigen (HBsAg) is the first serologic marker appearing in the serum 6 to 16 weeks following hepatitis B viral (HBV) infection. In acute cases, HBsAg usually disappears 1 to 2 months after the onset of symptoms. Persistence of HBsAg for more than 6 months indicates development of either chronic carrier state or chronic liver disease.

Hepatitis B surface antibody (anti-HBs) appears with the resolution of HBV infection after the disappearance of HBsAg. Anti-HBs also appears as the immune response following a course of inoculation with the hepatitis B vaccine.

Hepatitis B core antibody (anti-HBc) appears shortly after the onset of symptoms of HBV infection and may be the only serologic marker remaining years after exposure to hepatitis B.

The presence of hepatitis Be antigen (HBeAg) correlates with infectivity, the number of viral Dane particles, the presence of core antigen in the nucleus of the hepatocyte, and the presence of viral DNA polymerase in serum. Hepatitis Be antibody (anti-HBe) positivity in a carrier is often associated with chronic asymptomatic infection.

If the patient has a sudden exacerbation of disease, consider ordering hepatitis C virus antibody (anti-HCV) and hepatitis delta virus antibody (anti-HDV).

If HBsAg converts to negative and patient's condition warrants, consider testing for anti-HBs.

If HBsAg is positive, consider testing for anti-HDV.

The following algorithms are available in Special Instructions:

-HBV Infection-Diagnostic Approach and Management Algorithm

-Viral Hepatitis Serologic Profiles

Cautions

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

Consider administration of hepatitis B immune globulin and hepatitis B vaccine to individuals exposed to the patient's blood or body fluids.

Performance characteristics of these assays have not been established in patients under the age of 2 or in populations of immunocompromised or immunosuppressed patients. These assays are not licensed by the FDA for testing cord blood samples or screening donors of blood, plasma, human cell, or tissue products.

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 >3,000 mg/dL)

-Grossly hemolyzed (hemoglobin level of >61 mg/dL)

-Containing particulate matter

-Cadaveric specimen

Clinical Reference

1. Bonino F, Piratvisuth T, Brunetto MR, et al: Diagnostic markers of chronic hepatitis B infection and disease. Antiviral Therapy 2010;15(3):35-44

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

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

Performance

Method Description

Hepatitis B Surface Antigen (HBsAg):

Specimens are first tested by the VITROS 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 >100.0) do not require this confirmation. This immunometric technique involves the simultaneous reaction of HBsAg in the sample with mouse monoclonal 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 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 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 12.0, Ortho-Clinical Diagnostics, Inc. Rochester, NY, 06/22/2017)

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 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 non-neutralized control sample.(Package insert: VITROS HBsAg Confirmation assay, GEM4201, version 12.0, Ortho-Clinical Diagnostics, Inc., Rochester, NY, 6/22/2017)

Hepatitis Be Antigen (HBeAg):

This test is performed using the FDA-approved VITROS HBeAg Reagent Pack and the Immunodiagnostic Product HBeAg Calibrator on the VITROS Immunodiagnostic System based on chemiluminescence immunoassay principle. An immunometric technique is used. This involves the simultaneous reaction of HBeAg in the sample with biotinylated mouse monoclonal HBeAg antibody and HRP-labeled mouse monoclonal HBeAg antibody in the conjugate. The immune complex is captured by streptavidin on the wells; unbound materials are 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 (a substituted acetanilide) increases the level of light produced and prolongs its emission. The light signals are read by the system. The amount of HRP conjugate bound is indicative of the level of HBeAg present in the sample.(Package insert: VITROS Immunodiagnostic Product HBeAg Reagent Pack, No. GEM1222, version 8.0, Ortho-Clinical Diagnostics, Rochester, NY, 9/22/2017)

Hepatitis Be Antibody (Anti-HBe):

This test is performed using the FDA-approved VITROS Anti-HBe Reagent Pack and the VITROS Anti-HBe Calibrator on the VITROS Immunodiagnostic Systems based on chemiluminescence immunoassay principle. A competitive technique is used which involves preincubation of anti-HBe IgG in the sample with a fixed weight of HBeAg in the assay reagent, followed by incubation with a conjugate reagent that contains biotinylated mouse monoclonal anti-HBe IgG and HRP-labelled mouse monoclonal anti-HBe IgG. The immune complex is captured by streptavidin on the wells. Unbound materials are 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 (a substituted acetanilide) increases the level of light produced and prolongs its emission. The light signals are read by the system. The amount of HRP conjugate bound is indicative of the level of anti-HBe IgG present in the sample.(Package insert: VITROS Immunodiagnostic Product Anti-HBe Reagent Pack, No. GEM1223, version 8.0, Ortho-Clinical Diagnostics, Rochester, NY, 9/22/2017)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Saturday; Varies

Analytic Time

1 day

Maximum Laboratory Time

4 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees and 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 U.S. 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

86707

87340

87350

87341 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
CHSBP	Chronic Hepatitis Profile (Type B)	In Process

Result ID	Test Result Name	Result LOINC Value
EAG	Hepatitis Be Ag, S	13954-3
HEAB	HBe Antibody, S	33463-1
H_BAG	HBs Antigen, S	5196-1