

Overview

Useful For

Staging and prognosis of hepatitis B infection

Monitoring response to therapy in chronic hepatitis B infections (along with HBV DNA, hepatitis B surface [HBs] antigen, and HBs antibody) where seroconversion from hepatitis B e (HBe) antigen to HBe antibody indicates virological response

This test **should not** be used for screening in an asymptomatic setting.

Method Name

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available

No

Specimen

Specimen Type

Serum SST

Shipping Instructions

Specimens must be shipped refrigerated.

Specimen Required

Patient Preparation: Specimens **should not** be collected from patients receiving therapy with high biotin (vitamin B7) doses (eg, >5 mg/day) until at least 8 hours following the last biotin administration.

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions:

1. For serum gel tubes, allow blood to clot in an upright position for at least 30 minutes. Within 2 hours of collection, centrifuge and refrigerate.
2. For red top tubes, allow blood to clot in an upright position for at least 60 minutes. Within 2 hours of collection, centrifuge, aliquot serum into a plastic vial, and refrigerate. Clearly label tube as serum from a plain red-top tube.

Specimen Minimum Volume

See Specimen Required

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum SST	Refrigerated (preferred)	14 days	
	Ambient	7 days	
	Frozen	90 days	

Clinical & Interpretive

Clinical Information

Hepatitis B virus (HBV) is a circular, partially double-stranded DNA virus of the *Hepadnaviridae* family that is unrelated to the viruses causing hepatitis A or hepatitis C. HBV is transmitted by exposure to infected bodily fluids during sexual activity, sharing intravenous drug injection equipment, or exposure to infected maternal blood at birth.

Hepatitis B virus illness is characterized as either acute or chronic, with hepatic injury resulting from the body's immune response to clear the infection. Acute HBV infection typically causes short-term symptoms (eg, jaundice, nausea, vomiting) within 6 months of exposure to HBV. In the United States, acute HBV infection leads to chronic disease in 5% of cases, although the percentage is much higher in infections with an onset in infancy and young childhood. Chronic HBV is a serious, lifelong illness that may result in cirrhosis or hepatocellular carcinoma.(1)

Serologic markers specific for HBV are used to diagnose HBV infection. The markers identify the stage of the infection (past, present, or chronic) and those who are at highest risk for complications. Hepatitis B core IgM antibody (HBcAb) is the first antibody to appear following acute HBV infection and is the best serologic marker for acute HBV infection. It is typically ordered as the follow-up test for a positive screening total HBcAb (IgM and IgG) to help differentiate acute infections (<6 months) from chronic/resolved infections.(1)

The incubation period for HBV is 45 to 160 days, with an average of 100 days for symptom onset. Acute illness is typically mild (especially in young children), however 30% to 50% of adolescents and adults will present with symptoms (jaundice, anorexia, nausea, vomiting). The disease may become fulminant in 0.1% to 0.5% of acute HBV infections, and acute clinical deterioration of an individual with the HBV should prompt evaluation for hepatitis D virus superinfection.(2)

Risk factors for HBV transmission include living in a household with a person who is infected with HBV, sexual contact with a person with an HBV infection, men who have sex with men, immigrants from regions of high HBV infectivity, kidney dialysis, concurrent use of immunosuppression medication, HIV infection, abnormal liver enzymes, inmates, and intravenous drug use.(3)

Hepatitis B e antibody (HBeAb) appears in early convalescence during hepatitis B infection in response to the hepatitis B

viral e antigen. In most acute HBV infections, HBeAb appears after hepatic transaminases peak but before the disappearance of hepatitis B surface antigen (HBsAg). The loss of HBeAg and development of HBeAb is known as "HBeAg seroconversion" and is associated with reduced infectivity and eventual disease resolution; failure of HBeAb to appear implies ongoing disease activity and probable chronicity.(4)

In chronic infections (HBsAg present for greater than 6 months), HBsAg carriers may be either positive or negative for HBeAb but are less infectious when HBeAb is present. Treatment-induced HBeAg seroconversion is an important therapeutic goal in patients who are HBeAg positive and typically leads to decreased hepatic inflammation and decreased levels of HBV DNA in serum: the inactive carrier state.(2)

It should be noted that while HBeAb can persist for years, it usually disappears earlier than HBsAb or HBcAb, which is why HBeAb is not used as the sole serologic marker for prior HBV infection.

Reference Values

Nonreactive

Interpretation

Negative or nonreactive:

No evidence of hepatitis B virus (HBV) infection when hepatitis B surface antigen (HBsAg) negative, hepatitis B core antibody (HBcAb) negative, and hepatitis B surface antibody (HBsAb) negative.

Acute HBV infection when HBsAg positive, HBcAb (IgM) positive, hepatitis B e antigen (HBeAg) positive, and HBsAb negative.

Active (replicating) chronic HBV infection when HBsAg positive, HBcAb positive (IgG), HBeAg positive, HBsAb negative)

Positive or reactive:

Indicates rapid viral replication usually associated with high HBV DNA levels and high infectivity risk which may be seen in either acute or chronic HBV infections.

Cautions

A negative result does not rule out infectivity or chronic hepatitis B carrier status.

Clinical Reference

1. Hepatitis B Resources for Health Professionals. Centers for Disease Control and Prevention; Updated April 30, 2024. Accessed June 19, 2025. Available at www.cdc.gov/hepatitis-b/hcp/provider-resources/
2. Carey W. Hepatitis B. Cleveland Clinic Digestive Disease and Surgery Institute; August 2010. Accessed June 19, 2025. Available at <https://my.clevelandclinic.org/departments/digestive/medical-professionals/hepatology/hepatitis-b>
3. Hepatitis B. World Health Organization; Updated April 9, 2024. Accessed June 19, 2025. Available at www.who.int/mediacentre/factsheets/fs204/en/
4. Sacher RA, Peters SM, Bryan JA. Testing for viral hepatitis. A practice parameter. Am J Clin Pathol. 2000;113(1):12-17. doi:10.1309/XHBK-C91T-Y2C6-6LOB
5. Elgouhari HM, Abu-Rajab Tamimi TI, Carey W. Hepatitis B: a strategy for evaluation and management [published correction appears in Cleve Clin J Med. 2009 Feb;76(2):128]. Cleve Clin J Med. 2009;76(1):19-35. doi:10.3949/ccjm.76a.08025

Performance

Method Description

The Elecsys Anti-HBc (hepatitis B virus core antibody) IgM assay is based on the sandwich immunoassay principle and performed with an electrochemiluminescence immunoassay on the automated cobas e 801 immunochemistry analyzer. Anti-HBc IgM present in patient's sample is pretreated with anti-Fdy reagent to block specific IgG. After addition of biotinylated monoclonal human IgM-specific antibodies, the complexes formed from reaction of ruthenium-labeled HBc antigen, streptavidin-coated microparticles (solid phase), anti-HBc IgM present in the sample, and the biotinylated anti-human IgM bind to the solid phase via interaction of biotin and streptavidin. The reaction mixture is then aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode, and unbound substances are washed away. Voltage is applied to the electrode that induces chemiluminescent emissions, which are measured by a photomultiplier. Test result is determined by comparing the electrochemiluminescence signal generated from the sample to the cutoff index value set from reagent lot-specific assay calibration. (Package insert: Elecsys Anti-HBc IgM. Roche Diagnostics; v1.0, 09/2020)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

5 days

Specimen Retention Time

7 days

Performing Laboratory Location

Clinical Pathology Laboratories Inc.

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 account representative. For assistance, contact [Customer Service](#).

Test Classification

This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by the performing lab in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

86707

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
SHEAB	Hepatitis B e Antibody, S	Not Provided

Result ID	Test Result Name	Result LOINC® Value
SHEAB	Hepatitis B E Antibody, S	Not Provided