

## Overview

### Useful For

Determining infectivity of hepatitis B virus (HBV) carriers

Monitoring infection status of individuals with chronic hepatitis B

Monitoring serologic response of chronically HBV-infected patients receiving antiviral therapy

Determining the level of hepatitis B e antibody

### Testing Algorithm

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

### Additional Testing Requirements

If ordered with HBVQN / Hepatitis B Virus (HBV) DNA Detection and Quantification by Real-Time PCR, Serum; send separate vials.

### 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.

**Collection Container/Tube:** Serum gel

**Submission Container/Tube:** Plastic vial

**Specimen Volume:** 1 mL

**Collection Instructions:** Centrifuge and aliquot serum into plastic vial within 24 hours.

### Forms

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

### Specimen Minimum Volume

0.5 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 and Interpretive

### Clinical Information

During recovery from acute hepatitis B, the hepatitis B e antigen (HBeAg) level declines and becomes undetectable and hepatitis B e antibody (anti-HBe) appears in the serum. Anti-HBe usually remains detectable for several years after recovery from acute infection.

In hepatitis B virus (HBV) carriers and in patients with chronic hepatitis B, positive anti-HBe results usually indicate inactivity of the virus and low infectivity of the patients. Positive anti-HBe results in the presence of detectable HBV DNA in serum indicate active viral replication.

See the following in Special Instructions:

[-HBV Infection-Diagnostic Approach and Management Algorithm](#)

[-Viral Hepatitis Serologic Profiles](#)

### Reference Values

Negative

See [Viral Hepatitis Serologic Profiles](#) in Special Instructions.

### Interpretation

Absence of hepatitis B e antigen (HBeAg) with appearance of HBe antibody (anti-HBe) is consistent with inactivity of the virus and loss of hepatitis B virus (HBV) infectivity.

Although resolution of chronic HBV infection generally follows the appearance of anti-HBe, the HBV carrier state may persist.

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**Cautions**

Biotin (vitamin B7) is a common ingredient in multivitamins and dietary supplements to enhance hair, nail, and skin growth. Biotin can interfere with the assay performance and cause possible false-negative hepatitis B e-antigen (HBeAg) and false-positive HBe antibody (anti-HBe) results. Patients should be instructed to stop taking such multivitamins and dietary supplements for at least 24 hours prior to blood collection.

Appearance of anti-HBe in serum does not completely rule-out chronic hepatitis B carrier state or infectivity.

Performance characteristics of this assay have not been established in patients under the age of 2 or in populations of immunocompromised or immunosuppressed patients. This assay is not licensed by 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 (triglyceride level of >3000 mg/dL)
- Grossly hemolyzed (hemoglobin level of >124 mg/dL)

**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
2. Servoss JC, Friedman LS: Serologic and molecular diagnosis of hepatitis B virus. *Clin Liver Dis.* 2004;8:267-281
3. Terrault NA, Bzowej NH, Chang KM, et al: AASLD guidelines for treatment of chronic hepatitis B. *Hepatology.* 2016;63:261-283
4. WHO Guidelines Development Group: World Health Organization: Guidelines on hepatitis B and C testing. World Health Organization; 2017. Accessed September 29, 2020. Available at [www.who.int/hepatitis/publications/guidelines-hepatitis-c-b-testing/en](http://www.who.int/hepatitis/publications/guidelines-hepatitis-c-b-testing/en)
5. LeFebvre 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;161:58-66. doi:10.7326/M14-1018
6. Jackson K, Locarnini S, Gish R: Diagnostics of hepatitis B virus: Standard of care and investigational. *Clin Liver Dis (Hoboken).* 2018;12(1):5-11. doi: 10.1002/cld.729.
7. Coffin CS, Zhou K, Terrault NA: New and old biomarkers for diagnosis and management of chronic hepatitis B virus infection. *Gastroenterol.* 2019;156:355-368. doi: 10.1053/j.gastro.2018.11.037.
8. Centers for Disease Control and Prevention. Testing and public health management of persons with chronic hepatitis B virus infection. Accessed April 8, 2020. Available at [www.cdc.gov/hepatitis/hbv/testingchronic.htm](http://www.cdc.gov/hepatitis/hbv/testingchronic.htm)

**Performance****Method Description**

This test is performed using a competitive technique, which involves preincubation of anti-hepatitis B e (anti-HBe)

IgG in the patient sample with a fixed weight of hepatitis B e antigen in the assay reagent, followed by incubation with a conjugate reagent that contains biotinylated mouse monoclonal anti-HBe IgG and horseradish peroxidase (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 is 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\_US\_EN, version 9.1. [Ortho-Clinical Diagnostics, Inc](#); 09/06/2019)

### PDF Report

No

### Day(s) Performed

Monday through Saturday

### Report Available

Same day/1 to 2 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 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

86707

### LOINC® Information

Test ID	Test Order Name	Order LOINC Value
HEAB	HBe Antibody, S	33463-1

Result ID	Test Result Name	Result LOINC Value
HEAB	HBe Antibody, S	33463-1

