

---

## 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 Be antigen

### Testing Algorithm

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](#)

### Method Name

Chemiluminescence Immunoassay

### NY State Available

Yes

---

## Specimen

### Specimen Type

Serum SST

### Ordering Guidance

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.

**Reject Due To**

Gross hemolysis    Reject  
Gross lipemia      Reject  
Gross icterus        Reject

**Specimen Minimum Volume**

0.5 mL

**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Serum SST	Frozen (preferred)	28 days	
	Refrigerated	7 days	
	Ambient		

**Clinical & Interpretive****Clinical Information**

Hepatitis Be antigen (HBeAg) is found in the early phase of hepatitis B infection soon after hepatitis B surface antigen becomes detectable. Serum levels of both antigens rise rapidly during the period of viral replication. The presence of HBeAg correlates with hepatitis B virus (HBV) infectivity, the number of infectious virions, and the presence of HBV core antigen in the infected hepatocytes.

---

In HBV carriers and patients with chronic hepatitis B, positive HBeAg results usually indicate presence of active HBV replication and high infectivity. A negative HBeAg result indicates very minimal or no HBV replication.

See the following in Special Instructions:

[-Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management](#)

[-Viral Hepatitis Serologic Profiles](#)

### Reference Values

Negative

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

### Interpretation

Presence of hepatitis Be antigen (HBeAg) and absence of HBe antibody (anti-HBe) usually indicate active hepatitis B virus (HBV) replication and high infectivity.

Absence of HBeAg with appearance of anti-HBe is consistent with loss of HBV infectivity.

### 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 Be antigen (HBeAg) and false-positive anti-HBe results. Patients should be instructed to stop taking such multivitamins and dietary supplements for at least 24 hours prior to blood collection.

Disappearance of HBeAg or 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 specimens 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 >20 mg/dL)
  - Grossly lipemic (triolein level >3000 mg/dL)
  - Grossly hemolyzed (hemoglobin level >61 mg/dL)
  - Specimen containing particulate matter

**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. 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
5. 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.
6. Coffin CS, Zhou K, Terrault NA: New and old biomarkers for diagnosis and management of chronic hepatitis B virus infection. *Gastroenterol.* 2019;156:355-368doi: 10.1053/j.gastro.2018.11.037.
7. 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/)
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 an immunometric technique involving the simultaneous reaction of hepatitis B e antigen (HBeAg) in the sample with biotinylated mouse monoclonal HBeAg antibody, and horseradish peroxidase (HRP)-labeled mouse monoclonal HBeAg antibody in the conjugate. The immune complex is captured by streptavidin on the wells, and 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 HBeAg present in the sample. (Package insert: VITROS Immunodiagnostic Product HBeAg Reagent Pack, No. GEM1222\_US\_EN, version 9.1. Ortho-Clinical Diagnostics, Inc; 09/06/2019)

**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**

87350

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
EAG	Hepatitis Be Ag, S	13954-3

Result ID	Reporting Name	LOINC®
EAG	Hepatitis Be Ag, S	13954-3