

## Overview

### Useful For

Determining the presence or absence of detectable hepatitis B virus e antibody in monitoring infection status of individuals with chronic hepatitis B

Determining infectivity of hepatitis B virus (HBV) carriers

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

### Testing Algorithm

For more information 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

Electrochemiluminescence Immunoassay (ECLIA)

### NY State Available

No

## 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, patient **should not** take multivitamins or dietary supplements (eg, hair, skin, and nail supplements) containing biotin (vitamin B7).

**Supplies:** Sarstedt Aliquot Tube, 5 mL (T914)

**Collection Container/Tube:** Serum gel (red-top tubes are **not acceptable**)

**Submission Container/Tube:** Plastic vial

**Specimen Volume:** 0.7 mL

**Collection Instructions:**

1. Centrifuge blood collection tube per manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).
2. Aliquot serum into plastic vial.

**Forms**

If not ordering electronically, complete, print, and send 1 of the following with the specimen:

- [Infectious Disease Serology Test Request](#) (T916)
- [Gastroenterology and Hepatology Test Request](#) (T728)

**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)	90 days	
	Ambient	72 hours	
	Refrigerated	6 days	

**Clinical & Interpretive**

**Clinical Information**

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

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.

For more information, see the following:

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

**Reference Values**

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Negative

See [Viral Hepatitis Serologic Profiles](#).

**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.

**Cautions**

For diagnostic purposes, results should always be assessed in conjunction with the patient's medical history, clinical examination, and other findings.

Serum specimens from individuals taking multivitamins containing biotin or biotin supplements at 20 mg or more per day may have false-positive hepatitis B e antibody (anti-HBe) test results due to interference of biotin with the assay. Such individuals should stop taking these biotin-containing dietary supplements for a minimum of 12 hours before blood collection for this test.

In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin, or ruthenium can occur, causing false-positive anti-HBe results. These effects are minimized by suitable test design.

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

Assay performance characteristics have not been established when Elecsys Anti-HBe assay is used in conjunction with other manufacturers' assays for specific HBV serological markers.

Assay performance characteristics have not been established for the following specimen characteristics or specimen types:

- Grossly icteric (total bilirubin level of >66 mg/dL)
- Grossly lipemic (intralipid level of >2000 mg/dL)
- Grossly hemolyzed (hemoglobin level of >2000 mg/dL)
- Specimen types other than serum

**Clinical Reference**

1. LeFevre 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(1):58-66. doi:10.7326/M14-1018
2. Terrault NA, Bzowej NH, Chang KM, et al. AASLD guidelines for treatment of chronic hepatitis B. *Hepatology.* 2016; 63(1):261-283
3. WHO guidelines on hepatitis B and C testing. Geneva: World Health Organization; February 2017. Accessed December 21, 2023. Available at [www.who.int/publications/i/item/9789241549981](http://www.who.int/publications/i/item/9789241549981)
4. Jackson K, Locarnini S, Gish R. Diagnostics of hepatitis B virus: Standard of care and investigational. *Clin Liver Dis.* 2018; 12(1):5-11. doi:10.1002/cld.729
5. Coffin CS, Zhou K, Terrault NA. New and old biomarkers for diagnosis and management of chronic hepatitis B virus

infection. Gastroenterology. 2019; 156(2):355-368. doi:10.1053/j.gastro.2018.11.037

6. Connors EE, Panagiotakopoulos L, Hofmeister MG, et al. Screening and testing for hepatitis B virus infection: CDC Recommendations-United States, 2023. MMWR Recomm Rep. 2023;72(1):1-25

## Performance

### Method Description

The Elecsys Anti-HBe (hepatitis B e antibody) assay will be performed on the fully automated cobas e 801 electrochemiluminescence immunoassay analyzer. During the first incubation, anti-HBe present in the patient's sample binds to the added HBe antigen (HBeAg). In the second incubation, the still-free binding sites on the HBeAg become occupied after addition of biotinylated antibodies and ruthenium complex-labeled antibodies specific for HBeAg, together with streptavidin-coated microparticles. The entire complex becomes bound 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. Unbound substances are then washed away, and application of a voltage to the electrode then induces chemiluminescent emission, which is measured by a photomultiplier. Test result for each patient's sample is determined automatically by the assay-specific software program by comparing the electrochemiluminescence signal obtained from the sample with the cutoff index value set from reagent lot-specific assay calibrations.(Elecsys Anti-HBe. Roche Diagnostics; v1.0, 12/2021)

### PDF Report

No

### Day(s) Performed

Monday through Friday, Sunday

### Report Available

Same day/1 to 3 days

### Specimen Retention Time

7 days

### Performing Laboratory Location

Mayo Clinic Jacksonville Clinical Lab

## 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 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