

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

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, 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 | Ambient | 72 hours | |
| | Refrigerated | 6 days | |
| | Frozen (preferred) | 90 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

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
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 virus e antibody) assay is based on the competitive immunoassay principle and performed using an electrochemiluminescence method on the automated cobas e 801 immunochemistry analyzer. Anti-HBe present in the patient's sample binds to the added synthetic HBe antigen (HBeAg). The remaining unbound sites on the synthetic HBeAg become occupied with the added biotinylated antibodies and ruthenium complex-labeled antibodies specific for HBeAg. The entire complex becomes bound to streptavidin-coated microparticles (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. After unbound substances are washed away, voltage is applied to the electrode, which induces chemiluminescent emission that is measured by a photomultiplier. Test result is determined by comparing the electrochemiluminescence signal generated from the reaction product to the cutoff index value set from reagent lot-specific assay calibration. (Package insert: Elecsys Anti-HBe. Roche Diagnostics; v1.0, 12/2021)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

Same day/1 to 3 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

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 |