MAYO CLINIC LABORATORIES

Test Definition: HEAG

Hepatitis B Virus e Antigen and Hepatitis B Virus e Antibody, Serum

Overview

Useful For

Determining the presence or absence of detectable hepatitis B virus e antigen and 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

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
EAG	Hepatitis Be Ag, S	Yes	Yes
HEAB	HBe Antibody, S	Yes	Yes

Special Instructions

- Viral Hepatitis Serologic Profiles

Method Name

Electrochemiluminescence Immunoassay (ECLIA)

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, 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: 0.8 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 a plastic vial.

Forms
If not ordering electronically, complete, print, and send 1 of the following:
-Gastroenterology and Hepatology Test Request (T728)
-Infectious Disease Serology Test Request (T916)

Specimen Minimum Volume
0.7 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
Hepatitis B virus (HBV) e antigen (HBeAg) is a small polypeptide, which exists in a free form in the serum of individuals during the early phase of hepatitis B infection, soon after hepatitis B virus surface antigen (HBsAg) becomes detectable. Serum levels of both HBeAg and HBsAg rise rapidly during the period of viral replication. The presence of HBeAg in serum correlates with viral infectivity, the number of infectious virions, and the presence of HBV core antigen in the infected hepatocytes.

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

after recovery from acute HBV infection.

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. Positive anti-HBe test results usually indicate inactivity of the virus and low infectivity, and such positive results in the presence of detectable HBV DNA in serum also indicate active viral replication in these patients.

Reference Values

HEPATITIS Be ANTIGEN:
Negative

HEPATITIS Be ANTIBODY:
Negative

For more information see Viral Hepatitis Serologic Profiles.

Interpretation

Presence of hepatitis B virus e 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.

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

Cautions

Serum specimens from individuals taking multivitamins containing biotin or biotin supplements of 20 mg or more per day may have false-negative hepatitis B virus e antigen (HBeAg) and false-positive HBe antibody (anti-HBe) 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.

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

Performance characteristics of these 2 assays have not been established in patients younger than 2 years, pregnant women, or in populations of immunocompromised or immunosuppressed patients. These 2 assays are not licensed by US Food and Drug Administration 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 >25 mg/dL)
-Grossly lipemic (Intralipid level of >1000 mg/dL)
-Grossly hemolyzed (hemoglobin level of >2000 mg/dL)
-Specimen containing particulate matter

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. World Health Organization; 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. Conners 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

Hepatitis B Virus e Antigen:
The Elecsys HBeAg (hepatitis B e antigen) assay is based on the sandwich principle and performed using an electrochemiluminescence immunoassay on the automated cobas e 801 immunochemistry analyzer. HBeAg present in patient's sample reacts with 2 biotinylated monoclonal anti-HBeAg antibodies and a mixture of monoclonal anti-HBeAg antibody and polyclonal anti-HBeAg antibodies labeled with a ruthenium complex react to form a sandwich complex. After addition of streptavidin-coated microparticles (solid phase), the complexes bind to this solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then washed away, and voltage is applied to the electrode that induces chemiluminescent emissions, which are measured by a photomultiplier. The test result is determined by comparing the electrochemiluminescence signal generated from the patient's sample to the cutoff index (COI) value set from reagent lot-specific assay calibration.(Package insert: Elecsys HBeAg. Roche Diagnostics, v1.0, 10/2020)

Hepatitis B Virus e Antibody:
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 first binds to the added synthetic 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 the 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. Unbound substances are then washed away, and 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 COI value set from reagent lot-specific assay calibration.(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
Mayo Clinic Laboratories - Rochester Superior Drive

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
87350

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HEAG	Hepatitis Be Ag and Ab, S	77176-6

Result ID	Test Result Name	Result LOINC® Value
EAG	Hepatitis Be Ag, S	13954-3
HEAB	HBe Antibody, S	33463-1