MAYO CLINIC LABORATORIES

Test Definition: EAG

Hepatitis B Virus e Antigen, Serum

Overview

Useful For

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

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: 0.7 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:

-Gastroenterology and Hepatology Test Request (T728)

-Infectious Disease Serology Test Request (T916)

Specimen Minimum Volume

0.6 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject
Heat-inactivated specimen	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

Hepatitis B virus e antigen (HBeAg) is found in the early phase of hepatitis B infection soon after hepatitis B virus 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.

For more information, see the following:

-Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management

-Viral Hepatitis Serologic Profiles

Reference Values

Negative

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.

Cautions

This assay has not been licensed by the US Food and Drug Administration for testing cord blood specimens or screening donors of blood, plasma, human cell, or tissue products.

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

Specimens should not be taken from patients receiving therapy with high biotin doses (ie, >5 mg/day) until at least 8 hours following the last biotin administration.

Drug interference studies were performed in vitro and may not assess the potential interferences that might be seen after the drugs are metabolized in vivo.

A reactive hepatitis B virus e antigen (HBeAg) result does not exclude co-infection by another hepatitis virus. False positive results due to non-specific reactivity cannot be ruled out with the Elecsys HBeAg assay. In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur.

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

A non-reactive test result does not exclude the possibility of exposure to hepatitis B virus. Negative HBeAg results may occur during early infection due to delayed seroconversion. False negative results may occur due to antigen levels below the detection limit of this assay or if the patient's antigen does not react with the antibody used in this test.

Results obtained with the Elecsys HBeAg assay may not be used interchangeably with values obtained with different manufacturers' assay methods.

Performance characteristics of this assay have not been established in pregnant women, or in populations of immunocompromised or immunosuppressed patients.

Assay performance characteristics have not been stablished for the following specimen characteristics or specimen types:
-Grossly icteric (total bilirubin level >40 mg/dL)
-Grossly lipemic (intralipid level >2200 mg/dL)
-Grossly hemolyzed (hemoglobin level >2200 mg/dL)

-Specimen containing particulate matter
-Heat-inactivated specimens
-Specimens stabilized with azide
-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. 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

The Elecsys HBeAg (hepatitis B e antigen) assay is 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, the complexes bind to a 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, and unbound substances are washed away. Voltage is applied to the electrode, which induces chemiluminescent emission that 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 generated from the patient’s sample to the cutoff index value set from reagent lot-specific assay calibrations.(Package insert: Elecsys HBeAg. Roche Diagnostics; v1.0, 10/2020)

PDF Report

No

Day(s) Performed

Monday through Friday, Sunday

Report Available

1 to 3 days

Specimen Retention Time
7 days

Performing Laboratory Location
Jacksonville

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
87350

LOINC® Information

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

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