MAYO CLINIC LABORATORIES

Test Definition: HEAG

Hepatitis Be Ag and Ab, S

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 levels of both hepatitis B e antigen and antibody

Special Instructions

- Viral Hepatitis Serologic Profiles

Profile Information

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

Method Name

Chemiluminescence Immunoassay

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 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: 1.5 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

1 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 B e antigen (HBeAg) is a small polypeptide that exists in a free form in the serum of individuals during the early phase of hepatitis B infection, soon after hepatitis B 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 hepatitis B virus (HBV) 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 hepatitis B e 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 results usually indicate inactivity of the virus and low infectivity. Positive anti-HBe 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

See Viral Hepatitis Serologic Profiles in Special Instructions.

Interpretation

Presence of hepatitis B 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

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 B e antigen (HBeAg) and false-positive HBe antibody (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 these 2 assays have not been established in patients under the age of 2 or in populations of immunocompromised or immunosuppressed patients. These 2 assays are not licensed by FDA 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 >20 mg/dL)

-Grossly lipemic (triolein level of >3000 mg/dL)

-Grossly hemolyzed (hemoglobin level of >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. 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/

5. LeFebre 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

6. 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.

7. Coffin CS, Zhou K, Terrault NA: New and old biomarkers for diagnosis and management of chronic hepatitis B virus infection. Gastroenterol. 2019;156:355-368. doi: 10.1053/j.gastro.2018.11.037.

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

Performance

Method Description

Hepatitis B e antigen Assay:

This test is performed using tan immunometric technique is used. This involves the simultaneous reaction of hepatitis B e antigen (HBeAg) in the sample with biotinylated mouse monoclonal hepatitis B e antibody (anti-HBe) and horseradish peroxidase (HRP)-labeled mouse monoclonal anti-HBe 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)

Hepatitis Be antibody Assay:

This test is performed using a competitive technique, which involves pre-incubation of anti-HBe IgG in the sample with a fixed weight of HBeAg in the assay reagent, followed by incubation with a conjugate reagent that contains biotinylated mouse monoclonal anti-HBe IgG and HRP-labeled mouse monoclonal anti-HBe IgG. The immune complex is captured by streptavidin on the wells. 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 anti-HBe IgG present in the sample.(Package insert: VITROS Immunodiagnostic Product Anti-HBe Reagent Pack, No. GEM1223, 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

86707

87350

LOINC® Information

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

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