Test Definition: EAG

Hepatitis Be Ag, 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 level of hepatitis Be antigen

Testing Algorithm

See HBV Infection-Diagnostic Approach and Management Algorithm in Special Instructions.

Special Instructions

- Viral Hepatitis Serologic Profiles
- HBV Infection-Diagnostic Approach and Management Algorithm

Method Name

Chemiluminescence Immunoassay

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 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 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.

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)	28 days	
	Refrigerated	7 days	
	Ambient	24 hours	

Clinical and Interpretive

Clinical Information

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

See the following in Special Instructions:

-HBV Infection-Diagnostic Approach and Management Algorithm

-Viral Hepatitis Serologic Profiles

Reference Values

Negative

See Viral Hepatitis Serologic Profiles in Special Instructions.

Interpretation

Presence of hepatitis Be 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

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 Be antigen (HBeAg) and false-positive 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 this assay have not been established in patients under the age of 2 or in populations of immunocompromised or immunosuppressed patients. This assay is not licensed by FDA for testing cord blood specimens 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 >20 mg/dL)

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

-Grossly hemolyzed (hemoglobin level >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. 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.Â Ann Intern Med. 2014;161:58-66 doi:10.7326/M14-1018

5. Jackson K, Locarnini S, Gish R: Diagnostics of hepatitis B virus: Standard of care and investigational.Â Clin Liver Dis (Hoboken). 2018;12(1):5-11 doi: 10.1002/cld.729.

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

7. 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/

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

This test is performed using an immunometric technique involving the simultaneous reaction of hepatitis B e antigen (HBeAg) in the sample with biotinylated mouse monoclonal HBeAg antibody, and horseradish peroxidase (HRP)-labeled mouse monoclonal HBeAg antibody 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)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

1 to 3 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees and 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 Regional Manager. 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

Test Definition: EAG

Hepatitis Be Ag, S

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