Overview

Useful For
BioPharma clients for detection of hepatitis D virus (HDV)-specific total antibodies (combined IgG and IgM) in human serum.

Diagnosis of concurrent HDV infection in patients with fulminant acute hepatitis B virus (HBV) infection (acute coinfection), chronic hepatitis B (chronic coinfection), or acute exacerbation of known chronic hepatitis B (HDV superinfection).

Highlights
N/A

Method Name
Enzyme Immunoassay (EIA)

NY State Available
Yes

Reporting Name
HDV Total Ab, S

Aliases
- AHDV
- Anti-HDV
- Anti-HDV total
- Delta hepatitis
- HDV
- HDV total antibodies
- Hepatitis D
- Hepatitis D total antibodies
- Hepatitis D virus
- Hepatitis D virus antibodies
- Hepatitis delta total antibodies

Specimen

Specimen Type
Serum

Specimen Required
Container/Tube: Sarstedt Aliquot Tube, 5 mL (T914)
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.4 mL
Collection Instructions:
1. Centrifuge blood collection tube per collection tube manufacturer's instructions (e.g., centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).
2. Aliquot serum into plastic vial.

Specimen Minimum Volume
0.3 mL

Reject Due To

Gross hemolysis	Reject
Thawing	Cold, ok; Warm, reject
Gross lipemia	Reject
Gross icterus	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	30 days	
	Refrigerated	30 days	

Clinical & Interpretive

Clinical Information
Hepatitis D virus (HDV), also known as delta hepatitis virus, is a defective RNA virus comprised of a delta antigen and a hepatitis B surface antigen as the core and protein coat of the virus, respectively. This virus cannot replicate effectively by itself as it requires the presence of hepatitis B virus (HBV) to initiate and maintain its replication in the infected liver cells.

Infection with HDV occurs either as an acute coinfection with HBV or an acute superinfection of chronic HBV. Acute HBV-HDV coinfection usually follows a self-limited clinical course with spontaneous resolution but may have a fulminant clinical presentation. HDV superinfection in chronic HBV, or HBV carrier state, typically manifests as an acute exacerbation of chronic hepatitis B, with tendency to result in chronic HBV-HDV coinfection and early cirrhosis or liver failure. In the United States, chronic HDV infection is found in 1% of all individuals with a chronic HBV-infection.

Diagnosis of HDV can be established by detecting HDV antigen, HDV-specific IgM, HDV-specific total antibodies (combined IgM and IgG), or HDV RNA in the sera of infected patients with clinically evident acute or chronic hepatitis B. Anti-HDV IgM typically appears in serum at 2 to 3 weeks after onset of symptoms and disappears by 2 months after acute HDV infection, but it may persist up to 9 months in HDV superinfection. HDV total antibodies and HDV RNA persist in serum after resolution of acute HDV infection and in chronic coinfection.

Reference Values
Negative

Interpretation
This assay detects the presence of hepatitis D virus (HDV)-specific total (combined IgG and IgM) antibodies in serum.

Negative results indicate the absence of HDV infection and no past exposure to HDV.

Equivocal results indicate borderline level of anti-HDV total antibodies. Repeat testing in 1 to 2 weeks is recommended to determine the definitive HDV infection status.

Positive results usually indicate simultaneous acute or chronic coinfection with hepatitis B virus (HBV) and HDV; acute HDV infection in patients with known chronic HBV infection (i.e., HDV superinfection); or resolved HDV infection. Results should be correlated with medical history and clinical findings.

Cautions
Negative results may not rule out hepatitis D virus (HDV) infection during the early phase of infection or in

immunocompromised patients who have delayed or inadequate immune response.

False-positive results may be due to cross-reactive antibodies from other viral infections or underlying illnesses. Positive results should be correlated with the patient's clinical history, physical examination findings, and risk factors for HDV infection.

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 >500 mg/dL)
-Containing particulate matter
-Cadaveric specimens

Clinical Reference

1. Olivero A, Smedile A. Hepatitis delta virus diagnosis. Semin Liver Dis. 2012;32(3):220-227
2. Shah PA, Choudhry S, Reyes KJC, Lau DTY. An update on the management of chronic hepatitis D. Gastroenterol Rpt (Oxf). 2019;7(6):396-402. doi:10.1093/gastro/goz052
3. Chen LY, Pang XY, Goyal H, et al. Hepatitis D: challenges in the estimation of true prevalence and laboratory diagnosis. Gut Pathog. 2021;13(1):66. doi:10.1186/s13099-021-00462-0

Performance

Method Description

This test is performed using a competitive enzyme immunoassay in which hepatitis delta virus-specific antibodies (anti-HDV) compete with virus-specific polyclonal IgG antibody labelled with horseradish peroxidase (HRP) for a fixed amount of recombinant HDV protein coated on the microplate wells. Patient serum sample is added first to the microplate well, in which anti-HDV IgG and IgM antibodies will bind to the recombinant HDV protein coated in the well. After washing, a polyclonal anti-HDV-enzyme conjugate is added and allowed to bind to unbound recombinant HDV protein coated in the well. After another wash, a chromogenic mixture is added as a substrate for the HRP enzymatic reaction. Concentration of the enzyme conjugate bound to the coated well is inversely proportional to the amount of anti-HDV total antibodies present in the patient sample. The concentration of anti-HDV total antibodies present is determined by comparing the calorimetric reaction signal to a calibrated cut-off signal value. (Package insert: HDV AB. International Immuno Diagnostics; Rev. 6 0917)

Day(s) Performed

Monday, Friday. Days performed may be flexible if samples are scheduled to arrive in a batch.

Report Available

1 to 7 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

CLIA Laboratory Number

24D1040592

Test Classification

This test was developed and its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.