MAYO CLINIC LABORATORIES

Test Definition: AHDV

Hepatitis D Virus (HDV) Total Antibodies with Reflex to HDV RNA Detection and Quantitation, PCR, Serum

Overview

Useful 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)

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
HDVQU	HDV RNA Detect / Quant, S	Yes	No

Testing Algorithm

This test begins with hepatitis D virus (HDV) total antibodies by enzyme immunoassay. If the result is equivocal or positive, then HDV RNA detection/quantification will be performed at an additional charge.

For more information see Hepatitis D: Diagnostic Testing Algorithm.

Special Instructions

- Hepatitis D: Diagnostic Testing Algorithm

Method Name

Enzyme Immunoassay (EIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Necessary Information

Date of collection is required.

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 1.5 mL
Collection Instructions:
1. Centrifuge blood collection tube per collection tube 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:
-Kidney Transplant Test Request
-Gastroenterology and Hepatology Test Request (T728)
-Infectious Disease Serology Test Request (T916)

Specimen Minimum Volume

See Specimen Required

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	30 days	
	Refrigerated	5 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 (ie, HDV superinfection); or resolved HDV infection. All such antibody-positive specimens will automatically reflex to HDV RNA testing. 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. A positive result should be correlated with the patient's clinical history, physical examination findings, and risk factors for HDV infection. A positive antibody result with negative HDV RNA may be due to either false-positive antibody results or past/resolved hepatitis D.

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. 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
2. 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
3. Razavi HA, Buti M, Terrault NA, et al: Hepatitis D double reflex testing of all hepatitis B carriers in low-HBV- and high-HBV/HDV-prevalence countries. J Hepatol 2023;79:576-580. https://doi.org/10.1016/j.jhep.2023.02.041

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 that is labeled 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)

PDF Report

No

Day(s) Performed

Monday, Friday

Report Available

1 to 7 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 was developed and its performance characteristics 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.

CPT Code Information

86692
87523 if needed

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
AHDV	HDV Total Ab + reflex to HDV RNA, S	40727-0

Result ID	Test Result Name	Result LOINC® Value
9209	HDV Total Ab, S	40727-0