

## 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 HBV infection (chronic coinfection), or acute exacerbation of known chronic HBV infection (HDV superinfection)

### Special Instructions

- [Viral Hepatitis Serologic Profiles](#)

### Method Name

Enzyme Immunoassay (EIA)

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Necessary Information

Date of collection is required.

### Specimen Required

Collection Container/Tube:

**Preferred:** Serum gel

**Acceptable:** Red top

**Submission Container/Tube:** Plastic vial

**Specimen Volume:** 1 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 a [Gastroenterology and Hepatology Client Test Request](#) (T728) with the specimen.

### Specimen Minimum Volume

0.2 mL

**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	30 days	

**Clinical and 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 (HBsAg) 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 in 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. Chronic HDV infection is found in 1% of all chronically HBV-infected individuals in the United States.

Diagnosis of HDV can be established by detecting HDV antigen, HDV-specific IgM, or HDV-specific total antibodies (combined IgM and IgG) 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 IgG and HDV total antibodies 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 one of the following conditions: 1) simultaneous acute or chronic coinfection with

hepatitis B virus (HBV) and HDV, 2) acute HDV infection in patients with known chronic HBV infection (ie, HDV superinfection), or 3) resolved HDV infection. Results should be correlated with medical history and clinical findings.

See [Viral Hepatitis Serologic Profiles](#) in Special Instructions.

### 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 infection or underlying illnesses. Positive result 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 (triglyceride level of >3000 mg/dL)
- Grossly hemolyzed (hemoglobin level of >500 mg/dL)
- Containing particulate matter
- Cadaveric specimens

### Clinical Reference

1. Hughes SA, Wedemeyer H, Harrison PM: Hepatitis delta virus. *Lancet*. 2011;378:73-85
2. Pascarella S, Negro F: Hepatitis D virus: an update. *Liver International*. 2011;31(1):7-21
3. Olivero A, Smedile A: Hepatitis delta virus diagnosis. *Semin Liver Dis*. 2012;32:220-227

### 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 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 09/2017)

#### PDF Report

No

#### Day(s) and Time(s) Test Performed

Monday, Thursday; Varies

**Analytic Time**

1 day

**Maximum Laboratory Time**

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

**CPT Code Information**

86692

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
AHDV	HDV Total Ab, S	40727-0

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