

Hepatitis D Antigen, IgM Antibody, and Total HDV in Serum

Specimen Type	Serum		
Specimen Volume	1.0 mL		
Collection	Hepatitis D Total: Serum gel separator tube or Red top tube with no additives Hepatitis D IgM: Red top tube with no additives Hepatitis D Antigen: Red top tube with no additives Allow blood to clot for 30 minutes. Centrifuge then aliquot serum into a transfer tube. Freeze immediately.		
Minimum Volume	0.5 mL		
Handling	Ship frozen on dry ice.		
Rejection Criteria	Grossly hemolyzed specimens Grossly lipemic serum Specimens outside of listed stability		
Stability	IgM	Ag	Total
	Refrigerated for 7 days. Frozen for 180 days.	Refrigerated for up to 7 days Frozen for 90 days. Stable up to 3 freeze-thaw cycles.	Refrigerated for 14 days. Frozen for 30 days. Stable up to 3 freeze-thaw cycles.
Methodology	ELISA		
Reference Range	Negative		
Turnaround Time	Hepatitis D Total: Up to 7 business days. Hepatitis D IgM: Up to 7 business days. Hepatitis D Antigen: Up to 7 business days.		
CPT Code	IgM: 86692 Ag: 87380 Total: 86692		

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<p>Clinical Significance</p>	<p>The Hepatitis Delta Virus (HDV) is a defective RNA virus, composed of a core presenting the delta-specific antigen and encapsulated by Hepatitis B surface antigen, which requires the helper function of Hepatitis B virus (HBV) to support its replication.</p> <p>Infection by HDV occurs in the presence of acute or chronic HBV infection. When acute delta and acute HBV simultaneously occur, the illness becomes severe and clinical and biochemical features may be indistinguishable from those of HBV infection alone. In contrast, a patient with chronic HBV infection can support HDV replication indefinitely, usually with a less severe illness appearing as a clinical exacerbation.</p> <p>The determination of HDV specific serological markers (HDV Ag, HDV IgM and HDV IgG) represents, in these cases, an important tool to the clinician for the classification of the etiological agent, and follow up of infected patients and monitoring their treatment. The detection of HDV IgM and IgG antibodies allows the classification of the illness and the monitoring of the seroconversion event. The Hepatitis D antigen test is intended for the follow-up of HDV infected individuals.</p>
<p>Principle</p>	<p>Determination of IgM class antibodies, total anti-HDV antibodies, and the HDV antigen utilize sandwich enzyme immunoassay.</p> <p>The HDV assay utilizes microplates coated with a monoclonal anti-human IgM antibody that captures IgM antibodies in the patient sample. After washing out all the other components of the sample, bound anti-HDV IgM antibodies are detected by the addition of recombinant HDV antigen immunocomplexed with a specific antibody labeled with horseradish peroxidase. After another washing step, a substrate/chromogen mixture is added which generates an optical signal that is proportional to the amount of IgM antibodies present in the sample.</p> <p>In the antigen assay, the HDV antigen is captured by a specific monoclonal antibody during the first incubation. A detergent is added to the sample in order to dissolve the specific antigen from HDV particles. After washing, a tracer, composed of a second anti-HDV antigen antibody labeled with horseradish peroxidase (HRP), is added to the microplate and binds to the captured HDV antigen. The concentration of the enzyme bound on the solid phase is directly proportional to the amount of HDV antigen in the sample, and its activity is detected by adding the chromogen/substrate in the final incubation. The presence of HDV antigen in the sample is determined by means of a cutoff value that allows for the semi-quantitative detection of the antigen.</p>