WANTAI HDV-IgM ELISA

Developing Scientifically

Focusing on the Health

Sensitivity: **100%**
Specificity: **100%**
Incubation time: **30'+30'+15'**
Specimen volume: **10μl**
Shelf-life: **15 months**

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Principle of the Test

WANTAI HDV-IgM ELISA is a solid phase, two-step incubation, antibody capture ELISA method in which polystyrene microwell strips are pre-coated with antibodies directed to human immunoglobulin M proteins (anti-μ chain). The patient's serum/plasma sample is diluted and added into the wells, and during the first incubation step, any IgM antibodies will be captured. After washing out all the other components of the sample and in particular IgG antibodies, the specific HDV IgM captured on the solid phase is detected by the addition of purified HDV antigens conjugated to horseradish peroxidase (HRP-Conjugate). During the second incubation step, the conjugated antigens will react only with the specific HDV IgM antibodies and after washing to remove unbound HRP-conjugate, Chromogen solutions are added into the wells. In presence of the (anti-μ)-(HDV-IgM)-(HDV antigen-HRP) immunocomplex, the colorless Chromogens are hydrolyzed by the bound HRP conjugate to a blue-colored product. The blue color turns yellow after stopping the reaction with sulfuric acid. The amount of color can be measured and is proportional to the amount of antibody in the sample. Wells containing samples negative for HDV-IgM remain colorless.

Clinical Sensitivity

The clinical sensitivity of this assay has been calculated by a panel of samples obtained from 2500 hepatitis B acute and chronic patients in which, 2400 samples were found HBsAg positive. After testing with HDV RT-PCR, 150 individuals were diagnosed infected with HDV. During testing with this HDV-IgM ELISA kit, 107 of the HDV RT-PCR confirmed positive samples were found positive for HDV-IgM and 107 samples were confirmed HDV-IgM positive when tested with another commercially available HDV-IgM ELISA kit. The sensitivity is **100%**.

Clinical Specificity

The clinical specificity of this assay has been evaluated by a panel of samples obtained from 500 healthy individuals. No false positive results observed which indicates **100%** specificity of the test.

Analytical Specificity

No interferences have been observed when testing patients with other HDV-unrelated clinical conditions like HIV, HCV, HAV and TP.

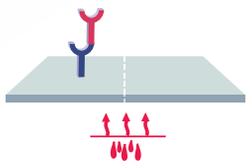
No interference was observed from rheumatoid factors up to **2000U/ml**.

Principle and Procedures

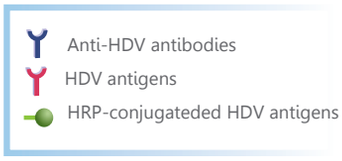
1

- Microwell strips pre-coated with anti-HDV antibodies (anti-μ chain)

2

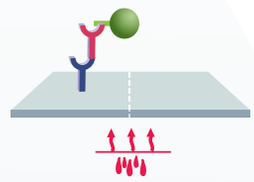


- Add 100μl of diluted specimens
  Add 10μl of Specimens/ Controls
  Incubation at 37℃ for 30 min



3 **5 Wash cycles**

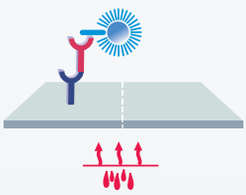
4



- Add 100μl of HRP-Conjugate
  Incubation at 37℃ for 30 min

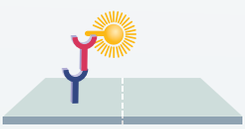
5 **5 Wash cycles**

6



- Add 50μl of Chromogen Solution A and 50μl of Chromogen Solution B
  Incubation at 37℃ for 15 min

7



- Add 50μl of Stop Solution

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- Read by single wavelength 450nm or dual wavelength 450/600~650nm

Ordering Info

Cat.	Product	Detection	Specimen	Pack size
WD-6296	WANTAI HDV-IgM ELISA	Antibody	Serum/Plasma	96T/kit