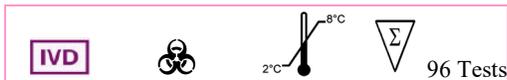


## AccuDiag™ HAV IgM ELISA Kit

REF 1718-12



<b>Test</b>	<b>HAV IgM ELISA</b>
<b>Method</b>	<b>Enzyme Linked Immunosorbent Assay</b>
<b>Principle</b>	<b>Competitive ELISA: Antibody Capture</b>
<b>Detection Range</b>	<b>Qualitative: Positive &amp; Negative Control</b>
<b>Sample</b>	<b>100 ul serum/plasma</b>
<b>Total Time</b>	<b>~ 85 min</b>
<b>Shelf Life</b>	<b>12 Months from the manufacturing date</b>

*\* Laboratory results can never be the only base of a medical report. The patient history and further tests have to be taken into account.*

### INTENDED USE

HAV IgM ELISA Test is an enzyme-linked immunosorbent assay (ELISA) test designed for the qualitative detection of IgM antibodies to HAV in human serum.

### TEST PRINCIPLE

DAI HAV IgM ELISA is a capture immunoassay. The wells were coated with antihuman IgM monoclonal antibody. All IgM antibodies in patient serum are captured during the first incubation period. After wash steps HAV recombinant-HRP is added. If Anti HAV IgM presents it catches recombinant-HRP conjugate during the second incubation period. After wash step and addition of TMB substrate, the bound enzyme generates color. The intensity of the color is directly proportional to the concentration of anti HAV IgM antibodies in the samples.

### SPECIMEN COLLECTION AND PREPARATION

Collect blood by venipuncture. Allow to clot and separate the serum by centrifugation. If samples cannot be assayed immediately, they must be stored at 2-8°C or frozen.

### MATERIALS AND COMPONENTS

#### Materials provided with the test kits

- Eight x 12 well strips coated with HAV recombinant antigen. The strips are packaged in a strip holder and sealed in an envelope with desiccant.
- Negative Control
- Positive Control
- HRP conjugate (6 ml)
- Substrate (TMB 11 ml)
- Stopping solution (10 ml)
- Wash buffer 25 ml (30 X)

#### Materials required but not provided

Microtiter plate reader capable of measuring optical density (OD) at 450 nm either with or without a reference filter of 620-690 nm. Micropipettes capable of delivering 5-200 µl, pipette tip and deionized or distilled water.

### ASSAY PROCEDURE

- Bring all reagents to room temperature and gently mix well.
- Dilute the wash buffer (30 X) and
- Dilute each specimen 1:50 with wash buffer (1X). Mix well.
- Dispense 100µl of negative control and positive control (No dilution needed) and 100µl of diluted serum specimen to the wells.
- Cover the wells and incubate at 37°C for 45 minutes.
- Wash the wells 5 x with diluted wash buffer.
- Blot wells to dry.
- Add 50 µl (1 drop) of HRP conjugate solution to each well and incubate at 37°C for 30 minutes.
- Wash the wells by repeating step 3 and 4.
- Add 100 µl (2 drop) of TMB substrate solution to each well and incubate for 10 minutes at 37°C. (Note: Do not mix TMB with other solutions for use. Use TMB solution only for this step.)
- Add 50-100 µl (1-2 drop) of stop solution to each well. Gently shake wells.
- Set the microplate reader wavelength at 450 nm. Measure the OD of each well. A filter of 620-690 nm can be used as a reference wavelength to optimize the assay result.

### RESULTS

The presence or absence of HAV IgM is determined by comparing the absorbance of the specimens with Cutoff Value of the test. The Cutoff Value for HAV IgM ELISA is calculated as 0.15 + the mean Absorbance of the negative control (if the mean value of negative is <0.050, Cutoff Value = 0.150 + 0.05= 0.200)

### Interpretations

#### Specimen OD ratio

Negative < Cutoff Value  
Positive ≥ Cutoff Value

The negative result indicates that there is no detectable anti HAV IgM antibodies in the specimen while positive result reveals that the patient might currently have been infected by HAV.

**STORAGE**

Store the kit at 2-8°C. Keep the microwell strips sealed with desiccants in the aluminum bag. All kit components are stable until the expiration date printed on the label if the recommended storage conditions are strictly followed.

**ISO 13485**  
**ISO 9001**



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