AccuDiag™ HAV IgG ELISA Kit

REF 1519-P1

IVD See External Label 2-8°C 96 Tests

HAV IgG ELISA	
Principle	Indirect ELISA
Detection	Qualitative
Sample	100 µL serum/plasma
Incubation Time	85 minutes
Sensitivity	100%
Specificity	99.38%
Shelf Life	12 Months from the manufacturing date

PRODUCT FEATURES

- Very easy to use with little training
- Highly specific and consistent Assay
- Provides accurate results quickly
- Reading of results both visually and as absorbance data

INTENDED USE

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

ASSAY PRINCIPLE

The wells of HAV IgG ELISA test are coated with HAV recombinant antigen. During the first incubation period HAV IgG if present, will react with HAV antigen bound to the wells. After addition of anti-human IgG HRP conjugate it binds to human IgG to form HRP-human IgG and HAV antigen sandwich. All unbound antibodies and unbound HRP conjugate is washed off. Upon addition TMB substrate, the bound enzyme generates color. The intensity of the color is directly proportional to the concentration of anti HAV IgG antibodies in the samples.

SPECIMEN COLLECTION & 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.

REAGENTS

Materials provided with the kit

1. 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.
2. Negative Control
3. Positive Control
4. IgG-HRP conjugate - 6ml
5. Substrate TMB – 11 ml
6. Stopping solution – 11 ml
7. Wash buffer 30 x -25 ml

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.

REAGENT PREPARATION

1. Bring all reagents to room temperature and gently mix well.
2. Dilute the wash buffer (30x) with deionized or distilled water. Mix well.

ASSAY PROCEDURE

1. Dilute specimens 1:50 with prediluted wash buffer.
2. Dispense 100 µl of negative control, positive control and diluted specimen, to the wells.
3. Cover the wells and incubate at 37°C for 45 minutes.
4. Wash the wells 5 x with diluted wash buffer.
5. Blot wells to dry.
6. Add 50 µl (1 drop) of HRP conjugate solution to each well and incubate at 37°C for 30 minutes.
7. Wash the wells by repeating step 3 and 4.
8. Add 100 µl (2 drops) of TMB substrate solution to each well and incubate for 10 minutes at room temperature. (Note: Do not mix TMB with other solutions for use. Use TMB solution only for this step.)
9. Add 50 µl (1 drop) of stop solution to each well. Gently shake wells.
10. 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 IgG is determined by comparing the absorbance of the specimens with Cutoff Value of the test. The Cutoff Value for HAV IgG ELISA is calculated as 0.1 + the mean Absorbance of the negative control. If the mean value of negative is <0.050, Cutoff Value = 0.100 + 0.05= 0.150.

INTERPRETATION

Specimen OD ratio	
Negative	**< Cutoff Value**
Positive	**≥ Cutoff Value**

The negative result indicates that there is no detectable anti HAV IgG antibodies in the specimen while positive result reveals that the patient might have been exposed to HAV before.

QUALITY CONTROL

The mean OD value of the positive controls deducts mean OD value of the negative control should be greater than 0.300. If not, the test should be considered invalid and should be repeated.

PERFORMANCE CHARACTERISTICS

Sensitivity

The sensitivity was determined by evaluating a panel of 100 HAV IgG positive sera. The HAV lgG ELISA picked up all 100 positive sera.

Specificity

The specificity has been determined on blood donors samples (162 samples tested) and results were confirmed by an FDA approved method. Of 162 samples 161 were tested negative and 1 was positive. The total relative specificity was 99.38%.

Cross Reactivity

No cross reactivity was observed with specimen from patients infected with HIV, HBV, HCV, and HTLV. Additional studies of potentially interfering diseases (rheumatoid arthritis, auto-immune or viral diseases: 64 samples tested) have shown no cross reactions.

Precision

Assay reproducibility was determined by assaying 4 positive specimens in replicates of 10 on 2 consecutive runs using the same production lot. The coefficient of variation (%CV) of Intra-assay and Inter-assay were calculated.

Table shows reproducibility of assay results:

Sample	Number of Tests	Intra-assay Precision %CV	Inter-Assay Precision %CV
1	10	6.8	6.6
2	10	6.7	7.3
3	10	8.1	7.1
4	10	7.2	6.9

STORAGE CONDITIONS

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.

MANUFACTURER AND BRAND DETAILS

ISO 13485:2016

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED

Diagnostic Automation/Cortez Diagnostics, Inc.
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Date Adopted	**2023-10**
Brand Name	**AccuDiag™**
REF 1519-P1	**AccuDiag™ - HAV IgG ELISA**
Revision Date: 2021-12-02	