AccuDiag™ HBsAb ELISA Kit

REF 1702-P1

IVD See External Label 2°C-8°C 96 Tests

HBsAb ELISA	
Principle	Indirect ELISA
Detection	Qualitative
Sample	50 µL serum/plasma
Incubation Time	70 minutes
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

DAI HBsAb ELISA Test is an enzyme-linked immunosorbent assay (ELISA) test designed for the qualitative detection of anti-hepatitis type B surface antibodies (HBsAb) in human serum or plasma.

REAGENTS

Materials provided with the kit

1. Twelve 1 x 8-well strips coated with purified HBsAg antigen. The strips are packaged in a strip holder and sealed in an envelope with desiccant.
2. Negative Control 0.75 ml (blue)
3. Positive Control 0.75 ml (pink)
4. HRP-HBsAb conjugate (6 ml white vial with yellow tip)
5. Wash buffer (25 ml) 30x concentrated
6. Substrate (TMB) solution (11 ml, black vial)
7. Stopping solution (11 ml, white vial with white tip)

Materials required but not provided

1. Microtiter plate reader capable of measuring optical density (OD) at 450 nm either with or without a reference filter of 620-630 nm.
2. 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. Label negative and positive control wells. Transfer 50 µl of negative control, positive control, and sample to the wells, duplicate for each negative and positive.
2. Add 50 µl of HRP conjugate solution to each well and mix well.
3. Cover the wells and incubate the wells at 37°C for 60 minutes.
4. Vigorously shake out the liquid from the wells and wash each well 5 times with 250-300 µl diluted wash buffer.
5. Add 100 µl (2 drops) TMB substrate to each well and incubate at 37°C for 10 minutes.
6. Add 50 µl (one drop) stop solution to each well. Gently shake wells.
7. 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

A. Calculations

Calculate an OD ratio for each specimen by dividing its OD value by the negative OD Value as follows:

$$\text{Specimen OD ratio} = \frac{\text{Specimen OD}}{\text{Negative OD}}$$

Note: If the negative control OD is less than 0.050, use 0.050 for calculations.

B. Interpretations

Specimen OD ratio	
Negative	< 2.10
Positive	≥ 2.10

The negative result indicates that there is no detectable HBsAb in the specimen while positive result revealed that the patient might have been infected by Hepatitis type B virus.

MANUFACTURER AND BRAND DETAILS

ISO 13485:2016

ISO 13485 Quality Management for Medical Devices CERTIFIED

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