



AccuDiag™ HBsAg ELISA Kit

REF 1701-P1

IVD See External Label 2°C 96 Tests

HBsAg 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 HBsAg ELISA Test is an enzyme-linked immunosorbent assay (ELISA) test designed for the qualitative detection of Hepatitis type B surface antigen (HBsAg) in human serum.

REAGENTS

Materials provided with the kit

- Twelve 1 x 8-well strips coated with anti HBsAg antibodies. The strips are packaged in a strip holder and sealed in an envelope with desiccant.
- Negative Control (0.6 ml)
- Positive Control (0.6 ml)
- HRP-anti-HBsAg conjugate (6 ml)
- Wash buffer (25 ml) 30x concentrated
- Substrate (TMB) solution (11 ml)
- Stopping solution (11 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 620-630 nm.
- Micropipettes capable of delivering 5-200 µl, pipette tip and deionized or distilled water.

REAGENT PREPARATION

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

ASSAY PROCEDURE

- Label negative and positive control wells. Transfer 50 µl of negative control, positive control and each sample to the wells, duplicate for both negative and positive.
- Add 50 µl of HRP conjugate solution to each well and mix well.
- Cover the wells and incubate the wells at 37°C for 60 minutes.
- Vigorously shake out the liquid from the wells and wash each well 5 times with 250-300 µl diluted wash buffer.
- Add 100 µl substrate TMB to each well and incubate for 10 minutes at room temperature.
- Add 100 µl 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

A. Calculations

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

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

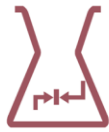
Note: If the negative OD is less than 0.05, use 0.05 for calculation.

B. Interpretations

Specimen OD ratio

Negative	< 2.10
Positive	≥ 2.10

The negative result indicates that there is no detectable HBsAg 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



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