



AccuDiag™ HBsAg ELISA Kit

REF 1701

PIC ID1701YX1

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

HBsAg ELISA	
Method	Enzyme Linked Immunosorbent Assay
Principle	Indirect ELISA
Detection	Qualitative
Sample	50 µL serum
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:

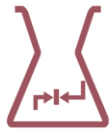
$$\text{Specimen OD ratio} = \frac{\text{Specimen OD}}{\text{Negative OD}}$$

If 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.



QUALITY CONTROL


The ranges for the controls are as follows:

Negative Control <0.200
Positive Control >0.700

MANUFACTURER AND BRAND DETAILS

ISO 13485:2016



 Diagnostic Automation/Cortez Diagnostics, Inc.
21250 Califa Street, Suite 102 and 116,
Woodland Hills, California 91367 USA

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