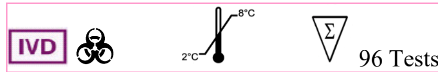
Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

AccuDiag™
HBsAg
ELISA

REF **1701-12**



BLOOD VIRUS SCREENING
HEPATITIS B VIRUS SURFACE
ANTIGEN ELISA

Test	HBsAg ELISA
Method	Enzyme Linked Immunosorbent Assay
Principle	Sandwich-ELISA Antibody Coated Plate
Detection Range	Qualitative: Positive & Negative Control
Sample	50ul
Total Time	~ 70 min
Shelf Life	12 Months from the manufacturing date

** Read the package insert carefully and completely before performing the assay. Follow the instructions and do not modify them. Only by strict adherence to these instructions, the erroneous results can be avoided and the optimal performance of Diagnostic Automation, Inc.(DAI) HBsAg ELISA achieved.*

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.

MATERIALS AND COMPONENTS

1. Twelve 1x 8-well strips coated with anti HBsAg antibodies. The strips are packaged in a strip holder and sealed in an envelope with desiccant.
2. Negative Control 0.6 ml
3. Positive Control 0.6 ml
4. HRP-anti-HBsAg conjugate (6 ml)
5. Wash buffer (25 ml) 30x concentrate
6. Substrate (TMB) solution (11 ml)
7. 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.

ASSAY PROCEDURE

1. Bring all reagents to room temperature and gently mix well.
2. Dilute one portion of wash buffer (30x) with 29 portions of deionized or distilled water. Mix well.
3. Label negative and positive control wells. Transfer 50µl of negative control, positive control and samples to the wells, duplicate for each negative and positive.
4. Add 50 µl of HRP conjugate solution to each well and mix well.
5. Cover the wells and incubate the wells at 37°C for 60 minutes.
6. Vigorously shake out the liquid from the wells and wash each well 5 times with 250-300 µl diluted wash buffer.
7. Add 100 µl substrate TMB to each well and incubate for 10 minutes at room temperature.
8. Add 100 µl stop solution to each well. Gently shake wells.
9. 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 the negative OD is less than 0.050, use 0.050 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.