AccuDiag™ HBsAg ELISA Kit

REF 1701-P1

IVD | See External Label | 2°C–8°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

1. 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.
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 concentrated
6. Substrate (TMB) solution (11 ml)
7. Stopping solution (11 ml)

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 each sample to the wells, duplicate for both 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 substrate TMB to each well and incubate for 10 minutes at room temperature.
6. Add 100 µl 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 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.

Diagnostic Automation/Cortez Diagnostics, Inc.
21250 Califa St, Suite 102 and 116, Woodland Hills, CA 91367 USA Phone: 818-591-3030, Fax: 818-591-8383
Email: onestep@rapidtest.com Website: www.rapidtest.com

MANUFACTURER AND BRAND DETAILS

ISO 13485:2016

ISO 13485 Quality Management for Medical Devices CERTIFIED

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

Date Adopted	2023-10
Brand Name	AccuDiag™
REF 1701-P1	AccuDiag™ - HBsAg ELISA
Revision Date: 2017-12-31	