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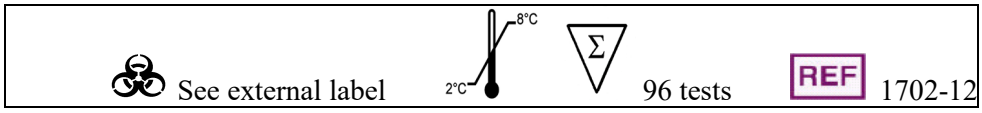

AccuDiag™ HBsAb ELISA

REF 1702-12

(Qualitative)
ANTIBODIES TO HEPATITIS B VIRUS CORE ANTIGEN ELISA

**** Laboratory and professional people perform only. Export only.*** *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. () HBsAb ELISA achieved.*

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 antigen antibodies (HBsAb) in human serum or plasma.

SUMMARY

Hepatitis B virus (HBV) is an enveloped, double-stranded DNA virus belonging to the Hepadnaviridae family and is recognized as the major cause of blood transmitted hepatitis together with hepatitis C virus (HCV). Infection with HBV induces a spectrum of clinical manifestations ranging from mild, inapparent disease to fulminant hepatitis, severe chronic liver diseases, which in some cases can lead to cirrhosis and carcinoma of the liver. Classification of a hepatitis B infection requires the identification of several serological markers expressed during three phases (incubation, acute and convalescent) of the infection. Now several diagnostic tests are used for screening, clinical diagnosis and management of the disease.

Hepatitis B surface antigen (HBsAg), which appears shortly after infection, is an important protein of the envelope structure of the virus. HBsAg is a key serological marker for detection

and diagnosis of HBV and is detectable in blood during the acute phase of the disease. Clearance after treatment shows recovery while presence for more than half year after infection indicates possible progression to long chronic carrier stage. During the acute phase of the infection, strong immunological response develops and increasing titers of HBsAg neutralizing antibodies (anti-HBs) are marker for recovery. The serological detection of anti-HBs has become important method for the follow up of patients infected by HBV, prospective prevalence studies, and the monitoring of recipients upon vaccination with synthetic and natural HBsAg based vaccines.

COMPONENTS

1. Twelve 1x 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- HBsAg 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

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.

PREPARATION FOR ASSAY

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 50µl 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.

INTERPRETATION OF RESULTS

A. Calculations

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

$$\text{Specimen OD ratio} = \frac{\text{Specimen OD}}{0.1 + \text{Negative OD}}$$

Note: If 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 immunized or been exposed to Hepatitis type B virus before.

Date Adopted	2020-04-24
REF **1702-12**	-HBsAb

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