



### AccuDiag™ HBcAb ELISA Kit

**REF** 1704

**PIC** ID1704YX1

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

HBcAb ELISA	
Principle	Competitive ELISA
Detection	Qualitative
Sample	10 µL serum/plasma
Incubation Time	75 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 HBcAb ELISA is a qualitative enzyme immunoassay (ELISA) for detection of antibody to hepatitis B core antigen (HbcAg) in human serum or plasma.

#### SUMMARY AND PRINCIPLE

Anti-HBc is found in serum shortly after appearance of hepatitis B surface antigen (HbsAg) in acute infection of hepatitis B virus and will persist after the disappearance of HbsAg and before the appearance of detectable HbsAb. Therefore, determination of total antibody to HbcAg can be of aid in diagnosis of ongoing or previous hepatitis B viral infection.

HBcAb ELISA is a competitive enzyme immunoassay. Microwells are coated with recombinant HbcAg. A serum specimen is added to the microwells together with HRP-Anti-HbcAg. After incubation, anti-HRc in specimen

compete with a constant amount of Horseradish Peroxidase (HRP) conjugated anti-HBc for a limited number of HbcAg immobilized on the microwells. The unbound enzyme conjugates will be washed away and the chromogen substrate solution containing hydrogen peroxide is added to the wells for color development. Thus, the amount of HRP-conjugated anti-HBc bound to the well is inversely proportional to the concentration of anti-HBc in the specimen. The absorbance of controls and specimens is determined using ELISA reader with wavelength set at – 450nm.

#### SPECIMEN COLLECTION

Fresh human plasma or serum are collected for the assay. Store specimens at 2 to 8°C if not assayed immediately or freeze samples if not assayed within 3 days.

#### REAGENTS

##### Materials provided with the kit

1. Microtiter wells coated with Hbc Antigens (HbcAg): 96 tests
2. Negative Control: 1 vial of 0.6 ml (blue)
3. Positive Control: 1 vial of 0.6 ml (pink)
4. Enzyme Conjugate: One vial of 6 ml (white vial with yellow tip)
5. Wash Buffer concentrated: One bottle of 25 ml, diluted 30 times (30x) with distilled water before use.
6. TMB Substrate Solution: One bottle of 11 ml (black vial)
7. Stop Solution: One bottle of 11 ml (white vial with white tip)

##### Materials required but not provided

1. Microwell holder.
2. Humidified box and 37°C incubator.
3. Plate washer or wash bottle.
4. ELISA reader.

#### ASSAY PROCEDURE

1. Allow all reagents to reach room temperature before use.
2. Dilute 10 ul of each specimen (serum or plasma) with 500 ul of diluted washing solution and dispense 50 ul of diluted specimen into each well. **DO NOT INCLUDE ANY CONTROLS IN THIS STEP.**
3. Dispense one drop (50 ul) of Positive Control and Negative Control into respective well.
4. Add one drop (50 ul) of Enzyme Conjugate to each well. Mix gently by swirling the plate on flat bench.
5. Place the plate into a humidified box at 37°C for 60 min.
6. Wash each well 5 times by filling each well with diluted wash buffer, then inverting the plate vigorously to get all water out and blocking the rim of wells on absorbent paper for a few seconds.
7. Add 2 drop (100 ul) of TMB Substrate to each well. Rock gently and incubate at 37°C for 15 min.
8. Visual inspection of the color reaction in each well or add 1 or 2 drops of Stop Solution to each well to stop the reaction.
9. Blank ELISA reader with a blank control well and then read O.D. values of all samples at 450 nm.



### RESULTS

A. Calculations of Cut-off Value & Specimen OD Ratio

$$\text{Cutoff Value} = \frac{\text{OD value of NC + PC}}{2}$$

$$\text{Specimen OD Ratio} = \frac{\text{OD value of specimen}}{\text{Cutoff Value}}$$

B. Determination of Positive or Negative specimens:

	Specimen OD Ratio
Positive (Pos.) Specimens	≤ 0.90
Negative (Neg.) Specimens	≥ 1.00
Equivocal (Eq.) Specimens	0.91-0.99

1. An OD ratio ≥ 1.00 indicates no detectable antibody to HBcAg. A negative result indicates no current or previous infection with HBcAg.
2. An OD ratio ≤ 0.90 is positive for IgG antibody to HBcAg. A positive value indicates a current or previous infection with HBcAg.
3. Specimen with OD ratio values in the equivocal range (0.91-0.99) should be retested.

### 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

<b>Date Adopted</b>	2023-10
<b>Brand Name</b>	AccuDiag™
<b>REF</b> 1704	AccuDiag™ - HBcAb ELISA
<b>PIC</b>	ID1704YX1
<b>Revision Date: 2023-04-30</b>	

### LIMITATIONS OF THE ASSAY

1. HBcAb ELISA is limited to the detection of antibody against HBcAg in serum or plasma.
2. As with all tests, a definitive conclusion should not be made based only on the results of a single test. A complete evaluation by physician is needed for final diagnosis.

### STORAGE CONDITIONS

All kit components are stored at 2 to 8°C.

### REFERENCES

1. Engvall E ,Perlmann P,Enzyme-Linked immunosorbent Assays (ELISA) Quantitative Assay of the Immunoglobulin G, Immunochem 1971;8:871-
2. Engvall E ,Jonsson K, Perlmann P, Enzyme-Linked immunosorbent Assays. Quantitative Assay of Protein Antigen, Immunoglobulin G, By Means of Enzyme-Labelled Antigen and Antibody-Coated Tubes. Biochem Biophys Acta 1971;251:427-34.
3. VanWeemen BK, Schuurs AHWM, Immunoassay Using Antigen-Enzyme Conjugates, FEBS Letters 1971;15:232-6.
4. Woltera G, Kuippers L, Kaoaki J, Schuurs A, Solid-phase Enzyme-Immunoassay for Detection of Hepatitis B Surface Antigen. J Clin Pathol 1978;29:873-9.
5. Goodall AH, Miescher G, Meek FM, Janossy G, et al. Monoclonal Antibodies in a Solid-Phase Radiometric Assay for Anti-HBc. Med Lab Sci 1981;38:349-54