

## DRG® Anti-Hepatitis B e Antigen ELISA (EIA-3891)

**Revised 8 Feb. 2010**

**Not for Sale in the USA**

### NAME AND INTENDED USE

Diagnostic Kit for Antibody to Hepatitis B e Antigen (ELISA) is an *in vitro* enzyme immunoassay for the detection of Anti-HBe in human serum or plasma.

### PRINCIPLE

The purified Anti-HBe is coated on the solid phase of multi-wells. Serum sample, recombined HBeAg and Horseradish peroxidase labeled with Anti-HBe (conjugated) are added to coated wells, and form competitive combination. After incubation, if Anti-HBe content is high in the sample, a complex of HBeAg-Anti-HBe-Anti-HBe labeled with HRP will form. Wash wells to remove the complex, and incubate with substrates (TMB), subsequently there is no color change or little color change. If Anti-HBe is not present in the sample, there is much color change. The test is special, sensitive, reproducible and easy to operate.

### STORAGE AND STABILITY

Store the kit at 2~8°C. The kit is stable within the expiration date printed on kit boxes. Do not freeze or use the kit beyond the expiration date.

### MATERIALS PROVIDED

1. Coated Microwell Plate (Anti-HBe)	1 block (96 wells)
2. Enzyme Conjugant	1 bottle (6 ml)
3. Positive Control Serum	1 vial (0.5 ml)
4. Negative Control Serum	1 vial (0.5 ml)
5. Wash Buffer (1:20 dilution prior to use)	1 bottle (30 ml)
6. Substrate A	1 bottle (6 ml)
7. Substrate B	1 bottle (6 ml)
8. Stop Solution	1 bottle (6 ml)
9. Neutralize Reagent	1 bottle (6 ml)
10. Seal Paper	1 piece

### PRECAUTIONS

1. Shake the bottled reagents well before use, discard 1~2 drops and drop vertically.
2. Bring Diagnostic Kit for Antibody to Hepatitis B e Antigen (ELISA) (all reagents), and samples to room temperature before use (approximately 30 minutes), put the remained reagents to the sealed pouch, and return to 2~8°C in time.
3. The NaN<sub>3</sub> can't be used to preserve the reagents.
4. Do not interchange reagents between kit lots.
5. Results should be read out within 10 minutes.
6. Resolve the concentrated wash solution at 37°C if crystals appear.
7. Handle all reagents, samples and controls as if capable of transmitting an infectious agent. It is recommended

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that these reagents and samples be handled using established good laboratory working practices.

8. The seal paper can't be used repeatedly.

9. Dilute the wash solution with distilled water to 1: 20 prior to use.

10. Do not use the kit beyond its expiration date. The date is printed on kit boxes.

11. The shelf life is 12 months.

**TEST PROCEDURE**

1. Set one blank, two positive and two negative controls for each test, add 0.05ml serum sample, positive and negative control serum into the coated wells, then add one drop (approximately 0.05ml) neutralize reagent into each well (blank is omitted), at last, add one drop (approximately 0.05ml) of enzyme conjugant into the same coated wells (The blank well is omitted), mix thoroughly, and incubate for 60 minutes at 37°C.

2. Manual Wash Procedure: Discard the liquid in the coated wells and bring them to dry. Fill the wells with wash solution, discard the liquid, and bring them to dry. Repeat 5 times.  
Automatic Wash Procedure: Select the automatic operations of washing 5 times and bring them to dry after the operation.

3. Add one drop (approximately 0.05ml) of substrate A and B respectively to each well, and incubate for 10 minutes at 37°C.

4. Add one drop (approximately 0.05ml) of stop solution into each well, mix thoroughly, and measure the absorbance at 450nm against the blank.

**INTERPRETATION OF RESULTS****Colorimetric Method**

Cut Off Value calculation:

COV = the average OD of negative controls  $\times$  0.5

Positive      OD<sub>450</sub> of sample < COV

Negative      OD<sub>450</sub> of sample  $\geq$  COV

Invalid      If the OD of negative control is below or equal to 1.000, the result is invalid. In any event, repeat the test. If the problem persists, contact the local distributor.

**PERFORMANCE CHARACTERISTICS**

Sensitivity    4NCU/ml (the Biological Reference Reagents of Chinese Clinical Test Center), OD  $\leq$  0.600

Specificity    the average OD of 20 normal negative samples  $\geq$  2.000

Precision      CV(%)  $\leq$  20% (n=10)