DRG® Hepatitis B e Antigen ELISA (EIA-3890)

Revised 8 Feb. 2010 **Not for Sale in the USA**

NAME AND INTENDED USE

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

PRINCIPLE

The purified Anti-HBe is coated on the solid phase of multi-wells. Serum sample and Horseradish peroxidase labeled with Anti-HBe (conjugated) are added to coated wells. After incubation, if HBeAg is present in the sample, a complex of Anti-HBe-HBeAg-Anti-HBe labeled with HRP will form. Wash wells to remove other unbounded serum components, incubate with substrates (TMB) to form a colored product, and measure the absorbance at 450nm to indicate the presence or absence of HBeAg in the sample. The test is special, sensitive, reproducible and easy to operate.

STORAGE AND STABILITY

Store the kit at 2~8℃. 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. 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 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℃ in time.
3. The NaN_3 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℃ if crystals appear.
7. Handle all reagents, samples and controls as if capable of transmitting an infectious agent. It is recommended 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) of enzyme conjugant into the same coated wells (The blank well is omitted), mix thoroughly, and incubate for 60 minutes at 37℃.
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℃.
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 × 2.1
Positive OD_{450} of sample ≥ COV
Negative OD_{450} of sample < COV
Invalid If the OD of positive control is below 0.80, the result is invalid. In any event, repeat the test. If the problem persists, contact the local distributor.
Notes If the absorbance of negative controls is below 0.05, calculate it as 0.05. If the absorbance of negative controls is above 0.05, calculate it as its original value.

PERFORMANCE CHARACTERISTICS

Sensitivity 2NCU/ml (the Biological Reference Reagents of Chinese Clinical Test Center), OD≥1.500
Specificity the average OD of 20 normal negative samples ≤0.030
Precision CV(%)≤15% (n=10)