DRG® Anti-HIV 1&2 sandwich (EIA-3897)

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NAME AND INTENDED USE

Diagnostic Kit for Antibody to Human Immunodeficiency Virus 1&2 (ELISA) is an *in vitro* enzyme immunoassay for the detection of Anti-HIV in human serum or plasma.

PRINCIPLE

The recombinant HIV antigen is coated on the multi-wells. When serum sample and HIVAg labeled with HRP (conjugated) are added to the coated wells, and if Anti-HIV is present in the sample, a complex of HIVAg-Anti-HIV-HIVAg labeled with HRP will form. This enzyme reaction produces a color change, and the intensity of the absorbance at 450nm indicates the presence or absence of Anti-HIV in the sample. The test is special, sensitive, reproducible and easy to operate. It is of vital importance in HIV diagnosis and blood screen.

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 (HIV Antigen)	1 block (96 wells)
2. Enzyme Conjugant	1 bottle (10 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 (50 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	2 pieces

PRECAUTIONS

1. Bring Diagnostic Kit for Antibody to Human Immunodeficiency Virus 1&2 (ELISA) (all reagents), and samples to room temperature before use (approximately 20 minutes), put the remained reagents to the sealed pouch, and return to 2~8° in time.
2. Fill each well fully with concentrated wash solution, and wash the dissociative enzyme clearly.
3. Do not interchange reagents between kit lots.
4. The samples should be fresh.
5. Only the HIV screen laboratories established under the approval of local sanitation department can use this diagnostic kit.
6. To prevent cross-contamination, wear gloves and working suits throughout the procedure, and execute the disinfection and isolation regulations strictly.
7. All pipetting devices should be used with care and calibrated regularly following the manufacturer's instructions.
8. 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.
9. The result judgment should be directly from microplate reader.
10. Dispose of all samples and materials used to perform the test. The 5.0g/L liquid sodium hypochlorite solution or 121° high pressure steam may be used to disinfect samples and materials before disposal.
11. The seal paper can't be used repeatedly.
12. Dilute the wash solution with distilled water to 1: 20 prior to use.

13.Do not use the kit beyond its expiration date. The date is printed on kit boxes.
14.The shelf life is 12 months.

TEST PROCEDURE

1. For each test, set one blank, two positive and two negative controls. Add 100µl positive and negative control serum into positive and negative control wells respectively, add 100µl test serum into test wells, mix thoroughly, incubate for 30 minutes at 37°, discard the liquid in all wells and bring them to dry.
2. Fill the wells with wash solution (>300µl per well), and do not let it spill out. Lay aside for 5 seconds, discard the liquid in all wells and bring them to dry. Repeat 5 times.
3. Add enzyme conjugant 2 drops or 100µl into the wells (The blank well is omitted), and incubate for 30 minutes at 37°. Wash 5 times as described in Step 2.
4. 4. Add substrate A and B one drop or 50µl respectively to each well, mix gently, protected from light and lay aside for 15 minutes at 37°.
5. Add one drop or 50µl of stop solution into each well to stop the reaction.
6. Measure the absorbance at 450nm against the blank.

INTERPRETATION OF RESULTS
Colorimetric Method
Cut Off Value calculation:
COV = the average OD of negative controls + 0.1
Positive OD_{450} of sample ≥ COV
Negative OD_{450} of sample < COV
Invalid If the average OD of positive controls is below or equal to 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 the agreement rate of the tests ≥97.5%
Specificity the agreement rate of the tests ≥97.5%
Precision CV(%)≤15% (n=10)