GBLISA HIV 1 & 2 (Elisa) Kit

Kit contents	Contents	Cat no.
GBLISA HIV 1 & 2	96T	GBLHIV096T

GENUINE BIOSYSTEM

[Intended Use]

Human Immunodeficiency Virus Antibody Diagnostic Kit (ELISA)
Diagnostic Kit for Antibody to HumanImmunodeficiency Virus (ELISA)
The reagent is used for the qualitative detection of HIV1/HIV2 antibodies in human serum or plasma, suitable for blood donor screening and Auxiliary diagnosis of clinical human immunodeficiency virus infection.

[INTRODUCTION]

This kit uses a double-antigen sandwich two-step method to detect HIV1/HIV2 antibodies in human serum or plasma. The microplate is pre-coated with genetically recombinant HIV (1+2) type antigens, and when there is HIV resistance in the added sample to be tested When in vivo, it will react to form an antigen-antibody complex, which is then combined with the added enzyme-labeled genetically engineered HIV(1+2) anti-Finally, the immune complex of "solid-phase HIV antigen-HIV antibody-enzyme-labeled HIV antigen" is formed.The compound forms a color reaction after adding the substrate..

[Reagents Composition]

Pre-coated microtiter plates 8*12 stripes (96 wells)	1 piece
Enzyme working liquid	1 bottle
HIV 1 Positive control	1 vial
HIV 2 Positive control	1 vial
Negative control	1 vial
Wash buffer concentrate	2 bottle
TMB substrate	1 bottle
Stopping solution	1 bottle

[Storage and Stability]

Store in the dark at 2~8℃, valid for 12 months.

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[Instruments]

The enzyme label instrument with 450nm/630nm wavelength.

[Specimen]

1. Serum or plasma samples can be used for plasma samples with conventional dosage of heparin, sodium citrate or EDTA anticoagulation.
2. Samples should be stored at 2~8℃. For long-term storage, it needs to be frozen at -20℃, and the samples should not be reversed. Refreeze and thaw.

[Test Procedure]

1. Equilibration: Take the components of the kit out of the box and equilibrate at room temperature for more than 30 minutes. After the microplate is opened, The rest should be sealed in ziplock bags in time.
2. Liquid preparation: Dilute the concentrated washing liquid 20 times with distilled water or deionized water.
3. Numbering: Correspond the sample to the microplate number, each plate should have 3 wells for negative control, HIV-1 positive control, 1 well for HIV-2 positive control and 1 well for blank control. (Blank control is not required for dual wavelength detection)
4. Add sample: Add 50μl of the sample to be tested and negative and positive controls to the corresponding wells in sequence.
5. Incubation: Cover with sealing film and incubate at 37°C for 60 minutes.
6. Washing: Carefully peel off the sealing film, set it in a plate washer and wash it with washing solution for 5 times, and then dry it after washing (each times should be maintained for 30-60 seconds of soaking time).
7. Add enzyme: Add 100 μl of enzyme-labeled antigen to each well.
8. Incubation: Cover with sealing film and incubate at 37°C for 30 minutes.
9. Washing: Carefully peel off the sealing film, set it in a plate washer and wash it with washing solution for 5 times, and dry it after washing (each times should be maintained for 30-60 seconds of soaking time).
10. Color development: add 100 μl of TMB substrate to each well, tap to mix well, and place in the dark at 37°C for 30 minutes.
11. Stop: Add 50 μl of stop solution to each well and mix well.
12. Determination: Measure the OD value of each well with a microplate reader at single wavelength 450nm or dual wavelength 450nm/(600~650)nm (When measuring with a single wavelength, it is necessary to use a blank control well for zero adjustment), and record the results.

[Expected Values]

Critical value=mean OD value of negative control+0.12
When the mean OD of the negative control is less than 0.02, it is calculated as 0.02

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[Interpretation of Test Results]

1. Those with a sample OD value S/C.O. ≥1 are HIV antibody positive in the primary screening; sample OD value S/C.O.< 1 were HIV antibody negative.
2. When the average OD value of the negative control is >0.1 or the average OD value of the positive control is ≤0.6, the experiment is invalid and should be tried again test.
3. Those who are positive in the initial screening should be re-sampled for double-hole re-examination, and those who are positive in the re-examination should follow the "National HIV Testing Technology". Send to HIV confirmation laboratory for relevant confirmation test

DESCRIPTON OF TEST REULTS

1.This reagent is only used for the detection of individual serum or plasma samples, and is not suitable for other body fluid samples.
2. For samples with negative test results, it cannot be absolutely guaranteed that there is no low-concentration antibody in the sample, and it cannot be completed. The possibility of HIV infection was completely ruled out.
3. The immunological test cannot absolutely rule out the existence of non-specific reactions. If you have any doubts about the test results, please use the relevant The corresponding confirmation reagents or methods should be used to confirm the results of the test samples.

[Performance Characteristics]

1. Negative reference compliance rate 20/20
2. Positive reference compliance rate 20/20
3. Minimum detection limit compliance rate ≥ 3/5
4. Precision (CV) ≤ 15%

[Limitations]

1. This reagent is only used for in vitro diagnosis and should be operated in strict accordance with the instructions. Different manufacturers, different product names, different Reagents of batch numbers cannot be mixed to avoid erroneous results.
2. Avoid operating in environments with volatile substances, hypochlorous acid disinfectants (such as 84 disinfectant) and sunlight exposure
3. Before adding the reagent, turn the reagent bottle several times to mix the liquid. Dosing must be done with a dosing device, and Calibrate the dispenser frequently.
4. When washing, each hole needs to be filled with lotion to prevent free enzyme in the hole that cannot be washed. Using a plate washer should be set to 30-60 second soak time. After each washing, the next operation must be carried out immediately to avoid prolonged exposure to
erroneous results.
5. Please use the microplate reader to read as soon as possible after termination to avoid wrong results caused by placing it for too long.
6. It is recommended to use a microplate reader to measure the test results. The assay reading of the sample does not correspond to the concentration of the antibody in the sample must be positively correlated.
7. For samples with negative test results, it cannot be absolutely guaranteed that there is no low-concentration antibody in the sample, and it cannot be completed. The possibility of HIV infection was completely ruled out.
8. The immunological test cannot absolutely rule out the existence of non-specific reactions. If you have any doubts about the test results, please use the relevant The corresponding confirmation reagents or methods should be used to confirm the results of the test samples.
9. The components of the kit will remain stable until the expiration date if they are properly handled and stored, and they cannot be used over the expiration date. In order to avoid erroneous results from the test.
10. All samples, reagents and various wastes should be treated as infectious agents.

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