Diagnostic Kit for Antibody to Human Immunodeficiency Virus Type 1 and Type 2 (Recombination Immunoblot Assay)

HIV 1/2 RIBA

State-of-the-Art **Confirmatory Test**

Focusing on the Health Developing Scientifically

- **Easy to read**
- **Clear background**
- **No interferential bands**

WANTAI®

Beijing WANTAI Biological Pharmacy Enterprise Co., Ltd.

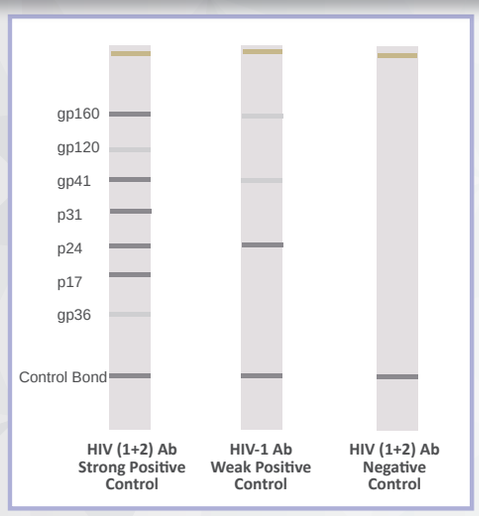
Product Description

Wantai Diagnostic Kit for Antibody to Human Immunodeficiency Virus Type 1 and Type 2 (Recombination Immunoblot Assay) is a recombinant immuno-blot assay intended for qualitative detection of antibodies to Human Immunodeficiency Viruses (HIV) type 1, or type 2 in human serum or plasma samples. The assay can be utilized as more specific diagnostic tool for patients found initially, or repeatedly positive for antibodies against HIV-1 and/or HIV-2 - the etiological agents of the acquired immunodeficiency syndrome (AIDS).

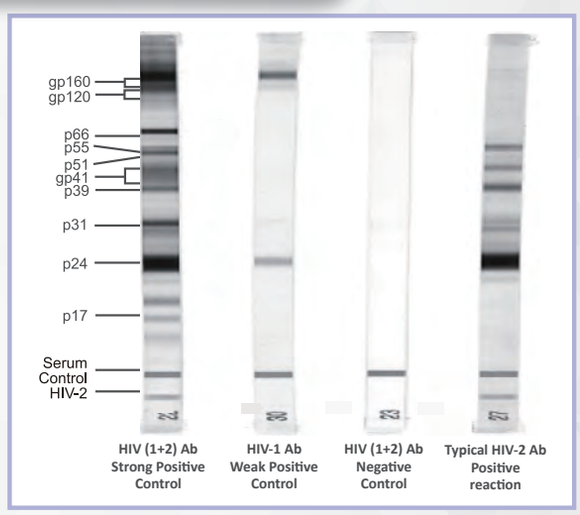
Principle of the test

Nitrocellulose strips are coated with recombinant HIV-1 antigens (gp160, gp120, gp41, p31, p24, p17), recombinant HIV-2 antigen (gp36) and control protein. The strip is soaked in the diluted serum or plasma sample. During the incubation step, the specific HIV-1/2 antibodies will be captured on the strip. The strip is then washed to remove unbound proteins. Alkaline Peroxidase conjugated anti-human IgG antibodies (AP-Conjugate) are then added, and during the second incubation, they will bind to the captured antibodies. The strip is then washed to remove unbound conjugate, and substrate solution is added for color development. After stopping the reaction, the result is interpreted according to the bands appeared.

Clear Background, No interferential Bands, Easy to read



Wantai HIV RIBA Patterns



Western Blot Test Patterns

Interpretations of the results

It is suggested for this test to use the following criteria to interpret the results (specific bands of HIV-1 antibodies include env bands: gp160, gp120, gp41; gag bands: p24, p17; pol band: p31.):

Patterns of Bands	Interpretations of the Results
No HIV specific bands	HIV antibody negative (N)
At least two env bands (gp41 and gp160/gp120) appear, or at least one env band and p24 band simultaneously appear	HIV-1 antibody positive (P)
Conform to the criteria of HIV-1 antibody positive, and HIV-2 gp36 specific band is clearly visible	HIV-1 antibody positive (P) and possible HIV-2 infection
HIV-1 antibody specific bands appear, but not enough to make a judgment on HIV-1 antibody positive, and HIV-2 gp36 specific band is clearly visible	HIV antibody indeterminate (IND) but possible HIV-2 infection
HIV antibody specific bands appear, but not enough to make a judgment on HIV antibody positive	HIV antibody indeterminate (IND)

* When only gp160 and gp41 bands simultaneously appear and their color intensity are weak, one of the following two methods can be used to assist the judgment:
(1) Directly perform nucleic acid testing (NAT) for the sample. If NAT result is positive and the patient has had the history of exposure to HIV, then interpret the result as positive; If NAT result is negative and the patient has not had the history of exposure to HIV, then interpret the result as negative.
(2) Perform a follow-up test after 4 weeks. If the number of bands increases, then interpret the result as positive; If no change of the bands, then NAT can be performed to assist the interpretation of the result.

Order Information

Catelog No.	Product Description	Detection	Specimen	Pack size
QZ-01	Antibody to HIV RIBA	Antibody	Serum/ Plasma	24 tests/ kit

Performance

Sensitivity:

An US FDA approved WB kit was used as the reference kit and a CE marked LIA kit was used as the third party kit. The evaluation results are as follows:

(1) Total **1237** samples were tested with this kit and reference kit. 783 samples were detected positive and 426 samples were detected negative by both kits. The **positive accordance rate is 783/783**, the negative coincidence rate is 426/433, the indeterminate rate is 1/21, and the **total accordance rate is 97.82%**. 20 out of 27 inconsonant results, were detected same by the reference kit and the third party kit.

(2) **26** samples from 6 HIV antibody seroconversion panels were tested with this kit and reference kit. The day since 1st indeterminate result obtained by reference kit was set as the base point, the average positive seroconversion days for this kit and the reference kit are 0.7d and 13.3d respectively, the positive detection rate are 25/26 and 17/26 respectively. **Wantai's early detection capability is 12.6 days earlier than reference kit.**

Specificity:

Total of **189** positive specimens, including TP-Ab, HAV-Ab, HBV-Ab, HCV-Ab, HDV,-IgG HEV-IgG, HTLV-ab, RF (strong positive) were detected with this kit, the **Specificity was 100%.**

Specimen type	TP-Ab POS	HBV-Ab POS	HCV-Ab POS	HAV-Ab POS	HEV-Ab POS	HDV-Ab POS	HTLV-ab POS	RF POS
No. of Specimen	30	30	40	9	10	10	10	50
Specificity	100%	100%	100%	100%	100%	100%	100%	100%

Procedures

1. Adding Specimen Diluent:
Add 1ml into each slot of tray.

2. Adding NC Strips:
Use the provided forceps to place one NC Strip to each slot carefully.

3. Adding Sample/Control:
Add 10μl into each designated slot.

4. Incubation:
Cover the tray and shake on the shaker for 60 minutes at room temperature.

5. Wash 3 times
Aspirate and discard the reaction liquid. Add 2ml of Wash Buffer into each slot. Shake on the shaker for 5 minutes, then aspirate and discard the wash buffer. Repeat this washing step 2 more times.

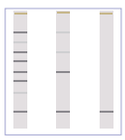
6. Adding AP-Conjugate:
Completely aspirate and discard the remaining wash buffer;
Add 0.5ml of AP-Conjugate reagent into each slot.

7. Incubation:
Cover the tray with the tray cover and shake on the shaker for 60 minutes at room temperature.

8. Wash 3 times (same as Step 5)

9. Adding Substrate:
Completely aspirate and discard the remaining wash buffer;
Add 0.5ml of Substrate Solution, put on shaker for 15 minutes at room temperature.

10. Stopping Reaction:
Aspirate and discard the substrate solution. Add deionized water to wash each strip 3 times. After the 3rd time, add 2ml of deionized water into each slot, shake on the shaker for 5 minutes to stop the reaction.



11. Results Reading:
Carefully take out the strips with the provided forceps. Place the strips on absorbing paper till they dry. After the strips are completely dry, record the results immediately.

Beijing WANTAI Biological Pharmacy Enterprise Co., Ltd.

Add: 31 Kexueyuan Rd. Changping District, Beijing, China. 102206

E-mail: wtexport@ystwt.com

Tel: +86 (10) 59528888

Web: www.ystwt.cn