



WHO
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CE
1293

AiD™ anti-HIV 1+2 ELISA

*Developing Scientifically
Focusing on the Health*

The **3rd** Generation

Sensitivity: **100%**

Specificity: **99.92%**

Specimen volume: **100μl**

Shelf-life: **15 months**

Product Description

Serological evidence of infection with HIV may be obtained by testing for presence of HIV antigens or antibodies in serum or plasma of individuals suspected for HIV infection. Antigen can generally be detected during both acute phase and the symptomatic phase of AIDS only. The antibodies to HIV-1 and/or HIV-2 can be detected throughout virtually the whole infection period, starting at or shortly after the acute phase and lasting till the end stage of AIDS. Therefore, the use of high sensitive antibody assays is the primary approach in serodiagnosis of HIV infection. Apart from sexual transmission, the principal route of infection with HIV is blood transfusion. HIV can present both in cellular and cell-free fractions of human blood. Therefore, all donations of blood or plasma should be tested due to the risk of HIV transmission through contaminated blood. This can be effectively achieved by testing for the antibodies to HIV-1 and HIV-2 by using a high sensitive ELISA test.

Wantai AiD™ anti-HIV 1+2 ELISA is an enzyme-linked immunosorbent assay intended for qualitative detection of antibodies to Human Immunodeficiency Viruses (HIV) type 1 (group M-O) or type 2 in human serum or plasma samples. The kit is intended for screening of blood donors and/or as an aid in the diagnosis of clinical conditions related to infection with HIV-1 and /or HIV-2 the etiological agents of the acquired immunodeficiency syndrome (AIDS).

WHO PQDx Studies

Wantai AiD™ anti-HIV 1+2 ELISA was evaluated by World Health Organization in 2012 using serum/plasma panel of 1118 specimens. The results were:

- **Initial sensitivity (95% CI) - 100%** (99.2%-100%)
- **Initial specificity (95% CI) - 99.09%** (98.0%-99.7%)
- **Final sensitivity (95% CI) - 100%** (99.2%-100%)
- **Final specificity (95% CI) - 99.54%** (98.7%-99.9%)

For eight seroconversion panels tested in the study, Wantai AiD™ anti-HIV 1+2 ELISA detected on average the same number of specimens as the benchmark assay. For the mixed titer panel, AiD™ anti-HIV 1+2 ELISA correctly classified 24 out of the 25 specimens. For the 1st International Reference Panel for anti-HIV [NIBSC code 02/210], Wantai AiD™ anti-HIV 1+2 ELISA correctly classified all specimens. In this study, 0% of the results were recorded as indeterminate. **The invalid rate was 0%.**

Complete study report available at www.who.int (PQDX No.0006-005-00)



CE Marking EU Studies Specificity

Evaluation study carried in Alkmaar, the Netherlands, between April and November 2005, demonstrated the following performance characteristics of Wantai AiD™ anti-HIV 1+2 ELISA was that:

When examined on 5471 negative samples,

- **Specificity was 99.92%** (95% CI 99.84-100%)

Panel	Number tested	Positive (A/C.O. ≥ 1)		Negative (A/C.O. < 1)	
		Number	%	Number	%
Random serum donor	2654	2	0.08	2652	99.92
Random plasma donor	1400	1	0.07	1399	99.93
First time donor	989	1	0.10	988	99.90
Total	5043	4	0.08	5039	99.92

Wantai AiD™ anti-HIV 1+2 ELISA test results on samples from hospitalized patients and samples containing potentially cross-reacting blood-specimens.

Type of sample	Number tested	Positive (A/C.O. ≥ 1)		Negative (A/C.O. < 1)	
		Number	%	Number	%
Mononucleosis	296	4	1.35	292	98.65
Pregnant woman	101	0	0	101	100
RF+	17	0	0	17	100
Anti - TPO	5	0	0	5	100
Anti - smooth muscle	5	0	0	5	100
Elevated IgG levels	4	0	0	4	100
Total	428	4	0.93	424	99.07

25 positive fresh serum samples tested in INSTITUTE FOR TROPICAL MEDICINE, BELGIUM have been tested with Wantai AiD™ anti-HIV 1+2 ELISA. All 25 positive fresh serum samples have been positive with Wantai AiD™ anti-HIV 1+2 ELISA.

Sensitivity

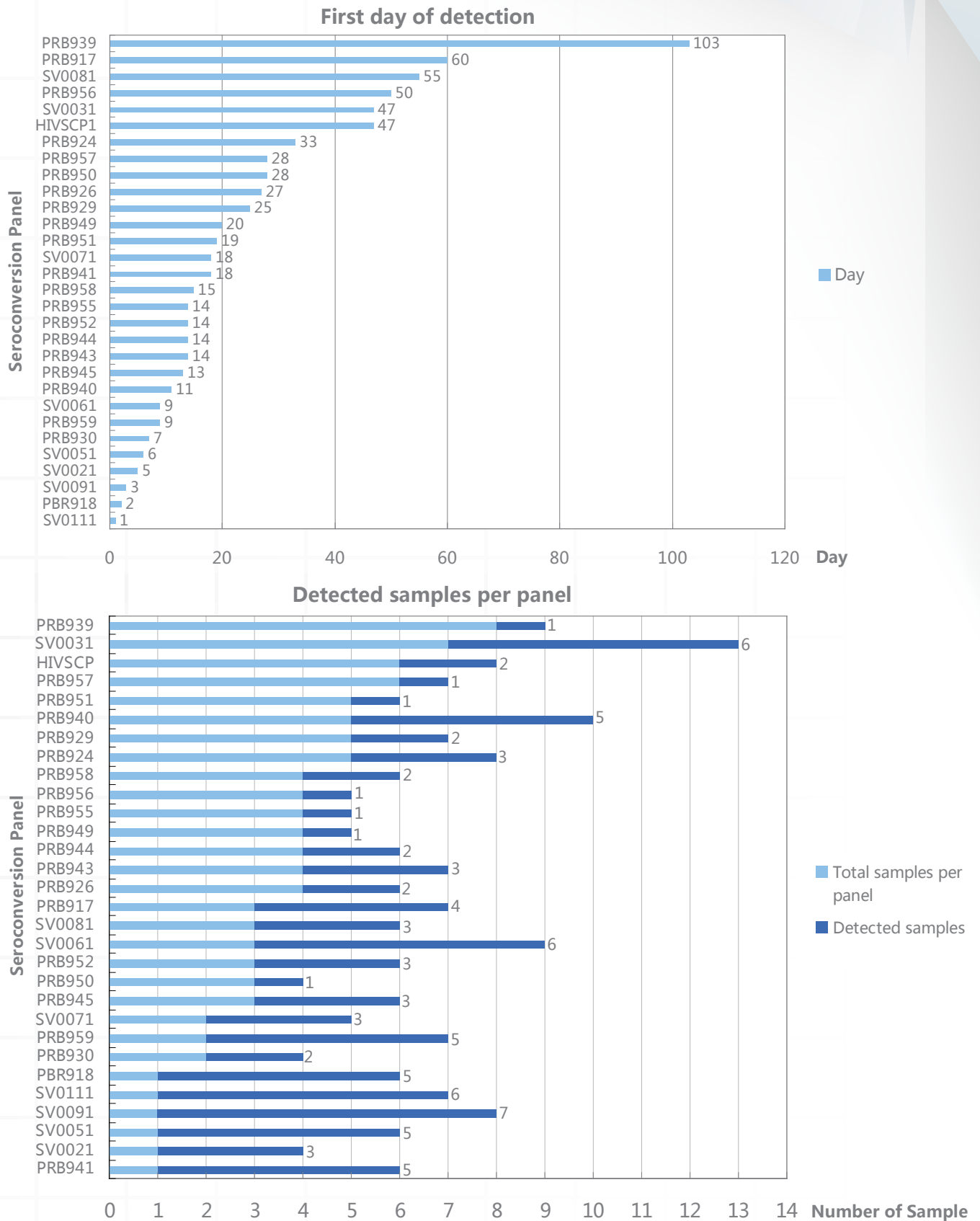
Testing Laboratory: Acrometrix B.V, Alkmaar, the Netherlands. In total 400 samples from HIV positive patients were tested. All samples were found positive in the Wantai ELISA,

- **Sensitivity : 100%**

Seroconversion Panel Testing

A total of 32 seroconversion panels, which represent 210 samples were tested. 41 samples were classified as negative. RNA and/or Antigen negative. 61 samples were classified as early-seroconversion and 95 samples were classified as seroconversion samples.

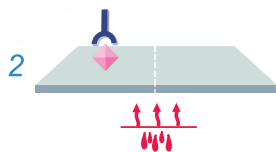
The testing results show that Wantai AiD™ anti-HIV 1+2 ELISA is a state-of-the-art compare to most of the currently available on the market CE-marked tests.



Principle and Procedures



- Microwell strips pre-coated with recombinant HIV antigens

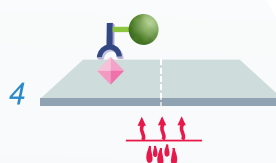


- Add 100µl of Specimens/ Controls
Incubation at 37 °C for 30 min

- HIV antibodies
- Recombinant HIV antigens
- HRP-conjugated HIV antigens

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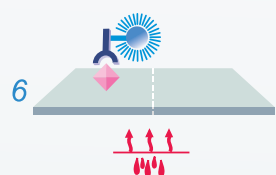
5 Wash cycles



- Add 100µl of HRP-Conjugate
Incubation at 37 °C for 30 min

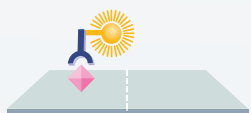
5

5 Wash cycles



- Add 50µl of Chromogen Solution A and 50µl of Chromogen Solution B
Incubation at 37 °C for 15 min

7



- Add 50µl of Stop Solution

8



- Read by single wavelength 450nm or dual wavelength 450/600~650nm

Ordering Info

Cat.	Product	Detection	Specimen	Pack size
WI-4396*	AiD™ anti-HIV 1+2 ELISA	Antibody	Serum/Plasma	96T/kit
WI-43480	AiD™ anti-HIV 1+2 ELISA	Antibody	Serum/Plasma	480T/kit

* PQ / CE: different regulatory versions of a same products

Beijing WANTAI Biological Pharmacy Enterprise Co., Ltd.