



CE  
1293

# AiD™ HIV 1+2 Ag/Ab ELISA<sup>Plus</sup>

*Developing Scientifically  
Focusing on the Health*

The **4<sup>th</sup>** Generation

Ag Sensitivity: **1.25U/ml**  
Sensitivity: **100%**  
Specificity: **99.96%**  
Incubation time: **60'+30'+30'**  
Specimen volume: **100µl**  
Shelf-life: **15 months**

# Ag Subtype Detection

Type	Subtype	WANTAI	CE ELISA
		Number of Reactive Samples / Total	
HIV-1	A/A	4/4	4/4
	B/B	4/4	4/4
	C/C	4/4	4/4
	D/D	4/4	4/4
	CRF01_AE	5/5	5/5
	F/F	3/3	3/3
	G/G	2/2	2/2
	CRF02_AG	4/4	4/4
	G/H	1/1	1/1
	H/H	3/3	3/3
	J/J	2/2	2/2
	O/O	4/4	4/4
	G/A	1/1	1/1
	N	1/1	1/1
K	1/1	1/1	
HIV-2	A	0/4	0/4
	B	0/3	0/3
	<b>TOTAL</b>	<b>43/50</b>	<b>43/50</b>

50 cell culture supernatants of different HIV subtypes were tested. AiD™ HIV Ag/Ab ELISA<sup>Plus</sup> was able to detect all HIV-1 subtypes. None of the HIV-2 strains were detected. This is within the expected performance since, the AiD™ HIV Ag/Ab ELISA<sup>Plus</sup> is not designed to detect HIV-2 antigen.

# Ab Diagnostic Sensitivity

the diagnostic sensitivity of AiD™ HIV Ag/Ab ELISA<sup>Plus</sup> was evaluated on the following panels of samples:

- 310 Anti-HIV-1 positive samples
- 100 Anti-HIV-2 positive samples
- 50 Anti-HIV-1 / HIV Ag positive samples
- 40 Positive non-B subtype samples

	Negative	Positive
Anti-HIV-1 Positive S/P	0	310
Anti-HIV-1 Positive Non-B	0	40
Anti-HIV-2 Positive	0	100
Anti-HIV-1 and HIV Ag Positive	0	50
<b>TOTAL</b>	<b>0</b>	<b>500</b>

The Diagnostic Sensitivity for anti-HIV antibody detection, calculated on 500 positive samples, is **100%**.

# Ag Analytical Sensitivity

Concentration of P24	OD value	S/CO
10U	1.308	10.22
5U	0.676	5.28
2.5U	0.415	3.24
1.25U	0.173	1.35
0.625U	0.054	0.42

HIV p24 antigen international standard (WHO 90/636) was diluted to concentrations from 10U/ml to 0.625U/ml. Wantai's AiD™ HIV Ag/Ab ELISA<sup>Plus</sup> demonstrates lowest detection limit of **1.25U/ml**.

# Specificity (Chinese blood donors)

	Results
Total	4232
Gray zone samples	7
False Positive	5
Specificity	99.8%

Total of 4232 specimens from normal blood donors were used to evaluate the diagnostic specificity of Wantai's AiD™ HIV Ag/Ab ELISA<sup>Plus</sup>. The kit demonstrated excellent specificity of **99.8%**.

# Specificity (European blood donors)

In total 5004 blood donor samples collected from 2 sites in Germany were tested. 39 samples were initially positive on the AiD™ HIV Ag/Ab ELISA<sup>Plus</sup>. After repeat testing in duplicate 37 samples were negative while on two samples, one negative and one positive result was obtained which gives **diagnostic specificity of 99.96%**

# Specificity (Hospital patients)

Samples from 200 hospitalized patients were evaluated. All samples obtained a negative result with the AiD™ HIV Ag/Ab ELISA<sup>Plus</sup>.



# Seroconversion Panels

20 commercially available seroconversion panels were tested with Wantai's AiD™ HIV Ag/Ab ELISA<sup>Plus</sup> (hereinafter referred to as Wantai ELISA). The performance of the kit was compared against the results of 21 CE-marked HIV Ag/Ab tests. AiD™ HIV Ag/Ab ELISA<sup>Plus</sup> demonstrated the following performances:

- Wantai ELISA performs equal to the most sensitive assays
  - Wantai ELISA performs between the most and the least sensitive assays
  - Wantai ELISA performs equal to the least sensitive assays
  - Wantai ELISA performs below the least sensitive assays
- No color:** All assays perform equally

## Number of Positive Bleeds

Panel	Wantai	CE marked HIV Ag/Ab tests																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
PRB945	● 4	3	3	4	3	4	3	3	3	3	3			2		4	4		4		2	3
PRB946	● 2	2	2	2	2	2	2	2	2	2	2		2	0							1	1
PRB947	● 3	3		4		3		3	3	3	3		3	2	3		3	3			3	
PRB949M	1												1					1				1
PRB950	● 3					3					3		2	2	3	3	3				1	
PRB955	● 3	4				4	4	3		3	4		3	1	4	4	4		4		3	3
PRB956	● 2					2				2	2		1		2	2	2		2		0	
PRB958	● 4	4	4	4		3		2			4				2	4			4	4	2	
PRB961	2	2	2	2	2				2		2	2						2				
PRB962	2	2	2	2	2	2			2		2	2					2	2				2
PRB963	● 2	2	2	2	2	2			2		2	2					2	2				1
PRB964	● 1	1	0	0	0	0			1		1	0					0	1		1		0
PRB967	● 3	3	3			3	3		3								3					3
PRB969	● 3	4	3	3			3		3		3											3
PRB970	● 3	4	4	4			4		4		4											3
PRB973	● 2	2	2	2			2		2													1
PRB974	2	2	2	2			2		2													1
PRB976	2	2	2	2			2		2													2
PRB977	2	2	2	2			2		2													2
PRB978	1	1	1				1		1													
nr of positive panels	20	17	15	14	6	11	11	5	15	5	13	4	6	5	5	5	9	6	4	2	7	14
nr of positive bleeds	46	43	34	35	11	28	28	13	34	13	35	6	12	7	14	17	23	11	14	5	12	26

**Wantai ELISA:**  
was equal to the most sensitive assay in 9 panels;

was scored in between in 2 panels;

was scored equal to the least sensitive assay in 2 panels.

## State-of-the-art SENSITIVITY

## The First Positive Day

Panel	Wantai	CE marked HIV Ag/Ab tests																					
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	
PRB945	● 7	13	13	7	13	7	13	13	13	13	13			15		15	7	7		7		15	13
PRB946	● 7	7	7	7	7	7	7	7	7	7	7			7	13							11	11
PRB947	● 9	9		0		9		9	9	9	9			9	11	9		9	9			9	
PRB949M	18													18					18				18
PRB950	● 18					18					18		21	21	18	18	18					28	
PRB955	● 7	3				3	3	7		7	3		7	14	3	3	3		3		7	7	
PRB956	● 47					47				47	47		50		47	47	47		47		52		
PRB958	● 7	7	7	7		9		15			7				15	7			7	7	15		
PRB961	27	27	27	27	27					27		27	27						27				
PRB962	14	14	14	14	14	14				14		14	14					14	14				14
PRB963	● 17	17	17	17	17	17				17		17	17					17	17				21
PRB964	● 22	22	24	24	24	24				22		22	24					24	22		22		24
PRB967	17	17	17			17	17			17								17					17
PRB969	● 70	63	70	70			70			70		70											70
PRB970	● 7	0	0	0			0			0		0											7
PRB973	● 7	7	7	7			7			7		7											11
PRB974	● 9	9	9	9			9			9		9											16
PRB976	7	7	7	7			7			7		7											7
PRB977	13	13	13	13			13			13		13											13
PRB978	33	33	33				33			33		33											
nr of positive panels	20	17	15	14	6	11	11	5	15	5	13	4	6	5	5	5	9	6	4	2	7	14	

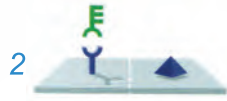
Compared to the least sensitive HIV Ag/Ab assay, AiD™ HIV Ag/Ab ELISA<sup>Plus</sup> was 2 bleeds earlier in 6 panels, one bleed earlier in 5 panels and equally positive in 9 panels. Overall the kit was positive in 17 more bleeds than the least sensitive CE-marked HIV Ag/Ab assay. This corresponds to a total of **63 days earlier.**

## Window Period Detection

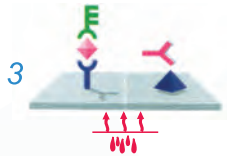
# Principle and Procedures



- Microwell strips pre-coated with
  - recombinant HIV(1+2) antigens (HIV-1 gp41, gp120, and HIV-2 gp36);
  - anti-HIV (p24) antibodies

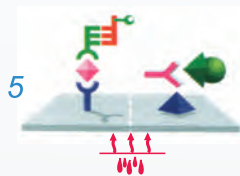


- Add 20µl of Biotin-conjugate



- Add 100µl of Specimens/ Controls  
Incubation at 37°C for 60 min

## 4 5 Wash cycles



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

## 6 5 Wash cycles



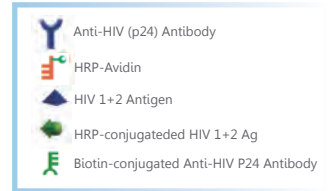
- Add 50µl of Chromogen Solution A and 50µl of Chromogen Solution B  
Incubation at 37°C for 30 min



- Add 50µl of Stop Solution



- Read by dual wavelength 450/ 600~650nm



## Ordering Info

Cat.	Product	Detection	Specimen	Pack size
WI-44S96	AiD™ HIV Ag/Ab ELISA <sup>Plus</sup>	Ab/Ag	Serum/Plasma	96T/kit