



AiD™ anti-HCV ELISA Plus

NEW HCV ELISA kit featuring **BIOTIN amplification**
Increased sensitivity and specificity

***Developing Scientifically
Focusing on the Health***

Sensitivity: **100%**
Specificity: **99.97%**
Incubation time: **60' + 30' + 30'**
Specimen volume: **50μl**
Shelf-life: **15 months**

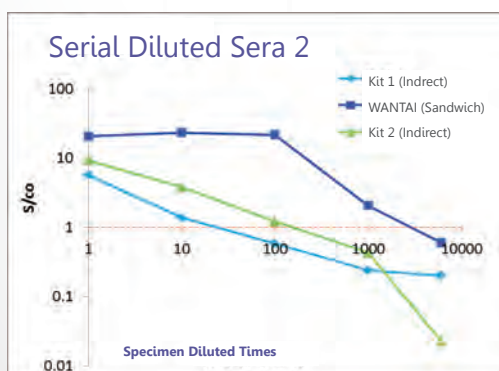
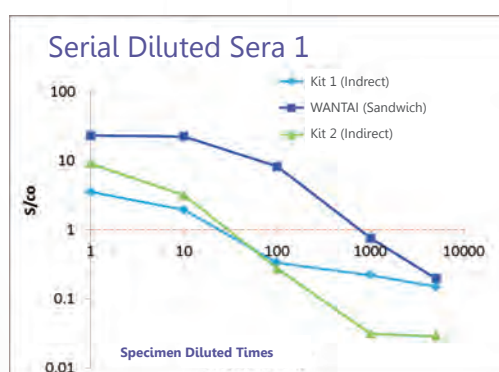
AiD™ anti-HCV ELISA ^{Plus}

is an enzyme-linked immunosorbent assay (ELISA) for qualitative detection of antibodies to hepatitis C virus (HCV) in human serum or plasma. It is intended for screening of blood donors and for diagnosing of patients related to infection with hepatitis C virus.



Analytical Sensitivity

Serial dilutions of positive anti-HCV samples showing the increase in analytical sensitivity of Wantai HCV (sandwich method) compared to indirect HCV ELISA.



Clinical Sensitivity

In clinical study conducted in Europe, total of 397 anti-HCV positive serum or plasma samples were tested, encompassing 200 genotypes samples, representing the major HCV genotypes 1-6.

Results: With respect to diagnostic sensitivity on clinical specimens and HCV genotypes 1-6, AiD™ anti-HCV ELISA ^{Plus} detected all positive samples as positive. The sensitivity is **100%**.

Clinical Specificity

- European blood donors (n=5083): **99.96%**
- Chinese blood donors (n=15,997): **99.97%**

Analytical Specificity

(Potentially interfering substances)

- 210 hospital patient blood samples were tested. All samples selected were found negative on the reference test (anti-HCV Ab Abbott PRISM).

Among these patients, six samples were initially reactive. One of them remained positive after repeat testing in duplicate. None of them showed anti-HCV antibodies with the confirmation test on immunoblot (Innogenetics INNO-LIA HCV).

	AiD™ HCV ELISA ^{Plus}		
	Negative	Positive	
		initial	repeat
Patients	204	6	1

Analytical Specificity

(Cross reacting substances/agents)

- 100 samples with potentially cross reacting substances were evaluated.

None of them were reactive with the AiD™ anti-HCV ELISA ^{Plus}

	AiD™ HCV ELISA ^{Plus}		
	Negative	Positive	
		initial	repeat
Anti-HBC positive	20	0	/
HBsAg positive	16	0	/
Anti-HIV-1 positive	14	0	/
Anti-HTLV 1/2 positive	16	0	/
Anti-HEV positive	15	0	/

Seroconversion Panels

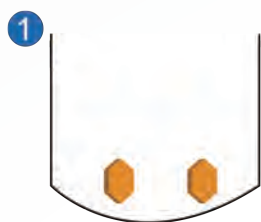
AiD™ anti-HCV ELISA ^{Plus} was also evaluated for sensitivity on 33 HCV commercial available seroconversion panels.

Results:

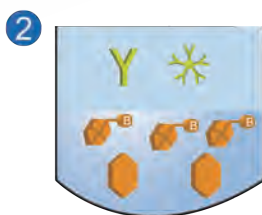
- AiD™ anti-HCV ELISA ^{Plus} detected **0.13 more positive samples** against the reference assays.
- The test detected positive samples **0.93 days earlier** compared to the reference assays.

Panel		Minimum standard		AiD™ anti-HCV ELISA ^{Plus}	
		# positive samples	1 st day positive	# positive samples	1 st day positive
1	PHV 904	3	14	2	21
2	PHV 905	4	18	2	25
3	PHV 907	2	21	3	18
4	PHV 908	8	19	7	25
5	PHV 912	1	7	3	0
6	PHV 913	2	7	0	11
7	PHV 914	4	19	3	24
8	PHV 915	2	12	0	16
9	PHV 918	2	24	0	29
10	ZMC 6211	2	186	0	191
11	ZMC 6212	4	32	8	12
12	ZMC 6213	2	43	2	43
13	ZMC 6216	0	25	0	25
14	ZMC 6222	1	40	0	42
15	ZMC 6224	0	24	0	24
16	ZMC 6225	2	78	1	80
17	ZMC 6228	2	44	4	37
18	ZMC 9045	1	41	1	41
19	ZMC 9047	3	30	4	28
20	ZMC 9054	2	77	0	84
21	ZMC 9055	0	67	0	67
22	ZMC 10047	2	117	0	124
23	ZMC 77890	5	99	5	99
24	PHV 906	2	17	7	0
25	PHV 911	2	21	3	14
26	PHV 915	0	0	3	5
27	PHV 919	3	28	3	28
28	PHV 920	6	16	7	13
29	PHV 921	7	18	7	18
30	PHV 922	3	10	1	17
31	ZMC 6215	0	40	1	20
32	ZMC 6229	1	32	4	17
33	ZMC 9058	2	10	3	7
Sum		80	1236	84	1205
Score		2.42	37.45	2.55	36.52

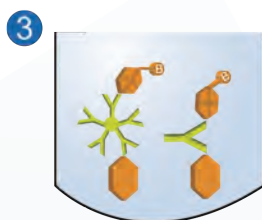
Principle and Procedures



Antigen Coated Plate



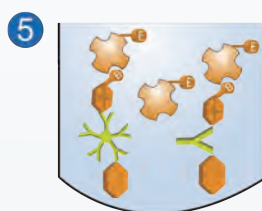
Add 50µl of Biotin-Conjugated Antigen and 50µl of specimen



Incubation at 37 °C for 60 min



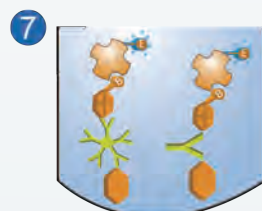
Wash



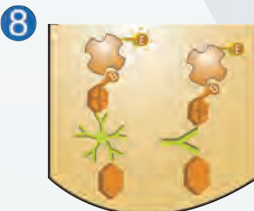
Add 100µl of HRP-conjugate
Incubation at 37 °C for 30 min



Wash



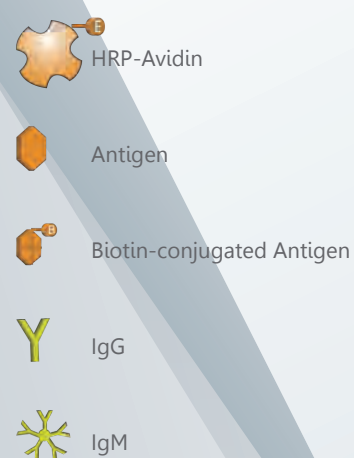
Add 50µl of Chromogen Solution A
and 50µl of Chromogen Solution B
Incubation at 37 °C for 30 min



Add 50µl of Stop Solution



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



Ordering Info

Cat.	Product	Detection	Specimen	Pack size
WC-31S96	AiD™ anti-HCV ELISA ^{Plus}	Antibody	Serum/Plasma	96T/kit
WC-31S480	AiD™ anti-HCV ELISA ^{Plus}	Antibody	Serum/Plasma	480T/kit