



AiD™ anti-HCV ELISA

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

Sensitivity: **100%**
Specificity: **99.55%**
Incubation time: **30'+30'+15'**
Specimen volume: **10μl**
Shelf-life: **13 months**

What is HCV?

Hepatitis C virus (HCV) is an envelope, single stranded positive sense RNA virus belonging to the family of Flaviviridae. Six major genotypes and series of subtypes of HCV have been identified. Isolated in 1989, HCV is now recognized as the major cause for transfusion associated non-A and non-B hepatitis. The disease is characterized with acute and chronic form although more than 50% of the infected individuals develop severe, life threatening chronic hepatitis with liver cirrhosis and hepatocellular carcinomas. Since the introduction in 1990 of anti-HCV screening of blood donations, the incidence of this infection in transfusion recipients has been significantly reduced.

- The first generation of HCV ELISA showed limited sensitivity and specificity and was produced using recombinant proteins complementary to the NS4 (c100-3) region of the HCV genome as antigens.
- Second generation tests, which included recombinant / synthetic antigens from the Core (c22) and nonstructural regions NS3 (c33c, c100-3) and NS4 (c100-3, c200) resulted in a remarked improvement in sensitivity and specificity.
- **The third generation tests include antigens from the NS5 region of the viral genome in addition to NS3 (c200), NS4 (c200) and the Core (c22).** Third generation tests have improved sensitivity and shorten the time between infection with HCV and the appearance of detectable antibodies (window period) to 60 days.

Product Description

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



Principle of the test

Wantai AiD™ anti-HCV ELISA is an indirect ELISA for detection of antibodies to HCV in two-step incubation procedure. Microwell strips are pre-coated with recombinant antigens corresponding to the **Core, NS3, NS4 and NS5** regions of HCV. During the first incubation step, HCV specific antibodies will be bound to the coated HCV antigens. The wells are then washed and anti-human IgG antibodies conjugated to the enzyme horseradish peroxidase are added. During the second incubation step, these HRP-conjugated antibodies will be bound to any antigen-antibody complexes previously formed and the unbound HRP-conjugate is then removed by washing. Chromogen solutions are then added to the wells, in presence of the antigen-antibody-HRP immunocomplex, the colorless Chromogens are hydrolyzed by the bound HRP to a colored product. The amount of color intensity can be measured and it is proportional to the amount of antibody in the sample. Wells containing samples negative for anti-HCV remain colorless.

Clinical Specificity

A blood donor population of 2948 individuals was tested with 3 different kits from different manufacturers. **The specificity of Wantai AiD™ anti-HCV ELISA was 99.55%.**

Manufacturers	-	+	False pos.	Specificity
Manufacturer 1	2896	38	14	99.52%
Manufacturer 2	2895	38	15	99.48%
Aid™ anti-HCV ELISA	2897	13	13	99.55%

Analytical Specificity

- No cross reactivity observed with samples from patients infected with HAV, HBV, HIV, CMV and TP. No interference was observed from rheumatoid factors up to 2000U/mL.
- The performance characteristics of this assay are unaffected from elevated concentrations of bilirubin, hemoglobin, and triolein.
- Same day and frozen specimens have been tested to check for interferences due to collection and storage.

Clinical Sensitivity

Among 480 clinical hepatitis C patients confirmed positive by RIBA 3.0, 480 were positive when tested with Aid™ anti-HCV ELISA. **The sensitivity was 100%.**

Seroconversion Panels

Six seroconversion/low titer performance panels were tested. The testing results show that AiD™ anti-HCV ELISA is a state-of-the-art comparing to most of the currently indirectly HCV ELISA kits available on the market.

BBI PHV205 ANTI-HCV MIXED TITER PERFORMANCE PANEL

No.	WB	ELISA 2.0 S/CO	ELISA 3.0 S/CO	Wantai Lot 1 S/CO	Wantai Lot 2 S/CO
1	POS	6.8	>4.9	7.2	6.4
2	NEG	0.1	0.1	0.0	0.0
3	POS	6.8	>4.9	7.8	11.3
4	POS	6.6	>4.9	8.0	10.9
5	IND	3.3	2.1	7.2	3.6
6	IND	>4.9	1.5	5.5	4.2
7	POS	1.5	2.4	5.4	4.2
8	IND	4.0	2.3	5.5	4.1
9	POS	>4.9	2.2	3.3	2.1
10	POS	3.9	4.5	7.6	6.8
11	POS	>4.9	>4.9	7.0	10.4
12	POS	>4.9	2.9	4.8	3.7
13	POS	>4.9	>4.9	9.4	9.8
14	POS	>4.9	>4.9	8.0	7.7
15	POS	>4.9	4.4	8.7	7.3
16	POS	>4.9	>4.9	7.7	8.6
17	POS	>4.9	>4.9	8.8	12.0
18	POS	>4.9	>4.9	6.3	12.7
19	POS	>4.9	>4.9	6.1	11.3
20	POS	>4.9	>4.9	6.0	21.4
21	POS	>4.9	>4.9	5.9	21.4
22	POS	>4.9	>4.9	6.1	21.4
23	POS	>4.9	>4.9	6.4	16.9
24	POS	>4.9	>4.9	6.5	21.4
25	NEG	0.0	NEG	0.0	0.0

BBI-PHV905 (genotype 1a)

Member ID#	Days since 1 st bleed	Confirmatory test Ortho RIBA 3.0				Wantai Lot 2 S/CO
		NS4	NS3	Core	NS5	
PHV-905-01	0	NEG	NEG	NEG	NEG	0.00
PHV-905-02	4	NEG	NEG	NEG	NEG	0.04
PHV-905-03	7	NEG	NEG	NEG	NEG	0.04
PHV-905-04	11	NEG	1+	NEG	NEG	0.05
PHV-905-05	14	NEG	1+	NEG	NEG	0.04
PHV-905-06	18	NEG	1+	+/-	NEG	0.08
PHV-905-07	21	NEG	2+	1+	NEG	1.2
PHV-905-08	25	NEG	4+	4+	NEG	1.7
PHV-905-09	28	NEG	4+	4+	NEG	3.8

HCV genotype antibody testing

Genotype	Samples	Positive
1a-b	15	15
2a-b	13	13
3a-b	10	10
4h	6	6
5	12	12
6	18	18
Total	74	74

BBI PHV105 ANTI-HCV LOW TITER PERFORMANCE PANEL

No.	WB	ELISA 2.0 S/CO	ELISA 3.0 S/CO	Wantai Lot 1 S/CO	Wantai Lot 2 S/CO
1	POS	2.2	>4.7	6.6	4.5
2	POS	>4.9	4.3	6.3	14.9
3	POS	1.3	4.5	6.7	5.4
4	POS	2.7	>4.7	4.2	4.7
5	POS	2.1	4.4	6.6	5.5
6	POS	2.1	3.3	4.8	6.0
7	IND	2.7	1.7	4.0	2.8
8	IND	3.8	2.9	3.6	3.3
9	IND	1.1	1.7	2.5	2.5
10	NEG	0.1	0.0	0.0	0.0
11	IND	2.3	>4.7	3.6	3.0
12	POS	2.5	4.4	2.4	2.0
13	IND	2.2	3.5	1.4	1.6
14	IND	2.7	3.7	5.6	4.2
15	POS	2.8	1.8	2.3	2.8

BBI-PHV908

Member ID#	Days since 1 st bleed	Confirmatory test Ortho RIBA 3.0				Wantai Lot 1 S/CO	Wantai Lot 2 S/CO
		NS4	NS3	Core	NS5		
PHV-908-01	0	NEG	NEG	NEG	NEG	0.05	0.05
PHV-908-02	3	NEG	NEG	NEG	NEG	0.07	0.06
PHV-908-03	6	NEG	NEG	NEG	NEG	0.04	0.07
PHV-908-04	11	+/-	+/-	NEG	NEG	0.04	0.04
PHV-908-05	13	1+	1+	NEG	NEG	0.02	0.04
PHV-908-06	19	2+	2+	NEG	NEG	0.05	0.95
PHV-908-07	25	3+	4+	NEG	NEG	1.5	1.5
PHV-908-08	27	3+	4+	NEG	NEG	2.20	2.90
PHV-908-09	32	3+	4+	NEG	NEG	7.70	6.30
PHV-908-10	35	3+	4+	NEG	NEG	>8.50	>8.50
PHV-908-11	41	3+	4+	NEG	NEG	>8.50	>8.50
PHV-908-12	45	3+	4+	NEG	NEG	>8.50	>8.50
PHV-908-13	48	3+	4+	NEG	NEG	>8.50	>8.50

BBI-PHV920

Member ID#	Days since 1 st bleed	Confirmatory test Ortho RIBA 3.0				Wantai Lot 1 S/CO	Wantai Lot 2 S/CO
		NS4	NS3	Core	NS5		
PHV-920-01	0	NEG	NEG	NEG	NEG	0.05	0.05
PHV-920-02	5	NEG	NEG	NEG	NEG	0.05	0.05
PHV-920-03	7	NEG	NEG	NEG	NEG	0.05	0.05
PHV-920-04	13	NEG	1+	IND	NEG	1.1	1.1
PHV-920-05	16	NEG	3+	1+	NEG	1.7	1.8
PHV-920-06	20	NEG	3+	1+	NEG	4.4	3.9
PHV-920-07	26	NEG	3+	1+	NEG	5.2	5.7
PHV-920-08	28	NEG	4+	2+	1+	7.3	7.3
PHV-920-09	33	1+	4+	2+	3+	8.8	12.2
PHV-920-10	35	1+	4+	3+	3+	9.0	10.7

BBI-PHV901 (genotype 1a)

Member ID#	Days since 1 st bleed	Confirmatory test Ortho RIBA 3.0				Wantai Lot 1 S/CO	Wantai Lot 2 S/CO
		NS4	NS3	Core	NS5		
PHV-901-01	0	NEG	NEG	NEG	NEG	0.03	0.03
PHV-901-02	65	NEG	NEG	NEG	NEG	0.03	0.03
PHV-901-03	97	3+	NEG	NEG	NEG	1.1	1.1
PHV-901-04	99	3+	4+	NEG	NEG	1.1	1.1
PHV-901-05	104	3+	4+	NEG	NEG	1.5	1.5
PHV-901-06	106	3+	4+	NEG	NEG	3.2	3.7
PHV-901-07	131	4+	4+	NEG	NEG	5.0	5.0
PHV-901-08	139	4+	4+	NEG	NEG	>8.0	>8.0
PHV-901-09	159	4+	4+	NEG	NEG	>8.0	>8.0
PHV-901-10	166	4+	4+	NEG	NEG	>8.0	>8.0
PHV-901-11	203	4+	4+	+/-	NEG	>8.0	>8.0

Principle and Procedures

1



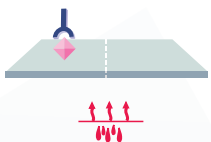
- Microwell strips pre-coated with
- recombinant, highly immunoreactive HCV
antigens (recombinant Core and NS3/4/5)

2



- Add 100µl of sample diluent

3

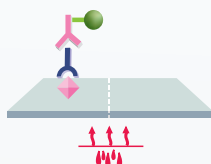


- Add 10µl of Specimens/ Controls
Incubation at 37 °C for 30 min

4

5 Wash cycles

5

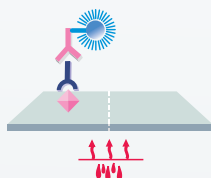


- Add 100µl of HRP-conjugate
Incubation at 37 °C for 30 min

6

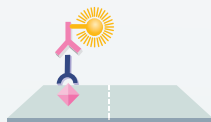
5 Wash cycles

7



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

8

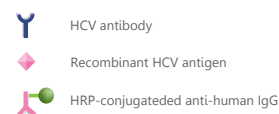


- Add 50µl of Stop Solution

9



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



Ordering Info

Cat.	Product	Detection	Specimen	Pack size
WC-3196	AiD™ anti-HCV ELISA	Antibody	Serum/Plasma	96T/kit