

Recombination Immunoblot Kit for Antibody to
Hepatitis C Virus (Recombination Immunoblot Assay)

HCV 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

Hepatitis C virus (HCV) is an envelope, single stranded positive sense RNA (9.5 kb) 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, 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. Therefore, the use of highly sensitive antibody assays is the primary approach in serodiagnosis of HCV infection. Initially or repeatedly positive results in a screening test should be confirmed with more specific supplementary assays, and the immuno-blot is the most frequently used technique including Western Blot (using purified viral antigen), or Recombinant Immunoblot (using recombinant antigens).

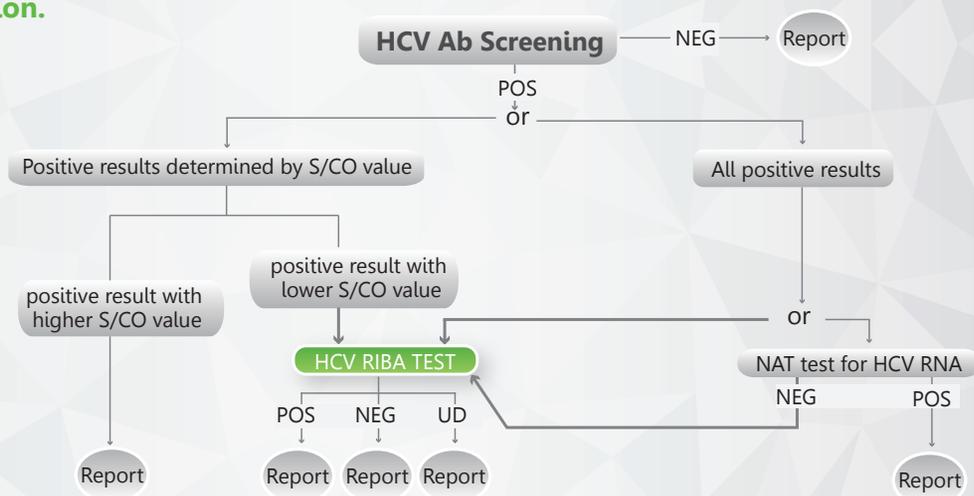
Principle of the test

Nitrocellulose strips are coated with synthetic and recombinant HCV antigens (Core, NS3, NS4, NS5) and control protein. The strips are submerged in the diluted patient's serum or plasma sample. During the incubation step, the specific HCV antibodies will be captured on the strips. The strips are then washed to remove unbound serum proteins. Anti-human IgG antibodies conjugated to the enzyme alkaline phosphatase (AP-Conjugate) are then added, and during the second incubation, they will bind to the captured antibodies. The strips are then washed to remove unbound conjugate, and substrate solution is added to the reaction tray. After stopping the reaction, the results can be interpreted according to the bands showed on the strip.

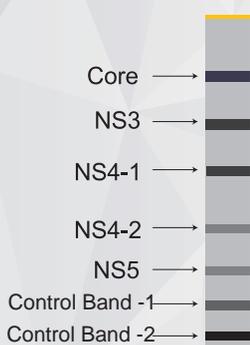
Guidelines for laboratory testing and result reporting of HCV, recommended by the U.S. Centers for Disease Control and Prevention.

"RIBA is a method for HCV confirmatory test."

---U.S. CDC



HCV RIBA Result Analysis



Color Intensity of Band	Score
Blank	—
< Control band-1	+/-
= Control band-1	1+
> Control band-1	2+

Band Intensity	Interpretations of the Results
Only one specific anti-HCV band (Core, NS3, NS4 and NS5) appears intensity 1+ or above	HCV Ab Negative (N)
At least two specific anti-HCV bands (Core, NS3, NS4 and NS5) appear intensity 1+ or above	HCV Ab Positive (P)
No specific anti-HCV bands appear intensity 1+ or above	HCV Ab indeterminate (IND)

HCV RIBA Performances

1102 clinical specimens from 3 Chinese Tier-one hospitals were detected in this test, results are shown in below:

Serum/plasma Specimens		Reference RIBA test			Total
		Postive	Negative	Undeterminate	
Wantai RIBA	Postive	588	0	3	591
	Negative	0	487	2	489
	Undeterminate	8	0	14	22
Total		596	487	19	1102

Positive accordance rate vs. Reference RIBA: 98.7% (588/596)

Negative accordance rate vs. Reference RIBA: 100% (487/487)

Uncertain accordance rate vs. Reference RIBA: 73.7% (14/19)

P.s. 11 discrepant samples were tested by a third-party reagent, all of them were detected positive.

High Specificity

139 specimens were tested, including HCV-Ab negative specimens, HBV-Ab specimens, HIV-Ab specimens, TP-Ab specimens, HAV-Ab specimens, HEV-IgG positive specimens, HDV-IgG positive specimens, HTLV positive specimens, results are shown in below:

Specimen Type	HBV-Ab POS.	HIV-Ab POS.	TP-Ab POS.	HAV-Ab POS.	HEV-IgG POS.	HDV-IgG POS.	HTLV POS.
No. of Specimen	30	40	30	9	10	10	10
Specificity	100%	100%	100%	100%	100%	100%	100%



High Sensitivity & Specificity

Coating sufficiently with antigens of major immunodominant region contributes to a high sensitivity and specificity.



Accurate Results

With the provided index of color intensity of control bands, the results is more easier to read and more reliable.



Flexible operation mode

Well-engineered design, suitable for both manual and automated operation.

Order Information

Catalog No.	Product Description	Detection	Specimen	Pack size
QZ-02	Antibody to HCV RIBA	Antibody	Serum/ Plasma	24 tests/ kit

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