Atlas Link (Beijing) Technology Co., Ltd

One Step Hepatitis C Virus (HCV) Antibody Rapid Test

Instructions For Use

Format: Cassette
Specimen: Serum/Plasma
Catalog Number: HCV272

CE 2265

* Please carefully read the instructions before use

INTENDED USE

Hepatitis C Virus (HCV) Antibody Rapid Test is a rapid and convenient immunochromatographic assay for qualitative detection of antibodies against HCV in human whole blood, serum or plasma sample. It is intended for professional use as an aid in diagnosis of HCV infection. This assay

provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

SUMMARY AND PRINCIPLE OF THE ASSAY

Hepatitis C virus (HCV) is a leading cause of hepatitis. The worldwide prevalence of HCV is 0.2% to 2% in blood donors and up to 80% in intravenous drug users. Hepatitis C virus (HCV) is single-stranded RNA virus, respectively that causes acute or chronic hepatitis. The viral particles are transmitted through exposure of infectious body fluids or blood, blood transfusion, and use of contaminated needles or syringes. Chronic hepatitis may progress to severe outcomes without prompt medical intervention, including cirrhosis and liver cancer (heptatocellular carcinoma). Diagnosis of HCV infections could be based on serological tests.

The test is an antibody-capture immunochromatographic assay, detecting presence of HCV antibodies in blood samples. Specific HCV antigens are 1) conjugated with colloidal gold and deposited on conjugate pad, and 2) immobilized on test line on the nitrocellulose membrane. When blood sample is added, it rehydrates the gold-antigen conjugate and the HCV antibodies, if any in samples, interact with the gold conjugated antigen. The antigen-antibody-gold complex will migrate toward test window until the Test Zone (T) where they are captured by immobilized antigen, forming a visible red line (Test line), indicate positive results. If HCV antibodies are absent in the sample, no red line will appear in the Test Zone (T).

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a colored control line in the Control Zone is an indication of an invalid result.

PACKAGE CONTENTS

- Pouch contents: Test Cassette, Sample dropper, Desiccant
- Test instruction

MATERIALS REQUIRED BUT NOT PROVIDED

- Lancet and blood collection device
- Glove
- Clock or timer

WARNING AND PRECAUTIONS

- For Professional *in vitro* diagnostic use only.
- Do not reuse.
- Do not use if the product sealed barrier or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious material and performing the assay.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
- Keep out of children's reach.

SPECIMEN PREPARATION

- Blood samples may be collected by fingerstick or venipuncture, following routine facility procedures.
- For serum samples, collect blood in a tube without anticoagulant and allow it to clot.
- For plasma samples, collect blood in a tube containing anticoagulant.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- The blood may be stored at 2ºC to 8ºC for up to three days if the tests cannot be performed immediately. Ensure that the blood samples should be allowed to attain room temperature prior to use.

TEST PROCEDURES

1 Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a leveled surface.

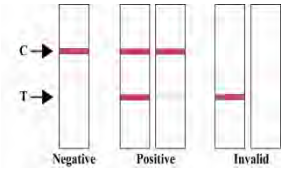
2 Holding the sample dropper vertically, add three full drops (120 µl) of specimen without air bubbles into the sample well that is marked with an arrow on the testing device.

4 Read the result in 10 minutes. Read results as shown under interpretation of Results.

NOTE: Specimens with high concentrations of HCV antibodies may produce positive results in as little as 1 minute. Confirm negatives in 10 - 20 minutes.

DO NOT INTERPRET RESULTS AFTER 30 MINUTES

RESULT INTERPRETATIONS



Negative
A pink colored band appears only at the control region (C), indicating a negative result for HCV infections.

Positive
A clear pink control line (C) and a detectable test line (T) appear, indicating a positive result for HCV infections.

Invalid
No visible band at the control region. Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND EXPIRATION DATE

- Test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
- The bottle containing the buffer should be stored at 2-30ºC.
- The test device should be kept away from direct sunlight, moisture and heat.
- 36 Months

LIMITATIONS

- This product is an *in vitro* diagnostic test designed for professional use only.
- Humidity and temperature can adversely affect results.
- The instruction for use of the test should be followed during testing procedures.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- Although the test demonstrates superior accuracy in detecting HCV infections, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

1. Diagnostic Sensitivity

A multi-center prospective study was conducted to evaluate the diagnostic sensitivity of Hepatitis C Virus Antibody Test in serum or plasma specimens from the patients clinically diagnosed as HCV infected. Total 411 positive samples including 6 genotypes were selected to evaluate the diagnostic sensitivity of HCV Antibody Rapid Test and compare the results with CE marked EIA. From study results, 410 of 411 HCV positive sera were tested positive by HCV Antibody Rapid Test, 1 tested as negative by HCV Antibody Rapid Test which showed inconsistent result with CE marked EIA was further confirmed positive by PCR. All the samples with known genotype 1-6

were tested as positive by both assays. The genotype of the false negative sample was unknown. The diagnostic sensitivity of HCV Antibody Rapid Test was 99.76% (410/411) and could identify HCV genotype 1-6.

Table 1 Summary of Diagnostic Sensitivity of HCV Antibody Rapid Test

Genotype		Results of HCV Antibody Rapid Test		Results of CE Marked EIA Test		Subtotal
		Positive	Negative	Positive	Negative	
1	1a	4	0	4	0	51
	1b	47	0	47	0	
2	2a	25	0	25	0	37
	2b	9	0	9	0	
	2a/2b	3	0	3	0	
3	3a	17	0	17	0	28
	3b	11	0	11	0	
4	4	7	0	7	0	20
	4a	7	0	7	0	
	4c/4d	6	0	6	0	
5a		7	0	7	0	7
6	6a	22	0	22	0	30
	6e	8	0	8	0	
1b/2a		3	0	3	0	3
Unknown genotype		234	1	235	0	235
Subtotal		410	1	411	0	411

2. Diagnostic Specificity

A multi-center prospective study was conducted to evaluate the diagnostic specificity of the Hepatitis C Virus Antibody Test in serum or plasma specimens from different populations including blood donors, inpatients, pregnant women and other potentially interfering diseases. From the 6 diagnostic specificity studies, total 1727 negative samples including 1091 from blood donors, 200 from inpatients, 200 from pregnant women, 236 from potentially interfering diseases were used to evaluate the specificity of HCV Antibody Rapid Test and Compare the results with CE marked EIA. Of the 1727 samples, 1720 were tested negative, 7 tested positive (5 from blood donors, 1 from potentially interfering diseases, 1 from pregnant women) by HCV Antibody Rapid Test. All the results which showed inconsistent with CE marked EIA were further confirmed negative by PCR. The diagnostic sensitivity of HCV Antibody Rapid Test was 99.59% (1720/1727), false positive rate is 0.41%.

Table 2 Summary of Diagnostic Specificity of HCV Antibody Rapid Test

	Results of HCV Antibody Rapid Test		Results of CE Marked EIA Test		Subtotal
	Negative	Positive	Negative	Positive	
Blood Donors	1086	5	1089	2	1091
inpatients	200	0	200	0	200
Pregnant Women	199	1	199	1	200
potentially interfering diseases	235	1	235	1	236
Subtotal	1720	7	1723	4	1727

3. Analytic Specificity

The effect of seromarkers associated with unrelated medical conditions on the specificity of the HCV Antibody Test was assessed using a panel of specimens. The seromarkers studied were : Human immunodeficiency virus(HIV), hepatitis B virus seromarkers (HBsAg, anti-HBc IgG/IgM, and anti-HBs), hepatitis A virus IgM (anti-HAV), herpes simplex virus IgG (HSV), cytomegalovirus(CMV) IgG/IgM, Epstein-Barr Virus (EBV)IgG/IgM, human T- Lymphotrophic virus(HTLV), rubella IgM, anti-E. Coli, *Helicobacter pylori*(HP) IgG/IgM, syphilis reagin (RPR/TPPA), mycoplasma IgM, C-reactive protein (CRP), antistreptolysin O titre (ASOT), rheumatoid factor (RF). Two tests from each of the two lots of HCV Antibody Rapid tests were carried out for each of the panel samples. The test panel was comprised of 185 HCV antibody negative specimens. Of the 185 specimens, 85 contained one or more of the seromarkers while 100 were health negative specimens. The results demonstrated that HCV Antibody Test kits have no significant cross-reactivity with these specimens.

4. Reactivity with Low Titre HCV Antibody Performance Panel and Worldwide Panel

A low titre HCV antibody panel consisting of 13 specimens and a Worldwide panel consisting of 20 members derived from multiple geographics representing six genotyoes and 12 subtypes(1a,1b, 2a, 2b, 3,3a, 4,4a,5a,6,6a and 1), obtained from a commercial source, were tested in comparison with CE licensed anti-HIV EIA tests. The results of the study demonstrated that HCV Antibody Test was capable of detecting antibodies to HCV similarly to the licensed anti-HIV EIA tests.

5. Seroconversion panels

The sensitivity, evaluated on 32 commercially available seroconversion panels. The 32 panels including 12 from commercial source containing sequential plasma specimens from individuals undergoing seroconversion as a result of HCV infection were evaluated with HCV Rapid Antibody Test and compared with a CE approved anti-HCV EIA test. The results showed that the HCV antibody test was as sensitive as the FDA approved HIV EIA assays in detecting anti-HIV antibodies.

6. Interference

The following substances and conditions were found not to interfere with the test. List of potentially interfering chemical analytes and concentrations tested are as follows:

Chemical analytes		Penicillin G	200 ug/ml
Acetaminophen	200 ug/ml	Quinine	200 ug/ml
Acetylsaclicylic Acid	200 ug/ml	Ranitidine	200 ug/ml
Amikacin	200 ug/ml	Sodium Salicylate	200 ug/ml
Ascorbic acid	200 ug/ml	Tryptophan	200 ug/ml
Aspartame	200 ug/ml	Tetracycline	200 ug/ml
Atropine Sulfate	200 ug/ml	Tetrahydrozoline	200 ug/ml
Benzoic Acid	200 ug/ml	Ethanol	1%
Caffeine	200 ug/ml	Methanol	1%
Deoxyephedrine	200 ug/ml	Heparin	1%
Dextromethorphan	200 ug/ml	Citrate	3.2%
EDTA	800 ug/ml	**Biological analytes**	
Gentesic acid	200 ug/ml	Albumin	2 mg/ml
Histamine	200 ug/ml	Glucose	2 mg/ml
Methaqalone	200 ug/ml	Bilirubin	2 mg/ml
Pendimetrazine	200 ug/ml	Hemoglobin	2 mg/ml

7. Reproducibility

The precision was determined by replicate assays of both positive and negative samples with devices from three different production lots. The resultant data indicated no appreciable difference between lot variation when testing both positive and negative samples across three different lots.

REFERENCES

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4. CDC, Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. *MMWR* 2001; 50 (RR-11):1-42.

5. L.M. Sehulster, F.B. Hollinger, G.R. Dreesman, and J.L. Melnick, Immunological and Biophysical Alteration of Hepatitis B Virus Antigens by Sodium Hypochlorite Disinfection. *Appl. Environ. Microbiol.* 1981; 42(5):762-767.

6. CDC, Guidelines for Laboratory Testing and Result Reporting of Antibody to Hepatitis C Virus. *MMWR* 2003; 52(RR03): 1-16.

7. CDC, Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV –Related Chronic Disease. *MMWR*, 1998; 47(RR19): 1-39.

INDEX OF SYMBOLS

	Do not reuse		Batch code
	In vitro diagnostic medical device		Use by
	Temperature limitation		Contains sufficient for < n > tests
	Caution		Catalog number
	Manufacturer		Consult instructions for use
	Authorized representative in the European community		CE Mark

MANUFACTURER CONTACT INFORMATION

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Doc No. ATARHCV272