RightSign®

HCV Rapid Test Cassette (Serum/Plasma) Package Insert

REF IHCV-C31	English

A rapid test for the qualitative detection of antibodies to Hepatitis C Virus in serum or plasma.
For professional in vitro diagnostic use only.

【INTENDED USE】

The HCV Rapid Test Cassette (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibody to Hepatitis C Virus in serum or plasma. HCV Rapid Test Cassette (Serum/Plasma) is not intended for blood donors and organs testing.

【SUMMARY】

Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA virus. [1] Hepatitis C virus is the cause of hepatitis C and some cancers such as liver cancer (hepatocellular carcinoma, abbreviated HCC) and lymphomas in humans.[2] HCV is now known to be the major cause of parenterally transmitted non-A, non-B hepatitis. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis.

Hepatitis C virus (HCV) is a major cause of liver diseases including liver cirrhosis and hepatocellular carcinoma. Approximately 3% of the world population is infected with HCV. Thus, HCV infection is considered a public healthy challenge. [1]

The hepatitis C virus (HCV) is a major blood borne human pathogen. There are approximately 120-130 million or 3% of the total world population that are HCV infected. [1] The epidemic caused by HCV affects all regions, with major differences between and within countries. The WHO Eastern Mediterranean Region and the European Region have the highest reported prevalence of HCV. [3]

Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens. Compared to the first generation HCV EIAs using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests. RDTs, including oral tests, have excellent sensitivity and specificity compared to laboratory-based methods for HCV antibody detection across a wide range of settings.[4]

The HCV Rapid Test Cassette (Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in a serum or plasma specimen. The test utilizes colloid gold conjugate and recombinant HCV proteins to selectively detect antibody to HCV in serum or plasma. The recombinant HCV proteins used in the test kit are encoded by the genes for both structural (nucleocapsid) and non-structural proteins.

【PRINCIPLE】

The HCV Rapid Test Cassette (Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibody to HCV in serum or plasma. The membrane is pre-coated with recombinant HCV antigen on the test line region of the cassette. During testing, the serum or plasma specimen reacts with recombinant HCV antigen conjugated colloid gold. The mixture migrates upward on the membrane chromatographically by capillary action to react with recombinant HCV antigen on the membrane and generate a colored line. Presence of this colored line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test cassette contains recombinant HCV antigen conjugated colloid gold and HCV antigen coated on the membrane.

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used tests, specimens and potentially contaminated materials should be discarded according to the local regulations.
- The test after open the pouch should be performed in one hour especially the relative humidity >60% and the temperature >30℃ can adversely affect results.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. The in-use buffer could be stored at room temperature or refrigerated (2-30°C) for 1.5 months. DO NOT FREEZE. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The HCV Rapid Test Cassette (Serum/Plasma) can be performed using either serum or plasma.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. Specimens should be kept below -20°C up to 6months.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

【MATERIALS 】

Materials provided

Test cassettes — Droppers
Buffer (0.09%NaN_3+0.025%Kanamycin Sulfate) — Package insert

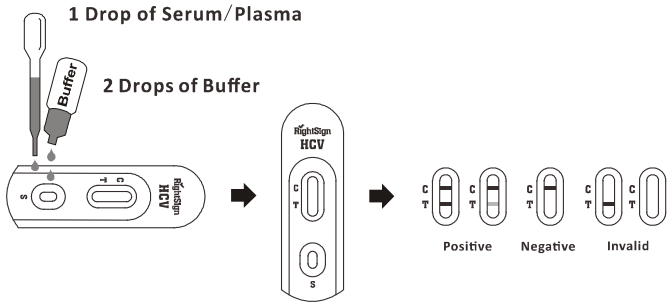
Materials required but not provided

Specimen collection containers — Centrifuge (for plasma only) — Timer

【DIRECTIONS FOR USE】

Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 1 **drop of serum or plasma (approximately 25 μL)** to the specimen well of the test cassette, then add **2 drops of buffer (approximately 80 μL)** and start the timer. Avoid trapping air bubbles in the specimen well. See the illustration below.
3. Wait for the colored line(s) to appear. The test result should be read at **10 minutes**. Do not interpret the result after **20 minutes**.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE: * Two distinct colored lines appear. One color line should be in the control region (C) and another color line should be in the test region (T).
*NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of HCV antibodies present in the specimen. Therefore, any shade of red in the test region should be considered positive.
NEGATIVE: One color line appears in the control region (C). No apparent red or pink line appears in the test region (T).
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal valid procedural control. It confirms adequate membrane wicking.
Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The HCV Rapid Test Cassette (Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of antibodies to HCV in serum or plasma specimen.
2. The HCV Rapid Test Cassette (Serum/Plasma) will only indicate the presence of antibodies to HCV in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis C viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of Hepatitis C Virus infection.

【EXPECTED VALUES】

The HCV Rapid Test Cassette (Serum/Plasma) has been compared with a leading commercial HCV EIA test. The correlation between these two systems is 99.8%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The recombinant antigen used for the HCV Rapid Test Cassette (Serum/Plasma) is encoded by genes for both structural (nucleocapsid) and non-structural proteins. The HCV Rapid Test Cassette (Serum/Plasma) has passed 30 seroconversion panels and compared with a leading commercial HCV EIA test using clinical specimens.
The results show that the diagnostic sensitivity of the HCV Rapid Test Cassette (Serum/Plasma) is 100.0%, and the diagnostic specificity is 99.8%.

Method			HCV Rapid Test Cassette		Agreement
	Results		Positive	Negative	
EIA result	Positive	HCV Serum/Plasma for Genotype 1~4	90	0	100.0% (90/90)
		HCV Serum/Plasma for Genotype 5	6	0	100.0% (6/6)
		HCV Serum/Plasma for Genotype 6	2	0	100.0% (2/2)
		All other HCV positive Serum/Plasma	312	0	100.0% (312/312)
	Total		410	0	100.0% (410/410)
	Negative	Blood Donations (Serum)	1	1024	99.9%(1024/1025)
		Clinical Negative Serum/Plasma	0	200	100.0%(200/200)
		Negative Samples from Pregnant Women(Serum)	1	199	99.5% (199/200)
		Potentially Interfering Samples(Plasma)	1	121	99.2% (121/122)
	Total		3	1544	99.8%(1544/1547)
Total Result			413	1544	99.8%(1954/1957)

Diagnostic sensitivity=410/410=100.0% (95%CI*: 99.3%~100.0%);
Diagnostic specificity=1544/1547= 99.8% (95%CI*: 99.4%~100%);
Accuracy= (410+1544)/ (410+0+1544+3) =99.8% (95%CI*:99.6%~100.0%).
*Confidence Intervals

Serum vs. Plasma

Specificity in Seronegative Paired Serum and Plasma Specimens

A total of 100 HCV seronegative specimens with paired serum and plasma were tested with HCV Rapid Test Cassette (Serum/Plasma), respectively.
There was a good correlation of testing results between serum and plasma with HCV seronegative samples.

Specimen Type	Number of Specimens Tested	Agreement for negative results by HCV Rapid Test
Ζεύγος ορών	100	100.0%(100/100)
Ζεύγος Πλάσματος	100	100.0%(100/100)

Sensitivity in Seropositive Paired Serum and Plasma Specimens

A total of 60 HCV seropositive specimens with paired serum and plasma were tested with HCV Rapid Test Cassette (Serum/Plasma), respectively.
There was a good correlation of testing results between serum and plasma with HCV seropositive samples.

Specimen Type	Number of Specimens Tested	Agreement for positive results by HCV Rapid Test
Paired Serum	60	100.0%(60/60)
Paired Plasma	60	100.0%(60/60)

Precision

Intra-Assay

Within-run precision has been determined by using 20 replicates of three specimens: a negative, a HCV low titer positive and a HCV high titer positive. The negative, HCV low titer positive and HCV high titer positive values were correctly identified 100% of the time.

Inter-Assay

Between-run precision has been determined by 20 independent assays on the same three specimens: a negative, a HCV low titer positive and a HCV high titer positive. Three different lots of the HCV Rapid Test Cassette (Serum/Plasma) have been tested over a 3-month period using negative, HCV low titer positive and HCV high titer positive specimens. The specimens were correctly identified 100% of the time.

Cross-reactivity

There was no cross reactivity for HCV Rapid Test Cassette (Serum/Plasma) to be tested by HAMA, HBsAg, HBsAb, HbeAg, HBeAb, HBcAb, anti-HIV, anti-Syphilis, anti-H. Pylori, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens. Some cross-reactivity was observed with samples positive for Rheumatoid Factor, and EBV IgM.

Interfering Substances

The following potentially interfering substances were added to HCV negative and positive specimens.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 2g/dL	Albumin: 2 g/dL
Creatine: 200 mg/dL	Hemoglobin 1000mg/dL
Bilirubin: 1g/dL	Oxalic Acid: 60mg/dL

None of the substances at the concentration tested interfered in the assay.

【BIBLIOGRAPHY】

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2. Ferri, Clodoveo (2015). "HCV syndrome: A constellation of organ- and non-organ specific autoimmune disorders, B-cell non-Hodgkin's lymphoma, and cancer". World Journal of Hepatology. 7 (3): 327.
3. World Health Organization. GLOBAL HEPATITIS REPORT, 2017. Available from: URL: http://www.who.int/mediacentre/factsheets/fs164/en.
4. Weiming Tang, Wen Chen, Ali Amini, Debi Boeras, Jane Falconer, Helen Kelly, Rosanna Peeling, Olivia Varsaneux, Joseph D. Tucker and Philippa Easterbrook. "Diagnostic accuracy of tests to detect Hepatitis C antibody: a meta-analysis and review of the literature". The Author(s) BMC Infectious Diseases 2017, 17(Suppl 1):695.

Index of Symbols

	Consult Instruction for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	**REF**	Catalog #
	Do not use if package is damaged				

Manufacturer
Hangzhou Biotest Biotech Co., Ltd.
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Yuhang District, Hangzhou, P. R. China

CE 1434

EC REP
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Number: RP5345200

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