HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF IHC-402	English

A rapid test for the qualitative detection of antibodies to Hepatitis C Virus in human whole blood, serum or plasma.

For professional in vitro diagnostic use only.

【INTENDED USE】

The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibody to Hepatitis C Virus in human whole blood, serum or plasma.

The test is intended for professional *in vitro* diagnostic use only. Not for screening.

【SUMMARY】

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV) that causes acute and chronic infection.[1,2] Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA Virus. 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. An estimated 71 million people had chronic hepatitis C infection worldwide in 2015.[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.

The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in a whole blood, serum or plasma specimen. The test utilizes colloid gold conjugate and recombinant HCV proteins to selectively detect antibody to HCV in whole blood, 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 (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibody to HCV in whole blood, serum or plasma. The membrane is pre-coated with recombinant HCV antigen on the test line region of the test. During testing, the whole blood, 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 the 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.
- Humidity and temperature may 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 must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum or plasma.
- **To collect Fingerstick Whole Blood specimens:**
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using a capillary tube:
    - Touch the end of the capillary tube to the blood until filled to approximately 50 μL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test cassette.
- **Venous whole blood:**
  - Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA K2, heparin sodium, sodium citrate or potassium oxalate) according to standard venous blood sampling process. Other anticoagulants may lead to incorrect results. Store whole blood specimen at 2-8 °C for up to 3 days if it is not used immediately after being sampled. Do not freeze whole blood specimen. Before testing, gently shake the blood tube to obtain a homogeneous specimen.
- **Serum:**
  - Collect whole blood specimen into a collection tube without anticoagulant according to standard venous blood sampling process. Leave to settle for 30 minutes for blood coagulation, then centrifuge at 3000 rpm for at least 5 minutes to obtain the serum supernatant.
- **Plasma:**
  - Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA K2, heparin sodium, citrate sodium or potassium oxalate) according to standard venous blood sampling process. Gently invert the collection tube for several times and leave to settle for 30 minutes for blood coagulation, then centrifuge at 3000 rpm for at least 5 minutes to obtain the plasma supernatant.
- 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. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days. For long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within 3 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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 local regulations.

【MATERIALS】

Materials provided

	Kit size		1T/ kit	10T/ kit	20T/ kit	25T/ kit	40T/ kit
Components	Test cassette		1	10	20	25	40
	Package insert		1	1	1	1	1
	Dropper or Capillary tube		1	10	20	25	40
	Buffer (3 mL vial or Disposable) (PBS, 0.02% Proclin 300, ≤0.02% NaN_3)	3 mL vial	1	1	1	1	2
		Disposable	1	10	20	25	40
	Sterile lancet (optional)		1	10	20	25	40
	Alcohol pad (optional)		1	10	20	25	40

Materials required but not provided

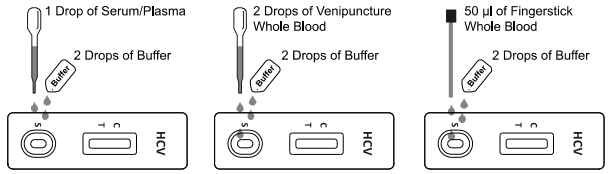
• Specimen collection containers • Centrifuge • Timer

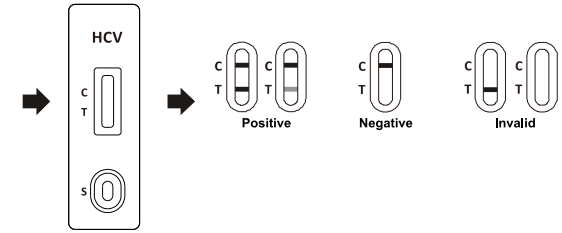
【DIRECTIONS FOR USE】

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 cassette on a clean and level surface.
   - For **Serum or Plasma** specimen: Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25 μL) to the **specimen well (S)**, then **add 2 drops of buffer** (approximately 80 μL), and start the timer, see illustration below.
   - For **Venipuncture Whole Blood** specimen: Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 μL) to the **specimen well (S)**, then **add 2 drops of buffer** (approximately 80 μL), and start the timer. See illustration below.
   - For **Fingerstick Whole Blood** specimen: To use a capillary tube: Fill the capillary tube **and transfer approximately 50 μL of fingerstick whole blood specimen** to the **specimen well (S)** of test cassette, then **add 2 drops of buffer** (approximately 80 μL) and start the timer. See 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**.

Note: It is suggested not to use the vial buffer beyond 6 months after opening the vial.





【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE: * Two colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T). Positive result in the Test region indicates detection of HCV antibodies in the specimen.

***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 color in the test region should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No colored line appears in the test region (T). Negative result in the Test region indicates negative results of HCV antibody in the specimen.

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. 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 colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

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 (Whole Blood/Serum/Plasma) is not screening device for blood donors.
2. The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HCV in whole blood, serum or plasma specimen.
3. The HCV Rapid Test Cassette (Whole Blood/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.

4. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
5. 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.
6. The hematocrit of the whole blood should be between 25% and 65%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) tested serum, plasma and whole blood specimens and was compared with CE marked EIA or CMIA test .The results show that the relative sensitivity of the HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is 100% and the relative specificity is 100%.

Method			HCV Rapid Test Cassette (Whole Blood/Serum/Plasma)		Agreement
	Results		Positive	Negative	
Predicated Test (EIA or CMIA)	Positive	HCV	397	0	>99.9% (397/397)
		Genotypes 1,2,3,4,5,6	93	0	>99.9% (93/93)
		Total	490	0	>99.9% (490/490)
	Negative	Blood Donation	0	1000	>99.9% (1000/1000)
		Clinical Negative	0	209	>99.9% (209/209)
		Pregnant Woman	0	200	>99.9% (200/200)
		Interference Substance	0	135	>99.9% (135/135)
		Total	0	1544	>99.9% (1544/1544)
Total Results			490	1544	>99.9% (2034/2034)

Sensitivity: 100% (95%CI*: 99.4%-100%)
Specificity: 100% (95%CI*: 99.8%-100%)
Accuracy: 100% (95%CI*: 99.9%-100%) *Confidence Intervals

Sero-conversion Panels

30 sero-conversion panels were studied with HCV Rapid Test Cassette (Whole Blood/ Serum/Plasma) and compared to results from CE marked test as reference assay. HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) has the similar detection capacity as reference assay.

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of four specimens: a negative, a HCV low positive, a HCV middle positive and a HCV high positive. The negative, HCV low positive, HCV middle positive and HCV high positive values were correctly identified 100% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same four specimens: a negative, a HCV low positive, a middle positive and a HCV high positive. Three different lots of the HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified 100% of the time.

Cross-reactivity

The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-Syphilis, anti-EBV, CEA, AFP, PSA, CA15-3, CA19-9, CA125, anti-HAV IgM, anti-HIV, anti-RF, anti-*H.pylori*, anti-CMV IgG, anti-Rubella IgG, anti-TOXO IgG, anti-HSV 1 IgG，anti-HSV 2 IgG positive and hCG positive specimens. The results showed no cross-reactivity.

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: 2 g/dL	Albumin: 2 g/dL
Creatin: 200 mg/dL	Hemoglobin: 1000 mg/dL
Bilirubin: 1 g/dL	Oxalic Acid: 60 mg/dL

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

【BIBLIOGRAPHY】

1. World Health Organization. New recommendations in the updated WHO guidelines for the screening, care and treatment of persons with chronic hepatitis C infection. Geneva: WHO; 2016. http://www.who.int/hepatitis/publications/hepatitis-c-guidelines-2016/en/.
2. Lavanchy D. The global burden of hepatitis C. Liver Int. 2009;29(s1):74–81.
3. World Health Organization. Global Hepatitis Report, 2017. Geneva; 2017. http://www.who.int/hepatitis/publications/global-hepatitis-report2017/en/. Accessed 6 Oct 2017.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests	30°C 2°C	Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Caution

Hangzhou AllTest Biotech Co.,Ltd.
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Hangzhou Economic & Technological Development Area
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CE 2934

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Statement: Information about manufacturer of lancet and alcohol pad is placed on the packaging.

Number: 146250203
Revision date: 2023-06-29