HCV Rapid Test Kit
(Serum / Plasma/ Whole Blood)

INTENDED USE

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

For in vitro diagnostic use only.

SUMMARY

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. 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.1, 2 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.3,4 The HCV Rapid Test kit (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.There combinant HCV proteins used in the test kit are encoded by the genes for both structural (nucleocapsid) and non-structural proteins.

PRECAUTIONS

1. This kit is for in vitro use only. Do not swallow.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Must use fresh specimen and avoid repetitive freezing, the result will be invalid.
5. Discard after use.The test device cannot be used more than once.
6. Old serum can not be used. If the serum is thick, it can be used only after being separated.
7. All specimens should be treated as potentially infectious diseases. Protection glove should be worn when handling the specimen. Wash hands thoroughly afterwards.
8. Disposal of the diagnostic: The used device, swab and extraction tube have the infectious risk. The process of disposing the diagnostic must follow the local infectious disposal law or laboratory rule.
9. The test is qualitative filter detection, it can not be used as the final test for blood donor.

MATERIAL

Material provided

1. 25 Individual sealed pouches, each containing:
   - Test device
   - Desiccant pouch
   - Extraction tubes.
2. One extraction buffer in a dropper bottle (6mL): 0.01M phosphate buffer saline (PBS).

Material Required But Not Provided

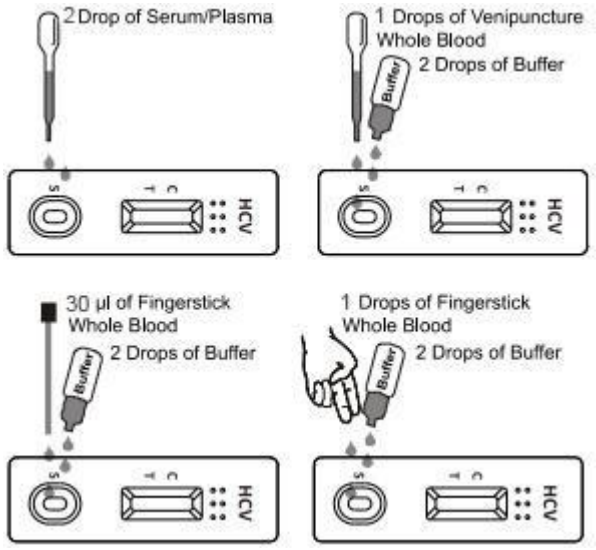
- Timer

STORAGE ANDSTABILITY

1. The test kit can be stored at room temperature (2℃ to 30℃)
2. Keep away from sunlight, moisture and heat.
3. In the sealed pouch to the date of expiration.
4. Patient samples perform best if tested immediately after collection.

TEST PROCEDURE

1. Open a pouch containing a cassette, lay the cassette.
2. Add 2 drops (approximately 60ul) of serum/plasma into sample well with a pipet.
3. If whole blood, add 1 drop (approximately 30ul) into sample well with a pipet.Then add 2 drop (approximately 80ul) of wash buffer provided in .
4. Read results within 10-15 minutes. Do not read results after 20 minutes.



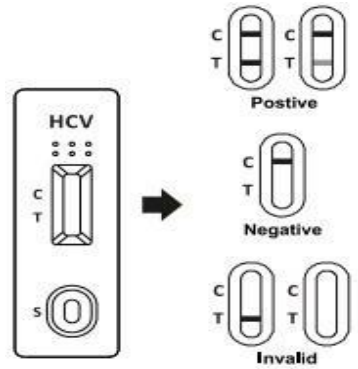
INTERPRETATION OF RESULTS

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).

Negative: One color line appears in the control region (C). No apparent red or pink line appears in the test region (T).

Invalid: If the control line (C) does not appear in the test bar, the test result is invalid regardless of whether there are other visible lines in the test bar. Retest with a new reagent cassette.

***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.



QUALITY CONTROL

Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal positive 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 OF PROCEDURE

1. The HCV Rapid Test Kit (Serum / Plasma/ Whole Blood) is for in vitro use only. This test should be used for the detection of antibodies to HCV in whole blood, serum or plasma specimen.

2.The HCV Rapid Test Kit (Serum / Plasma/ Whole Blood) 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.

REFERENCE

1.Choo, Q.L., G. Kuo, A.J. Weiner, L.R. Overby, D.W. Bradley,m and M. Houghton. Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome. Science 1989; 244:359
2.Kuo, G., Q.L. Choo, H.J. Alter, and M. Houghton. An assay for circulating antibodies to a major etiologic Virus of human non-A, non-B hepatitis. Science 1989; 244:362
3.Van der Poel, C. L., H.T.M. Cuypers, H.W. Reesink, and P.N.Lelie. Confirmation of hepatitis C Virus infection by new four-antigen recombinant immunoblot assay. Lancet 1991; 337:317
4.Wilber, J.C. Development and use of laboratory tests for hepatitis C infection: a review. J. Clin. Immunoassay 1993; 16:204

INDEX OF SYMBOLS

	See instruction for use		Tests per kit		Manufacturing
	For *in vitro* diagnostic use only		Expiry date		Do not reuse
	Store between 2 ~ 30 ºC		Batch number		Catalog #
	Keep away from sunlight		Keep dry		Authorized Representative

our company is certified by ISO quality system