Hepatitis C Virus Cassette Rapid Test

(Serum/Plasma)

INTENDED USE

The HCV One Step Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of antibody to Hepatitis C Virus in serum or plasma. For professional in vitro diagnostic use only.

INTRODUCTION

Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA Virus. 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 One Step Rapid Test is a rapid test to qualitatively detect the presence of antibody to HCV in a serum or plasma specimen. The test utilises a combination of protein A coated particles and recombinant HCV proteins to selectively detect antibody to HCV in serum or plasma. The recombinant HCV proteins used in the test are encoded by the genes for both structural (nucleocapsid) and non-structural proteins.

PRINCIPLE

The HCV One Step Rapid Test is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The membrane is coated with recombinant HCV antigen on the test line region of the device. During testing, the serum or plasma specimen reacts with the HCV antigen coated particles. The mixture migrates upward on the membrane chromatographically by capillary action to react with recombinant HCV antigen on the membrane and generate a coloured line. Presence of this coloured line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear at the control line region, indicating that the correct volume of specimen has been added and membrane wicking has occurred.

PRODUCT CONTENTS

The HCV One Step Rapid Test contains containing HCV antigen coated particles and HCV antigen coated on the membrane.

MATERIALS SUPPLIED

1.Test device 2 Pipette dropper 3.Desiccant 4.Buffer 5.Package Insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or Timer

2. Specimen collection containers.

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C.

If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

WARNINGS AND PRECAUTIONS

1. For professional In Vitro diagnostic use only.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re- use under any circumstances.

SPECIMEN COLLECTION

1. The HCV One Step Rapid Test can be performed using either serum or plasma. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens can be used.

2. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. 3. Specimens may be stored at 2-8°C for up to 3 days.

For long term storage, specimens should be kept below -20°C.

4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing.

5. Specimens should not be frozen and thawed repeatedly.

6. If specimens are to be shipped, they should be packed in compliance with usual regulations for transportation of aetiological agents.

TEST PROCEDURE

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

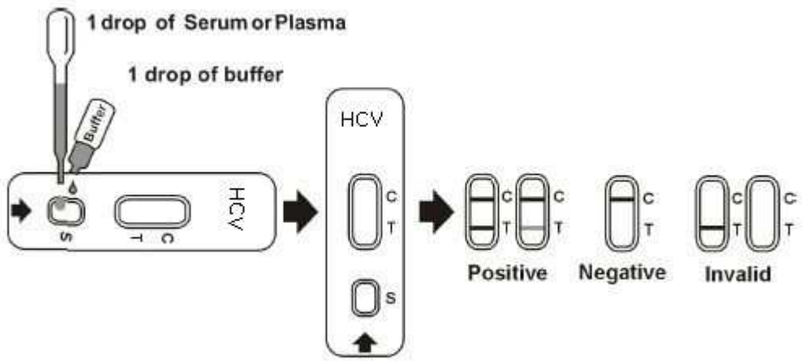
1. Remove the test from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

2. Place the test on a clean and level surface. Hold the dropper vertically and transfer 1 drop of serum or plasma (about 25µl) then add one drop (about 25µl) of sample buffer immediately. Avoid air bubbles. See illustration below.

3.Set up timer

4. Wait for the coloured line(s) to appear. Read results in 15 minutes. *Do not interpret the result after 15 minutes.*

INTERPRETATION OF RESULTS



Positive: Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T).

Negative: One coloured line appears in the control line region(C). No line appears in the test line region (T).

Invalid: Control line fails to appear.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

1. The HCV One Step Rapid Test 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 One Step Rapid Test 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.

PERFORMANCE CHARACTERISTICS

Sensitivity: The HCV One Step Rapid Test has passed a seroconversion panel and compared with leading commercial HCV EIA test using clinical specimens.

Specificity: The recombinant antigens used for the HCV One Step Rapid Test are encoded by genes for both structural (nucleocapsid) and non-structural proteins. The HCV One Step Rapid Test is highly specific for antibodies to Hepatitis C Virus compared with a leading commercial HCV EIA test.

Method		EIA		Total
HCV	Results	Positive	Negative	Results
Test	Positive	91	21	112
Device	Negative	2	1889	1891
Total Results		93	1910	2003

Relative sensitivity: 97.8%

Relative specificity: 99.0%

Accuracy: 98.9%

REFERRENCE

1. Choo, Q.L., G. Kuo, A.J. Weiner, L.R. Overby, D.W. Bradley, 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.