# HCV Hepatitis C Virus Rapid Test (Serum/Plasma)(Cassette)

CE 0123

REF GCHCV-302a

## INTENDED USE

The HCV Hepatitis C Virus Rapid Test (Serum/Plasma)(Cassette) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM, and IgA) to Hepatitis C virus (HCV) in human serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HCV. Any reactive specimen with the HCV Hepatitis C Virus Rapid Test Cassette must be confirmed with alternative testing method(s) and clinical findings.

## 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).HCV Hepatitis C Virus 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 a combination of recombinant antigen to selectively detect elevated levels of HCV antibodies in serum or plasma.

## PRINCIPLE

The HCV Hepatitis C Virus Rapid Test (Serum/Plasma)(Cassette) is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The test Cassette consists of: 1) a burgundy colored conjugate pad containing HCV antigens conjugated with colloidal gold (HCV Ag conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane Cassette containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated HCV antigens, and the C band is pre-coated with goat anti-rabbit IgG. When an adequate volume of test specimen is dispensed into the sample well of the Cassette, the specimen migrates by capillary action across the Cassette. The antibodies: either the IgG, the IgM, or the IgA, to HCV if present in the specimen will bind to the HCV Ag conjugates. The immunocomplex is then captured on the membrane by the precoated HCV antigens, forming a burgundy colored T band, indicating a HCV Ab positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-rabbit IgG and rabbit IgG-gold conjugate regardless the presence of any antibodies to HCV. Otherwise, the test result is invalid and the specimen must be retested with another Cassette.

## PRODUCT CONTENTS

HCV Hepatitis C Virus Rapid Test (Serum/Plasma)(Cassette) containing HCV antigen (HCV antigen includes core, NS3, NS4 and NS5 segment) coated particles and HCV (HCV antigen includes core, NS3, NS4 and NS5 segment) antigen coated on the membrane.

## MATERIALS SUPPLIED

1. 25 sealed pouches each containing a test cassette, a pipette dropper and a desiccant
(Test Cassette T band is pre-coated with non-conjugated HCV antigens, and the C band is pre-coated with goat anti-rabbit IgG on the nitrocellulose and coupled to colloidal gold on label pad)
2. 1 Package insert

| | | |
|---|---|---|
| 3. 1 Buffer (4 mL) (Casein-salt: 1%, NaCl: 0.9%, Na2HPO4: 0.286%, NaN3: 0.5%) | Warning | Warning: 0.5% NaN3<br>Harmful if swallowed; Harmful to aquatic life with long lasting effects<br>Prevention<br>Wash face, hands and any exposed skin thoroughly after handling<br>Wear protective gloves/protective clothing/eye protection /face protection<br>Do not breathe dust/fume/gas/mist/vapors/spray<br>Do not eat, drink or smoke when using this product<br>Avoid release to the environment<br>Response<br>IF SWALLOWED: rinse mouth. Do NOT induce vomiting<br>Get medical attention/advice if you feel unwell |

## MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Centrifuge (for plasma only)
3. Timer

## 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. DO NOT FREEZE. Do not use beyond the expiration date.

## WARNINGS AND PRECAUTIONS

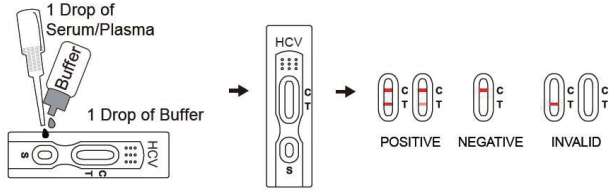
1. For professional *in vitro* diagnostic use only. Do not use after expiration date.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of 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.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Do not perform the test in a room with strong air flow, ie. an electric fan or strong airconditioning.

## SPECIMEN COLLECTION

1. The HCV Hepatitis C Virus Rapid Test (Serum/Plasma)(Cassette)can be performed using serum or plasma.
2. For plasma: K2EDTA, Sodium Heparin, Sodium citrate Sterile and Lithium heparin should be used as the anticoagulant. Other anticoagulants have not been tested and may give incorrect results
3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
4. 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℃ for up to 3 days. For long term storage, specimens should be kept below -20℃.
5. 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.
6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

## TEST PROCEDURE

**Allow the test cassette, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.**
1. Remove the test cassette 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 cassette on a clean and level surface. Hold the dropper vertically and transfer one drop of serum or plasma (about 30 µL) to the sample well (S) then add one drop (about 40 µL) of sample buffer immediately. Avoid air bubbles. See illustration below.
3. Set up timer.
4. Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 30 minutes.




## INTERPRETATION OF RESULTS

(Please refer to the illustration above)
**Positive:** Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
**Negative:** One colored line appears in the control line region(C). No line appears in the test line 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

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 Hepatitis C Virus Rapid Test (Serum/Plasma)(Cassette) 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 Hepatitis C Virus Rapid Test (Serum/Plasma)(Cassette) 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.

6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
7. 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.
8. Results should not be used to determine the serotype of HCV infections.
9. Due to possible cross reactivity, the appearance of lines in T line does not necessarily indicate co-infection from IgG, IgM or IgA, nor can it identify the serotype.
10. The recommended anticoagulants are K2EDTA, Sodium Heparin, Sodium citrate Sterile and Lithium heparin for venous whole blood. Other anticoagulants have not been evaluated with this test.

## PERFORMANCE CHARACTERISTICS

### Relative Sensitivity

A total of 506 HCV positive specimens were tested using the HCV Hepatitis C Virus Rapid Test (Serum/Plasma)(Cassette) and a commercially available test (Table 1). The relative sensitivity of the test is >99% (95% confidence interval: 99.27% – 100%).

**Table 1: Sensitivity of HCV Hepatitis C Virus Rapid Test (Serum/Plasma)(Cassette)**

| Population | Specimen Type | Number of Specimens Tested | Positive by HCV Hepatitis C Virus Rapid Test | Positive by Commercially Available Test |
|---|---|---|---|---|
| Anti-HCV (any genotype) | plasma | 329 | 329/329 (100%) | 329/329 (100%) |
| Anti-HCV (any genotype) | Serum | 26 | 26/26 (100%) | 26/26 (100%) |
| Anti-HCV (genotype 1, 2, 3, 4 (non-subtype A), 4, 5, 6) | Serum/Plasma | 151 | 151/151 (100%) | 151/151 (100%) |
| Total | | 506 | 506/506 (100%) | 506/506 (100%) |

**30 Serocoversion panels have been done and details of the 30 seroconversion are in the table below.**

| No. | Panel | Specimens No. | Results |
|---|---|---|---|
| 1 | PHV907 | 7 | Positive from 0 days since first bleed |
| 2 | PHV908 | 13 | Positive from 3 days since first bleed |
| 3 | PHV206(M) | 25 | / |
| 4 | PHV911(M) | 5 | Positive from 3 days since first bleed |
| 5 | PHV919 | 7 | Positive from 28 days since first bleed |
| 6 | PHV920 | 10,No. 2 can't be got because of out of stock from the vendor | Positive from 16 days since first bleed |
| 7 | HCV9047 | 10 | Positive from 28 days since first bleed |
| 8 | HCV9046 | 5 | Positive from 69 days since first bleed |
| 9 | HCV6229 | 8 | Positive from 17 days since first bleed |
| 10 | HCV10041 | 3 | Positive from 6 days since first bleed |
| 11 | HCV9041 | 8 | Positive from 62 days since first bleed |
| 12 | HCV9045 | 8 | Positive from 37 days since first bleed |
| 13 | HCV6222 | 3 | Positive from 40 days since first bleed |
| 14 | HCV6224 | 8 | Positive from 19 days since first bleed |
| 15 | HCV6227 | 7 | Positive from 75 days since first bleed |
| 16 | HCV6228 | 12 | Positive from 31 days since first bleed |
| 17 | HCV10071 | 7 | Positive from 84 days since first bleed |
| 18 | HCV6220 | 6 | Positive from 18 days since first bleed |
| 19 | HCV10185 | 5 | Positive from 130 days since first bleed |
| 20 | HCV10235 | 5 | Positive from 96 days since first bleed |
| 21 | HCV6215 | 4 | Positive from 20 days since first bleed |
| 22 | HCV9042 | 6 | Positive from 8 days since first bleed |
| 23 | HCV9058 | 5 | Positive from 10 days since first bleed |
| 24 | HCV9094 | 5 | Positive from 9 days since first bleed |
| 25 | HCV9095 | 5 | Positive from 10 days since first bleed |
| 26 | HCV9055 | 11 | Positive from 65 days since first bleed |
| 27 | HCV9054 | 10 | Positive from 72 days since first bleed |
| 28 | HCV9044 | 6 | Positive from 21 days since first bleed |
| 29 | HCV10165 | 9 | Positive from 19 days since first bleed |
| 30 | HCV6226 | 12 | Positive from 39 days since first bleed |

### Relative Specificity

A total of HCV 1259 negative specimens were tested using the HCV Hepatitis C Virus Rapid Test (Serum/Plasma)(Cassette) and a commercially available test (Table 2). The relative specificity of the test is ＞99% (95% confidence interval: 99.71%  100%).

**Table 2: Specificity of the HCV Hepatitis C Virus Rapid Test (Serum/Plasma)(Cassette)**

| Population | Specimens Tested | Number of Specimens Tested | Negative by HCV Hepatitis C Virus Rapid Test | Negative by Commercially Available Test |
|---|---|---|---|---|
| Clinical Negative | Serum/plasma | 202 | 202/202 (100%) | 202/202 (100%) |
| Potentially cross-reacting | Serum/Plasma | 30 | 30/30 (100%) | 30/30 (100%) |
| Unselected Donors | Serum | 1000 | 1000/1000 (100%) | 1000/1000 (100%) |
| Inhibition Panel | Serum | 27 | 27/27 (100%) | 27/27 (100%) |
| Total | | 1259 | 1259/1259 (100%) | 1259/1259 (100%) |

### Precision

**Intra Assay**

Within-run precision has been determined by using 20 replicates of four specimens: a negative, a low positive, medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.

**Inter-Assay**

Between-run precision has been determined by 5 independent assays on the same four specimens: a negative, a low positive, medium positive and a high positive. Three different lots of the HCV Hepatitis C Virus Rapid Test (Serum/Plasma)(Cassette)have been tested using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

### Cross Reactivity

No cross-reactivity was observed when samples positive for other diseases such as HIV, Syphilis, Infectious Mononucleosis, HBV, Rheumatoid Factor, HAMA, Hyper IgG, Hyper IgM, anti-HAV, anti-HSV2,anti-HEV,anti- EBV and anti-CMV were tested.

### Interfering Substances

No interference was observed in samples with high concentrations of Uric acid, Ascorbic Acid, Hemoglobin, Gentistic Acid, Acetaminnophen, Oxalic Acid, Albumin, Caffein, Bilirubin, EDTA, Aspirin and Methanol.

| Analytes | Conc | Analytes | Conc |
|---|---|---|---|
| Control | 0 | Control | 0 |
| Uric acid | 0.15mg/mL | Albumin | 20mg/mL |
| Ascorbic Acid | 0.2mg/mL | Caffein | 0.2mg/mL |
| Hemoglobin | 5.0mg/mL | Bilirubin | 0.3mg/mL |
| Gentistic Acid | 0.2mg/mL | EDTA | 0.2mg/mL |
| Acetaminnophen | 1.0mg/mL | Aspirin | 0.2mg/mL |
| Oxalic Acid | 0.2mg/mL | Methanol | 1.0% |

## REFERENCE


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 189; 244: 359
2. Kuo, G., Q.L. Choo, H.J. Alter, and M. Houghton. An assay for circulating antibodies to a major etiolog 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 Cinfection: a review. J. Clin. Immunoassy 1993; 16: 204


## INDEX OF SYMBOLS

| | | | | | |
|---|---|---|---|---|---|
|  | Consult instructions for use |  | Tests per kit | EC REP | Authorized Representative |
| IVD | For *in vitro* diagnostic use only |  | Use by |  | Do not reuse |
|  | Store between 2-30°C | LOT | Lot Number | REF | Catalog # |
|  | Manufacturer |  | Warning | | |


Healgen Scientific Limited Liability Company
Address: 3818 Fuqua Street, Houston, TX 77047, USA.
Tel: +1 713-733-8088 Fax: +1 713-733-8848
Website: www.healgen.com

EC REP QARAD b.v.b.a.
Cipalstraat 3, B-2440 Geel, Belgium



B21306-03
Revision Date: 2021-12-13