# **HCV Hepatitis C Virus Schnelltest** (Vollblut/Serum/Plasma)(Kassette)



REF GCHCV-402a

### INTENDED USE

The HCV Hepatitis C Virus Schnelltest (Vollblut/Serum/Plasma)(Kassette) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IoG, IoM, and IoA) to Hepatitis C virus (HCV) in human Vollblut, 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 Henatitis C Virus Schnelltest Kassette 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 henatitis. 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 pentides 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 Schnelltest (Vollblut/Serum/Plasma)(Kassette) is a Schnelltest to qualitatively detect the presence of antibody to HCV in a Vollblut. serum or plasma specimen. The test utilizes a combination of recombinant antigen to selectively detect elevated levels of HCV antibodies in Vollblut, serum or plasma.

#### PRINCIPLE

The HCV Hepatitis C Virus Schnelltest Kassette is a lateral flow chromatographic immunoassay based on the principle of the double antigensandwich technique. The test Kassette 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 Kassette 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 Kassette, the specimen migrates by capillary action across the Kassette. 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 Kassette.

#### PRODUCT CONTENTS

HCV Hepatitis C Virus Schnelltest (Vollblut/Serum/Plasma)(Kassette) containing HCV antigen (HCV antigen includes core, NS3, NS4 and NS5 segment) coated particles and HCV antigen (HCV recombinant antigen includes core, NS3, NS4 and NS5 segment) coated on the membrane.

### MATERIALS SUPPLIED

1. 25 sealed pouches each containing a test Kassette, a pipette dropper and a desiccant (Test Kassette 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%,  $\langle \mathbf{i} \rangle$ Warning: 0.5% NaN3 Na2HPO4: 0.286%, NaN3: 0.5%) Harmful if swallowed; Harmful to aquatic life with long Warning lasting effects Prevention Wash face, hands and any exposed skin thoroughly after handling Wear protective gloves/protective clothing/eve protection/face protection Do not breathe dust/fume/gas/mist/vapors/spray Do not eat, drink or smoke when using this product Avoid release to the environment. Response IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Get medical attention/advice if you feel unwell

#### MATERIAL REQUIRED BUT NOT PROVIDED

- 1. Specimen collection containers 2. Sterile lancets (for fingerstick Vollblut only) 4. Timer
- 3. Centrifuge (for plasma only)
- 5. Heparinized capillary tubes and dispensing bulb (for fingerstick Vollblut only)

#### STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test Kassette is stable through the expiration date printed on the sealed pouch. The test Kassette 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 eve protection when specimens are assaved.
- 7 Humidity and temperature can adversely affect results
- 8. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong airconditioning.

#### SPECIMEN COLLECTION

1. The HCV Hepatitis C Virus Schnelltest (Vollblut/Serum/Plasma) (Kassette) can be performed using Vollblut (from venipuncture and fingerstick) serum or plasma

2. For venipuncture Vollblut and 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. To collect Fingerstick Vollblut specimens:
- Wash the patient's hand with soap and warm water or clean with an alcohol wipe. Allow to dry.
- Massage the hand without touching the nuncture site by rubbing down the hand towards the fingertin of the middle or ring finger
- Puncture the skin with a new sterile lancet for each person. 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 Vollblut specimen to the test device by using a capillary tube:
- Touch the end of the capillary tube to the blood until filled to approximately 60 µL. Avoid air bubbles.

• Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the Vollblut into the specimen well (S) of the test device

Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, nonhemolyzed specimens,

4. Testing should be performed immediately after specimen collection. 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 and may be stored at -20°C for 6 months. Vollblut collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze Vollblut specimens, Vollblut collected by fingerstick should be tested immediately.

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 usual regulations for transportation of etiological agents.

#### TEST PROCEDURE

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

1. Remove the test Kassette 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 Kassette on a clean and level surface.

For Serum or Plasma Specimens: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 30 µL) to the specimen well (S) of the test Kassette, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

For Venipuncture Vollblut Specimens: Hold the dropper vertically and transfer 2 drops of venipuncture Vollblut (approximately 60 uL) to the specimen well (S) of the test Kassette, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below. For Fingerstick Vollblut specimens: To use a capillary tube: Fill the capillary tube and transfer approximately 60 uL of fingerstick Vollblut specimen to the specimen well (S) of the test device, then add 1 drops of buffer (approximately 40 µL) and start the timer. See illustration below. 3. Wait for the red line(s) to appear. The result should be read 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 Kassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

#### OUALITY 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 Schnelltest (Vollblut/Serum/Plasma)(Kassette) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HCV in Vollblut, serum or plasma specimen.

2. The HCV Hepatitis C Virus Schnelltest (Vollblut/Serum/Plasma)(Kassette) 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.

5. A negative result can occur if the quantity of the antibodies to HCV present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.

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 genotype 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 Vollblut. 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 Schnelltest (Vollblut/Serum/Plasma)(Kassette) 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 Schnelltest (Vollblut/Serum/Plasma)(Kassette)

Population	Specimen Type	Number of Specimens Tested	Positive by HCV Hepatitis C Virus Schnelltest	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 ofout 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 Schnelltest (Vollblut/Serum/Plasma)(Kassette) 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 Schnelltest (Vollblut/Serum/Plasma)(Kassette)

Population	Specimens Tested	Number of Specimens Tested	Negative by HCV Hepatitis C Virus Schnelltest	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%)

#### Vollblut vs. Serum vs. Plasma

Total 25 clinical negative samples (Vollblut, serum, plasma) have been collected from patients in local hospital. The Vollblut collected and separated into three tubes. One was stored as Vollblut. One was collected into tube for plasma, one was collected into tube for serum (Table 3). There is a very good correlation of results between Vollblut, serum, and plasma with HCV negative samples.

Table 3: A Comparison of HCV Hepatitis C Virus Schnelltest (Vollblut/Serum/Plasma)(Kassette) Specificity in negative Vollblut and Paired Serum and Plasma Specimens

Specimen Type	Number of Specimens Tested	Negative by HCV Ab	
Serum	25	25/25 (100%)	
Plasma	25	25/25 (100%)	
Vollblut	25	25/25 (100%)	

A total of 25 positive specimens (Vollblut, serum, plasma) were tested using the HCV Hepatitis C Virus Schnelltest (Vollblut/Serum/Plasma)(Kassette) (Table 4). There is a very good correlation of results between Vollblut and paired plasma with HCV positive samples.

Table 4: A Comparison of HCV Hepatitis C Virus Schnelltest (Vollblut/Serum/Plasma)(Kassette) Specificity in positive Vollblut and Paired Serum and Plasma Specimens.

Specimen Type	Number of Specimens Tested	Positive by HCV Ab
Serum	25	25/25 (100%)
Plasma	25	25/25 (100%)
Vollblut	25	25/25 (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 Schnelltest (Vollblut/Serum/Plasma)(Kassette) 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

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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

Ţ	Consult instructions for use	$\Sigma$	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by	8	Do not reuse
2'C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
***	Manufacturer	$\langle \rangle$	Warning		

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