ACCUCARE®

ONE STEP HEPATITIS C VIRUS RAPID TEST

(Whole Blood/Serum/Plasma)

One step rapid Card Test for detection of antibody against Hepatitis C Virus in Whole Blood/Serum/Plasma

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
10 Tests	HCVC 10
25 Tests	HCVC 25
50 Tests	HCVC 50

CLINICAL SIGNIFICANCE

Hepatitis C Virus (HCV) is a small, enveloped positive-sense, single-stranded RNA Virus. HCV is now known to be the major cause of parentally transmitted non-A, non-B hepatitis. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis. On the basis of Phylogenetic analysis, HCV has been grouped into six major genotypes each of which contains one or more subtypes.

The first generation HCV antibody test became in early 1990s and was widely used more recombinant antigen. Third generation assays were introduced recombinant NS5 antigen in the late 1990s. The first, second and third generation HCV antibodies assays still lack sensitivity in seroconversion or show inexplicable discrepancies with confirmatory assay. To solve this problem fourth generation assays using antigen from multiple HCV genotype that includes genotypes 2 & 3 apart from Genotype 1 containing universal conserved epitopes are been developed and evaluated.

PRINCIPLE

ACCUCARE® ONE STEP HEPATITIS C VIRUS RAPID TEST utilizes the principle of immunochromatography. The method uses multiple epitope of HCV recombinant peptide conjugated to colloidal gold and immobilized on nitrocellulose membrane in thin line. As the test sample flows through the membrane assembly of the test device formed the colored multiple epitope of HCV recombinant peptide gold conjugate complexes with the HCV Ab in the sample. This complex moves further on the membrane to the test region where it is immobilized by a multiple epitope of HCV recombinant peptide coated on the membrane leading to formation of a pink-purple colored band. The formation of first purple band (T zone) confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

CONTENTS

Test Device, Desiccant
Instruction for Use (IFU)
Assay Buffer
Disposable (Dropper) 25 µl sampling device

STORAGE & STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed aluminum pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test device, if the pouch is damaged or seal is broken.

PRECAUTIONS

1. For professional *In-vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Read the Instruction for use carefully before performing the test.

LIMITATIONS

1. Though ACCUCARE® ONE STEP HEPATITIS C VIRUS RAPID TEST is a reliable screening assay, it should not be used as a sole criterion for diagnosis of Hepatitis C infection.
2. The ACCUCARE® ONE STEP HEPATITIS C VIRUS RAPID TEST will only indicate the presence or absence of Hepatitis C antibodies in the specimen and other consideration like clinical symptoms should be noted before making final diagnosis.
3. For confirmation, further analysis of the specimens should be performed, such as ELISA and/or CLIA analysis. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. Interference due to heterophile antibodies, RF (Rehumatoid Factors) and other non-analyte substances in high titer in patient's serum express erroneous analyte detection in immunoassays interferences. Both laboratory professionals and clinicians must be vigilant to this possibility of antibody interferences.
5. Most positive results develop within 15 minutes. However, certain sera samples may take longer time to flow. Do not read results after 20 minutes.

SPECIMEN COLLECTION & PREPARATION

1. The ACCUCARE® ONE STEP HEPATITIS C VIRUS RAPID TEST can be performed using Whole Blood or Serum or Plasma.
2. Collect Whole Blood into an appropriate blood collection tube with or without anticoagulant (EDTA, citrate or heparin). If you want use serum or plasma than separate the serum or plasma from whole blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens must be used.
3. 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°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. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, it should be packed in compliance with federal regulations for transportation of etiologic agents.

PROCEDURE FOR TEST DEVICE

1. Allow test device and specimen equilibrate to room temperature (15-30°C) prior to testing.
2. Remove the test device from the aluminum foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the test device on a clean and flat surface. Carefully dispense 1 drop (25 µl) of Whole Blood/Serum/Plasma in the sample well "S" using the dropper provided.

ISO 13485:2016

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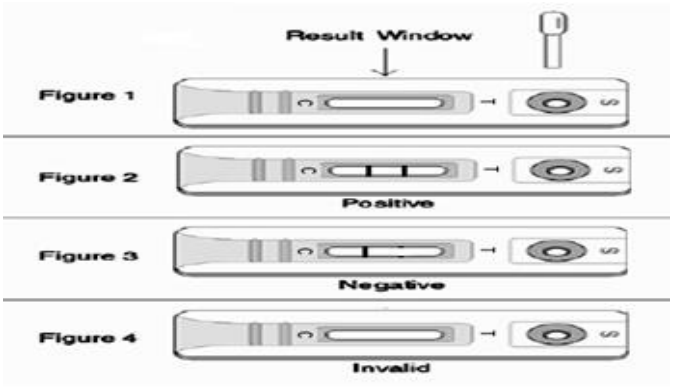
4. After that add 1 drop (appx. 40 µl) of Assay Buffer in the sample well "S".
5. Allow reaction to occur and read the results at 15 minutes. Do not interpret the results after 20 minutes.

INTERPRETATION OF RESULTS



1. **Negative**: Only one pink-purple coloured line appears at the control zone 'C' (Control line) the test result is negative

2. **Positive**: In addition to the coloured line in the control region a clearly distinguishable pink purple coloured line also appears in the test region 'T' (Test line) indicating a positive result.

3. **Invalid**: If no line appears in the control as well as the test region, the test should be repeated with fresh card.

NOTE: The intensity of the color band in the test line region will vary depending on the concentration of Hepatitis C virus present in the specimen. However, neither the quantitative value nor the rate of increase in Hepatitis C virus can be determined by this qualitative test.

INTERFERING SUBSTANCES

No interference in the ACCUCARE® ONE STEP HEPATITIS C VIRUS RAPID TEST was evident when the following substances were tested:

Sample Type	Number of Samples Tested	Positive	Negative
Clinical Specimens	100	01	99
Pregnant women	100	01	99
Other disease Samples*	100	04	96

*Other disease Samples: These are the samples that potentially interfere with HCV immunoassays. Details of the samples are as follow:

Sample Type	No. of Sample Tested
HBsAg Positive	20
HIV Positive	20
Syphilis Positive	15
Anti-HAV Positive	15
Rubella Positive	15
Anti-HTLV Positive	15
Total	**100**

PERFORMANCE CHARACTERISTICS

The ACCUCARE™ ONE STEP HEPATITIS C VIRUS RAPID TEST has been evaluated with positive and negative samples confirmed by ELISA examination.

Specimen	Positive	Negative	Sensitivity
Positive	300	00	100 %

Specimen	Positive	Negative	Specificity
Negative	23	1420	98.41 %

BIBLIOGRAPHY

1. Choo, Q.L. 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 immunobiot assay. Lancet 1991: 337:317
4. Wiber, J.Decelopment and use of laboratory tests for hepatitis C infection: a review. J. Clin. Immunoassay 1993; 16:204.

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
IVD	For *in vitro* Diagnostic use only		Keep Dry
Σ	Tests per Kit		Do Not Use if Damaged

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