ACCUCARE™

ONE STEP HEPATITIS C VIRUS TEST DEVICE

(Serum/Plasma)

One step rapid card test for detection of antibody against Hepatitis C Virus in serum/plasma.

Only for *In vitro Diagnostics* use

ORDER INFORMATION

REF	Cont.
HCVC 5	5 Test
HCVC 50	50 Test
HCVC 25	25 Test
HCVC 10	10 Test

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 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. 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 ad evaluated.

PRINCIPLE

One step card test for HCV ab. utilizes the principle of immunochromatography. The method uses multiple epitope HCV recombinant peptide conjugated to colloidal gold and immobilized on nitrocellulose strip in thin line. As the test sample flows through the membrane assembly of the test device, the colored multiple epitope 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 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.

KIT COMPONENTS

Test Device, Sample Dropper, Assay Buffer and product insert

STORAGE & STABILITY

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

PRECAUTIONS

1. Wear protective gloves while handling specimens wash thoroughly afterwards.
2. The device is sensitive to humidity as well as heat. Therefore take out the device from seal pouch before test.
3. Do not mix reagents from different lot.
4. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
5. Follow the testing procedure exactly as mention in the insert.

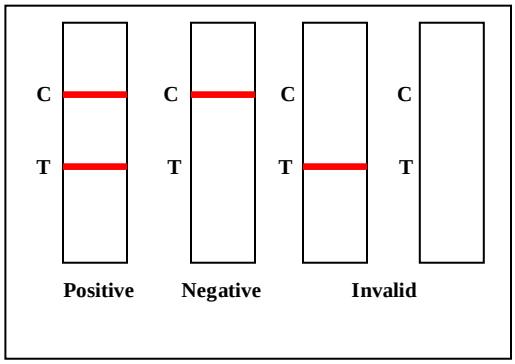
SPECIMEN COLLECTION & PREPARATION

1. Collect whole blood into an appropriate blood collection tube with or without anticoagulant (EDTA and heparin) for plasma or serum respectively.
2. Separate plasma or serum by centrifugation.
3. Carefully withdraw the plasma or serum, label and store in at 2-8°C for up to two weeks.

DIRECTIONS FOR USE

1. Place the test device on a clean and level surface. Add 1 drops (25 µl) of serum or plasma to the sample well “S” of the test device using of sample dropper provided.
2. Add 1 drops of assay buffer in sample well “S”.
3. Immediately after start the timer.
4. Wait for the red line(s) to appear. The test line should be read at 15-20 minutes. It is important that the background is clear before the result is read.

INTERPRETATION OF RESULTS



1. POSITIVE
Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

2. NEGATIVE
One red line appears in the control region (C). No apparent red or pink line appears in the test regions (T).

3. INVALID
Control line fails to appear. In sufficient 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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributors.

LIMITATIONS

1. The One-step HCV test device (Serum/Plasma) is for in vitro use only. The test should be used for the detection of antibodies to HCV in serum or plasma specimen.
2. The One-step HCV test device (Serum/Plasma) 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 interpreted together with other clinical information available to the physician.

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No. 3225, Chemical Zone, GIDC Sarigam,
SARIGAM - 396 155 (Dist. Valsad). INDIA
Tel : 91-22-2554 2109 / 2554 1558 .Fax : 2554 3541
Email : accucare@labcarediagnostics.com
Website : www.labcarediagnostics.com

4. If the test result is negative and clinical symptoms persist, additional follow-up tests using other clinical methods are recommended. A negative result at any time does not preclude the possibility of Hepatitis C Virus infection.

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.

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No. 3225, Chemical Zone, GIDC Sarigam,
SARIGAM - 396 155 (Dist. Valsad). INDIA
Tel : 91-22-2554 2109 / 2554 1558 .Fax : 2554 3541
Email : accucare@labcarediagnostics.com
Website : www.labcarediagnostics.com