

## HCV Ab Rapid Test Serum/Whole Blood/Plasma (Cassette)

Cat. No.:DTS371

Pkg.Size:

### Intended use

One Step Cassette Style Anti-HCV Test is a rapid, direct binding test for the visual detection of hepatitis C antibodies (anti-HCV) in serum and whole blood. It is used as an aid in the diagnosis of hepatitis C infection. One Step Anti-HCV Test is based on the principle of double antigen sandwich immunoassay for determination of anti-HCV in serum and whole blood. Purified recombinant antigens are employed to identify anti-HCV specifically. This one step test is very sensitive and only takes 10-20 minutes for the result to be read. Test results are read visually without any instrument.

### General Description

Hepatitis C virus (HCV or sometimes HVC) is a small (55–65 nm in size), enveloped, positive-sense single-stranded RNA virus of the family Flaviviridae. Hepatitis C virus is the cause of hepatitis C in humans. The hepatitis C virus particle consists of a core of genetic material (RNA), surrounded by an icosahedral protective shell of protein, and further encased in a lipid (fatty) envelope of cellular origin. Two viral envelope glycoproteins, E1 and E2, are embedded in the lipid envelope.

### Reagents And Materials Provided

1. Cassette test kit
2. Dropper bottle (diluent)

### Storage

The test kit can be stored at temperatures between 2 to 30°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

### Specimen Collection And Preparation

The One Step HCV Test can be run on serum or whole blood samples. The test works best on fresh samples. For serum, collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the clot. Use the serum for testing.

If the specimen cannot be tested on the day of collection, store the serum specimen in a refrigerator (at 2 to 4°C) for up to 3 days. If testing cannot be done within 3 days, serum should be stored in a freezer (at -20°C or colder). Whole blood specimens cannot be frozen. Make sure to stir and bring the specimen to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

### Assay Procedure

1. Before testing, please read the test instruction details.
2. When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the cassette test kit from the pouch and use it as soon as possible.
3. Add 3µL of serum/Whole Blood/ Plasma samples by an accurate pipette, and apply it to the sample well on the cassette test kit
4. Add 3 drops (~120µL) of diluent provided into the reagent well of the cassette test kit.
5. Wait for 10 minutes and read the results. It is important that the background is clear before the result is read. Do not read the

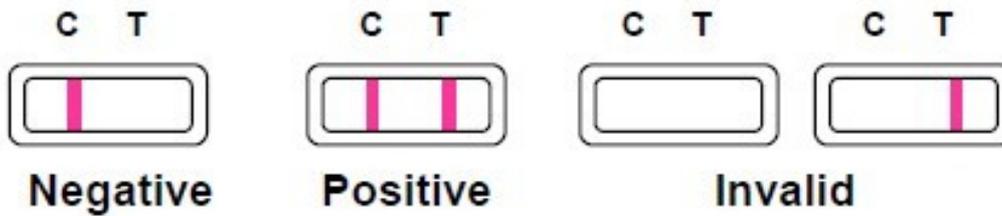
results after 20 minutes.

## Interpretation of Results

**Negative:** Only one color band appears on the control (C) region. No apparent band on the test (T) region.

**Positive:** In addition to a pink colored control (C) band, a distinct pink colored band will also appear in the test (T) region.

**Invalid:** A total absence of color in both (C) and (T) regions or no colored band appears on the control (C) region is an indication of procedure error and/or the test reagent has deteriorated. Repeat with a new test kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



## Precautions

1. Do not use test kit beyond expiry date.
2. The test device should not be reused.
3. For Samples that test positive by the One step Anti HCV test, a more specific confirmatory test should be done. A clinical evaluation of the patient situation and history should also be made before a final diagnosis is established. The use of a rapid test is not sufficient to diagnose HCV even if antibodies are present. Also, a negative result does not preclude the possibility of infection with HCV.
4. The instruction for the using and reading of the test must be followed exactly in order for the test to perform properly.

## Limitations

1. This test should be used for the detection of antibodies to HCV in serum samples.
2. Only detect the presence of Anti-HCV, it 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. A definite clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result any time does not preclude the possibility of Hepatitis C Virus infection.

## REFERENCES

1. Kapoor A, Simmonds P, Gerold G, Qaisar N, Jain K, Henriquez JA, Firth C, Hirschberg DL, Rice CM et al. (2011). "Characterization of a canine homolog of hepatitis C virus". Proc Natl Acad Sci USA 108 (28): 11608–11613.
2. Op De Beeck A, Dubuisson J (2003). "Topology of hepatitis C virus envelope glycoproteins". Rev. Med. Virol. 13 (4): 233–41.
3. Kato N (2000). "Genome of human hepatitis C virus (HCV): gene organization, sequence diversity, and variation". Microb. Comp. Genomics 5 (3): 129–51.