

## Introduction

One Step ANTI-HCV Rapid Screen Test is a lateral flow, immunochromatographic screening test. Two Purified recombinant antigens of HCV are used in test band as capture materials and gold conjugates. If the antibody of Anti-HCV is present in the sample in concentration above the labeled, complex will be formed. This complex is then captured by antigen immobilized in the Test Zone of the membrane, producing a visible pink-rose color band on the membrane. The color intensity will depend on the concentration of the anti-HCV present in the sample. This one step test is very sensitive and only takes about 10-15 minutes. Test results are read visually without any instrument.

## Intended Use

This product is used for qualitative detection of the presence of Anti-HCV(Core,NS3, NS4, NSS) in human serum or plasma, and the clinical auxiliary diagnosis of HCV infection, and test results also need to be further confirmed by the clinician in connection with symptoms, signs and other test results.

## Materials Provided

Individually sealed foil pouches containing:

1. One cassette test device.
2. One Buffer
3. One Lancet
4. One Alcohol Wipe
5. One Pipette
6. One package insert (instruction for use)

## Materials Required but Not Provided

1. sample collection containers
2. timer or clock

## Storage And Stability

The test kit can be stored at room temperature (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.

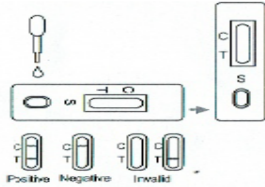
## Specimen Collection

For serum, collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the clot. For plasma, collect whole blood into a purple, blue or green top collection tube (containing EDTA, citrate or heparin, respectively) by vein puncture, separate plasma from whole blood.

Use the specimen inside an hour. If the specimen can not be tested inside an hour, store the specimen in 4 °C cold closet or refrigerator but Don't freeze. Bring the specimens to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

## Test Procedure

1. Open a pouch containing a cassette, lay the cassette.
2. Using the plastic pipettor provided, draw 2-3 drops of sample into the sample well of the cassette.
3. Read results within 10-15 minutes. Do not read results after 20 minutes.



## Interpretation Of Results

1. Negative: Only one color band appears on the control region. No apparent band on the test region. This indicates that there is no detectable anti-HCV in the serum.
2. Positive: Distinct color bands appear on the control and test regions. Both test line and control line indicate that the specimen contains a detectable amount of anti-HCV.
3. Invalid: No visible band at all or only one colored band appears on the test region, this is an indication of a possible error in performing the test. The test should be repeated using a new device.
4. A control line in the control zone indicates a valid result. A valid result indicates a suitable sample was collected and the test functioned properly. The control line will appear on all valid tests, whether or not the result is reactive (Refer to Test Results). Performances

## Sensitivity and Specificity

To use L11:8, L11:16 and L21:64, L21:128 standard product for inspection, observe the result within fifteen minutes the test line will turn red.

Positive reference (20 samples): Correspondence between positive reference samples=20/20  
 Negative reference (20 samples): Correspondence between negative reference samples=20/20  
 Reproducibility (10 reference samples), Identical reactivity

## The Limitation Of The Testing Methods

The detection of HCV with this kit depends on the content of Anti-HCV in the sample, sampling methods and the patient's condition: such as age, general disease history, whether there is a symptom and other conditions shall affect the detection.

## Precaution

1. Must use fresh specimen and avoid repetitive freezing, the result will be invalid
2. Use it before expiry date.
3. The package of kit should not be opened until it reaches room temperature if it is taken out from the refrigerator.
4. Old Serum can not be used. If the serum is thick, it can be used only after being separated.

## Limitations

1. The test is for in-vitro diagnostic use only.
2. The test is qualitative filter detection, it can not be used as the final test for blood donor.