

# One-Step HCV Rapid Test

【For the qualitative detection of HCV antibodies in serum/plasma and whole blood】

## INTRODUCTION

The HCV Rapid Test is a Chromatographic immunoassay (CIA) for direct qualitative detection of antibodies to Hepatitis C type virus (HCV) in human serum/ plasma and whole blood.

## PRINCIPLE

The HCV Rapid Test is a chromatographic immunoassay (CIA) for the detection of antibodies to HCV in human serum/plasma and whole blood. HCV recombinant antigens are precoated onto membrane as a capture reagent on the test region. During the test, specimen is allowed to react with the colloidal gold particles, which have been labeled with HCV recombinant antigens. If antibodies to HCV present, a pink colored band will develop on the membrane in proportion to the amount of HCV antibodies present in the specimen. Absence of this pink colored band in the test region suggests a negative result. To serve as a procedural control, a purple colored band in the control region will always appear regardless the presence of antibodies to HCV.

## REAGENTS AND MATERIALS PROVIDED

1. One pouched cassette with desiccant.
2. Blood diluent in a dropper bottle, stored at 2-8°C.
3. One piece of operating instruction.

## WARNING AND PRECAUTIONS

1. FOR IN VITRO DIAGNOSTIC USES ONLY
2. All patient samples should be treated as if capable of transmitting diseases.
3. Do not interchange reagents from different lots or use test kit beyond expiration date.
4. Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.

## STORAGE

The kits should be stored at temperature 4-30°C, the sealed pouch for the duration of the shelf life (24 months).

## SAMPLE COLLECTION AND PREPARATION

Fingerstick Specimens(Whole Blood)

1. Clean the area to be lanced with an alcohol swab.
2. Squeeze the end of the fingertip and pierce it with a sterile lancet.
3. Wipe away the first drop of blood with sterile gauze or cotton.
4. Use micropipet to obtain about 100ul fresh blood .

### Plasma

1. Have a certified phlebotomist collect whole blood into a purple, blue or green top collection tube (containing EDTA, citrate or heparin, respectively) by veinpuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma for testing, or label and store it at 2-8°C for up to two weeks. Plasma may be frozen at -20°C for up to one year.

### Serum

1. Have a certified phlebotomist collect whole blood into a red top collection tube (containing no anticoagulants) by veinpuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.

- Carefully withdraw the serum for testing or label and store it at 2-8°C for up to two weeks. Serum may be frozen at -20°C for up to one year.

### ASSAY PROCEDURE

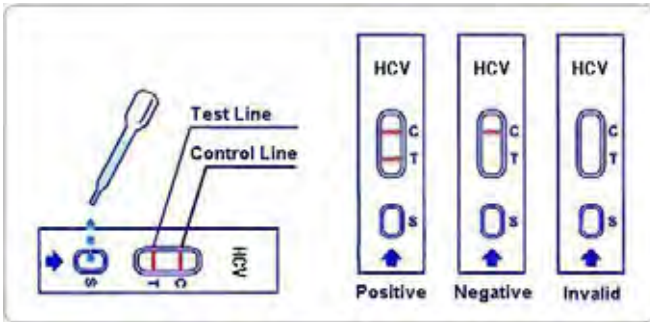
Serum or Plasma Sample

Add 70-100ul or 2-3 drops of serum or plasma into sample well. Observe the result in 5-30 minutes.

Whole Blood Sample

Add 1 drop of whole blood into sample well, after all blood completely absorbed. Add 1 drop of whole blood diluent. Observe the result in 5-30 minutes.

### INTERPRETATION OF RESULTS



- Negative: No apparent band in the test region (T), a pink-colored band appears in the control region (C). This indicates that no HCV antibody has been detected.
- Positive: In addition to a pink-colored band in the control region (C), a pink-colored band will appear in the test region (T). This indicates that the specimen contains HCV antibodies.
- Invalid: If no band appears in the control region (C), regardless of the presence or absence of line in the test region (T). It indicates a possible error in performing the test. The test should be repeated using a new device.

### LIMITATION OF THE PROCEDURE

- The test is to be used for the qualitative detection of antibodies to HCV.
- A negative result does not rule out infection by HCV because the antibodies to HCV may be absent or may not be present in sufficient quantity to be detected at early stage of infection.

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