iCARE One Step Anti-HCV Rapid Test
(Whole Blood/Serum/Plasma)

FOR IN VITRO DIAGNOSTIC USE ONLY

INTENDED USE

THE iCARE ANTI-HCV RAPID TEST IS A COLLOIDAL GOLD ENHANCED, RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HEPATITIS C VIRUS (HCV) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS A SCREENING TEST AND ALL POSITIVES MUST BE CONFIRMED USING AN ALTERNATE TEST SUCH AS WESTERN BLOT. THE TEST IS INTENDED FOR FIELD AND PROFESSIONAL USE ONLY.

SUMMARY AND EXPANATION OF THE TEST

The assay starts with a sample applied to the sample well and add provided sample diluent immediately. The HCV antigen -colloidal gold conjugate embedded in the sample pad reacts with the HCV antibody present in blood; serum or plasma sample forming conjugate/HCV antibody complex. As the mixture is allowed to migrate along the test strip, the conjugate/HCV antibody complex is captured by a recombinant HCV antigen which contains core, NS3, NS4, NS5 immobilized on a membrane forming a colored test band in the test region. A negative sample does not produce a test line due to the absence of colloidal gold conjugate/HCV antibody complex. The antigens used in the test are recombinant proteins corresponding to highly immunoreactive regions of HCV. A colored control band in the control region appears at the end of test procedure regardless of test result. This control band is the result of colloidal gold conjugate binding to an anti-HCV antibody immobilized on the membrane. The control line indicates that the colloidal gold c onjugate is functional. The absence of the control band indicates that the test is invalid.

MATERIALS PROVIDED

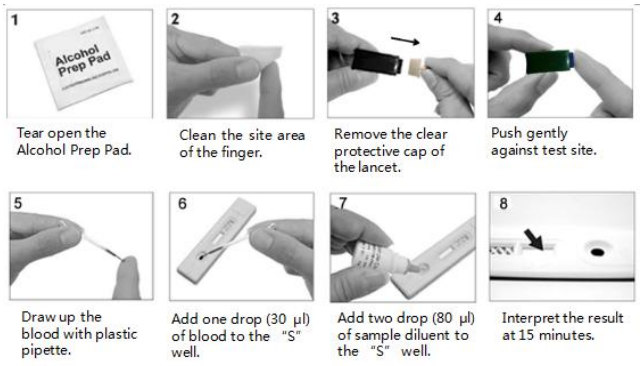
Each Kit Contains:
- Test cards individually foil pouched with a desiccant.
- Plastic dropper
- Sample diluent
- Safety lancet
- Alcohol swab
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED
- Positive and negative controls

STORAGE CONDITIONS
- All the kit reagents must be stored at 2-30°C in the sealed pouch and under dry conditions until expiration date.

WARNINGS AND PRECAUTIONS
1. For in vitro diagnostic use only.
2. Treat all samples as though potentially infectious.
3. Wear gloves and protective clothing when handling samples.
4. Operate according to standard safety precautions when dispose biohazardous materials.
5. Clean and disinfect all spills of samples using a suitable disinfectant, such as 1% Sodium Hypochlorite.
6. Sterilize all kit reagents used in this assay prior to disposal.
7. Do not use kit reagents beyond their expiration dates.
8. Do not interchange kit reagents from different lots.
9. Do not re-use the test card or any single use accessories.
10. Do not use the test card that has become wet or if the foil pouch is damaged.

ASSAY PROCEDURES FOR FINGER BLOOD
1. Bring the Anti-HCV test card, sample diluent, alcohol swab, safety lancet, plastic dropper to room temperature.
2. Take out the test card from the sealed pouch.
3. To perform the test, please follow the steps closely as follow (from picture 1 to picture 8).



ASSAY PROCEDURE FOR VENOUS BLOOD COLLECTED BY REGULAR CLINICAL LABORATORY PROCEDURES

SAMPLE COLLECTION
VENIPUNCTURE WHOLE BLOOD
1. Use standard venous phlebotomy procedure to collect a whole blood sample by a tube containing any of the following anticoagulants: EDTA, heparin, or sodium citrate. Other anticoagulants have not been tested and may give an incorrect result. If the samples are not tested at the time of collection, the whole blood can be stored at 2-8℃ for 3 days. Before testing, mix the blood tube gently by inversion several times to ensure a homogeneous sample.
2. Pick up an unused sample collection plastic dropper to collect the drop of blood.
3. Using the blood samples in the long-term keeping more than 3 days may cause non-specific reaction.

SERUM OR PLASMA

1. SERUM

Use the standard venous phlebotomy procedure to collect a whole blood sample by a tube **NOT** containing any of the following anticoagulants: EDTA, heparin, or sodium citrate. Leave to settle for 30 minutes for blood coagulation and then centrifuge the blood to get serum sample of supernatant.

2. PLASMA

Use the standard venous phlebotomy procedure to collect a whole blood sample by a tube containing any of the following anticoagulants: EDTA, heparin, or sodium citrate. And then centrifuge the blood to get a plasma sample.

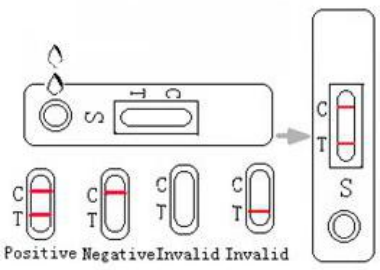
Note:
1. *If serum or plasma samples are not tested immediately, they should be refrigerated at 2-8℃. For storage period longer than 7days, freezing is recommended. Please bring the samples to room temperature before testing.*
2. *Serum or plasma samples containing a precipitate may yield inconsistent test results. Such samples must be clarified before testing.*

ASSAY PROCEDURES
1. Bring all reagents and specimens to room temperature.
2. Remove the test card from the foil pouch and place on a clean dry surface.
3. Identify the test card for each specimen or control.
4. Dispense one drop (30µl) of sample or control into the sample well on the card using the plastic dropper provided, then add two drops (80µl) of sample diluent into the same well.
5. Interpret test results at 15 minutes.

Caution: Use a clean capillary tube or pipette tip for every sample to avoid cross-contamination.

READING THE TEST RESULT

Do not interpret test result after 20 minutes
1. *Positive:* A purplish test band appearing in the test region indicates a positive result. The lower the concentration is, the weaker the test band may be.
2. *Negative:* The absence of a purplish test band in the test region indicates a negative result.
3. *Invalid:* There should always be a purplish control band in the control region regardless of test result. If control band is not seen, the test is considered invalid and should be repeated using a new test card.



PERFORMANCE CHARACTERISTICS

1. Specificity:

The specificity of the Rapid Anti-HCV Test is based on clinical studies using confirmed negative serum samples from blood bank and hospital patients in USA (66 samples) and China (90 samples). The studies were performed comparing the results from Rapid Anti-HCV test and that from Abbott's ELISA as a reference test. The overall specificity was found to be 97 - 99%.

2. Sensitivity:

In the same studies mentioned above, Rapid Anti-HCV Test was evaluated with 61 confirmed positive serum samples (USA: 31 samples and China: 30 samples). All 61 samples were found reactive.

LIMITATIONS

The test is for in-vitro diagnostic use only.

BIBLIOGRAPHY

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2. Alter HJ, Purcell RH, Shih JW, Melpolder JC, Houghton M, Choo Q-L, Kuo G. Detection of antibody. to hepatitis C virus in prospectively followed transfusion recipients with acute and chronic non-A, non-B hepatitis. ·A Engl J Med 1989;321: 1494-500.
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