HCV Hepatitis C Virus Antibody Rapid Test Kit

(Immunochromatography)

Product Name

HCV Hepatitis C Virus Antibody Rapid Test Kit (Immunochromatography)

Intended Use

The reagent is used to detect the Hepatitis C Virus Antibody in serum / plasma qualitatively.

Test Principle

The test utilizes antibodies including a recombinant protein mixed HCV antigen and rabbit anti-HCV antibody on the nitrocellulose membrane with colloidal gold marked mixed HCV antigen as a mark tracer. The reagent is used to detect the HCV antibody in serum / plasma according to the principle of double antigen sandwich method and gold immunochromatography assay.

The sample mixing up HCV antigen–marker move along the membrane to the T line, and form the T line when the sample contains HCV antibody, which a positive result. Conversely, it is a negative result.

Main Components

Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board.

Storage and Expiry

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

Sample Requirement

1. The reagent can be used for the serum, plasma samples. After collection, separate the serum and plasma as soon as possible, in order to avoid hemolysis.

2. A serum / plasma sample must be collected in a clean and dry container. EDTA, sodium citrate, sodium oxalate, heparin can be used as the anticoagulants. Detect immediately after collecting blood. If blood coagulation occurs, serum samples are suggested to use.

3. Samples may be stored at 2-8℃ for 3 days prior to assay, and at -20 ℃.

Test Procedure

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20℃-30℃) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10℃-50℃)

Strip and Cassette:

1. Take off the outer packing, put the strip/cassette onto the desk with the sample adding area of the strip/ the sample window of the cassette up.

2. Serum / Plasma: Drop 1 drop (25ul) serum/plasma vertically into the sample adding area of the strip/the sample hole of cassette. Add 2 drops (80-100ul) of sample buffer into the sample adding area of the strip/the sample hole of cassette.

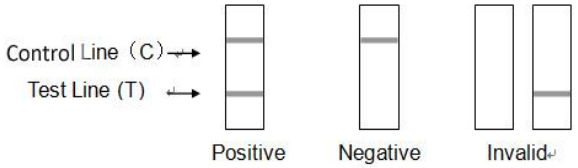
3. Observe the test results immediately within 10-20 minutes, the result is invalid over 20 minutes.

Result Judgment

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

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

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.



Limitation

1. This reagent is designed for the qualitative screening test. Concentration of HCV cannot be determined by this qualitative test.

2. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.

3. Negative result may occur when detecting short-term infected samples, indicate that the specific antibodies of HCV does not exist or the concentration is below detection limit.

4. Positive results of the patients who used to receive blood transfusions or other blood products therapy, should be analyzed cautiously.

5. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.

Precaution

1. For IN VITRO diagnose only.

2. Do not use after the expiration date.

3. The test result is invalid over 20 minutes.

4. The strength of the quality control line doesn’t indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.