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 / whole blood qualitatively. HCV is a single-stranded positive sense RNA virus, which belongs to the family of Flaviviridae. Hepatitis C caused by HCV is an infectious disease with liver as a target organ. The incubation period of hepatitis C virus infection was 2 to 26 weeks, most of the symptoms occurrs in 5 to 12 weeks after transfusion, on an average of 7.4 weeks. There is a long window period with an average of 70 days after the hepatitis C virus infection, however, some patients' window period can be extended to 6~9 months or even longer. Hepatitis C virus antibody can be detected in most infections with a slow appearance. Generally positive results may occur 2~6 months after the attack, while some positive results occur 12 months later.

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 / whole blood 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

The testing kit is in the form of strip and cassette. Basic components: Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board. Colloidal gold marked pad coated with mixed HCV antigen (expression vector pBVIL1), nitrocellulose membrane coated with recombinant protein mixed HCV antigen (expression vector pBVIL1)，control line coated with goat rabbit anti-HCV antibody (polyclonal antibody, rabbit-derived). The sample dilution is made of 20mM phosphate buffer (PBS).

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 and whole blood samples.

2. A serum / plasma / whole blood 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 sample is suggested to use. Use the fresh whole blood samples.

3. Samples may be stored at 2-8℃ for 1 week prior to assay, and at -20 ℃ for 2 years. Frozen refrigerated samples should be recovered to room temperature before detection and thoroughly mixed. Repeat freeze and thaw for no more than 3 times. Samples exhibiting visible precipitates, stink or muddy should not be used. Centrifuged, filtered, or allowed to settle to obtain a clear sample for testing.

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/Whole blood: Drop 25μl serum/plasma/whole blood vertically into the sample adding area of the strip/the sample hole of cassette. Add about 2 drops of (80μl-100μl) sample buffer into the sample adding area of the strip/the sample hole of cassette.

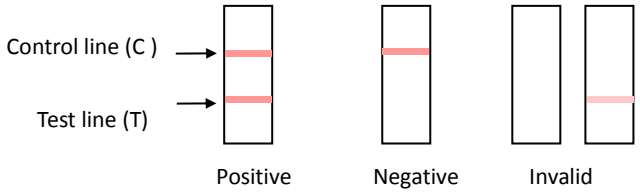
3. Observe the test results immediately within 10-20 minutes, the result is invalid over 20 minutes.

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. Abnormal results may occur according to operator error or drug use. If HCV infection is still suspected, the sample should be collected later and carry the parallel detection with the first sample.

Performance Characteristics

1. Using national quality control samples:

Negative specificity: The coincidence rate should exceed 19/20 when detecting national negative quality control samples with 20 kits of HCV.

Positive specificity: The coincidence rate should be 19/20 when detecting internal negative quality control samples with 20 kits of HCV.

Limit of detection: The results should all be positive when detecting the internal quality control samples or the diluted national HCV positive quality control samples: L1≥1：8；L2 ≥1：64.

Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the precision control samples by 10 kits of the same batch.

2. Clinical trial results

A clinical evaluation was conducted on 1158 samples comparing the results obtained using the Diagnostic Kit for Hepatitis C Virus Antibody（Colloidal Gold）and other commercially available HCV tests. The results demonstrated a 99.31% positive agreement, 99.22% negative agreement, and a 99.49% overall agreement of the Diagnostic Kit for Hepatitis C Virus Antibody （Colloidal Gold） when compared to the other HCV test.

3. Analytical sensitivity: 1000 mol/L bilirubin, 5.65mmol/L triglyceride, 6.5g/L hemoglobin has no effect on the detection result. The reagent is not affected by the rheumatoid factor, antinuclear antibodies, anti-mitochondrial antibodies, non-specific IgG and IgM.

The addition of HBV, HAV, HEC, TP, HIV, toxoplasm, RV, RMV, HSV-Ⅰ, HSV-Ⅱ, HGV, EB and influenza A virus showed no cross-reactivity.

4. Hook effect: the hook effect will not occur even the HCV diluents rate is 1:1024..

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.

5. All samples and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.

6. 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.