HCV Antibody Rapid Test Kit

INTENDED USE

The Hepatitis C Surface Virus (HCV) Antibody Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies to Hepatitis C in whole blood serum or plasma to aid in the diagnosis of Hepatitis C virus.

INTRODUCTION

Hepatitis C is an infectious disease caused by the hepatitis C virus (HCV) that primarily affects the liver. Hepatitis C virus (HCV) is a single-stranded RNA virus of the Flaviviridae family and is the causative agent of Hepatitis C. Hepatitis C is a chronic disease affecting approximately 130-170 million people worldwide. According to thhe WHO, annually, more than 350,000 people die from hepatitis C-related liver diseases, and 3-4 million people are infected with HCV. Approximately 3% of the world's population is estimated to be infected with HCV. Individuals infected with HCV produce antibodies to the virus, and the presence of these antibodies in the blood indicates present or past infection with HCV.

The HCV Antibody Rapid Test is a lateral flow chromatographic immunoassay based on the principle of the double-antigen technique. The membrane is coated with recombinant HCV antigen on the test line region of the kit. During testing, specimen reacts with the HCV antigen-coated gold nanoparticles. The presence of this colored line indicates the presence of antibodies to HCV in samples.

PRINCIPLE

HCV Rapid Test is a qualitative, membrane-based immunoassay for the detection of antibodies to HCV in samples. The membrane is pre-coated with recombinant HCV antigen on the test line region of the kit. During testing, the specimen reacts with recombinant HCV antigen conjugated with colloid gold. A visible colored line will show up in the test line region indicating a positive result. If antibodies to HCV are not present or are present below the detectable level, a colored line will not form in the test line region indicating a negative result.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS SUPPLIED

1. Individual sealed pouches, each pouch containing:
   a. 1 × Test Kit
   b. 1 × Desiccant Pouch
   c. 1 × Dropper
2. Buffer

STORAGE AND STABILITY

- Keep the test kit between 2 - 30°C in a dry, cool place. Avoid freezing.
- The kit is stable within the expiry date printed on the product label and outer packaging. Do not use later than the specified date.
- The package should be sealed until it is required for use.

SPECIMEN COLLECTION AND PREPARATION

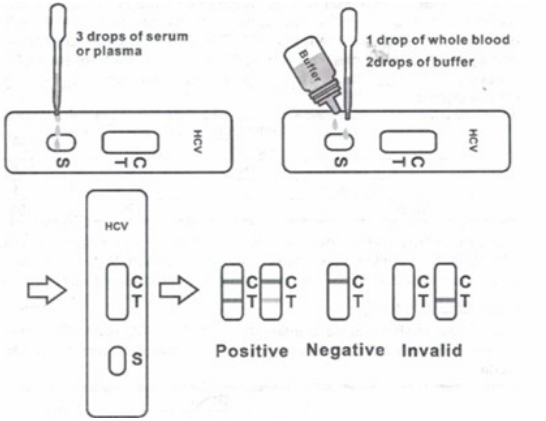
1. The HCV Antibody Rapid Test can be performed using Whole Blood, Serum or Plasma.
2. Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear, non-haemolyzed specimens.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
4. Whole Blood, Serum and plasma specimens may be stored at 2-8 °C for up to 3 days. For long-term storage, specimens should be kept below -20 °C. Do not freeze a whole blood specimen. Bring specimens to room temperature prior to testing.
5. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

6. Do not use samples showing gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

TEST PROCEDURE

Allow the test kit, specimen, and buffer to equilibrate to room temperature (15-30 °C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test kit from the sealed pouch and use it within one hour.
2. Place the kit on a clean and level surface.
3. **For Whole Blood specimens**: Hold the dropper vertically and transfer 1 drop of whole blood (approx. 35 µL) to the specimen area and then add 2 drops of buffer (approximately 70 µL), and start the timer.
4. **For Serum or Plasma specimens**: Hold the dropper vertically and transfer 3 drop of serum or plasma (approx. 100 µL) to the specimen area, and start the timer.
5. Wait for the colored line(s) to appear. Read the results in 10 minutes. Do not interpret the result after 20 minutes.



RESULT:

1. Two Pink Lines - (POSITIVE)
2. One Pink Line at (C) - (NEGATIVE)
3. No Pink Line - (INVALID)

PERFORMANCE CHARACTERISTICS

A side-by-side comparison was conducted using the HCV Antibody Rapid Test and commercially available HCV rapid tests. A statistical comparison was made between the results, yielding a clinical sensitivity of 98%, a clinical specificity of 100% and an accuracy of 99.3%.

LIMITATIONS

1. The HCV Antibody Rapid Test Kit(Whole Blood/ Serum/ Plasma) is limited to providing a qualitative detection. The intensity of the test line does not necessarily correlate with the concentration of the antibody in the blood.
2. The results obtained from this test are intended to be an aid in diagnosis only. Each physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.
3. A negative test result indicates that antibodies to HCV are either not present or at levels undetectable by the test.

REFERENCES

1. Hepatitis C. Fact sheet No. 164. World Health Organization. http://www.who.int/mediacentre/factsheets/fs164/en/index.html(Update on Jun 2011)
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