HCV Rapid Test Kit

INTENDED USE

The Hepatitis C Surface Virus (HCV) Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies to Hepatitis C in 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. The HCV One Step Rapid Test is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The membrane is coated with recombinant HCV antigen on the test line region of the device. During testing, the serum or plasma specimen reacts with the HCV antigen coated gold nanoparticles. Presence of this colored line indicates 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 cassette. During testing, the specimen reacts with recombinant HCV antigen conjugated with colloid gold.

MATERIALS SUPPLIED

Each pack contains: One test device, one disposable dropper, and Silica gel pouch.

STORAGE AND STABILITY

Storage: Store in temperature 2℃ to 30℃. Open the pouch just before use.

SPECIMEN COLLECTION AND PREPARATION

1. Collect Serum / Plasma specimens following regular clinical laboratory procedures.
2. Storage: A specimen should be refrigerated if not used on the same day of collection. Specimens should be frozen if not used within 3 days of collecting. Avoid freezing and thawing the specimens more than 2-3 times before using.

ASSAY PROCEDURE

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the cassette on a clean and level surface.
3. For the serum or plasma specimen: Hold the dropper vertically and add three drops (about 100µl) to the test device's specimen well (S). Then, set the timer.
4. For whole blood specimens: Hold the dropper vertically and transfer 1 drop of whole blood (approx. 35 µL) to the specimen area, then add 2 drops of buffer (approx. 70 µL), 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.

Notes:

1. Applying a sufficient amount of sample diluent is essential for a valid test result. If migration (the wetting of membrane) is not observed in the test window after one minute, add one more drop of diluent to the sample well.
2. The positive results could appear as soon as one minute for a sample with high levels of HCV antibodies.
3. Do not interpret results after 20 minutes

INTERPRETATION OF RESULTS

RESULT:

1. Positive: Both a pink band and a purplish pink control band appear on the membrane. The lower the antibody concentration, the weaker the test band.
2. Negative: Only the purplish red control band appears on the membrane. The absence of a test band indicates a negative result.
3. Invalid result: There should always be a purplish red control band in the control region, regardless of the test result. If a control band is not seen, the test is considered invalid. Repeat the test using a new test device. Note: It is normal to have a slightly lightened control band with very strong positive samples, as long as it is distinctly visible.

LIMITATIONS OF THE TEST

1. Only clear, fresh, free flowing Serum/ Plasma can be used in this test.
2. Fresh samples are best but frozen samples can be used. If a sample has been frozen, it should be allowed to thawed and checked for fluidity.
3. Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the Specimen.