

HCV Rapid Test **Diagnostic Test for Detecting Hepatitis C Infection**

Name and Intended Use

HCV Rapid Test is a visual, qualitative immunoassay for *in vitro* detection of antibodies to Hepatitis C virus. The test is intended as an aid to diagnosis of HCV infection.

Summary and Explanation of the Test

Hepatitis C virus (HCV) is a single stranded RNA virus of the Flaviviridae family and is the causative agent of almost all non-A, non-B hepatitis. 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.

Biological Principles of the Procedure

HCV Rapid Test is a recombinant antigen based, two-sided lateral flow immunoassay. It is composed of a pad containing colloidal gold particles coated with recombinant HCV antigens (core, ns3, ns4, ns5). A second area of the test strip has a membrane that is coated with the same HCV antigens. During the test, if HCV antibodies are present in the sample they bind to the antigens on the colored particles. The complex of antibody-antigen then migrates through the membrane and is captured by the recombinant antigens immobilized in the test region. This captured complex shows up as a pink to red line.

Absence of a line in the test region (T) suggests a negative result. The test contains an internal control in the control region (C) that should always show up as a pink-red line regardless of the test line result.

Materials Provided

HCV Rapid Test contains the following components to perform the assay:

1. Test Device (cassette)
2. Sample loop (5 microliter)
3. Assay buffer
4. Instruction manual

Accessories (required, but not provided):

1. Micropipette (if loop not used)
2. Timer

Storage and Stability

The test devices are sealed in a moisture-proof foil laminate pouch, containing desiccant. These should be stored in the coolest and driest area available, preferably at 4-30°C. The kit has a shelf life of 15 months from the date of manufacture. The devices should not be frozen and must be protected from exposure to humidity; once a pouch is opened, the device should be used within one hour.

Precautions

To obtain reproducible results, the following instructions must be followed:

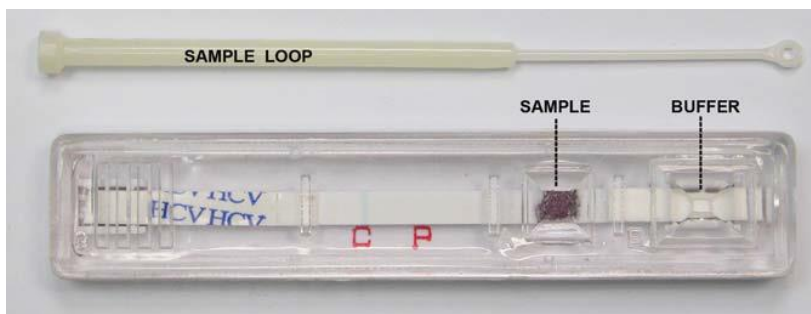
1. For *in vitro* diagnostic use only with whole blood. Not for use with serum or plasma samples.
2. Use disposable gloves while handling potentially infectious material and performing the assay.
3. Do not use the kit beyond the expiration date.
4. Do not eat, smoke, or drink while handling specimens.
5. Do not combine reagents from different batch numbers as the components are optimized for individual batch to give best results.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Do not open the foil pouch until it attains room temperature to prevent formation of condensation.
8. For best results, follow the test procedure and storage instructions strictly.

Specimen Collection and Storage

1. Collect whole blood in a clean container by venipuncture. Use either plain tubes for serum or tubes containing anti-coagulant (EDTA, citrate or heparin) for plasma. Separate the serum or plasma. If samples are not immediately tested, they should be stored at 4-8°C for not more than 2 weeks
2. Fresh blood from a finger prick may also be used as a test sample. The sample application area of the device will separate the cells from the plasma.

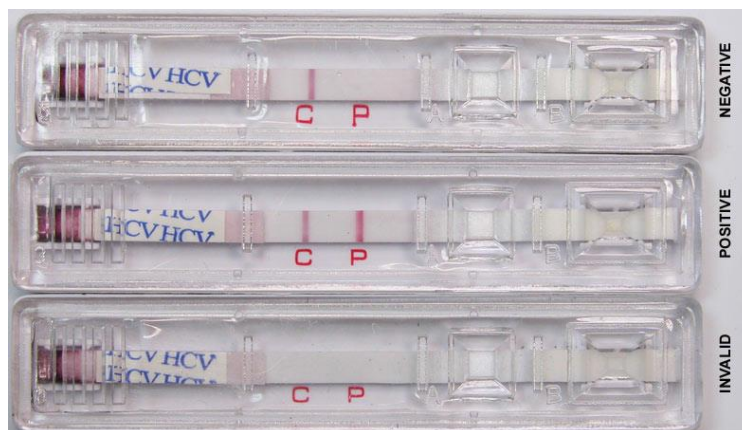
Test Procedure

1. Bring the complete kit and sample to be tested to room temperature prior to testing. Once the device pouch is opened, it must be used within one hour.
2. Using the sample loop provided, or a suitable micropipette, place **two** loops of blood (10 microliters) or **one** loop (5 microliters) of serum/plasma into the sample window of the device. If using the loop, press gently against the bottom of the sample window, twist slightly, and allow the sample to flow out of the loop.
3. Add 3-4 drops of assay buffer to the buffer window as shown below.
4. The buffer will rehydrate the red colloidal gold conjugate, which will mix with the sample and flow onto the membrane. After 10-15 minutes all the pink color from the conjugate will clear from the membrane except for test and controls lines which form. The result of the test can then be read.



Interpretation of Results

As shown below, a reactive test shows as two colored lines, one in the test area, one in the control area. The test should be considered reactive if any visible line is evident in the test area, even if it is very faint. A non-reactive test shows only one colored line in the control area. If no lines are visible or if the control line is not visible, the test is invalid.



Performance Characteristics

The test can detect parasitemia levels of 100 parasites per microliter of blood (0.002% parasitemia) based on evaluation of microscopically characterized samples of *P. falciparum* infected blood. The test has been evaluated with positive and negative clinical samples with results as follows:

Sample	Total Number	Positive	Negative	Sensitivity (%)	Specificity (%)
HCV Negative	150	0	150	-	100%
HCV Positive	80	80	0	100%	-

Limitations and Interferences

1. The test procedure, precautions and interpretation of results for the test must be followed strictly.
2. The test is a qualitative screening assay and is not for quantitative determination of antibodies to HCV. There is no meaning attributed to line color intensity or width.
3. **This is only a screening test.** The test does not rule out HCV infection because the antibodies may not be present in sufficient quantity to be detected at a very early stage of infection.
4. The results obtained must be confirmed by other diagnostic procedures and clinical data.