

AT+FIRST HCV

Hepatitis C Virus Rapid Test Device (Whole Blood/Serum/Plasma) Package Insert

A rapid test for the qualitative detection of antibodies to Hepatitis C Virus (HCV) in whole blood, serum or plasma.

For professional in vitro diagnostic use only.

INTENDED USE

The HCV Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibody to Hepatitis C Virus in whole blood, serum or plasma.

SUMMARY

Hepatitis C Virus is a small, enveloped, positive-sense, single-stranded RNA Virus. HCV is now known to be the major cause of parenterally transmitted non-A, non-B hepatitis. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis.

Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens.^{1,2} Compared to the first generation HCV EIAs using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests.^{3,4}

The HCV Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibodies to HCV in whole blood, serum or plasma specimen. The test utilizes a combination of protein A coated particles and recombinant HCV proteins to selectively detect antibody to HCV in whole blood, serum or plasma. The recombinant HCV proteins used in the test kit are encoded by the genes for both structural (nucleocapsid) and non-structural proteins.

PRINCIPLE

The HCV Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibody to HCV in whole blood, serum or plasma. The membrane is coated with recombinant HCV antigen on the test line region of the device. During testing, the whole blood, serum or plasma specimen reacts with the Protein A coated particles. The mixture migrates upward on the membrane chromatographically by capillary action to react with recombinant HCV antigen on the membrane and generate a colored line. Presence of this colored line indicates a positive result, while its absence indicates 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.

REAGENTS

The test device contains protein A coated particles and HCV antigen coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The HCV Rapid Test device (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma.
- To collect Fingerstick Whole Blood specimens:
 - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
 - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
 - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
 - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingersitck Whole Blood specimen to the test device by using a capillary tube:
 - Touch the end of the capillary tube to the blood until filled to approximately 25 µl. Avoid air bubbles.
 - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood onto the specimen well (S) of the test device.
- Add the Fingersitck Whole Blood specimen to the test device by using hanging drop:
 - Position the patient's finger so that the drop

of blood is just above the specimen well (S) of the test device.

- Allow 1 hanging drops of fingerstick whole blood to fall onto the specimen well (S) of the test device, or move the patient's finger so that the hanging drop touches the specimen well (S). Avoid touching the finger directly to the specimen well (S).
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. 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. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

- Test devices
- Disposable specimen droppers
- Buffer (for whole blood only)
- Package insert

Materials Required But Not Provided

- Specimen collection containers
- Lancets (for fingerstick whole blood only)
- Disposable heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)
- Centrifuge (for plasma only)
- Timer

DIRECTIONS FOR USE

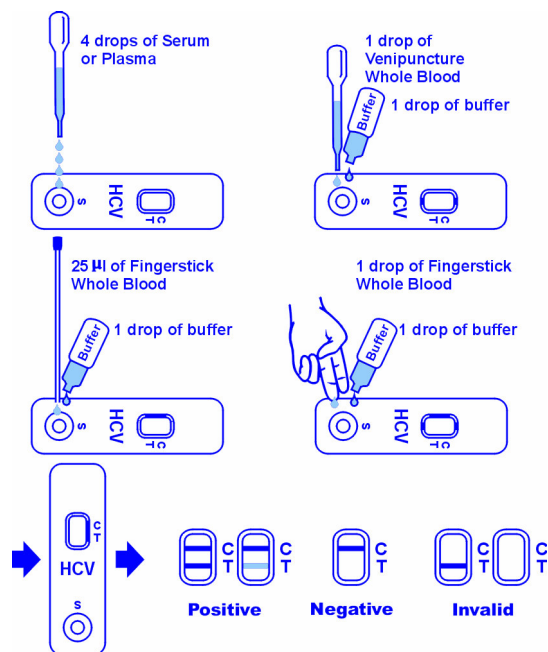
Allow the test device, specimen, buffer, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.
For ~~Serum or Plasma~~ specimen: Hold the dropper vertically and transfer 4 drop of serum or plasma (approximately 100 µl) to the specimen well (S) of the test device, and start the timer. See illustration below.
For ~~Venipuncture Whole Blood~~ specimen: Hold the dropper vertically and transfer 1 drop of venipuncture whole blood (approximately 25 µl) to the specimen well (S) of the test device, then add 1 drop of buffer

(approximately 40µl) and start the timer. See illustration below.

For **Fingerstick Whole Blood** specimen:

- To use a capillary tube: Fill the capillary tube and transfer approximately 25 µl of fingerstick whole blood specimen to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µl) and start the timer. See illustration below.
 - To use hanging drop: Allow 1 hanging drop of fingerstick whole blood specimen (approximately 25 µl) to fall into the center of the specimen well (S) on the test device, then add 1 drop of buffer (approximately 40 µl) and start the timer. See illustration below.
3. Wait for the red line(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

***NOTE:** The intensity of the red color in the test line region (T) will vary depending on the concentration of HCV antibody present in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.

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

INVALID: **Control line fails to appear.** Insufficient

specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATION

- The HCV Rapid Test Device (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of antibodies to HCV in whole blood, serum or plasma specimen. Neither the quantitative value nor the rate of increase in HCV antibodies can be determined by this qualitative test.
- The HCV Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of antibodies to HCV in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis C viral infection.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of Hepatitis C Virus infection.

EXPECTED VALUES

The HCV Rapid Test Device (Whole Blood/Serum/Plasma) has been compared with a leading commercial HCV EIA test, demonstrating an overall accuracy of 99.3%.

PERFORMANCE CHARACTERISTICS

Sensitivity

The HCV Rapid Test Device (Whole Blood/Serum/Plasma) has been tested with a seroconversion panel and compared with a leading commercial HCV EIA test using clinical specimens. The results show that the relative sensitivity of the HCV Rapid Test Device (Whole Blood/Serum/Plasma) is over 99.0%.

Specificity

The recombinant antigens used for the HCV Rapid Test Device (Whole Blood/Serum/Plasma) is encoded by genes for both structural (nucleocapsid) and non-structural

proteins. The results show that the relative specificity of the HCV Rapid Test Device (Whole Blood/Serum/Plasma) is 98.6%.

HCV Test Device	Method	EIA		Total Results
	Results	Positive	Negative	
		Positive	Negative	
	Positive	145	2	147
	Negative	0	144	144
	Total Results	145	146	291

Relative sensitivity: >99.0%

Relative specificity: 98.6%

Accuracy: 99.3%

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens: a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified 98% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same three specimens: a negative, a low positive and a high positive. Three different lots of the HCV Rapid Test Device (Whole Blood/Serum/Plasma) have been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified 98% of the time.

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