

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

For professional *in vitro* diagnostic use only.

INTENDED USE

The HCV Rapid Test (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 (HCV) 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 (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in a whole blood, serum or plasma specimen. The test utilizes colloid gold conjugate 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.

PRINCIPLES

The HCV Rapid Test (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 pre-coated with recombinant HCV antigen on the test line region of the dipstick. During testing, the whole blood, serum or plasma specimen reacts with recombinant HCV antigen conjugated colloid gold. 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.

MATERIALS

Materials provided

- Test dipsticks
- Droppers
- Buffer
- Package insert

Materials required but not provided

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

WARNINGS AND 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 dipstick is stable through the expiration date printed on the sealed pouch. The test dipstick must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

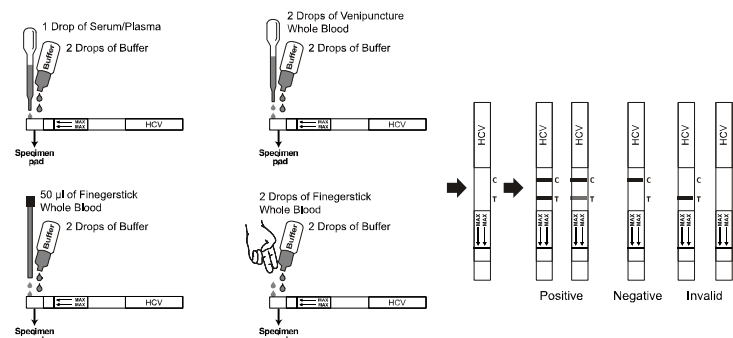
SPECIMEN COLLECTION AND PREPARATION

- The HCV Rapid Test (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 Fingerstick Whole Blood specimen to the test by using a **capillary tube**:
 - Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.
 - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test dipstick.
 - Add the Fingerstick Whole Blood specimen to the test by using **hanging drops**:
 - Position the patient's finger so that the drop of blood is just above the specimen well of the test dipstick.
 - Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen well on the test dipstick, or move the patient's finger so that the hanging drop touches the center of the specimen well. Avoid touching the finger directly to the specimen well.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. 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 for transportation of etiologic agents.

DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the test dipstick from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. For **Serum or Plasma** specimen:
Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25 µL) to the specimen well, then **add 2 drops of buffer** (approximately 120 µL), and start the timer, see illustration below.
For **Venipuncture Whole Blood** specimen:
Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 µL) to the specimen well, then **add 2 drops of buffer** (approximately 120 µL), and start the timer. See illustration below.
For **Fingerstick Whole Blood** specimen:
 - To use a capillary tube: Fill the capillary tube and **transfer approximately 50 µL of fingerstick whole blood specimen** to the specimen well of test dipstick, then **add 2 drops of buffer** (approximately 120 µL) and start the timer. See illustration below.
 - To use hanging drops: Allow **2 hanging drops of fingerstick whole blood specimen** (approximately 50 µL) to fall into the specimen well of test dipstick, then **add 2 drops of buffer** (approximately 120 µL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **The test 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 colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).

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

NEGATIVE: One colored line appears in the control region (C). No colored 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 dipstick. 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 colored line appearing in the control region (C) is an internal 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.

LIMITATIONS

1. The HCV Rapid Test (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HCV in whole blood, serum or plasma specimen.
2. The HCV Rapid Test (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.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. 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.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The recombinant antigen used for the HCV Rapid Test (Whole Blood/Serum/Plasma) is encoded by genes for both structural (nucleocapsid) and non-structural proteins. The HCV Rapid Test (Whole Blood/Serum/Plasma) has passed 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 (Whole Blood/Serum/Plasma) is 98.8%, and the relative specificity is 99.1%.

Method	EIA		Total Results
	Results	Positive	Negative
HCV Rapid Test (Whole Blood/Serum/Plasma)	Positive	252	7
	Negative	3	731
Total Results		255	738
		993	

Relative sensitivity: 98.8% (95%CI:* 96.6%-99.8%)

Relative specificity: 99.1% (95%CI:* 98.1%-99.6%)

Accuracy: 99.0% (95%CI:* 98.2%-99.5%)

*Confidence Intervals

Limitation of Detection

The minimum detection level is 1:2048 for HCV positive specimen.

Precision

Intra-Assay

Within-run precision has been determined by using 20 replicates of three specimens: a negative, a HCV low titer positive and a HCV high titer positive. The negative, HCV low titer positive and HCV high titer positive values were correctly identified 100% of the time.

Inter-Assay

Between-run precision has been determined by 20 independent assays on the same three specimens: a negative, a HCV low titer positive and a HCV high titer positive. Three different lots of the HCV Rapid Test (Whole Blood/Serum/Plasma) have been tested over a 3-month period using negative, HCV low titer positive and HCV high titer positive specimens. The specimens were correctly identified 100% of the time.

Cross-reactivity

The HCV Rapid Test (Whole Blood/Serum/Plasma) has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, Syphilis, HIV, *H. Pylori*, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to HCV negative and positive specimens.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 2 g/dL	Albumin: 2 g/dL
Creatin: 200 mg/dL	Hemoglobin: 1000 mg/dL
Bilirubin: 1 g/dL	Oxalic Acid: 60 mg/dL

None of the substances at the concentration tested interfered in the assay.

BIBLIOGRAPHY

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INDEX OF SYMBOLS

	Consult instructions for use		Contains sufficient for <n> tests
	In vitro diagnostic medical device		Use-by date
	Temperature limit		Batch code
	Do not use if package is damaged		Manufacturer
	Catalogue number		Do not re-use



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