Rapid Response™

HCV Test Strip
(Whole Blood/Serum/Plasma)
REF HCV-13S50 Product Insert

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 Rapid Response™ HCV Test Strip 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 Rapid Response™ HCV Test Strip 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 antibodies 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 Rapid Response™ HCV Test Strip is a qualitative, membrane-based immunoassay for the detection of antibodies to HCV in whole blood, serum or plasma. The membrane is pre-coated with recombinant HCV antigen on the test line region of the Strip. 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.

Reagents

The test Strip contains recombinant HCV antigen conjugated colloid gold 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.

Materials

Materials provided

- Test strips
- Droppers
- Buffer
- Product insert

Materials required but not provided

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

Storage and Stability

The kit can be stored at room temperature or refrigerated (35.6-86°F; 2-30°C). The test Strip is stable through the expiration date printed on the sealed pouch. The test Strip must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

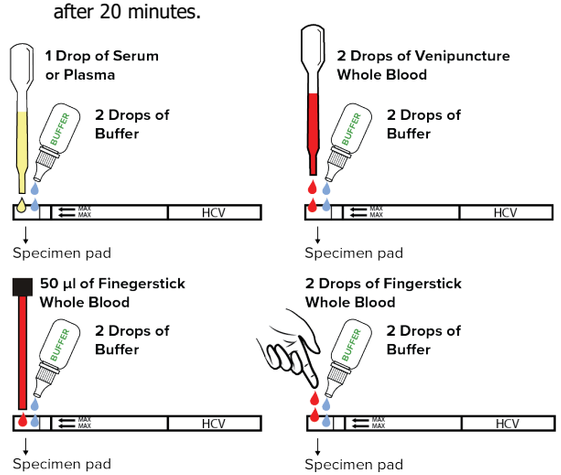
Specimen Collection and Preparation

- The Rapid Response™ HCV Test Strip 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 area of the test Strip.
- 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 area of the test Strip.
- Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test Strip, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
- 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 35.6-46.4°F (2-8°C) for up to 3 days. For long term storage, specimens should be kept below -4°F (-20°C). Whole blood collected by venipuncture should be stored at 35.6-46.4°F (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.

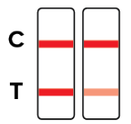
Test Procedure

Allow test Strip, specimen, and/or controls to equilibrate to room temperature (59-86°F; 15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test Strip 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 area, 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 area, 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 area of test Strip, 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 area of test Strip, 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.

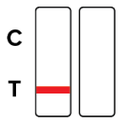


Results Interpretation



POSITIVE: * Two colored lines appear. One colored line should be in the control region (C) and another color line should be in the test region (T).
***NOTE:** The intensity of the color 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 color 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 Strip. 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 color 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.

Limitations

1. The Rapid Response™ HCV Test Strip 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 Rapid Response™ HCV Test Strip 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.

Expected Values

The Rapid Response™ HCV Test Strip has been compared with a leading commercial HCV EIA test. The correlation between these two systems is over 99%.

Performance Characteristics

Sensitivity and Specificity

The recombinant antigen used for the Rapid Response™ HCV Test Strip is encoded by genes for both structural (nucleocapsid) and non-structural proteins. The Rapid Response™ HCV Test Strip 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 Rapid Response™ HCV Test Strip is 98.8%, and the relative specificity is 99.1%.

Method		EIA		Total Results
Rapid Response™ HCV Test Strip	Result	Positive	Negative	
	Positive	252	7	259
	Negative	3	731	734
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

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 Rapid Response™ HCV Test Strip 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 Rapid Response™ HCV Test Strip 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: 2g/dL	Albumin: 2 g/dL
Creatin: 200 mg/dL	Hemoglobin 1000mg/dL
Bilirubin: 1g/dL	Oxalic Acid: 60mg/dL

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

Bibliography

1. Choo, Q.L., G. Kuo, A.J. Weiner, L.R. Overby, D.W. Bradley,and M. Houghton. Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome. Science 1989; 244:359
2. Kuo, G., Q.L. Choo, H.J. Alter, and M. Houghton. An assay for circulating antibodies to a major etiologic Virus of human non-A, non-B hepatitis. Science 1989; 244:362
3. van der Poel, C. L., H.T.M. Cuypers, H.W. Reesink, and P.N.Lelie. Confirmation of hepatitis C Virus infection by new four-antigen recombinant immunoblot assay. Lancet 1991; 337:317
4. Wilber, J.C. Development and use of laboratory tests for hepatitis C infection: a review. J. Clin. Immunoassay 1993; 16:204

Glossary of Symbols

Consult instructions for use
Test per Kit
Do not use if package is damaged
Store between 35.6°F to 86°F
Use by
Do Not Reuse
LOT Lot Number
IVD For *in vitro* diagnostic use only
REF Catalogue #
Manufacturer

BTNX Inc.
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Pickering, ON L1W 4B2
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