HCV DEVICE (2-30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADHCV2	20 Tests

Intended Use:
The HCV Test Device (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative, presumptive detection of antibodies to HCV in human serum or plasma specimens. This kit is intended for use as an aid in the diagnosis of HCV infection.

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. Antibodies to HCV are 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. 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. The HCV Rapid Test Device (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.

Test Principle:
The HCV 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 pre-coated with recombinant HCV antigen on the test line region of the device. 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 coloured line. Presence of this coloured line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured 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 recombinant HCV antigen conjugated colloid gold and HCV antigen coated on the membrane.

Materials Provided
Individually pouched test devices
Disposable pipettes
Package Insert
Buffer

Materials not provided: Timer, Specimen collection container, Centrifuge, Lancet (for fingerstick whole blood only), Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

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.

Reagent Preparation 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 Storage:
- 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 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 device.
- 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 device.
  - Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test device, 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 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.

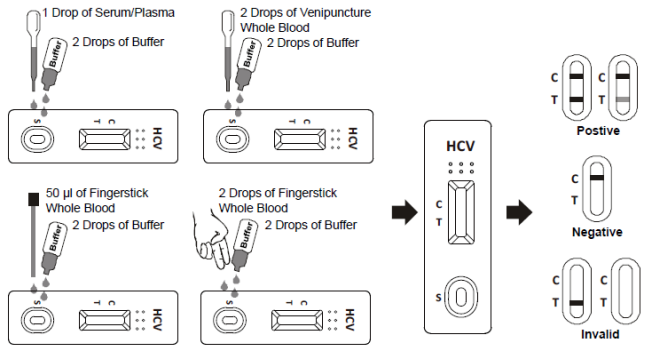
Assay Procedure:

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
2. Place the device on a clean and level surface.
   - 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 80 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 80 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 device, then **add 2 drops of buffer** (approximately 80 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 device, then **add 2 drop of buffer** (approximately 80 µL) and start the timer. See illustration below.

Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
As the test begins to work, you will see colour move across the membrane.

3. Wait for the coloured band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.



Interpretation of Results:

POSITIVE: Two coloured bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one coloured band appears, in the control region (C). No apparent coloured band appears in the test region (T).

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INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:
The intensity of the colour 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.

Quality Controls:
Internal procedural controls are included in the test. A colour 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 of the Test:
1. The HCV Rapid Test Device (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 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.
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 HCV Rapid Test Device (Whole Blood/Serum/Plasma) has been compared with a leading commercial HCV EIA test. The correlation between these two systems is 99.6%.

Performance Characteristics:

Sensitivity and Specificity:
The recombinant antigen used for the HCV Rapid Test Device (Whole Blood/Serum/Plasma) is encoded by genes for both structural (nucleocapsid) and non-structural proteins. The HCV Rapid Test Device (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 Device (Whole Blood/Serum/Plasma) is 99.9%, and the relative specificity is 99.5%.

HCV Rapid Test vs. EIA

Method		Elisa		Total Results
HCV Rapid Test Device	Result	Positive	Negative	
	Positive	187	3	190
	Negative	0	603	603
Total Result		187	606	793

Relative Sensitivity: >99.9% (95% Confidence Interval: 98.4% - 100%)
Relative Specificity: 99.5% (95% Confidence Interval: 98.6% - 99.9%)
Accuracy: 99.6% (95% Confidence Interval: 98.9% - 100%)

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 Device (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 Device (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: 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.

References:

1. Choo QL, Kuo G, Weiner AJ, Overby LR, Bradley DW, Houghton M. Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome. Science. 1989 Apr 21; 244(4902): 359-62.
2. Kuo G, Choo QL, Alter HJ, Gitnick GL, Redeker AG, Purcell RH, Miyamura T, Dienstag JL, Alter MJ, Stevens CE, et al. An assay for circulating antibodies to a major etiologic virus of human non-A, non-B hepatitis. Science. 1989 Apr 21; 244(4902): 362-4.
3. Van der Poel CL, Cuypers HT, Reesink HW, Weiner AJ, Quan S, Di Nello R, Van Boven JJ, Winkel I, Mulder-Folkerts D, Exel-Oehlers PJ, et al. Confirmation of hepatitis C virus infection by new four-antigen recombinant immunoblot assay. Lancet. 1991 Feb 9; 337(8737): 317-9.
4. Wilber JC. Development and use of laboratory tests for hepatitis C infection: a review. J Clin Immunoassay. 1993; 16: 204-207.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse