HCV TEST STRIP (2–30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADHCV1	50 Tests

Intended Use:
The HCV Rapid Test Strip (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibody to HCV in human 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. 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 Strip (Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in a serum or plasma specimen. The test utilizes colloid gold conjugate and recombinant HCV proteins to selectively detect antibody to HCV in 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 Rapid Test Strip (Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibody to HCV in serum or plasma. The strip is coated with recombinant HCV antigen at the test line region of the strip. During testing, the serum or plasma specimen reacts with recombinant HCV antigen conjugated to particles coated at the specimen area. The mixture migrates upwards chromatographically where it reacts with the HCV antigen at the test region. The development of a coloured line indicates a positive result, while no line appearing in the test region indicates a negative result. To serve as a procedural control, a coloured line should 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 strip.

Materials Provided
Individually pouched test strips
Disposable pipettes
Buffer
Instructions for Use sheet

Materials not provided: Timer, specimen collection container, centrifuge

Precautions:
- For professional *in vitro* diagnostic use only. Do not use after expiry 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 including laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
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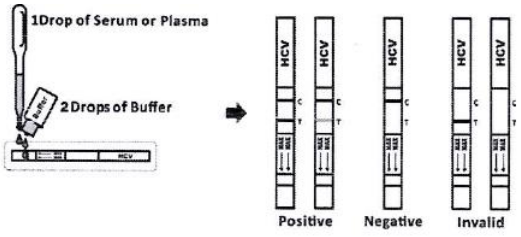
Storage and Stability:
The kit can be stored at room temperature or refrigerated (2-30°C). The Test Strip is stable until the expiry date printed on the sealed pouch. The Test Strip must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiry date.

Specimen Collection and Storage:
- The HCV Test Strip (Serum/Plasma) can be performed using serum or plasma.
- Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed 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.
- 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.

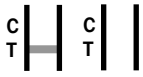
Assay Procedure:
Bring tests, specimens, buffer and controls to room temperature (15-30°C) before use.
1. Remove the Test Strip from its sealed pouch and perform the test within one hour. Lay the test cards on a clean level surface.
2. Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 25 µl) to the specimen area, then add 2 drops of buffer (approximately 120 µl) and start the timer, see illustration below.
3. Wait for coloured line(s) to appear. Record results at 10 minutes. Do not interpret results 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).
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.

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



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.

Quality Controls:
Internal procedural controls are included in the test. A colour 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 of the Test:
- The HCV Rapid Test Strip (Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HCV in serum or plasma.
- The HCV Rapid Test Strip (Serum/Plasma) will only indicate the presence of HCV antibodies in the specimen and should not be used as the sole criteria for the diagnosis of HCV 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.

Performance Characteristics:
Sensitivity and Specificity
The HCV Rapid Test Strip (Serum/Plasma) has passed using a seroconversion panel and was compared with a licenced HCV EIA test using clinical specimens. The correlation between the two systems was 99.0%. The results also showed that the relative sensitivity of the HCV Rapid Test Strip (Serum/Plasma) is 98.7% and the relative specificity is 99.1%.

Method		EIA		Total Result
HCV Rapid Test Strip (Serum/Plasma)	Results	Positive	Negative	
	Positive	235	6	241
	Negative	3	692	695
Total Result		238	698	936

Relative sensitivity: 98.7% (95%CI:*96.4%~99.7%)
Relative specificity: 99.1% (95% CI: *98.1%~99.7%)
Accuracy: 99.0% (95% CI:*98.2%~99.6%)
*Confidence Intervals

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

Inter-Assay
Between-run precision has been determined by 20 independent assays on the three specimens: a negative, a low positive and a high positive. Three different lots of the HCV Rapid Test Strip (Serum/Plasma) were tested using negative, low positive and high positive specimens. The specimens were correctly identified 100% of the time.

Cross-reactivity
The HCV Rapid Test Strip (Serum/Plasma) has been tested using HAMA, RF HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, Syphilis, HIV, H.pylori, MONO, CMV, Rubella and TOXO positive specimens. The tests showed no cross-reactivity.

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

Acetaminophen: 20mg/dl	Caffeine: 20mg/dl
Acetylsalicylic Acid: 20mg/dl	Gentisic Acid: 20mg/dl
Ascorbic Acid: 2g/dl	Albumin: 2g/dl
Creatine: 200mg/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, Q.L. *et al.* Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome. Science 1989; 244:359
2. Kuo, G. *et al.* An assay for circulating antibodies to a major etiologic Virus of human non-A, non-B hepatitis. Science 1989; 244:362

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3. van der Poel, C. L. *et al*. 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

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

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