SPECTRUM

The Creative Approach to Bioscience

HCV Ab Rapid Test Cassette

(Serum/Plasma /Whole Blood)

REF: 1219 001 25 test

INTENDED USE

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

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.
The HCV Rapid Test Cassette (Serum, Plasma or whole blood) is a rapid test to qualitatively detect the presence of antibody to HCV in a 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 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 Cassette (Serum, Plasma or whole blood) is a qualitative, membrane based immunoassay for the detection of antibody to HCV in serum or plasma. The membrane is coated with recombinant HCV antigen on the test line region of the device. During testing, the serum ,plasma or whole blood specimens react 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 AND MATERIALS PROVIDED

The test cassette contains recombinant HCV antigen conjugated colloid gold and HCV antigen coated on the membrane.

1. Test Cassettes
2. Buffer
3. Droppers
4. Package inserts.

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer
- Centrifuge

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 and 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.

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Temperature Limitation
IVD	For in-vitro diagnostic use		Use by/Expiration Date
LOT	Batch Code/Lot number		CAUTION. Consult instructions
REF	Catalogue Number		for use
	Consult instructions for use		Manufactured by

• 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 STORAGE INSTRUCTION

All reagents are ready to use as supplied. Store unused test devices unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND PREPARATION

- The HCV Rapid Test Cassette (Serum/Plasma or Whole Blood) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.

To collect Fingerstick Whole Blood specimens:

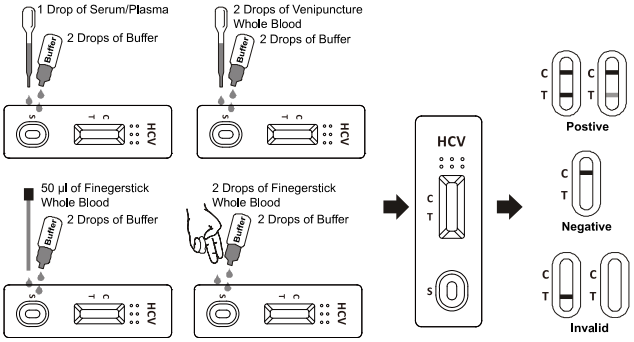
- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- 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 cassette.
- 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 cassette.
- Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test cassette, 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.

TEST PROCEDURE

Allow test cassette, 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 cassette 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. Place the cassette 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 80µL), 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 cassette, 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 cassette, then **add 2 drop of buffer** (approximately 80 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 distinct colored lines appear. One color 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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal Quality Control

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

External Quality Control

It is recommended that a positive and negative external control be run every 20 tests, and as deemed necessary by internal laboratory procedures. Some commercial controls may contain interfering preservatives; therefore, interpretation of results with external quality controls should be done with caution.

Procedure for External Quality Control Testing

1. Using a disposable dropper or pipette, transfer 5 µL to the Specimen well (S) as in procedure Step 2.
2. Continue with Step 3 of Directions For Use. If the controls do not yield the expected results, do not use the test results. Repeat the test or contact your distributor.

LIMITATIONS OF TEST

1. The HCV Rapid Test Cassette (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 Cassette (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.
5.

Expected Values

The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial HCV EIA test. The correlation between these two systems is 99%.

PERFORMANCE CHARACTERISTICS

Sensitivity

The The HCV One Step Test Device (Serum/Plasma) has passed a seroconversion panel and compared with a leading commercial HCV EIA test using clinical specimens.

Specificity

The recombinant antigen used for the HCV One Step Test Device (Serum/Plasma) is encoded by genes for both structural (nucleocapsid) and non-structural proteins. The HCV One Step Test Device (Serum/Plasma) is highly specific for antibodies to Hepatitis C Virus compared with a leading commercial HCV EIA test.

HBsAg Reference Method

Method		**EIA**		**Total Result**
HCV Rapid Test Cassette (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	187	3	190
	Negative	0	603	603
Total Result		187	606	793

Relative Sensitivity: > 99.0%
Relative Specificity: 99.5%
Accuracy: 99.6%

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 One Step Test Device (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..

REFERENCES

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3. Wilber, J.C. Development and use of laboratory tests for hepatitis C infection: a review. J.Clin. Immunoassay 1993; 16:204
4. 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