Ref: 0557

IMMUNOQUICK® HCV

CE 2265

A rapid test for the qualitative detection of antibodies to Hepatitis C Virus in serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The IMMUNOQUICK® HCV Rapid Test Cassette (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibody to Hepatitis C Virus in 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 Cassette (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 IMMUNOQUICK® HCV Rapid Test Cassette (Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibody to HCV in serum or plasma. The membrane is pre-coated with recombinant HCV antigen on the test line region of the cassette. During testing, the 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 cassette contains recombinant HCV antigen conjugated colloid gold and HCV antigen coated on the membrane.

MATERIAL PROVIDED

- Test cassettes
- Droppers
- Buffer
- Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

- Specimen collection containers
- Centrifuge (for plasma only)
- Timer

STORAGE AND STABILITY

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

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.

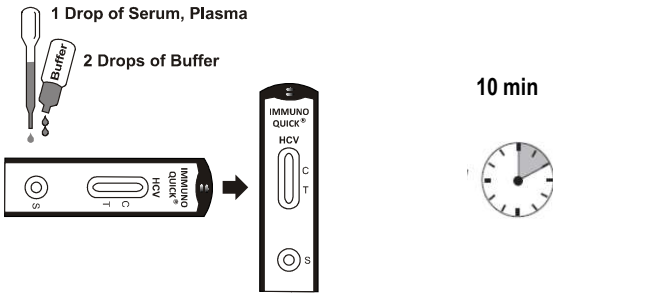
SPECIMEN COLLECTION AND STORAGE

- The IMMUNOQUICK® HCV Rapid Test Cassette (Serum/Plasma) can be performed using either serum or plasma.
- 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. 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.

PROCEDURE

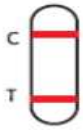
Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

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 test cassette on a clean and level surface. Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 25 µL) to the specimen well of the test cassette, then add 2 drops of buffer (approximately 80 µL) and start the timer. Avoid trapping air bubbles in the specimen well. See the 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

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).

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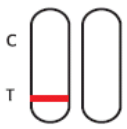

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal valid 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.

TEST LIMITATIONS

1. The IMMUNOQUICK® HCV Rapid Test Cassette (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 specimen.
2. The IMMUNOQUICK® HCV Rapid Test Cassette (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 IMMUNOQUICK® HCV Rapid Test Cassette (Serum/Plasma) has been compared with a leading commercial HCV ELISA test. The correlation between these two systems is >99%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The recombinant antigen used for the HCV Rapid Test Cassette (Serum/Plasma) is encoded by genes for both structural (nucleocapsid) and non-structural proteins. The IMMUNOQUICK® HCV Rapid Test Cassette (Serum/Plasma) has passed a seroconversion panel and compared with a leading commercial HCV ELISA test using clinical specimens.
The results show that the relative sensitivity of the IMMUNOQUICK® HCV Rapid Test Cassette (Serum/Plasma) is 99.1%, and the relative specificity is 99.6%.

Method		ELISA		Total Result
HCV Rapid Test Cassette (Serum/Plasma)	Results	Positive	Negative	
	Positive	462	6	468
	Negative	4	1585	1589
Total Result		466	1591	2057

Relative sensitivity: 462/466= 99.1% (95%CI*: 97.8%~99.8%);
Relative specificity: 1585/1591= 99.6% (95%CI*: 99.2%~99.9%);
Accuracy: (462+1585)/2057= 99.5% (95%CI*: 99.1%~99.8%).
*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 HCV Rapid Test Cassette (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

There was no cross reactivity for HCV Rapid Test Cassette (Serum/Plasma) to be tested by HAMA, HBsAg, HBsAb, HbeAg, HBeAb, HBcAb, anti-HIV, anti-Syphilis, anti-H. Pylori, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens. Some cross-reactivity was observed with samples positive for Rheumatoid Factor, and EBV IgM

Interfering Substances

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

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

SYMBOLS

	Attention, see instructions for use	LOT	Lot number
IVD	For *in vitro* diagnostic use only		Manufacturer
2°C 30°C	Store between 2-30°C		Do not reuse
Σ	Tests per kit	REF	Catalog #
	Use by		Do not use if package is damaged

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