

HCV Rapid Test Cassette (Serum/Plasma) Package Insert

REF L031-10331 English

A rapid test for the qualitative detection of antibodies to Hepatitis C Virus (HCV) in serum or plasma.

For professional in vitro diagnostic use only.

INTENDED USE

ACON HCV Rapid Test Cassette (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to Hepatitis C Virus in serum or plasma.

SUMMARY

Hepatitis C Virus 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. ¹² 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}

ACON HCV Rapid Test Cassette (Serum/Plasma) is a rapid test to qualitatively detect the presence of antibodies to HCV in serum or plasma specimen. The test utilizes a combination of recombinant HCV proteins coated particles and recombinant HCV proteins coated on NC membrane to selectively detect antibodies 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.

PRINCIPLE

ACON HCV Rapid Test Cassette (Serum/Plasma) is a qualitative, membrane and double antigen based immunoassay for the detection of antibodies to HCV in serum or plasma. The membrane is coated with recombinant HCV antigen including NS3, NS4, NS5 and CORE on the test line region of the cassette. The conjugate pad is treated with gold particles which are conjugated with antigen including NS3, NS4, NS5 and CORE. During testing, the serum or plasma specimen reacts with the recombinant HCV antigen 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

The test cassette contains recombinant HCV antigen coated particles 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.

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 use the components beyond the expiration date.
- DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

- ACON HCV Rapid Test Cassette (Serum/Plasma) can be performed using serum or plasma.
 Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. 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 covering the transportation of etiologic agents.

MATERIALS

Materials Provided

- Test cassettes
- Disposable specimen droppers
- Package insert

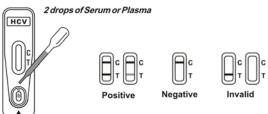
Materials Required But Not Provided

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

DIRECTIONS FOR USE

Allow the test cassette, specimen to equilibrate to room temperature (15-30 $^{\circ}$ C) prior to testing.

- Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results
 will be obtained if the assay is performed immediately after opening the foil pouch.
- Hold the dropper vertically and transfer 2 drops of serum or plasma (approximately 60 μl) onto the sample well and start the timer. See illustration below.
- Wait for the red line(s) to appear. The 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 red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

* NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of HCV antibody present in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.

NEGATIVE: One red 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 procedural controls are included in the test. A red 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.

LIMITATION

- ACON HCV Rapid Test Cassette (Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of antibodies to HCV in serum or plasma specimen. Neither the quantitative value nor the rate of increase in HCV antibodies can be determined by this qualitative test.
- ACON 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

ACON HCV Rapid Test Cassette (Serum/Plasma) has been compared with a leading commercial HCV EIA test, demonstrating an overall accuracy of 99.89%.

PERFORMANCE CHARACTERISTICS

Sensitivity

ACON HCV Rapid Test Cassette (Serum/Plasma) has been tested with 553 clinical specimens and low titer specimens compared with a leading commercial HCV EIA test. The results show that the relative sensitivity of the HCV Rapid Test Cassette Serum/ Plasma) is over 99.0%.

Specificity

The recombinant antigens used for ACON HCV Rapid Test Cassette (Serum/Plasma) is encoded by genes for both structural (nucleocapsid) and non-structural proteins. Specificity of ACON HCV Rapid Test Cassette (Serum/Plasma) was also tested with Hepatitis A positive specimen, Hepatitis B positive specimen, Hepatitis D positive specimen and Hepatitis E positive specimen. They all yielded negative results. The results show that the relative specificity of ACON HCV Test Cassette (Serum/Plasma) is over 99.0%.

ſ	Metho	od	E	A	Total Results
ſ	HCV Test Cassette	Results	Positive	Negative	
		Positive	261	3	264
		Negative	0	289	289
ſ	Total Results		261	292	553

Relative Sensitivity: >99.9% (98.6%-100%)* Overall Agreement: 99.5% (98.42%6-99.89%)* Relative Specificity: 99.0% (97.03%-99.79%)*

*95% Confidence Interval

Precisio

Intra-Assav

Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.

Inter-Assav

Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of ACON HCV Rapid Test Cassette (Serum/Plasma) have been tested using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99.0% of the time.

BIBLIOGRAPHY

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Index of Symbols

	Manufacturer		Σ	Tests per kit	
IVD	For in vitro diagnostic use only		\square	Use by	
LOT	Lot Number		REF	Catalog #	

Store between 2-30°C

Do not reuse





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