Atlas Medical

HCV

Hepatitis C Virus

Rapid Test Device (Serum/Plasma)

A rapid, one step test for the qualitative detection of antibodies to Hepatitis C Virus in serum or plasma.

For In-vitro diagnostic use only

INTENDED USE:
The HCV Rapid TEST device (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 antigen (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 Tests Device (Serum/Plasma) 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 protein 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

PRINCIPLE:
The HCV Rapid Test Device (Serum/Plasma) 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 or plasma specimen reacts 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 red line in the control region will appear confirming that the test has been performed properly.

REAGENTS:
The test device contains protein A coated particles and HCV antigen coated on the membrane.

PRECAUTIONS:
* For 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 microbiology 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:
Store as packaged in the sealed pouch at 2-30 °C. The test device is stable through the expiration date 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 PREPARATION:
* The HCV Rapid Test Device (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 specimen can be used.
* Testing should be performed immediately after the specimens have been collected. Do not leave the specimen 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.

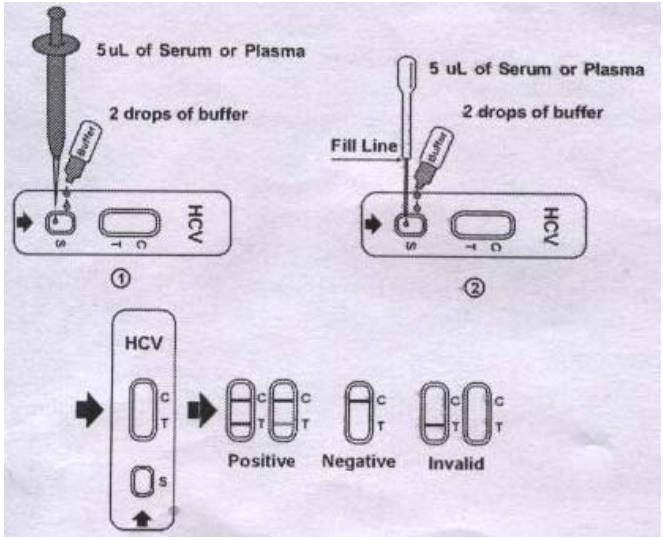
MATERIALS
Materials Provided:
***** Test devices.
* Disposable pipette.
***** Buffer
***** Package insert.

Materials Required But Not Provided:
* Specimen collection container
* Centrifuge
* Timer

DIRECTIONS FOR USE:
Allow test device, serum or plasma specimen, and/or controls to equilibrate to room temperature (15-30ºC) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device 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 device on a clean and level surface. Transfer the specimen by a pipette or a dropper :
. To use a pipette : Transfer 5 µl of serum or plasma to the specimen well (S) of the test device , then add 2 full drops of buffer (approximately 80 µl) and start the timer. Avoid trapping air bubbles in the specimen well (S).See illustration below.
. To use a Disposable specimen Dropper . Hold the dropper vertically, draw the specimen up to the Fill Line as shown in illustration below (approximately 5 µl) . Transfer the specimen to the specimen well (S) of the test device , then add 2 full drops of buffer (approximately 80 µl) and start the timer. Avoid trapping air bubbles in the specimen well (S).
3. Wait for the red line(s) to appear. The test result should be read at 10 minutes. It is important that the background is clear before the result is read.

Note: Low titers of anti-HCV antibodies might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS:
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).

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 device. If the problem persists, discontinue the test kit immediately and contact your local distributor.

NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of anti-HCV antibodies present in the specimen. However, neither the quantitative value nor the rate of increase in anti-HCV antibodies can be determined by this qualitative test.

QUALITY CONTROL:
A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

LIMITATION:
1. The HCV Rapid Test Device (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 HCV Rapid Test Device (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 Devise (Serum/Plasma) has been compared with a leading commercial HCV EIA test. The correlation between these two systems is 98%.

PERFORMANCE CHARACTERISTICS:
Sensitivity:
The HCV Rapid Test Device (Serum/Plasma) has been tested with a seroconversion panel and compared with leading commercial HCV EIA test using clinical specimens.

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

	Reference HCV Method		
		Positive	**Negative**
ATLAS HCV Method	**Positive**	**145**	**2**
	Negative	**0**	**144**

Precision:
Intra-Assay
Within-run precision has been determined by using 15 replicates of three specimens: 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 Rapid Test Device (Serum/Plasma) has been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified 98% of the time.

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