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Hepatitis C Virus Test Cassette (Whole Blood)

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

For professional in vitro diagnostic use only.

Intended Use

The SMI One-Step Hepatitis C Virus (HCV) Test 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 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 recombinant antigens have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests (3, 4).

This HCV Test Device is a rapid test to qualitatively detect the presence of antibody to HCV in a serum, plasma or whole blood specimen. The test utilizes a combination of recombinant antigens coated particles and recombinant HCV proteins to selectively detect antibody to HCV in serum, plasma or whole blood. The recombinant HCV proteins used in the test kit are encoded by the genes for both structural (nucleocapsid) and non-structural proteins

Principle

This One-Step HCV Test Device (Serum/Plasma/Whole blood) is a qualitative, membrane-based immunoassay for the detection of antibody to HCV in serum, plasma or whole blood. The membrane is coated with recombinant HCV antigens on the test line region of the device. During testing, the serum, plasma or whole blood specimen reacts with the HCV antigens 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 if the test has been performed properly.

Reagents

The test device contains recombinant HCV antigens 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 testing 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 being tested.
- Humidity and temperature can adversely affect results.

Storage & Stability

The kit can be stored at room temperature or refrigerated (2-30℃). The test device is stable through the expiration date printed 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.

Materials

Materials Provided:

- Test cassette
- Instructions
- 20uL transfer pipette
- Buffer

Materials required but not provided:

- Centrifuge (for serum or plasma samples)
- Timer

Specimen Collection & Preparation

- This one-step HCV test can be performed using serum, plasma or whole blood.
- Separate the serum or plasma 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℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.
- 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.

Directions for Use:

Allow test device, serum, plasma or whole blood specimen, and/or controls to equilibrate to room temperature (15-30℃) 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 cassette on a clean and level surface. Add 20µl of serum, plasma or whole blood specimen to the “S” well of the cassette using the transfer pipette.
3. Add 1 drop (50µl) of HCV buffer to the sample well (S) of the cassette immediately after the specimen is added, and then start the timer.
4. Wait for the red line(s) to appear. The test result should be read at 15 to 20 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 30 minutes.

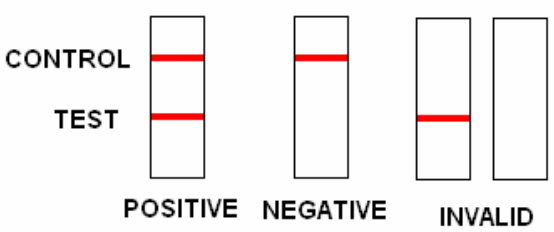
Interpretation of Results:

(Please refer to illustration)

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 using 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.

Limitations

1. This HCV test is for in vitro diagnostic use only.
2. This HCV test 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.

The recombinant antigens used for the SMI HCV cassette are encoded by genes for both structural (nucleocapsid) and non-structural proteins. This test is highly specific for antibodies to Hepatitis C Virus compared with a leading commercial HCV EIA test.

Bibliography

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