ASPEN® HCV

Hepatitis C Virus Rapid Test Device (Serum/Plasma) Package Insert

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 HCV 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 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 Test 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 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.

PRINCIPLE

The HCV 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 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 device contains protein A 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 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.
- 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 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.

SPECIMEN COLLECTION AND PREPARATION

- The HCV 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, nonhemolyzed 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 ompliance with federal regulations for transportation of etiologic agents.

MATERIALS PROVIDED

Materials Provided

- Test devices
- Disposable specimen droppers
- Buffer
- Package insert

Materials Required But Not Provided

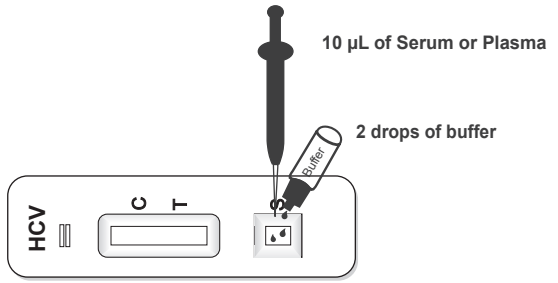
- Specimen collection container
- Pipette and disposable tips (optional)
- Centrifuge (for plasma only)
- Timer

DIRECTION OF USE

Note: Bring the test device, specimen and buffer to the room temperature if stored at 2-8^{0}C

Take out the test device from the pouch and place on a clean & flat surface

- Add **1 drop** (10µl) of **serum / plasma** to the specimen well of test device using dropper / pipette.Then **add 2 drops** of **buffer** (70µl). Read result at **20 minutes**. (Do not interpret the result after 30 minutes)



INTERPRETATION OF RESULTS

NEGATIVE: Pink/Purple line at **C** only

POSITIVE: Pink/Purple lines at **C & T**

INVALID: If control line does not appear, the test is invalid. In this case, please repeat the test using another device following the test procedure correctly.

QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the control region (C) is considered 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.

LIMITATIONS

1. The HCV Test Device (Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of anibodies to HCV in serum or plasma specimen.
2. The HCV Test Device (Serum/Plasma) will only indicate the presence of antibodies to HCV in the specimen and should not be used as the sole criteriafor 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 Test Device (Serum/Plasma) has been compared with a leading commercial HCV EIA test. The correlation between these two systems is 99%.

PERFORMANCE CHARACTERISTICS

Sensitivity

The HCV Test Device (Serum/Plasma) compared with a leading commercial HCV EIA test using clinical specimens.

Specificity

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

Sample	Total No. of samples tested	Accurate HCV		sensitivity (%)	Specificity (%)
		Positive	Negative		
Negative	1500	2	1498	-	99.8
Positive	300	299	01	99.6	-

BIBLIOGRAPHY

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2. H.T.M. Cuypers, H.W. Reesink, van der Poel, C. L., and P.N.Lelie. *Confirmation of hepatitis C Virus infection by new four-antigen recombinant immunoblot assay*. Lancet 1991; 337:317

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