OneStep HCV RapiCard™ InstaTest (Serum/Plasma)

INTENDED USE

The Cortez Diagnostic, Inc. HCV RapiCard™ (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibody to Hepatitis C Virus in serum or plasma.

SUMMARY AND EXPLANATION

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 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 HCV RapiCard™ (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 colloidal 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 colloidal gold and HCV antigen coated on the membrane.

SPECIMEN COLLECTION AND PREPARATION

- The HCV RapiCard™ (Serum/Plasma) can be performed using 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. 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 for transportation of etiologic agents.

ASSAY 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 within one hour. Best results will be obtained if the assay is performed as soon as possible.
2. Place the cassette on a clean and level surface.

For Serum or Plasma specimen: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 25 μL) to the specimen area, then add 2 drops of buffer (approximately 80 μL), and start the timer, see illustration below. Wait for the colored line(s) to appear. The test result should be read at 10 minutes. Do not interpret the results after 20 minutes.

MATERIALS PROVIDED

- Test cassettes
- Droppers
- Buffer

MATERIALS REQUIRED BUT NOT PROVIDED

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

PRECAUTION

- For professional in vitro 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.
**RESULTS**

(Please refer to the illustration above)

**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).

**NEGATIVE:** One color 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 color 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.

**LIMITATIONS OF PROCEDURE**

1. The HCV RapiCard™ (Serum/Plasma) is for in vitro use only. This test should be used for the detection of antibodies to HCV in serum or plasma specimen.
2. The HCV RapiCard™ (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 RapiCard™ (Serum/Plasma) has been compared with a leading commercial HCV EIA test. The correlation between these two systems is 99%.

**STORAGE**

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.

**PERFORMANCE CHARACTERISTICS**

**Sensitivity and Specificity**

The recombinant antigen used for the HCV RapiCard™ (Serum/Plasma) is encoded by genes for both structural (nucleocapsid) and non-structural proteins. The HCV RapiCard™ (Serum/Plasma) has passed a seroconversion panel and compared with a leading commercial HCV EIA test using clinical specimens. The results show that the relative sensitivity of the HCV RapiCard™ (Serum/Plasma) is 98.7%, and the relative specificity is 99.1%.

<table>
<thead>
<tr>
<th>Method</th>
<th>EIA Results</th>
<th>Total Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV RapiCard™ (Serum/Plasma)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>235</td>
<td>241</td>
</tr>
<tr>
<td>Negative</td>
<td>3</td>
<td>692</td>
</tr>
<tr>
<td>Total Result</td>
<td>238</td>
<td>698</td>
</tr>
<tr>
<td>Relative sensitivity: 98.7% (95% CI: 96.4%-99.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relative specificity: 99.1% (95% CI: 98.1%-99.9%)</td>
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<tr>
<td>Accuracy: 99.0% (95% CI: 98.9%-99.6%)</td>
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</tbody>
</table>

*Confidence Intervals

**REFERENCE**

four-antigen recombinant immunoblot assay. Lancet 1991; 337:317