Anti-HCV dipstick

Immunochromatographic assay for the detection of hepatitis C antibodies in serum or plasma

Intended use

The Cypress Anti-HCV dipstick is a rapid chromatographic immunoassay for the qualitative detection of antibodies to hepatitis C virus in human serum or plasma. It can be used for clinical diagnosis of HCV infection and for screening of blood donors at the scene.

Summary and Explanation

Hepatitis C Virus is a small, enveloped, positive-sense, single-stranded RNA Virus. Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscopy. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens. Compared to the first generation HCV EIA's 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.

Principle

The Cypress Anti-HCV dipstick is a qualitative, membrane based immunoassay for the detection of antibody to HCV in serum or plasma. The test device contains membrane strip that is pre-coated with HCV recombinant antigen on the test band region and goat-ß-glob on the control band region. The Protein A -colloid gold conjugate pad is placed at the end of the membrane. During testing, the antibodies of serum or plasma specimen reacts with the Protein A coated particles. This mixture then migrates to the test band region and forms a visible line as the Protein A -antibody-antigen complex forms. Therefore, the formation of a visible precipitation in the test band region occurs when the sample is possible for the HCV specific antibodies. When the HCV specific antibodies are absent in the sample, no visible color band will form on the test line region. Therefore, the absence of the color band on the test line region indicates a negative result. A colored band will always appear at the control region. This control band serves as a procedural indicator for the proper performance of the test and the device.

Materials provided:

- Each kit contains the items to perform 50 tests:
  - 2 desiccated containers, each containing 25 dipsticks.
  - 1 Instruction leaflet.

Additional Materials Required:

- Timer
- Specimen collection container

Storage and Stability

The Cypress Diagnostics anti-HCV dipstick kit should be stored at room temperature (up to 30°C) in the desiccated container, kept away from direct sunlight, moisture and heat. Do not use expired test kits.

Precautions

1. The test is for in vitro diagnostic and for professional use only. Use the test only in accordance with instructions supplied with the kit.
2. The dipstick should remain in the desiccated container until use. Do not use after the expiration date.
3. There should be no smoking or eating where antigen containing materials are being handled. Wear disposable gloves and lab coat while handling specimens. Wash hands thoroughly afterwards.
4. Standard guidelines for handling infectious agents and chemical reagents should be observed throughout all procedures. All contaminated waste such as patient samples and used dipsticks should be properly disposed of.

Specimen Collection:

Remove by centrifugation the serum or plasma from the clot or red cells, respectively, as soon as possible to avoid hemolysis. Lipemic, icteric or hemolyzed specimens may give inconsistent test results.

5. If the patient has been infected before, the antibodies will be present in the body for a long time, so the positive result does not mean that the patient is infected.

6. Negative result does not rule out infection by HCV because the antibodies to HCV may be absent or may not be present in sufficient quality to be detected at early stage of infection.

Quality Control

A coloured line should always appear in the control area if the test has been performed correctly and the dipstick is working properly. It serves as an internal test procedural control.

Performance characteristics

Sensitivity

The Cypress Anti-HCV dipstick detects hepatitis C antibodies in serum or plasma specimens as indicated by the development of a colored band in the test area of the dipstick.

Specificity

The recombinant antigens used for the Cypress Anti-HCV dipstick is encoded by genes for both structural (nucleocapsid) and non-structural proteins. For the other hepatologic diseases, patients will not produce positive results with Cypress Anti-HCV dipstick.

Clinical study

The accuracy of the Cypress Anti-HCV dipstick was evaluated in comparison to EIA results of human plasma/serum specimens. 1283 serum/plasma samples were collected. The results are given in the table below:

<table>
<thead>
<tr>
<th></th>
<th>Cypress Anti-HCV</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>Positive</td>
<td>81</td>
<td>1</td>
</tr>
<tr>
<td>Inconclusive</td>
<td>4</td>
<td>1183</td>
</tr>
<tr>
<td>Total</td>
<td>85</td>
<td>1188</td>
</tr>
</tbody>
</table>

Relative sensitivity: 95.29%
Relative specificity: 98.75%
Overall accuracy: 98.52%

Interferences

Common drugs such as acetaminophen, aspirin and penicillin have no significant interference to the Cypress Anti-HCV dipstick.

Endogenous chemicals, such as triglycerides, uric acid and bilirubin has no significant interference to the Cypress Anti-HCV dipstick.

Bibliography

5. Langdorp, T. 2010