HEPATITIS C VIRUS (HCV) RAPID TEST

INTENDED USE

Nuvision HCV Rapid Test is a rapid immunochromatographic assay for the qualitative detection of antibodies against Hepatitis C Virus in human Serum/Plasma samples. It is intended for professional use as a tool in the diagnosis of Hepatitis C infection.

SUMMARY

Hepatitis C virus (HCV) is a leading cause of hepatitis. Hepatitis C virus has a single stranded RNA virus that causes acute or chronic hepatitis. The viral particles are transmitted through exposure of infectious body fluids, blood transfusion, and use of contaminated needles or syringes. Chronic hepatitis may progress to severe outcomes like cirrhosis and liver cancer (heptatocellular carcinoma). Diagnosis of HCV infections could be based on serological tests.

PRINCIPLE OF THE ASSAY

Nuvision Hepatitis C Virus (HCV) Antibody Test is rapid immune chromatographic assay, detecting the presence of HCV antibodies in either human serum or plasma. Specific HCV antigens are conjugated with colloidal gold and deposited on the conjugate pad, and also immobilized on the test line of the nitrocellulose membrane. When a serum or plasma sample is added, it rehydrates the gold-antigen conjugate and the HCV antibodies, if present in the sample, interacts with the gold conjugated antigen. The antigen-antibody-gold complex will migrate towards the test window until the test region (T) where they are captured by the immobilized antigens, forming a visible pink line (test line), indicating a positive result. If HCV antibodies are absent in the sample, no pink line will appear in the test region. To serve as an internal process control, a control line should always appear in the control region (C) after the test is completed. Absence of a pink control line in the control region is an indication of an invalid result.

PACKAGE CONTENTS

- **HCV Test pouches**
- **Pouch contents: Test Cassette, Sample dropper, Desiccant.**
- **1 Test instruction per box**

MATERIALS REQUIRED (BUT NOT PROVIDED)

- **Clean, specimen collection container.**
- **Clock or timer.**

WARNINGS AND PRECAUTIONS

- **For professional *in vitro* diagnostic use only. NOT FOR MEDICINAL USE.**
- **Do not reuse.**
- **Do not use if the product seal or the packaging is compromised.**
- **Do NOT swallow Desiccant pouch, it can cause harm.**
- **Do not use after the expiration date shown on the pouch.**
- **Do not use if the Desiccant pouch's color is changed to pink or colorless when the test pouch is opened.**
- **Do not mix and interchange different specimens.**
- **Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.**
- **Wash hands thoroughly after finishing the test.**
- **Do not eat, drink or smoke in the area where the specimens or kits are handled.**
- **Clean up spills thoroughly with appropriate disinfectants.**
- **Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.**
- **Dispose of all specimens and used devices in a proper bio- hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.**
- **Keep out of children's reach.**

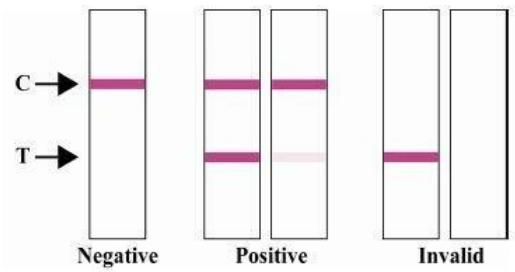
SPECIMEN PREPARATION

- **For serum samples, collect blood in a tube without anticoagulant and allow it to clot.**
- **For plasma samples, collect blood in a tube containing anticoagulant.**
- **Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.**
- **Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.**
- **It is recommended that Fresh samples should be used for testing. However, the serum/plasma may be stored at 2° to 8°C for up to three days and at -20°C for upto 2 months, if the tests cannot be performed immediately. Ensure that the samples are allowed to attain room temperature prior to use. Note: Hemolytic samples should not be used!**
- **Mix each specimen thoroughly prior to use. Do not heat or repeatedly freeze/thaw specimen.**

PROCEDURE

- **Bring the kit components to room temperature before testing.**
- **Open the pouch and remove the Test. Once opened, the test must be used immediately.**
- **Label the test card with patient's identity.**
- **Hold the sample dropper vertically. Add three full drops (120 µL) of serum/plasma without air bubbles into the sample well that is marked with arrow on the testing device.**
- **Read the results at the end of 10 minutes. Note:**
  1. Some strong positive samples may show positive results before 5 minutes.
  2. DO NOT READ RESULTS AFTER 30 MINUTES. To avoid confusion, discard the test device after interpreting the results.

INTERPRETATION OF RESULTS



Negative

A pink colored band appears only at the control region (C), No band appears in Test region.

Positive

A clear pink control band (C) and a detectable test band (T) appears on their respective regions, indicating a positive result for Hepatitis C virus infections.

Invalid

No visible band at the control region (C). Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

Note:

This test is designed for primary screening test of Hepatitis C Virus infections. Although this kit can provide fast and easy way to get a result, the testing can alone be used to diagnose HCV infections and also the testing do not completely exclude the possibility of false positive or false negative result caused by various factors. So refer to the result of this kit and make a final decision with symptoms, other test results, and doctor's view, collectively. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

STORAGE AND STABILITY

- **Test device in the sealed pouch should be stored at 2°-30°C. Do not freeze the test device.**
- **If stored at 2°-8°C, ensure that the device is brought to room temperature before opening.**
- **The test device should be kept away from direct sunlight, moisture and heat.**
- **Do not expose the kit over 30°C.**

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity studies were carried out in-house on fresh as well as frozen samples, from low risk as well as high risk groups.

HCV Samples	Positive	Negative	Total
Positive	39	01	40
Negative	01	109	110
Total	40	110	150

Relative Sensitivity: 97.50%, Relative Specificity: 99.09%, Overall agreement: 98.29%

LIMITATIONS

- **This product is an *in vitro* diagnostic test designed for professional use only.**
- **Humidity and temperature can adversely affect results.**
- **The instructions for the use of the test should be followed during testing procedures.**
- **There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.**
- **Although the test demonstrates superior accuracy in detecting Hepatitis C virus, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.**

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