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**“See Now”Anti-HCV Cassette Test
Serum/Plasma**

For in vitro Diagnosis Use
Product Code: SN 5.4

INTRODUCTION

The “See Now” HCV Test is a rapid direct binding test for the visual detection of hepatitis C antibodies (anti-HCV) in serum or plasma as an aid in the diagnosis of hepatitis C infection. The “See Now” HCV Test is based on the principle of double antigen sandwich immunoassay for determination of anti-HCV in serum or plasma. Purified recombinant antigens are employed to identify anti-HCV specifically.

SUMMARY OF THE TEST

Hepatitis C virus (HCV) is now a main cause of hepatitis. The worldwide prevalence of HCV is 0.2 to 2 % on blood donors and up to 80% in intravenous drug users. Transmission of HCV is by transfusion and other parenteral means such as sharing of needles, occupational exposure to blood and hemodialysis. Chronic infection can lead to cirrhoses and hepatocellular carcinoma. However, chronic infection is often asymptomatic even in the presence of liver damage discernible on biopsy.

The principle of HCV Antibody Test is a double antigen sandwiched, immunochromatographic assay. The purified recombinant HCVs are conjugated to colloidal gold and dry-immobilized on the nitrocellulose membrane. When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate to form antigen-antibody-gold complex if HCV antibody is present in the sample. These complexes will continue to migrate along the strip until the Test Zone (T) of the membrane where they are captured by the HCV antigens to form a visible red line. The un-bound gold conjugate will continue to move to the Control Zone (C) forming a visible red line. To serve as an internal process control, a control band should always be seen after test is completed. Absence of a colored control line in the control region is an indication of an invalid result.

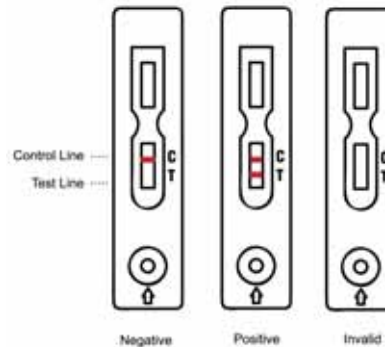
SPECIMEN COLLECTION AND STORAGE

- 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 (EDTA, citrate or heparin, respectively).
- 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

TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test .Label the test device with patient or control identification
- Remove the test device from the sealed pouch by tearing at the notch. Then place the testing device on a level surface
- Holding the sample dropper vertically, add 5 drops (0.2 ml) of specimen without air bubbles into the sample well that is marked with an arrow on the testing device
- Read the results at 15 minutes. Ensure that the background of the test area is white before interpreting the result

INTERPRETATION OF RESULTS



Negative
Only one pink colored band appears at the control region.
Positive
Distinct pink colored bands appear at the control and test line regions.
Invalid
No visible band at the control region. Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

STORAGE AND STABILITY

The test kit can be stored at temperature (2 to 30°C) in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

PRECAUTION

- **FOR IN VITRO DIAGNOSTIC USE ONLY.**
- Don't use it after the expiration date.
- The test device should not be reused.

PERFORMANCE CHARACTERISTICS

Sensitivity

The “See Now” HCV Test detects hepatitis C antibodies concentration in serum or plasma specimens as indicated by the development of a colored band in the test region of the device.

Specificity

Antibodies used for the “See Now” HCV Test were raised against whole hepatitis C antibody. Hepatitis C antibody show positive results with “See Now” HCV Test. On the other Hepatologic diseases patients do not produce positive with “See Now” HCV Test.