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"See Now" Anti-HCV Cassette Test Serum/Plasma/Whole Blood

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, plasma or whole blood 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 an envelope, single stranded positive sense RNA (9.5 kb) virus belonging to the family of Flaviviridae. Six major genotypes and series of subtypes of HCV have been identified. Isolated in 1989, HCV is now recognized as the major cause for transfusion associated non-A, non-B hepatitis. The disease is characterized with acute and chronic form. More than 50% of the infected individuals develop severe, life threatening chronic hepatitis with liver cirrhosis and hepatocellular carcinomas. Since the introduction in 1990 of anti-HCV screening of blood donations, the incidence of this infection in transfusion recipients has been significantly reduced. Clinical studies show that significant amount of HCV infected individuals develop antibodies to NS5 non-structural protein of the virus. For this, the third generation tests include antigens from the NS5 region of the viral genome in addition to NS3 (c200), NS4 (c200) and the Core (c22). Third generation tests have improved sensitivity and shorten the time between infection with HCV and the appearance of detectable antibodies (window period) to 60 days.

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.

REAGENTS AND MATERIALS SUPPLIED

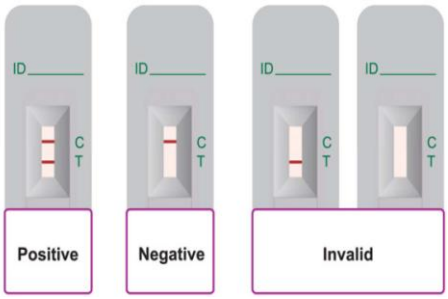
- Test instruction
- Assay diluent
- Pouch Contents: Cassette, Desiccant.

SPECIMEN COLLECTIONAND STORAGE

- For serum samples collect blood in a tube without anticoagulant and allow it to clot.
- For **whole blood or 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.
- **Finger puncture whole blood**
  Clean the finger with an alcohol pad and let dry
  Take a lancet and make a quick deep slab on the side of the finger.
  Avoid squeezing the fingertip to accelerate bleeding as this tends to dilute the blood with excess tissue fluid.
- 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
- **SERUM/PLASMA** :Holding the sample dropper vertically, add 1 drop (**40-50µL**) of specimen and 2 drops of diluent..
- **WHOLE BLOOD**: Add 2 drops, **80** - **100µL** of whole blood and 2 drops, of diluent into the sample well.
- Read the results at **10 minutes**. Ensure that the background of the test area is white before interpreting the result.
- Do not read after 30 minutes.



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.*
- Wear disposable gloves and lab coat while handling specimens. Wash hands thoroughly afterwards. Use appropriate precautions in the collection, handling, storage and disposal of specimens, used pipette, and gloves. Discard used materials in a proper biohazard container.
- Don't use it after the expiration date.
- The test device should not be reused.

PERFORMANCE CHARACTERISTICS

Relative sensitivity: >99,9% (95% CI; *98,4%-100%)
Relative specificity: 99,5% (95% CI; *98,6%-99,9%)
Accuracy: 99,6% (95% CI; *98,9%-100%)

*CI = Confidence Interval