**Camp Medica Distribution S.R.L.** - No. 29 Stanei Street, Bucharest, Romania
phone: +4021-450 58 90
e-mail: export@campmedica.ro
http : //www.campmedica.ro

# *"See Now"* HCV Strip Test

## Serum/Plasma/Whole blood

**For in vitro Diagnosis Use**

## INTENDED USE

The *"See Now"* Hepatitis C (HCV) Antibody Test is a rapid and convenient immunochromatographic *in vitro* assay for detection of antibodies to Hepatitis C virus in human serum, plasma or whole blood.

This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test. It is intended for healthcare professional use.

## PRINCIPLE

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 haemodialysis. 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 "See Now" 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.

## MATERIALS SUPPLIED

- Test strip, desiccant, buffer, test instruction

## MATERIALS REQUIRED BUT NOT SUPPLIED

- Specimen collection container, Timer

## STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 2-30ºC up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

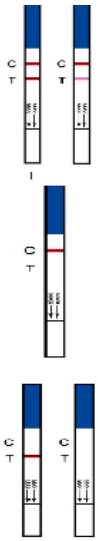
## SPECIMEN COLLECTION AND STORAGE

- 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 cassette from pouch when ready to perform the test .Label the test strip with patient or control identification.
- Hold the dropper vertically and **transfer 1 drop of whole specimen** (approximately 40 μL) to the sample pad area, then **add 1 drop of buffer**(approximately 40 μL).
- Read the result at 20 minutes. Ensure that the background of the test area is white before interpreting the results.


## INTERPRETATION OF RESULTS



**Positive: Two** colored lines should be observed. The line in the test region **(T)** is the probe line; the line in the control region **(C)** is the control line, which is used to indicate proper performance of the device.

**The color intensity of the test line may be weaker or stronger than that of the control line.**

**Negative:** The control line appears in the test, but the test line is not visible.

**Invalid:** No line appears in the control region. Under no circumstances should a positive sample be identified until the control line forms in the viewing area. If the control line does not form, the test result is inconclusive and the assay should be repeated.

## LIMITATION OF PROCEDURE

- This product is designed for in vitro diagnostic use only.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- 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.