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"See Now" 3 tests panel (anti-HIV 1+2, HBsAg, anti-HCV) Whole Blood/Serum / Plasma

For in vitro Diagnosis Use

Product Code: SN 5.X.3

INTRODUCTION

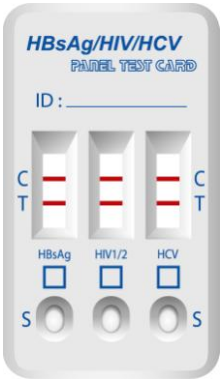
The *"See Now"* 3 tests panel anti-HIV 1+2, HBsAg, anti-HCV is intended for the qualitative detection of antibodies specific to human immunodeficiency of virus anti-HIV 1+2, for detection of Hepatitis B Surface Antigen (HbsAg) and for detection of antibodies to Hepatitis C virus (anti-HCV) in serum, plasma or whole blood.
The device is designed for professional use.
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

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
- The human serum, plasma or whole blood specimen should be collected under standard laboratory conditions.

TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test .Label the test device with patient or control identification.
- Using the transfer pipet to draw up the sample (whole blood, serum, or plasma), dispense 2-3 drops (80-120 µl) of sample in a vertical position into the each sample well individually
- Read the results at 20 minutes. Ensure that the background of the test area is white before interpreting the result.



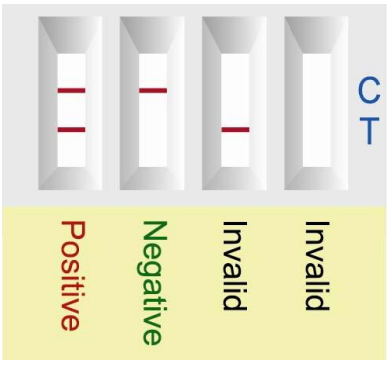
INTERPRETATION OF RESULTS

- **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.



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.

PRECAUTION

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

PERFORMANCE CHARACTERISTICS

- **anti-HIV 1+2**

The *"See Now"* anti-HIV 1+2 Test is for the qualitative detection of antibodies specific to human immunodeficiency of virus (HIV) in human serum, plasma or whole blood.

Relative sensitivity: 99,6%

Relative specificity: 99,7%

- **HBsAg**

The *"See Now"* Hepatitis B Surface Antigen (HBsAg) Test is a rapid and convenient immunochromatographic *in vitro* assay for detection of HBsAg in human serum, plasma or whole blood.

Relative sensitivity: 99,6%

Relative specificity: 99,6%

- **anti-HCV**

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.

Relative sensitivity: 99,7%

Relative specificity: 99,5%