Vultureni nr. 80, S 4, Bucharest - ROMANIA
Phone/fax : +4-021- 450.58.90; +4-021- 451.00.08

"See Now" HBsAb Cassette Test

Serum/Plasma

For in vitro Diagnosis Use
Product Code: SN 5.6

INTENDED USE

The*"See Now"* HBsAb Test is a rapid and convenient immunochromatographic *in vitro* assay for detection of HBsAb in human serum or plasma. The test provides a visual, qualitative result, and all positive specimens must be confirmed with other qualified assays. The test is intended for healthcare professional use only.

PRINCIPLE

The "See Now" HbsAb Test is a double antigen sandwiched, immunochromatographic assay. The purified recombinant HbsAgs 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 HbsAb 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 HBsAg 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

MATERIALS SUPPLIED

- Test Device, Specimen Pipette, Test instruction

MATERIALS REQUIRED BUT NOT SUPPLIED

- Specimen collection container; Timer

STORAGE AND STABILITY

- The*"See Now"* HBsAb Test should be stored at room temperature (10-30ºC) in the sealed pouch or desiccated container.
- Do not use it after the expiration date.

PRECAUTIONS

- *FOR PROFESSIONAL AND IN VITRO DIAGNOSTIC USE ONLY.*
- The test device should remain in the sealed pouch until use.
- There should be no smoking or eating where antigen containing materials are being handled. Wear disposable gloves and lab coat while handling specimens. Wash hands thoroughly afterwards.

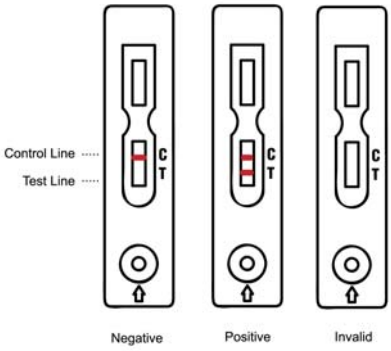
SPECIMEN COLLECTION AND STORAGE

- 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 (containing 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 6 drops (0.2 ml) of specimen without air bubbles into the sample well that is maked 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. **Do not interpret result 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.

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.

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality

control samples should be tested according to the standard quality control requirements of your laboratory.