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“See Now” HBcAb Cassette Test

Serum/Plasma

For in vitro Diagnosis Use

Product Code: SN 5.8

INTENDED USE

The “See Now” HBcAb Test is a rapid and convenient immunochromatographic *in vitro* assay for detection of HBcAb 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’ HBcAb Test is a competitive immunochromatographic assay. When serum is added to sample pad, it moves through the conjugate pad and dissolves the solid gold-anti-HbcAg antibody conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and competes with each other to bind to HBcAg that is coated on the test region. If anti-HBcAg antibody is present, the result is no color band in T line. If there is no anti-HBcAg antibody in the sample, the T line will show a color band. The sample continues to move to the control area and forms a pink color. 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 Device, Specimen Pipette
- Test instruction

MATERIALS REQUIRED BUT NOT SUPPLIED

- Specimen collection container, Timer

STORAGE AND STABILITY

- The “See Now” HBcAb Test should be stored at room temperature (10-30°C) 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 (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 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. **Do not interpret result after 30 minutes**

INTERPRETATION OF

RESULTS

Positive

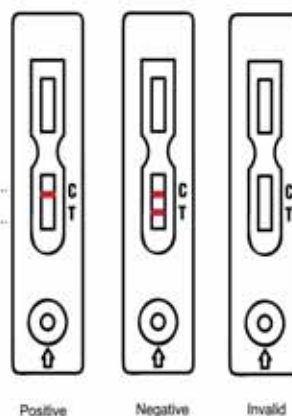
Only one pink colored band appears at the control region.

Negative

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 established by your laboratory.