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"See Now" HBcAb StripTest

Serum/Plasma

For in vitro Diagnosis Use
Product Code: SN 5.7

INTENDED USE

The *"See Now"* Hepatitis B Core Antibody (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 HBV core antigen (HBcAg) is a protein of 185 amino acids that constitutes together with the antigen e (HBeAg), the inner core of HBV. The HBcAg had a strong immunogenicity and it induces the production of antibodies (anti-HBC) that persist generally for lifetime. Anti-HBc appears shortly after the onset of infection with HBV and can usually be detected in serum soon after the appearance of circulating HBsAg and HBeAg. Testing for anti-HBc is currently being introduced at different blood banks worldwide to reduce HBV related post-transfusion hepatitis and fully employed in epidemiological survey of HBV infection spread among different population.

The principle of *"See Now"* HBcAb Test is a competitive immunochromatographic assay. When serum is added to sample pad, it moves through the conjugate pad and dissolve the solid gold-anti-HbcAg antivody conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and compete 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 noanti-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 Strip, Desiccant
- 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.

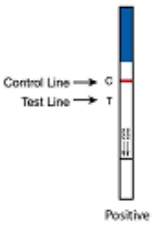
SPECIMEN COLLECTION AND STORAGE

- 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-demolished specimens
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature

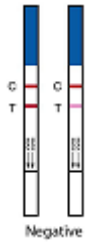
TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test .Label the test strip with patient or control identification
- Immerse the strip into the sample tube with the arrow end pointing towards the sample. Let it stay immersed until you see liquid traveling up past the MAX word.
- Take the strip out after a minimum of 10 seconds. Lay the strip (MAX side facing up) flat on a clean, dry, non-absorbent surface
- Read the result at 15 minutes. Ensure that the background of the test area is white before interpreting the results. Do not read the results after 30 minutes.

INTERPRETATION OF RESULTS



Positive:
Only one color band appears at the control region.



Negative:
Two distinct color bands appear at the control and test regions.

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.

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.