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"See Now" HBsAg Cassette Test

Whole blood/Serum/Plasma

For in vitro Diagnosis Use
Product Code: SN 5.2

INTENDED USE

The*"See Now"* HBsAg Test is used for the qualitative determination of Hepatitis B surface antigen (HBsAg) in human serum, plasma or whole blood. This test is intended for the screening of blood and blood products to be used for transfusion and an aid for the diagnosis of existing or previous hepatitis B infection.

PRINCIPLE

The*"See Now"* HBsAg Test is a chromatographic immunoassay (CIA) for the rapid qualitative determination of human hepatitis B surface antigen (HBsAg) in serum, plasma or whole blood. The membrane is pre-coated with anti-HBsAg capture antibody on the test band region and Rabbit anti-goat IgG on the control band region. During testing， the serum specimen is allowed to react with the colloidal gold particles which have been coated with goat-anti-HBsAg. The mixture then moves laterally on the membrane by capillary action. For a positive result, a pink colored band with a specific antibody-HBsAg-antibody-colloidal gold particle complex will form on the test band region. Absence of colored band in the test band region indicates a negative result. To serve as a procedural control, a pink colored band at the control region will always appear regardless the presence of HBsAg.

MATERIALS SUPPLIED

- Test Device, Desiccant, Test Instruction

MATERIALS REQUIRED BUT NOT SUPPLIED

- Specimen collection container, Timer

STORAGE AND STABILITY

- The*"See Now"* HBsAg Test should be stored at room temperature (15-25ºC) 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.
- Decontaminate and dispose of specimens and all potentially contaminated materials if they contain infectious agent.
- As with all diagnostic tests, a definitive clinical 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 have been evaluated.

SPECIMEN COLLECTIONAND STORAGE

- For serum samples collect blood in a tube without anticoagulant and allow it to clot.
- For whole blood or 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.
- **Finger puncture whole blood**

  Clean the finger with an alcohol pad and let dry

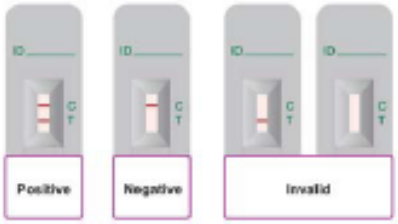
  Take a lancet and make a quick deep slab on the side of the finger.

  Avoid squeezing the fingertip to accelerate bleeding as this tends to dilute the blood with excess tissue fluid.
- 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 2 - 3 drops (80 - 120μL) of specimen without air bubbles into the sample well that is maked with an arrow on the testing device
- Read the results in 20 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

Distinct pink colored bands appear at the control and test line regions.

Negative

Only one pink colored band appears at the control region.

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

- HBsAg test device is used for the detection of HBsAg in human serum, plasma, whole blood. Based on a single reactive test result, a sample should not be considered HBsAg positive. Further testing, including confirmatory testing, should be performed before a specimen is considered positive for HBsAg. A non-reactive test result does not exclude the possibility of exposure to hepatitis B virus. Levels of HBsAg may be undetected both in early infection and late after infection. Specimens containing precipitate may give inconsistent test results.
- The positive control in the test kit is not to be used to quantify assay sensitivity. The positive control is used to verify that the test kit components are capable of detecting a reactive specimen provided the procedure is followed as defined in the kit and the storage conditions have been strictly adhered to.

QUALITY CONTROL

A procedural control is included in the test. A colored band appearing on the control region of the membrane indicates proper performance and reactive reagents.

Good laboratory practices the use of external control specimens to ensure proper kit performance. Each day of testing， two level of commercial controls should be tested on the *"See Now"* HBsAg Test cassette. The two level of control should consist of a negative control and a positive control containing low level of HBsAg. The use of the low level positive control will assure that the test cassettes have not been adversely affected.