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"See Now" Tuberculosis CassetteTest

CE

Serum/ Plasma/ Whole Blood

For in vitro Diagnosis Use
Product Code: SN 9.1

INTENDED USE

The **"See Now"** Tuberculosis Ab. (TB) Test Card is a rapid chromatographic immunoassay for the qualitative detection of anti-TB (M. tuberculosis, M. bovis and M. africanum) antibodies (all isotypes: IgG, IgM, IgA,.) in human whole blood, serum or plasma.

.PRINCIPLE

The **"See Now"** rapid Tuberculosis (TB) Test Card is a qualitative, solid phase, two-site sandwich immunoassay for the detection of anti-TB antibodies in whole blood, serum or plasma. The membrane is pre-coated with TB recombinant antigen on the test line region of the Device. During testing, Serum or plasma specimen reacts with the particle coated with TB recombinant antigen. The mixture migrates upward on the membrane chromatographically by capillary action to react with TB recombinant antigen on the membrane and generate a colored line. The presence of this colored line in the test region (T) indicates a positive result while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region (C) indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS SUPPLIED

- Test Device; pipette; test instruction

MATERIALS REQUIRED BUT NOT SUPPLIED

- Specimen collection container, Timer

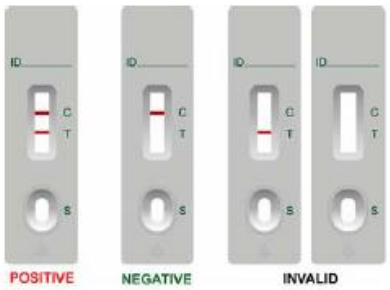
SPECIMEN PREPARATION

- Collect blood in a tube without anticoagulant for serum samples and allow to clot.
- For plasma samples, collect the blood in a tube containing anticoagulant.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Whole blood samples should be refrigerated at 2–8°C, instead of being frozen. Allow sample to reach room temperature before proceeding.
- For better results testing should be performed immediately after the specimens have been collected.

TEST PROCEDURE

- Remove the test device from the sealed pouch by tearing at the notch. Then place the testing device on a level surface
- **Serum/ Plasma/ Whole blood:** add **80µL -120µL (2-3 drops)** of specimen without air bubbles into the sample well and start the timer.
- Read the result at 15 - 20 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



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.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 4-30ºC up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Test device should remain sealed until use.
- Do not used after the expiration date shown on the pouch.

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.

Sensitivity:	99.2% (with International Standard Reference Panels of WHO and Sigma QC Panels.
Specificity:	100%. No cross reactivity tested against Mycobaterium Avium, Mycobacterium Leprae