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Tuberculosis Test Disk
for Whole Blood, Plasma or Serum

REF
Catalog No:R11-550
IVD
For In Vitro Diagnostic Use Only

EXPLANATION OF THE TEST
Tuberculosis (TB) is spread primarily via airborne transmission of aerosolized droplets developed by coughing, sneezing and talking.

The Immunospec TB test is a chromatographic immunoassay for the qualitative detection of human anti-TB (M. tuberculosis, M. bovis and M. africanum) antibodies (all isotypes: IgG, IgM, IgA, etc.). This test is intended for use as an aid in the diagnosis of TB.

The identification aids in the diagnosis of tuberculosis and provides epidemiological information on this disease. *Mycobacterium tuberculosis* is the common causative organism in human tuberculosis, a chronic infectious disease characterized by formation of tubercles (small rounded nodules) and tissue necrosis (destruction), usually occurring in the lung.

MATERIALS PROVIDED
The TB test kit contains the following items to perform the assay:
1. TB test cassette.
2. Disposable sample dropper.
3. Instructions for use.

PRECAUTIONS
The **TB** test devices should be stored at room temperature 4-30°C (40-86°F). The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

SPECIMEN COLLECTION AND STORAGE
Whole Blood specimen collection: Collect an anti-coagulated blood sample (sodium heparin or lithium heparin). Whole blood samples must be tested within 24 hours of drawing.

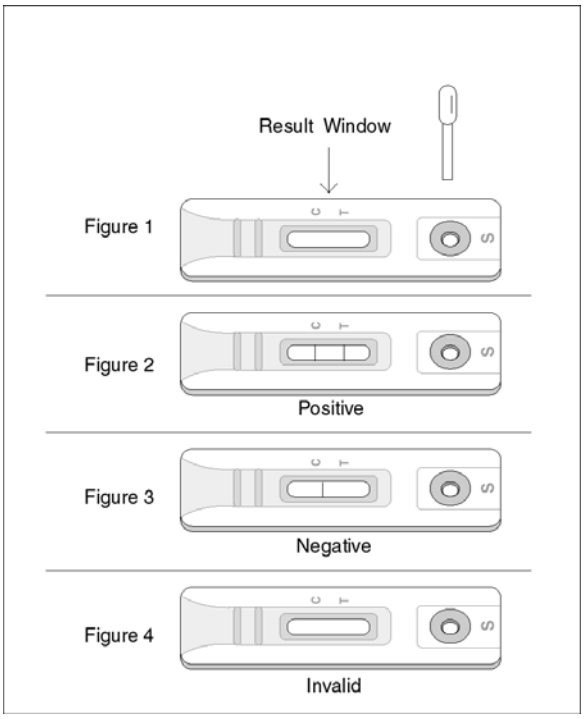
Plasma/Serum specimen collection:
1. Centrifuge whole blood to get plasma/serum specimen.
2. If specimens are not immediately tested they should be refrigerated at 2-8 °C. For storage periods greater than three days, freezing is recommended.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

WARNINGS
1. For in vitro diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7. Do not use the test kit if the pouch is damaged or the seal is broken.

PROCEDURE OF THE TEST
1. Remove the test disk from the foil pouch, and place it on a flat, dry surface.

2. Holding the sample dropper above the test disk (Figure 1) and add 1 hanging drop into the Sample Well. After the drop is absorbed into the Sample Well, add another hanging drop, repeat the procedure until a total of 3 hanging drops have been added to the Sample Well. If specimen drops are added too quickly, specially for blood specimen, it may cause clogging of the Sample Well.
3. As the test begins to work, you will see purple color move across the Result Window in the center of the Test Disk.
4. Interpret test results at 10 to 15 minutes. Do not interpret test result after 20 minutes.

Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30 °C. If your room temperature is significantly lower than 15 °C, then the interpretation time should be properly increased.



INTERPRETATION OF THE TEST
1. A color band will appear at the left section of the result window to show that the test is working properly. This band is the Control Band.
2. The right section of the result window indicates the test results. If another color band appears at the right section of the result window, this band is the Test Band.

POSITIVE RESULT: TWO COLOR BANDS
The presence of two color bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result (Figure 2). Note: Generally, the higher the analyte level in the specimen, the stronger the "T" band color will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the color of the "T" band will be very faint.

NEGATIVE RESULT: ONE COLOR BAND
The presence of only the "C" band within the Result Window indicates a negative result (Figure3).

INVALID RESULT:
After performing the test and no purple color band is visible within the result window, this result is considered invalid. The direction may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested (Figure 4).

Note: A positive result will not change once it has been established at 20 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after 20 minutes.

LIMITATIONS OF THE TEST
A negative result does not preclude the possibility of infection with TB. Other clinically available tests are required if questionable results are obtained. 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.

SPECIFICITY STUDY
An in-house study is conducted with 3 separate lots of the TB serum/plasma Test to determine the Specificity of the TB test. Compounds tested include: Serum with triglyceride concentrations up to 500 mg/ml, Serum with Bilirubin concentrations up to 60 mg/100ml, Hemolyzed specimens with hemoglobin concentrations up to 500mg/dl, Prostatic acid phosphatase with concentrations up to 1000 mIU/ml and Albumin with concentrations up to 20 mg/ml.

All of the above were analyzed and did not show interference or cross reactivity with the test.

REFERENCES

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2. Green GM, Daniel TM, and Ball WC: Koch Centennial Memorial. Am Rev Resp Dis 125:1-31 (Suppl), 1982.
3. Pennington JE: Respiratory Infections: Diagnosis and management. New York, Raven Press, 1983.

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