

ONE STEP Anti-TB(Mycobacterium Tuberculosis) TEST

(Whole Blood/Serum/Plasma)

FOR IN VITRO DIAGNOSTIC USE ONLY

I INTENDED USE

THE ONE STEP ANTI-TB (MYCOBACTERIUM TUBERCULOSIS) TEST IS A RAPID, SEROLOGICAL, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF ANTIBODIES TO MYCOBACTERIUM TUBERCULOSIS (TB) ANTIGEN IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS USED TO OBTAIN A VISUAL, QUALITATIVE RESULT AND IS INTENDED FOR HEALTHCARE PROFESSIONAL USE.

SUMMARY AND BIOLOGICAL PRINCIPLE OF THE ASSAY

The One Step Anti-TB(Mycobacterium Tuberculosis) Test uses a double antigens “sandwich principle”¹ for the detection of Tuberculosis antibody in human whole blood, serum or plasma. Two recombinant Tuberculosis antigens (TB Ag 1&2) were mixed and immobilized on the test band region, and an antibody to Tuberculosis on the control band region of nitrocellulose membrane. Another Tuberculosis antigen (TB Ag 3), coupled with colloidal gold particles, is dried on a conjugate pad. During the assay, the specimen is allowed to react with the colored conjugate (antigen-colloid gold conjugate); the mixture then migrates chromatographically along the membrane by capillary action. If the specimen contains Tuberculosis antibody, the recombinant antigen immobilized on the membrane will capture the antibody-antigen-colloidal gold complex and form a colored test band on the membrane, indicating a positive result. Absence of the test band suggests a negative result. To serve as a procedural control, a colored band at control region always appears in the test area.

STORAGE AND EXPIRATION

The test kits must be stored at 2-30 in the sealed pouch and under dry conditions.

PRECAUTIONS

It is recommended that all specimens be handled in accordance with Biosafety Level 2 practices as described in the CDC NIH Publication, Biosafety in Microbiological and Biomedical Laboratories², or other equivalent guidelines.³⁻⁴

1. For in vitro diagnostic use only.
2. All specimens should be treated as infectious material. Do not contact the test card without wearing safety gloves.
3. Clean and disinfect all spills of specimens and reagents using a suitable disinfectant,⁵ such as 1% Sodium Hypochlorite.
4. Devices used for the assay should be sterilized before being disposed.
5. Do not use beyond expiration date.

REAGENTS AND MATERIALS SUPPLIED

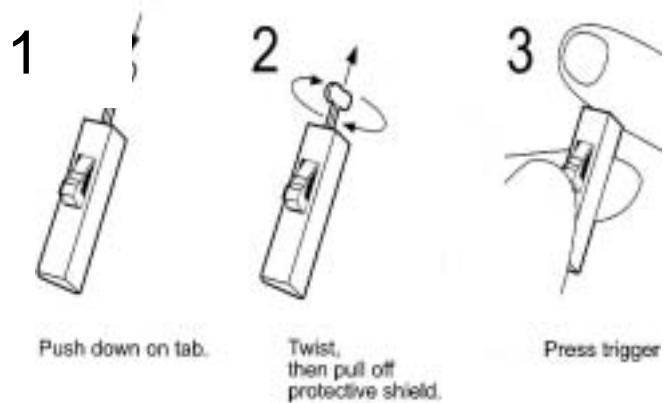
- Test cards individually foil pouched with a desiccant.
- Plastic dropper
- Sample Diluent
- Safety lancet
- Alcohol swab
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Positive and negative controls

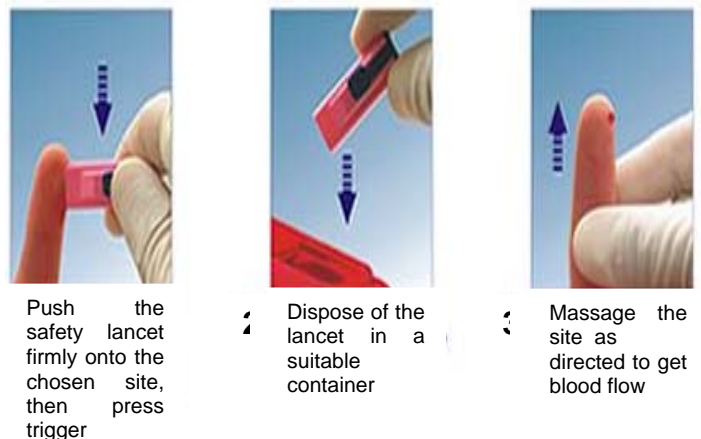
BEFORE TESTING

1. Bring the TB test device, sample diluent, alcohol swab, safety lancet, plastic tube.
2. Remove test card from the sealed pouch.
3. Read the instruction for safety lancet.



SPECIMEN COLLECTION

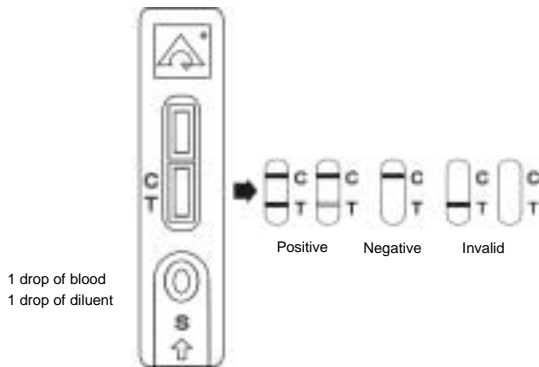
1. Clean the area to be lanced with an alcohol swab.
2. Squeeze the end of the fingertip and pierce with the safety lancet as instructions below.



Note: Whole blood, serum or plasma collected following regular clinical Laboratory Procedures can be used for this test.

ASSAY PROCEDURE

1. With the plastic tube to collect blood.
2. Dispense one drop (50ul) of whole blood, serum or plasma to the "S" well of the test card using the plastic dropper according to the figure.
3. Add one drop of Sample Diluent to the "S" well *immediately* after the specimen is added.
4. Interpret test results at 15 minutes. Do not interpret the results after 30 minutes.



INTERPRETATION OF RESULTS

1. **Negative:** Only one purplish red colored band appears on the control region.
2. **Positive:** In addition to the control band, a distinct colored band also appears on the test region.
3. **Invalid:** Neither purplish red test band nor purplish red control band appears. The specimen should be tested again using a new device.

LIMITATIONS

1. The assay should be performed in normal room temperature.
2. Test cards should be used immediately after being taken from the package. Avoid exposing the test strips in the air for too long before use.
3. The test cards may be stored under room temperature and dry condition. If refrigerated, the strips should be brought to room temperature before testing.
4. Although the test is very accurate, a low incidence of false results can occur.
5. If negative or questionable results are obtained, the test should be repeated on a fresh whole blood, serum or plasma specimen using a new device.
6. A negative result does not rule out TB infection because the antibodies to TB may be absent at the time the specimen is taken or may not be present in sufficient quality to be detected at early stage of infection.
7. The test detects anti-TB antibody as a general indication of TB infection. It does not differentiate between different types of infection (current, ongoing, etc.). 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.

BIBLIOGRAPHY

1. Dye L. Scheele S, V. Pathania, et al: 1999 Global Burden of Tuberculosis Estimated Incidence, Prevalence, and Mortality by Country JAMA, 282:677-686.
2. Dolin, P.J., Ravigliione, M.C., Kochi, A. Global Tuberculosis Incidence and Mortality during 1990-2000. Bull. World Health Organization. 1994; 72:213-220.
3. Murray C.J.L., Styblo, K., Rouillon, A., Tuberculosis In Developing Countries: Burden, Intervention and Cost. Bull. Int. Tuberc. Lung Dis. 1990;65:6-24.
4. Schaaf, H. S. P. Botha, N. Beyers, R. P. Gie, H. A. et, al 1996. The 5-year outcome of multi drug resistant tuberculosis patient in the Cape Province of South Africa. Trop. Med. Int. Health 1:718-722.
5. Merlin TL, Gibson DW, and DH Connor 1994. Tuberculosis. P400-404 in Rubein E and Farber JL (ed)- Pathology, 2nd edition . JB. Lippincott Company.
6. Daniel T. M. 1996. Immunodiagnosis of tuberculosis. P. 223-231. In W.N. Rom, and S. Garay (ed). Tuberculosis, Little, Brown & Co Boston, Mass,
7. Wilkens, E.G.L. 1994. The serodiagnosis of tuberculosis .p. 367-379. In P.D.O. Davies 9 ED0 .Clinical tuberculosis. Chapman & Hall, Ltd, London, England.
8. Krambovitis, E. Serodiagnosis of Tuberculosis in Perspective. 1987; Serodiagn. Immunoth. 1:7-19.