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ONE STEP™ TUBERCULOSIS TEST – Lateral Flow (*Serum or Plasma*) (*Mycobacterium Tuberculosis*)

FOR *IN VITRO* DIAGNOSTIC USE ONLY

INTENDED USE

The **One Step™ Tuberculosis Test** is a rapid, Serological, Immunochromatographic Assay for the detection of all antibodies (IgG, IgM, IgA) to *Mycobacterium Tuberculosis* (TB) antigen (*M.Tuberculosis*, *M.Bovis*, *M.Africanum* in human serum or plasma. The test is used to obtain a visual, qualitative result and is intended for professional use.

SUMMARY AND BIOLOGICAL PRINCIPLE OF THE ASSAY

The **One Step™ Tuberculosis Test** uses a double antigens “*Sandwich Principle*”¹ for the detection of Tuberculosis Antibody in human serum. Two recombinant Tuberculosis Antigens (*TB Ag 1 & 2*) were mixed and immobilized on the test band region of the Nitrocellulose membrane, and an antibody to Tuberculosis was immobilized on the control band region of the Nitrocellulose membrane. Another Tuberculosis antigen (*TB Ag 3*), conjugated to Colloidal Gold particles, is dried on the sample pad. During the Assay, the serum/plasma specimen is allowed to react with the antigen-colloid gold conjugate forming a reddish colored complex. The mixture is allowed to migrate 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 band on the membrane, indicating a positive result. Absence of the band suggests a negative result. To serve as a procedural control, a colored band should always appear at the control region of the Nitrocellulose.

STORAGE

Store the test kit between 2°- 30° C (36°- 86° F). Do not store in direct sunlight. Do not use the test after the expiration date.

WARNINGS AND 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

- For in vitro diagnostic use only.
- For professional, laboratory, medical and/or legal use only, unless otherwise authorized by regulation in the country of use.
- Keep out of reach of children.
- All positive results may be confirmed by an alternate method.
- Treat all specimens as though potentially infectious. Wear gloves and protective clothing when handling specimens.
- All serum or plasma specimens should be treated as infectious material.
- Do not contact the test slide without wearing safety gloves.
- Clean and disinfect all spills of specimens and reagents using a suitable disinfectant, such as 1% Sodium Hypochlorite.
- Devices used for testing should be autoclaved before disposal.

- Do not use kit materials beyond their expiration dates.

INSTRUCTIONS: SPECIMEN COLLECTION AND ASSAY PROCEDURE

The One Step Tuberculosis Test can be performed using human serum or plasma.

To obtain a serum specimen, collect blood aseptically by venipuncture into a clean tube without anticoagulants. Permit blood to clot for twenty (20) to thirty (30) minutes at room temperature. Centrifuge to obtain clear serum and transfer serum into a clean plastic or glass tube. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying. Alternatively, plasma specimens may be used.

If the specimens are not tested immediately they should be refrigerated at 2-8°C. For storage periods greater than three days, freezing is recommended.

MATERIALS PROVIDED

- 1 Test slide sealed in an aluminum foil pouch with a desiccant.
- Plastic Dropper
- Package insert.

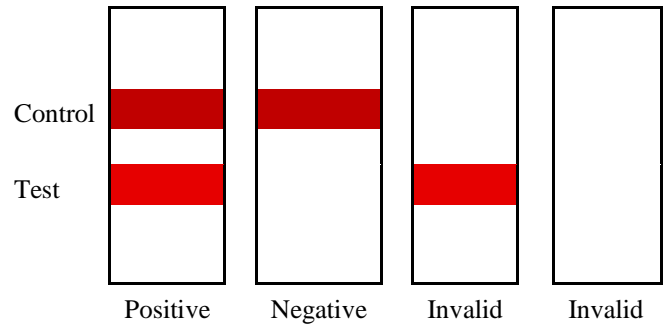
MATERIALS REQUIRED BUT NOT PROVIDED

- Pipettes to deliver 100µL of sample
- Positive and negative controls

ASSAY PROCEDURE

Do not open the foil pouch until you are ready to perform the test

1. Bring all reagents and specimens to room temperature.
2. Remove the test slide from the foil pouch and place on a clean dry surface.
3. Identify the test slide with the patient's name, for each specimen or control.
4. Dispense 100µls (3 drops) of the specimen or control into the circular sample well on the slide.
5. Do not interpret the test results before 15 minutes.
6. **Do not interpret the results after 20 minutes.**



Caution: Use a clean pipette or tip, for every sample to avoid cross-contamination.

INTERPRETATION OF THE RESULTS

1. *Positive:*

In addition to the Control line, a distinct reddish colored line appears in the Test region. Any shade of red appearing in the Test region is considered as a Positive.

2. *Negative:*

Only one reddish colored line appears at the Control region.

3. *Invalid:*

There should always be a reddish colored control band in the Control region, regardless of the test result. If a Control line is not seen, the test is considered invalid and the specimen should be tested again using a new device.

LIMITATIONS

1. The Assay should be performed at room temperature.
2. The test slide should be used immediately after opening the foil pouch.
3. The test slides may be stored at room temperature in dry conditions. If refrigerated, the strips should be brought to room temperature, in their sealed foil pouch, 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 using a new sample of fresh serum or plasma specimen, with 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 quantity 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.
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