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Special Properties: Test duration is 15 minutes

1. Description

M. tuberculosis is the etiologic agent of tuberculosis. The bacteria itself appears as a thin, beaded, straight, or bent rod (bacillus). It is Gram positive and an acid-fast species.

One primarily contracts TB through breathing in infectious aerosolised droplets. These droplets are transmitted by TB infected people when they cough, talk, or sneeze. According to the WHO, more than 8 million new cases are reported yearly. Estimates reveal that nearly 3 million deaths per year result from TB.

Over the years, several methods have been developed to detect TB: skin test (purified protein derivative), sputum smear, culture, and chest x-ray. These methods, however, have low sensitivity and specificity. Modern tests like DNA probes have a high tendency for false positives in regions endemically affected by TB. In addition, DNA amplification tests are costly, rendering their use impractical in developing nations.

Newer serological tests like the TB-ST Test Kit are among the simplest and fastest methods for detecting M. tuberculosis.

2. Test Methodology

TB-ST is a membrane-based screening test for the rapid detection of antibodies for M. tuberculosis in active tuberculosis. This innovative rapid screening test is based on lateral flow immunochromatography and is among the easiest point of care (POC) assay diagnostics. The TB-ST Test Kit is suitable to test for antibodies in both serum and in whole blood.

Properties of the Test:
1) a special antibody binding protein that’s affixed to a gold particle (conjugate).
2) a membrane with a unique combination of immobilized TB-specific antigens.

After the serum or whole blood sample and diluent are put into the well on the test card using a pipette, the diluted sample passes through the gold-marked antibody binding protein (conjugate). The conjugate attaches to the immunoglobulins contained in the sample. This antibody-conjugate complex then flows through the membrane to the point where the TB-specific antigens are. If the sample has antibodies for M. tuberculosis, then the antibody-conjugate complex attaches itself to the TB antigens immobilized on the membrane. A pink-purple band then appears in the “T” zone of the test card. The rest of the antibody-conjugate complex then passes through the card until it reaches the control zone “C”. Again, a pink-purple band appears, indicating that the test has been performed properly.

3. Kit Components

Each test kit contains:
1. 10 or 20 TB-ST Tests (incl. pipette for serum or whole blood)
2. Diluent in 1 or 2 dropper vials
3. 1 set of instructions

4. General Precautions and Safety Procedures

- The test is suitable ONLY for in vitro diagnostic.
- Prescribed infection precautions and laboratory guidelines must be observed.
- Do NOT smoke, eat, or drink while using the test.
- Wear appropriate protective clothing and gloves when handling patient samples and conducting the test.
- NEVER use your mouth to suck samples or reagents into a pipette.
- All materials should be considered highly infectious. Disinfect wastes and leftover reagents for 1 hour at 121° Celsius in an autoclave or treat all materials with a 1 % sodium hypochlorite solution.
- Do NOT USE tests after expiry date.

5. Sample Collection and Preparation

The TB-ST Test Kit is suitable to test for antibodies in both serum and in whole blood. Use the freshest possible samples. In case the test cannot be performed immediately after sample collection, samples may be stored at 2-8° Celsius for up 3 days. For longer periods of storage, collected serum samples should be frozen at -20° Celsius (or colder). Whole blood samples cannot be frozen. It is recommended to use EDTA blood. Package and ship etiologic agents only in compliance with local laws and guidelines.

6. Conducting the Test

1. Open only as many test kits as you’ll be needing and lay these on a clean, flat surface.
2. Fill either 20 µl whole blood or serum into the sample well on the card, marked “S”.
3. Add 2 drops of diluent from the vial dropper to the sample, already in test zone “S”.
4. Strong Positives can be read in 10 minutes. Weak Positives or Negatives can be read within 15 minutes.

ATTENTION: If the solution has not passed through the membrane OR the sample in zone “S” of the card hasn’t moved, add one more drop of diluent.

7. Interpreting Test Results

READ RESULTS

Interpretation
NEGATIVE: Only one pink-purple band appears in control zone “C”.
POSITIVE: Two pink-purple bands appear – one appears in control zone “C” and the other in test zone “T”.

Diagram: TB-ST test cards: (a) POSITIVE (b) NEGATIVE

PLEASE NOTE: Changes in test results should not be considered after 25 minutes. Any band appearing in test zone “T” within this time – regardless of intensity – is interpreted as POSITIVE. Unclear Results:
The test remains undeterminable when only a band appears in test zone “T” or when no band appears at all in control zone “C”. In these cases, it is recommended to repeat the test with a NEW test card, according to the enclosed instructions.

8. Test Limitations

For the test to function properly, the directions and guidelines for interpreting the results must be followed very carefully.

The TB-ST Test Kit has been developed to detect antibodies in serum or whole blood to M. tuberculosis in active tuberculosis. Using this test for other bodily fluids has not yet been validated and can yield incorrect results.

The TB-ST Test Kit is specific for active tuberculosis. Infections with other pathogenic mycobacteria cannot be substantiated with this test, because the “antigen cocktail” was designed especially for the detection of antibodies to M. tuberculosis. Samples taken from patients who have been treated recently or are taking antibiotics can lead to faulty results. Antibody levels in the blood diminish rapidly after treatments with antibiotics. Sometimes antibody levels in the blood can be so low in patients that antibodies cannot even be detected at all in blood/serum – even when a infection is present.

When a patient sample tests POSITIVE with TB-ST, more confirmatory testing should be done. Any final diagnosis, should be preceded by a comprehensive clinical evaluation of the patient’s medical history. The results of this rapid test taken by themselves should not be a basis for a final diagnosis – even when antibodies are present. Likewise, a NEGATIVE test result does NOT preclude a possible TB infection.

9. Performance Characteristics

Since there are no standards for detecting the absence or presence of TB antibodies in serum/whole blood, it’s recommended to compare the performance of the Test Kit with other established sero-conversion panels or reference materials. The TB-ST Test Kit has almost as high a sensitivity as ELISA, and controls/smears. According to independent studies, the TB-ST Test Kit compared to other methods (ELISA, culture, smear) has a sensitivity of 60-80 % and a specificity of 100%.

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