

TUBERCULOSIS SERUM RAPID SCREEN TEST

INTENDED USE

TB Antibody (IgG-IgM) onsite rapid Screening Kit (the TB IgG-IgM 3 Rapid Test) is to be used for the qualitative differentiation of IgG and IgM antibodies to *Mycobacterium Tuberculosis* in human serum and plasma. It is intended for professional use only.

All positive specimens must be confirmed with other confirmatory methods.

SUMMARY AND EXPLANATION OF THE TEST:

Tuberculosis (B) represents an infection with *Mycobacterium Tuberculosis*. Known since ancient Egypt, it became the scourge of 19th century Europe and North America. There has been exponential decline in the prevalence of TB in the 20th century and the advent of anti TB drugs has further diminished the impact of the disease. However, the recent emergence of drug-resistant strains, particularly among patients with AIDS, has rekindled interest in TB. The incidence of TB is expected to increase from 7.5 million cases per year in 1995 to 11.9 million in 2005. The fatality rate is estimated at 55% in untreated patients and 15% in treated patients.

The traditional laboratory test in diagnosis of TB infection includes sputum examination for the presence of *Mycobacterium Tuberculosis*, culture of sputum or other body fluid, the tuberculin skin test and radiology, which is either insensitive or time consuming.

The TB IgG / IgM 3 Line Rapid Test is a one-step chromatographic immunoassay, which specifically detect the antibodies to *Mycobacterium Tuberculosis* in human serum or plasma. The test is user friendly, highly sensitive and specific.

TEST PRINCIPLE:

The TB IgG/IgM 3 Line Rapid Test is a two sided-lateral flow chromatographic immunoassay. It is composed of a conjugate pad containing recombinant TB specific antigens (for IgM test) and anti human IgG (for IgG test) conjugated with burgundy colored colloid gold (conjugates) and a test regions of nitro cellulose membrane pre-coated with anti human IgM (T1) or non-conjugated TB specific antigens (T2)

During the test, TB antibodies (IgG or IgM) if present in the patient sample migrate through the conjugate pad where they bind to the conjugates. The antibody conjugates are then captured by anti human IgM immobilized on T1 region, or the TB antigen immobilized on the T2 region of the membrane, forming a burgundy colored band on the test region (T1 or T2), indicating a positive test result. Absence of this band in the test region suggests a negative result.

The test contains an internal control in the control region (C) which should always demonstrate a burgundy colored band regardless the presence of TB antibodies,

REAGENTS AND MATERIALS PROVIDED:

1. Each kit contains 25 test devices, each sealed in foil pouch with three items inside.
 - a) One cassette test device.
 - b) One pipette dropper.
 - c) One desiccant.
2. One set of package insert (instruction)

MATERIALS REQUIRED BUT NOT PROVIDED:

- 1) Clock or timer.
- 2) A container for specimen collection.

STORAGE AND STABILITY:

- 1) Store the test kit at room temperature (4-30⁰ C).
- 2) Each device may be used until the expiration date printed on the label if it remains sealed in the foil pouch-containing desiccant.
- 3) Do not freeze the kit and or expose the kit to the temperature of over 30⁰ C.

WARNINGS AND PRECAUTIONS:

- 1) This kit is for professional *in-vitro* diagnostic use only.
- 2) Instructions must be followed to obtain accurate results.
- 3) Do not open the sealed pouch, unless ready to conduct the assay.
- 4) Do not use expired devices.
- 5) All patient samples should be treated as if capable of transmitting diseases.
- 6) Dispose of all the specimens and used assay materials in a proper biohazard container.

SAMPLE COLLECTION AND STORAGE:**PLASMA:**

- 1) Collect whole blood into an appropriate blood collection tube containing EDTA or citrate, or heparin following approved vein puncture guides.
- 2) Separate the plasma by centrifugation.
- 3) Carefully withdraw the plasma, label and store in at 2-8⁰ C for up to two weeks. Plasma may be frozen below -20⁰ C for up to one year.

SERUM:

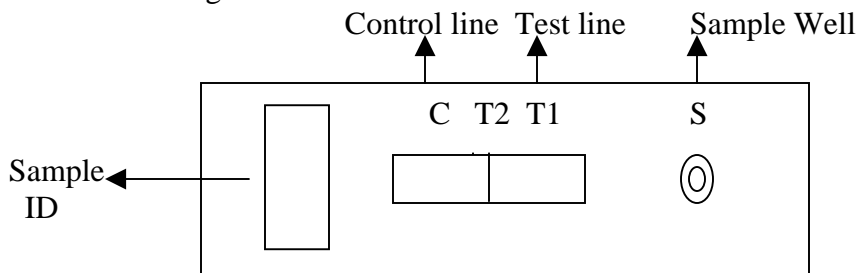
1. Collect whole blood into an appropriate blood collection tube without anticoagulants following approved vein puncture guides.
2. Allow the blood to clot.
3. Separate the plasma by centrifugation.
4. Carefully withdraw the serum, label and store in at 2-8⁰ C for up to two weeks. Serum may be frozen below -20⁰ C for up to one year.

ASSAY PROCEDURE:

1. Allow test device, buffer, serum or plasma specimen, and/or controls to equilibrate to room temperature (15-30⁰ C) prior to testing if refrigerated. Mix the frozen sample well prior to assay after it is completely thawed.
2. When ready to test, open the pouch at the notch and remove the test device. Place the test device on a clean flat surface.
3. Label the device with specimens ID.
4. Fill the pipette dropper with the specimen. Holding the dropper vertically, dispense 2-3 drops (about 50-90 ul) into the sample well without air bubble. Set up the timer.
Add one drop (about 30 ul) of saline or PBS balance buffer into the sample well if flow migration is not observed in 30 seconds in the result window, which could occur with high viscous specimen.
5. Read the test result in five (5) to ten (10) minutes after adding the specimen. Positive result could be visible as short as 1 minute.
Don't read result after 10 minutes.

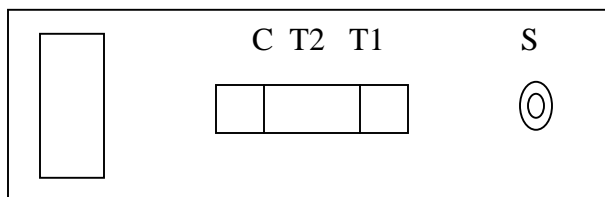
INTERPRETATION OF RESULT:

1. **NEGATIVE RESULT:** If only the C line is present, the absence of a line in the test region (T1 and T2) indicates that no TB antibodies are detected.
The result is negative.

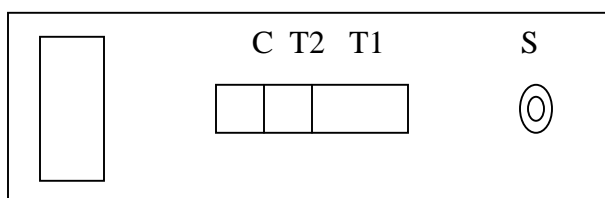


2. **POSITIVE RESULT:**

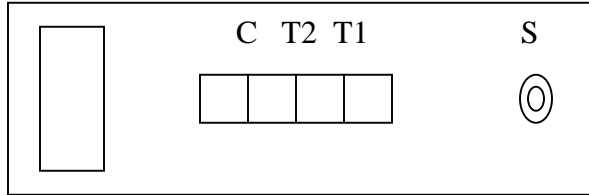
2.1 **IgM positive only:** In addition to the presence of C line, if T1 line is developed, indicates presence of IgM antibodies to M. TB



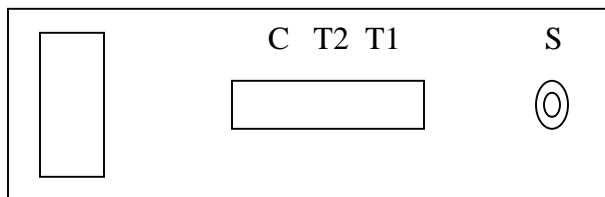
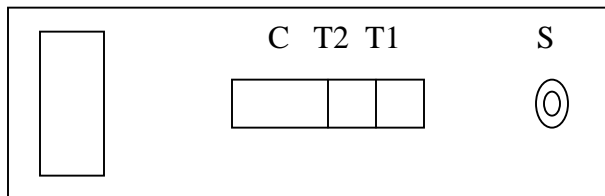
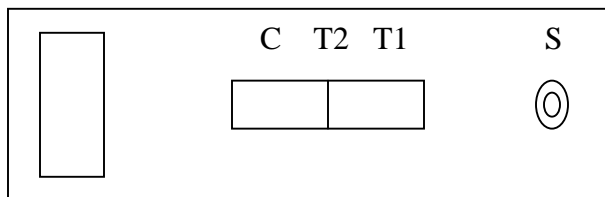
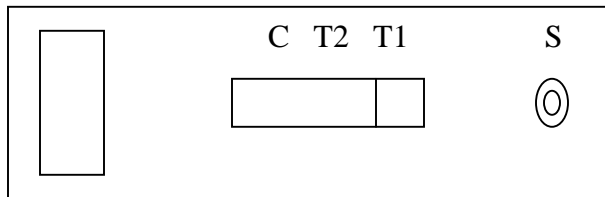
2.2 **IgG Positive Only :** In addition to the presence of C line, if only T2 line is developed, the test indicate the presence of IgG antibodies to M.TB.



2.3 IgG and IgM Positive: In addition to the presence of C line, both T1 and T2 lines are developed, indicates presence of both IgG and IgM antibodies to M. TB.



INVALID : If no C line develops the assay is invalid in this case repeat the assay with a new test device.



LIMITATIONS OF THE TEST

The TB IgG/IgM 3 Line Rapid Test is limited to the qualitative detection of antibodies to M. Tuberculosis in human serum, plasma. It also recognizes antibodies of M. bovis and M. africanum.

The test is a qualitative screening assay and is not for determining quantitative concentration of TB antibodies. There is no meaning attributed to line color intensity or width.

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.

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 evaluation of all clinical and laboratory findings, particularly as currently there is no effective TB diagnostic tool

PERFORMANCE CHARACTERISTICS:

Sensitivity : Sera were collected from patients under anti TB treatment. Results of sputum examination were not available. Among 75 sera collected, samples were positive by the TB onsite Rapid screening Test Thus, the test sensitivity is 93%.

Specificity : In 53 sera derived from Northern America, all the samples were negative.

Precision: Within run between run precisions have been determined by testing 15 replicates with three samples: a negative, a weak positive, and strong positive sample. The negative, weaker positive and strong positive sample were correctly identified in all the tests each time.

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