Tuberculosis Rapid Test (Cassette)

(Whole Blood/Serum/Plasma)

INTENDED USE

Tuberculosis Rapid Test (Whole Blood/Serum/Plasma) is is a membrane-based screening test for the rapid detection of IgM anti-Mycobacterium Tuberculosis and IgG anti- Mycobacterium Tuberculosis in human whole blood,serum or plasma. This innovative rapid screening test is based on lateral flow immunochromatography and is among the easiest point of care (POC) assay diagnostics. The Tuberculosis Rapid Test (Whole Blood/Serum/Plasma)is suitable to test for antibodies in whole blood,serum or plasma. It is for professional *in vitro* diagnostic use only.

INTRODUCTION

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.

PRINCIPLE

Tuberculosis Rapid Test (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay. The test consists of: 1) a burgundy colored conjugate pad containing recombinant *TB* antigens conjugated with colloid gold (*TB* conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (T1 and T2 bands) and a control band (C band). The T1 band is pre-coated with monoclonal anti-human IgM for detection of IgM anti-*TB*，T2 band is pre-coated with reagents for detection of IgG anti-*TB*， and the C band is pre-coated with goat anti rabbit IgG.

When an adequate volume of test specimen is applied into the sample pad of the test, the specimen migrates by capillary action across the strip. IgM anti-TB if present in the specimen will bind to the *TB* conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a burgundy colored T1 band, indicating a *TB* IgM positive test result.

IgG anti-*T*B if present in the specimen will bind to the *TB* conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a burgundy colored T2 band, indicating a *TB* IgG positive test result.

Absence of any T bands (T1 and T2) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the T bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

PRODUCT CONTENTS

Tuberculosis Rapid Test (Whole Blood/Serum/Plasma) contains a special antibody binding protein that is affixed to a gold particle (conjugate), and a membrane with a unique combination of immobilized TB-specific antigens.

MATERIALS SUPPLIED

1.Test Cassette　2 Pipette Dropper　3.Desiccant　4.Buffer (for whole blood only)　5.Package Insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Specimen collection containers.
3. Timer
4. Lancets (for fingerstick whole blood only)
5. Centrifuge (for plasma only)

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C.

If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

WARNINGS AND PRECAUTIONS

1.For professional *In Vitro* diagnostic use only.

2.Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.

3.Do not use it if the tube/pouch is damaged or broken.

4. Test is for single use only. Do not re- use under any circumstances.

5. Handel all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens

6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.

7. Humidity and temperature can adversely affect results

SPECIMEN COLLECTION

1. The TB Tuberculosis Rapid Test (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick) serum, or plasma specimens.

2. To collect Venipuncture Whole Blood Specimens: Collect anti-coagulated blood sample (EDTA, heparin, and sodium citrate) following standard laboratory procedures.

3. To collect Fingerstick Whole Blood Specimens:

- Wash the patient’s hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.

Add the Fingerstick Whole Blood specimen to the test cassette by using hanging drop:

Position the patient’s finger so that the drop of blood is just above the sample pad (S) of the test cassette.

Allow 3 hanging drops of fingerstick whole blood to fall into the center of sample pad (S) on the test cassette, or move the patient’s finger so that the hanging drop touches the center of the sample pad (S). Avoid touching the finger directly to the sample pad (S).

Gently form a rounded drop of blood over the puncture site and add the fingerstick whole blood specimen to test device using a capillary tube

Touch the end of capillary tube to blood until filled to approximately 75ul

Place the bulb onto the top end of the capillary tube dispense the whole blood into the specimen well (s) of the test device.

4. Separate Whole Blood,serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

5. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8° C for up to 3 days. For long term storage, specimens should be kept below -20° C. Whole blood collected by venipuncture should be stored at 2-8° C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.

6. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

7. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

TEST PROCEDURE

Allow the test cassette, specimen, buffer, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.

2. Peel off the tape from the test card, and stick the test cassette in the middle of the test card with arrows pointing downwards as illustrated.

3**. For serum or plasma Specimens:**

Hold the dropper vertically, transfer 3 drops of serum or plasma (approximately 75 uL) to the sample pad (S) of test cassette and then start the timer. See illustration below.

For Venipuncture Whole Blood Specimens:

Hold the dropper vertically and transfer 3 drops of venipuncture whole blood (approximately 75 ul) to the sample pad (S) of test cassette, then add 1 drop of buffer (approximately 40 uL) and start the timer. See illustration below.

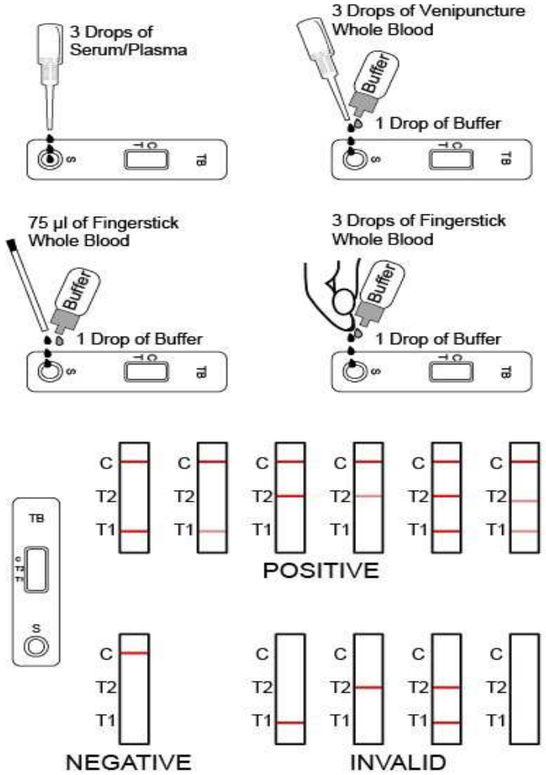
For Fingerstick Whole Blood Specimens:

Allow 3 hanging drops of fingerstick whole blood (approximately 75 uL) to fall into the center of the sample pad (S) of test cassette, then add 1 drop of buffer (approximately 40 uL) and start the timer. See illustration below.

To use a capillary tube: Fill the capillary tube and transfer approximately 75ul of fingerstick whole blood specimen into the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40ul) and start the timer. See illustration below.

4. Wait for the colored line(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 15minutes.

INTERPRETATION OF RESULTS



Positive: 1.In addition to the presence of C band, if only T1 band is developed, indicates for the presence of IgM anti-*TB* in the specimen. The result is positive.

2.In addition to the presence of C band, if only T2 band is developed, the test indicates for the presence of IgG anti-*TB* in the specimen. The result is positive.

3.In addition to the presence of C band, both T1 and T2 bands are developed, indicating for the presence of IgG and IgM anti-*TB* in the specimen. The result is also positive.

Negative: Only the C band shows color development. The two T bands (T1 and T2) show no color development.

Invalid: Control line fails to appear.

QUALITY CONTROL

Each reaction device has its own built-in quality control indicator. After performing the test and no line in either the (T) or (C) region of the reaction device is visible, the sample has been added in the wrong window or the test may have deteriorated.

LIMITATIONS

1) The Tuberculosis Rapid Test (Whole Blood/Serum/Plasma)will only indicate the antibodies presence against TB in the specimen.

2) As with all diagnostic tests, all results must be interpreted together with other clinical information available to the veterinarian.

3) If the test result is negative and clinical symptom persists, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of TB.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance For IgM Test

The samples from susceptible subjects were tested by Tuberculosis Rapid Test (Whole Blood/Serum/Plasma) and by a commercial IgM EIA kit.

Relative Sensitivity: 98.6%, Relative Specificity: 99.3%, Overall Agreement: 97.9%

2. Clinical Performance For IgG Test

The samples from susceptible subjects were tested by Tuberculosis Rapid Test (Whole Blood/Serum/Plasma) and by a commercial IgG EIA kit.

Relative Sensitivity: 99.8% , Relative Specificity: 99.0%, Overall Agreement: 98.8%

REFERRENCE

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