Chuangxingwell

Tuberculosis (TB) Rapid Test Kit
Package Insert

A rapid test for the qualitative detection of anti-TB antibodies (Isotypes IgG, IgM and IgA) in whole blood, serum or plasma specimens.
For professional in vitro diagnostic use only.

IVD

【INTENDED USE】

The Tuberculosis Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of anti-TB antibodies (Isotypes IgG, IgM and IgA) in whole blood, serum or plasma specimens.

【SUMMARY】

Tuberculosis (TB) is spread primarily via airborne transmission of aerosolized droplets developed by coughing, sneezing and talking. Areas of poor ventilation pose the greatest risk of exposure to infection. TB is a major cause of morbidity and mortality worldwide, resulting in the greatest number of deaths due to a single infectious agent. The World Health Organization reports that more than 8 million new cases of active tuberculosis are diagnosed annually. Almost 3 million deaths are attributed to TB as well.[1,2] Timely diagnosis is crucial to TB control, as it provides early initiation of therapy and limits further spread of infection. Several diagnostic methods for detecting TB have been used over the years including skin test, sputum smear, and sputum culture and chest x-ray. But all these methods have some limitations. Newer tests, such as PCR-DNA amplification or interferon-gamma assay, have been recently introduced. However, the turn-around time for these tests is long, they require laboratory equipment and skilled personnel, and some are neither cost effective nor easy to use.[3] These tests are also expensive and not practical for developing countries. Serological methods constitute an attractive alternative, since TB serodiagnosis is simple, inexpensive, relatively non-invasive, and it does not depend on detection of mycobacteria.[4,5,6]

The Tuberculosis Rapid Test Kit is a rapid test for qualitative detection of anti-TB antibodies (Isotypes IgG, IgM and IgA) in whole blood, serum or plasma specimens. The test utilizes a combination of recombinant antigens to detect elevated levels of anti-TB antibodies in whole blood, serum or plasma specimens.

【PRINCIPLE】

The Tuberculosis Rapid Test Kit is a qualitative, solid phase, two-site sandwich immunoassay for the detection of anti-TB antibodies in whole blood, serum or plasma specimens. The membrane is pre-coated with TB recombinant antigen on the test line region of the Kit. During testing, the anti-TB antibodies, if present in whole blood, serum or plasma specimen react with the particles coated with TB recombinant antigen. The mixture migrates upward on the membrane chromatographically by capillary action to react with TB recombinant antigen on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test kit contains TB recombinant antigen coated particles and TB recombinant antigen coated on the membrane.

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if the package is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- The used test should be discarded according to local regulations.
- Do not use potassium oxalate as anticoagulant to collect plasma or venous blood samples.

【STORAGE AND STABILITY】

Store as packaged at room temperature or refrigerated (2-30°C) with a valid period of 24 months. The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch until use. Use the test kit within 1 hour once the foil pouch is opened. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The Tuberculosis Rapid Test Kit can be performed using whole blood (from venipuncture or fingerstick) serum, or plasma specimens.
- To collect Venipuncture Whole Blood Specimens: Collect anti-coagulated blood sample (EDTA, heparin, and sodium citrate) following standard laboratory procedures.
- 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.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test Kit by using hanging drop:
    - Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test cassette.
    - Allow 3 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well(S).
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- 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.
- 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.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

【MATERIALS】

Materials Provided

- Test cassettes
- Package insert
- Disposable specimen droppers
- Buffer (for whole blood only)

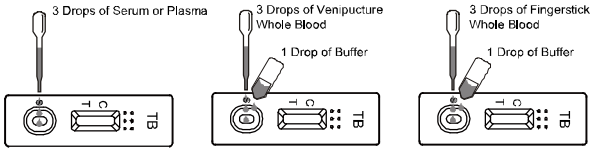
Materials Required But Not Provided

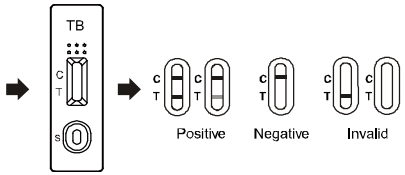
- Specimen collection containers
- Centrifuge
- Lancets (for fingerstick whole blood only)
- Timer

【 DIRECTIONS FOR USE】

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. Twist off the tab of the buffer vial without squeezing
2. Place the cassette on a clean and level surface.
   For **Serum or Plasma** Specimens:
   Hold the dropper vertically, transfer 3 drops of serum or plasma (approximately 75 μL) to the specimen well (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 μL) to the specimen well (S) of test cassette, then add 1 drop of buffer (approximately 40 μL) and start the timer. See illustration below.
   For **Fingerstick Whole Blood** Specimens:
   Allow 3 hanging drops of fingerstick whole blood (approximately 75 μL) to fall into the center of the specimen well (S) of test cassette, then add 1 drop of buffer (approximately 40 μL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 30 minutes.





【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two distinct colored lines appear. One line should be in the control region (C) and another line should be in the test region (T).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of anti-TB antibodies present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test Cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Some preservatives may interfere with the operation of the test. External controls should be validated before use to ensure valid results.

【LIMITATIONS】

1. The Tuberculosis Rapid Test Kit is for in vitro diagnostic use only.
2. The test should be used for the detection of anti-TB antibodies in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in anti-TB antibodies concentration can be determined by this qualitative test.
3. The Tuberculosis Rapid Test Kit will only indicate the presence of anti-TB antibodies in the specimen and should not be used as the sole criteria for the diagnosis of active tuberculosis diagnosis.
4. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

【PERFORMANCE CHARACTERISTICS】

Clinical Sensitivity, Specificity and Accuracy

The Tuberculosis Rapid Test Kit has been calibrated against specimens that have been collected from individuals found to be either smear positive/negative or culture positive/negative. The results show that the relative sensitivity of the Tuberculosis Rapid Test Kit is 86.4%, the relative specificity is 99.0 % and the relative accuracy is 96.7%.

Tuberculosis Rapid Test Kit **vs. Smear/Culture**

Method		Smear/Culture		Total Results
Tuberculosis Rapid Test Kit	Results	Positive	Negative	
	Positive	95	5	100
	Negative	15	500	515
Total Results		110	505	615

Relative Sensitivity: 86.4% (95%CI*: 78.5%~92.2%);
Relative Specificity: 99.0% (95%CI*: 97.7%~99.7%);
Relative Accuracy: 96.7% (95%CI*: 95.0%~98.0%). *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 20 replicates of four specimens: a negative, a low positive, a middle positive and a high positive. The negative, low positive, middle positive, high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 5 independent assays on the same four specimens: The negative, low positive, middle positive, high positive values. Three different lots of the Tuberculosis Rapid Test Kit have been tested using negative, low positive, middle positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-Reactivity

The Tuberculosis Rapid Test Kit has been tested with specimens positive for: anti-HIV, pulmonary diseases, anti-CMV, Rheumatoid factor (RF), anti-HCV and specimens from children below 15 years, who have been administered BCG vaccine. No cross-reactivity was observed, indicating that the performance of the Tuberculosis Rapid Test Kit is stable in presence of these factors.

Interfering Substances

The Tuberculosis Rapid Test Kit has been tested for possible interference from visibly hemolyzed and lipemic specimens, as well as serum specimens containing high bilirubin levels. Results indicate that no interference was observed in specimens containing up to 500 mg/dL hemoglobin; up to 30 mg/dL bilirubin; and up to 2,000 mg/dL human serum albumin.

【BIBLIOGRAPHY】

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5. Lyashchenko K., Colangeli R., Houde M., Jahdali H.A., Menzies D., and Gennaro M.L. Heterogenous antibody responses in tuberculosis. Infect. Immun. (1998), 66: 3936-3940.
6. Lyashchenko K.P., Singh M., Colangeli R., and Gennaro M.L. A multi-antigen print immunoassay for the serological diagnosis of infectious diseases. *J. Immunol. Methods* (2000), 242: 91-100.

Index of Symbols

	Caution	IVD	In Vitro Diagnostic Medical Device		Do Not Use if Package is Damaged
	Manufacturer	LOT	Batch Code	Σ	Contains Sufficient for <n> Tests
CE	CE Marking	REF	Catalogue Numbe	EC REP	Authorized representative in the European Community
	Keep Dry		Use-By Date		Keep Away From Sunlight
	Temperature Limit		Do Not Re-use		Date of Manufacture

Manufacturer
Jinan Chuangxingwell Biotech Co., Ltd.
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