Tuberculosis Device (2–30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADTB01	20 Tests

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

Summary:
Tuberculosis (TB) is spread primarily via airborne transmission of aerosolised droplets formed during coughing, sneezing and talking. Poorly ventilated areas pose the greatest risk of exposure to infection. TB is a major cause of morbidity and mortality worldwide, resulting in the highest number of deaths due to a single infectious agent, and with 8 million new cases of active TB diagnosed annually. Prompt diagnosis enables early initiation of therapy and limits further spread of infection. Serological tests for TB are a useful alternative to early methods such as the skin test, sputum smear, sputum culture and chest X-ray and expensive and complicated PCR-DNA amplification and interferon-gamma assays, as serum testing is cost effective and non-invasive and does not depend on detection of mycobacteria.

Test Principle:
The Tuberculosis Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative, solid phase, two-site sandwich immunoassay. In the test the membrane is coated with TB recombinant antigen within the test region. During the test, whole blood, serum or plasma is added to the sample area (S) and if anti-TB antibodies are present these react with recombinant TB antigen coated on particles in the test strip. The reaction mixture migrates up the membrane by capillary action and reacts with the recombinant TB antigen there. The development of a coloured line in the test region indicates a positive result, no coloured line in the test region indicates a negative result. To serve as a procedural control, a coloured line should always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Reagents:
The test device contains TB recombinant antigen coated particles and TB recombinant antigen coated on the membrane.

Materials Provided
Test devices in individually sealed pouches
Disposable pipettes
Buffer
Instructions for Use

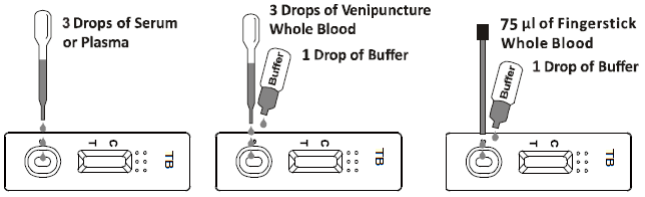
Materials not provided: Micropipette, timer, specimen collection container, centrifuge

Precautions:
1. For professional in vitro diagnostic use only. Do not use after the expiry date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The used test should be discarded according to local regulations.

Reagent Preparation and Stability:
Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiry date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiry date.

Specimen Collection and Storage:
1. The Tuberculosis Rapid Test Device can be performed using whole blood, serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear, non-haemolysed samples.
3. Testing should be performed immediately after sample collection. Do not leave the samples at room temperature for prolonged periods. Serum and plasma samples may be stored at 2-8°C for up to 3 days. For long term storage, samples should be kept below -20°C.
4. Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.
5. To collect Fingerstick Whole Blood Samples:
   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.
6. Add the Fingerstick whole blood sample to the test device by using hanging drop:
   Position the patient's finger so that the drop of blood is just above the sample well (S) of the test device.
   Allow 3 hanging drops of blood to fall into the centre of the sample well or lower the patient's finger so that the hanging drop (but not the finger) touches the centre of the sample well.
7. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

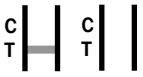
Assay Procedure:
Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.
1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results the assay should be performed immediately after opening the pouch.
2. For serum or plasma samples:
   Hold the dropper vertically, draw up the sample and transfer 3 drops (approximately 75 µl) into the sample well of the test device. Start the timer.
3. For venipuncture whole blood samples:
   Hold the dropper vertically, draw up the sample and transfer 3 drops (approximately 75 µl) into the sample well of the test device. Add one drop of buffer (approximately 40 µl) and start the timer.
4. For Fingerstick whole blood samples:
   Allow 3 hanging drops of blood to fall into the centre of the sample well (approximately 75 µl). Add one drop of buffer (approximately 40 µl) and start the timer.
5. Wait for the coloured lines to appear. Read the result in 10 minutes, do not interpret the result after 30 minutes.



Interpretation of Results:

POSITIVE: Two coloured bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one coloured band appears, in the control region (C). No apparent coloured band appears in the test region (T).



INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:
1. The intensity of the colour in the test region (T) will vary depending on the concentration of anti-Tuberculosis antibody present in the specimen. Therefore, any shade of colour in the test region (T) should be considered positive.

Quality Controls:
- Internal procedural controls are included in the test. A coloured band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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.

Limitations of the Test:
1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of Tuberculosis in serum or plasma from individual subjects. Failure to follow the procedures may give inaccurate results.
2. The Tuberculosis Rapid Test Device is limited to the qualitative detection of anti-Tuberculosis antibody in whole blood, serum or plasma. Neither the quantitative value or the rate of increase in the concentration of anti-Tuberculosis antibody can be determined by this test.
3. The Tuberculosis Rapid Test Device will only indicate the presence of anti-Tuberculosis antibody and should not be used as the sole criteria for diagnosis, the results obtained with this test should be interpreted in conjunction with other diagnostic procedures and clinical findings.

Expected Values:
The Tuberculosis Rapid Test Device (Whole Blood/Serum/Plasma) has been tested using samples collected from individuals found to be either smear or culture positive or negative. Results for the relative sensitivity and specificity of the Tuberculosis Rapid Test Device were as follows:

Performance Characteristics:
Sensitivity and Specificity

Method		Smear / Culture		Total Results
Tuberculosis Rapid Test Device	Result	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 %) *Confidence Intervals
Relative Specificity: 99.0% (95%CI*: 97.7 - 99.7 %)
Relative Accuracy: 96.7 % (95%CI*: 95.0 - 98.0 %)

Precision
Intra-Assay
Within-run precision has been determined by using 20 replicates of four samples: a negative, a low positive, a mid positive and a high positive. The samples were correctly identified >99 % of the time.

Inter-Assay

Between-run precision has been determined by 5 independent assays on four samples: a negative, a low positive, a mid positive and a high positive. Three different lots of the Tuberculosis Rapid Test Device (Whole Blood/Serum/Plasma) have been tested using these samples. The samples were correctly identified >99 % of the time.

Cross-Reactivity

The Tuberculosis Rapid Test Device has been tested using samples positive for anti-HCV, anti-HIV, anti-CMV and RF, and the results showed no cross-reactivity.

Interferences

The Tuberculosis Rapid Test Device has been tested for possible interfering substances and results indicate that no interference was observed in samples containing up to 500 mg/dl haemoglobin, up to 30mg/dl bilirubin and up to 2000 mg/dl human serum albumin.

References:

1. Global tuberculosis control. WHO Report 2003; 1-40 mg/dl.
2. Raviglione MC, Snider DE and Kochi A. Global epidemiology of tuberculosis. JAMA, 1995; 273: 220-225.
3. Lazio A. Tuberculosis: laboratory aspects of diagnosis. CMAJ, 1999; 160: 1725-1729.
4. Bothamly GH. Serological diagnosis of tuberculosis. Eur Resp J, 1995; 8: 676s-688s.
5. Lyashhenko K, Colangeli R, Houde M, Jahdali HA, Menzies D and Gennaro ML. Heterogeneous antibody responses in tuberculosis. Infect Immun, 1998; 66: 3936-3940.
6. Lyashhenko K, Singh M, Colangeli R and Gennaro ML. A multi-antigen print immunoassay for the serological diagnosis of infectious diseases. J Immunol Methods, 2000; 242: 91-100.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

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AMS U.K Ltd., Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL. Tel: +44(0)28 25656268
www.amslabs.co.uk info@amslabs.co.uk

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