SYMBOLS USED

	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
I V D	In vitro diagnostic medical device
	Test Device
	Disposable Plastic Dropper
	Sample running buffer
	Manufactured By
	Date of Manufacture
	Contains sufficient <n> tests

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UNITED KINGDOM

Version En2 – 07/2010

Core™ Tuberculosis

Rapid test for detection of antibodies to *Mycobacterium tuberculosis*
(Device)
CAT N°: TB-160002

INTRODUCTION

Core™ Tuberculosis is a rapid, self performing, qualitative, two site sandwich immunoassay for the detection of antibodies to *Mycobacterium tuberculosis* in human serum / plasma or whole blood.

SUMMARY

Lack of specificity of AFB smear, delayed reporting of mycobacteria by culture and requisite of expertise and expensive newer automated techniques, has led to the development of rapid and relatively simple serological tests based on the detection of serum antibodies to selected mycobacterial antigens , 14 kDa, 38 kDa , 16 kDa and 6 kDa.

PRINCIPLE

Core™ Tuberculosis utilizes the principle of immunochromatography. As the test sample flows through the membrane assembly of the device, after addition of the sample running buffer, the colored recombinant tuberculosis antigens (14 kDa,38 kDa,16 kDa and 6 kDa)-colloidal gold conjugate complexes with *Mycobacterium tuberculosis* specific antibodies in the sample. This complex moves further on the membrane to the test region where it is immobilized by the recombinant tuberculosis antigens (14 kDa,38 kDa,16 kDa and 6 kDa) coated on the membrane leading to formation of a pink-purple colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result for tuberculosis.
The unreacted conjugate and rabbit immunoglobulin conjugated to colloidal gold move further on the membrane and are subsequently immobilized by the anti-rabbit antibodies coated on the membrane at the control region, forming a pink-purple coloured band. The control band formation is based on the 'Rabbit / anti-Rabbit globulin' system. Since it is completely independent of the analyte detection system, it facilitates formation of consistent control band signal independent of the analyte concentration. This control band serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

Core™ Tuberculosis kit contains:
A. 25 Individual pouches, each containing:
1. Test device: Membrane assembly pre-dispensed with recombinant tuberculosis antigens (14 kDa,38 kDa,16 kDa and 6 kDa) - colloidal gold conjugate, rabbit immunoglobulin-colloidal gold conjugate, recombinant tuberculosis antigens (14 kDa,38 kDa,16 kDa and 6 kDa) and anti-rabbit antibody at the respective regions.
2. Disposable Plastic Sample Dropper.
3. Desiccant Pouch.

B. Sample Running Buffer in a dropper bottle.
C. Package insert.

STORAGE AND STABILITY

The sealed pouches in the test kit & the kit components may be stored between 4-30°C till the duration of the shelf life as indicated on the pouch/ carton. DO NOT FREEZE.

NOTES

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Do not intermix reagents from different lots.
4. Read the instructions carefully before performing the test.
5. Handle all specimens as potentially infectious.
6. Follow standard biosafety guidelines for handling and disposal of potentially infective material.

7. Sample running buffer contains Sodium azide (0.1%). Avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build up in the plumbing.

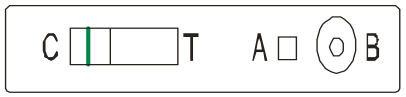
SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient is necessary prior to specimen collection by approved techniques.Though fresh serum / plasma is preferable, specimens may be stored at 2-8°C for upto 24 hours, in case of delay in testing. Do not use turbid, lipaemic and haemolysed serum / plasma specimens. Do not use haemolysed, clotted or contaminated whole blood samples. Blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate can also be used. Do not freeze whole blood samples.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the **Core™ Tuberculosis** kit components to room temperature before testing.
2. Open the pouch and remove the device, sample dropper and desiccant. Check the color of the desiccant. It should be blue. If it has turned colorless or pink, discard the device and use another device. ***Once opened, the device must be used immediately.***
3. Label the test device with patients identity.
4. Tighten the vial cap of the sample running buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
5. Add one drop of serum / plasma or whole blood with the sample dropper provided in the sample port 'A'.
6. Immediately dispense 5 drops of sample running buffer into port 'B', by holding the plastic dropper bottle vertically.
7. At the end of 15 minutes read the results as follows:

Negative for antibodies to *Mycobacterium tuberculosis*:



Only one pink-purple band appears in the control Window 'C'.

Positive for antibodies to *Mycobacterium tuberculosis*:
In addition to the control band, a pink-purple band appears in the test window 'T'.

8. The test should be considered invalid if no bands appear on the device. Repeat the test with a new device ensuring that the test procedure has been followed accurately.

LIMITATIONS OF THE TEST

1. As with all diagnostic tests, the test results must always be correlated with clinical findings.
2. The results of the test are to be interpreted within the epidemiological, clinical and therapeutic context.
3. Any modifications to the above procedure and / or use of other reagents will invalidate the test procedure.
4. Do not compare the intensity of the test line and control line to determine the concentration of the antibodies in the test specimen.
5. Testing of pooled samples is not recommended.
6. In immunocompromised TB patients, such as in patients with HIV, since antibodies to *Mycobacterium tuberculosis* may not be present at levels indicative of active disease, the test may give a negative result.
7. Patients with recent case of active tuberculosis infection may continue to have antibody titer within the detectable limits of the test and such samples may give positive test results, after such patients have been cured.
8. Positive test results may be obtained in Leprosy patients. However, the clinical presentation of leprosy cannot be confused with that of tuberculosis.

PERFORMANCE CHARACTERISTICS

In an in-house evaluation, thirty known positive and one hundred and ten known negative specimens were tested with **Core™ Tuberculosis** and compared with a licensed commercially available test. The results obtained are as follows:

Specimen Data	Number	Licensed Test	Core™ Tuberculosis
Negative for Ab. to M. tuberculosis	110	110	110
Positive for Ab. to M.tuberculosis	30	30	30

Based on the above study the specificity and sensitivity of **Core™ Tuberculosis** is 100%.

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