TB IgG/IgM Rapid Test Cassette (Colloidal Gold)

Cassette

Instruction for Use

A lateral flow immunochromatographic assay for the qualitative detection and differentiation of IgG anti-Mycobacterium tuberculosis and IgM anti-Mycobacterium tuberculosis in human whole blood, serum or plasma

CE IVD REF

In Vitro Diagnosis
For Professional Use

PROUDCT SPECIFICATION

1T/BOX,10T/BOX,20T/BOX,25T/BOX,40T/BOX，50T/BOX

INTENDED USE

The TB IgG/IgM Rapid Test Cassette is a lateral flow immunochromatographic assay for the qualitative rapid detection of IgG anti-Mycobacterium tuberculosis and IgM anti-Mycobacterium tuberculosis in human whole blood, serum or plasma. It is intended for professional use as an aid in the detection of Tuberculosis infection in human whole blood,serum or plasma. All results must be interpreted together with other clinical information available to the physician.

SUMMARY

Tuberculosis, MTB, or TB (short for tubercle bacillus) is a common, and in many cases lethal, infectious disease caused by various strains of mycobacteria, usually Mycobacterium tuberculosis. Mycobacterium tuberculosis (M.TB) is the causative agent of most cases of tuberculosis. Tuberculosis is passed almost exclusively by aerosol transmission from the respiratory secretions of diseased patients to their contacts. Tuberculosis affects especially the lungs and more than 80% of all cases of tuberculosis were limited to the lungs.

Tuberculosis is spread through the air when people who have an active MTB infection cough, sneeze, or otherwise transmit their saliva through the air. Most infections in humans result in an asymptomatic, latent infection, and about one in ten latent infections eventually progresses to active disease, which, if left untreated, kills more than 50% of those infected. In 2007 there were an estimated 13.7 million chronic active cases, 9.3 million new cases, and 1.8 million deaths, mostly in developing countries.

The classic symptoms of tuberculosis are a chronic cough with blood-tinged sputum, fever, night sweats, and weight loss (the last giving rise to the formerly prevalent colloquial term "consumption"). Infection of other organs causes a wide range of symptoms. It's not easy to detect TB disease at the beginning of infection since there are few symptoms. Tuberculin skin test or chest X-ray can be used to screen TB. However, these methods require complex procedures or may not confirm that a person has TB disease. Serologic test can overcome these disadvantages with its simple and rapid method. TB IgG/IgM Rapid Test is an immunochromatographic assay that uses specific antigen-coated colloidal gold to detect the presence of IgG anti-Mycobacterium tuberculosis and IgM anti-Mycobacterium tuberculosis in whole blood, serum or plasma specimens. The test is simple and easy to perform and the test results can be visually interpreted within 15 minutes.

TEST PRINCIPLE

The TB IgG/IgM Rapid Test is a qualitative, membrane based immunoassay for the qualitative detection and differentiation of IgG anti-Mycobacterium tuberculosis and IgM anti-Mycobacterium tuberculosis in human whole blood, serum or plasma. The membrane strip in the cassette contains 3 pre-coated lines: T1-Test line for M.TB IgG; T2-Test line for M.TB IgM; and "C"-control line. During testing, the specimen added into the sample well of the test cassette migrates by capillary action across the membrane strip. M.TB IgM and/or IgG antibodies if present in the specimen react with the Tuberculosis proteins of colloidal gold conjugates and forms an immunocomplex, which migrates alone the test strip, and then captured by the pre-coated lines of anti-human IgG or anti-human IgM. If the red colored T1-line appears, it indicates a result of M.TB IgG positive. If the red colored T2-line appears, it indicates a result of M.TB IgM positive. Absence of any of the T1-line or T2-line suggests a negative M.TB IgG or M.TB IgM result. The test contains an internal control ("C" line) which should exhibit a red line regardless of the color development on any of the test lines. Otherwise, the test result is invalid and the test must be repeated with a new device.

REAGENTS AND MATERIALS PROVIDED

Test devices. Each test cassette is packed in a foil pouch with a dropper and a package of desiccant.
Assay buffer (3.0 ml)
Instruction for use

MATERIALS REQUIRED BUT NOT PROVIDED

Timer
Clean containers for the collection of specimen
Lancets (for fingerstick whole blood only)
Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

PRECAUTIONS

1. For professional and IN VITRO diagnostic use only.
2. The test should remain in the sealed pouch until use.
3. Do not use the kit if the foil pouch is punctured or not well sealed.
4. Do not reuse or use kits after the expiration date.
5. Do not mix components from kits with different lot number.
6. Avoid microbial contamination of reagents.
7. Wear gloves during the whole process and avoid reagents or specimen spilling-out. Wash hands thoroughly afterwards.
8. Dispose the used kit after decontamination of all liquids or solid wastes by following the local law or laboratory rule.
9. The testing results should be read at 15 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 15 minutes may give erroneous results.

STORAGE AND STABILITY

Store the kit in cool and dry places at a temperature between 2-30°C. **Do not freeze.** The shelf-life of the kit under these storage conditions is 24 months.

SPECIMEN COLLECTION AND HANDLING

The TB IgG/IgM Rapid Test Cassette can be performed using whole blood (from either venipuncture or fingerstick), serum or plasma.

To collect Fingerstick Whole Blood specimens:

1) Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
2) Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
3) Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
4) Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
5) **Add the Fingerstick Whole Blood specimen to the test by using a capillary tube:**
   a) Touch the end of the capillary tube to the blood until filled to approximately 50µL. Avoid air bubbles.
   b) Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test cassette.
   Add the Fingerstick Whole Blood specimen to the test by using hanging drops:
   a) Position the patient's finger so that the drop of blood is just above the specimen well of the test cassette.
   b) Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.

1. 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.**
2. Separate the **serum or plasma** from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
4. 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.
5. If specimens are to be shipped, they should be packed in compliance with national regulations covering the transportation of etiologic agents.

ASSAY PROCEDURE

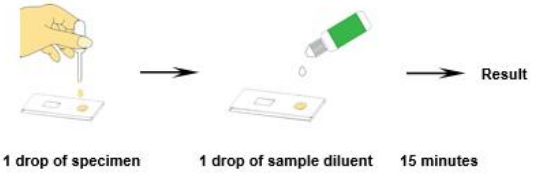
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
Step 3: Be sure to label the device with specimen's ID number.
Step 4: <u>**For whole blood test**</u>
Apply 1 drop of whole blood (about 30 µL) into the sample well.Then add 1 drop (about 40 µL) of Sample Diluent immediately.

1 drop of whole blood 1 drop of sample diluent

For serum or plasma test

Fill the pipette dropper with the specimen.

Holding the dropper vertically, dispense 1 drop (about 30 μL) of specimen into the sample well making sure that there are no air bubbles.Then add 1 drop (about 40 μL) of Sample Diluent immediately.

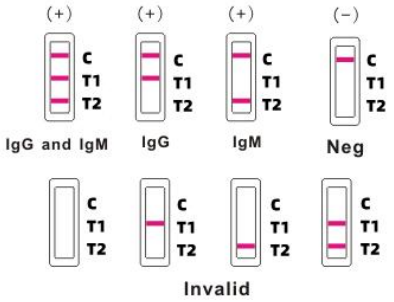


Step 5: Set up timer.

Step 6: Results can be read in 15 minutes.

Don't read result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF ASSAY RESULT



(Please refer to above illustration)

NEGATIVE: Only the Control line (C) appears and no T1 line or T2 line. The result is negative.

POSITIVE:

IgG positive-The Control line (C) and T1 line appear. It indicates the presence of anti-TB IgG in the specimen. The result is IgG positive.

IgM positive- The Control line (C) and T2 line appear. It indicates the presence of anti-TB IgM in the specimen. The result is IgM positive.

IgG and IgM positive-Three colored lines, the Control line, T1 test line and T2 test line all appear on the test strip. It indicates the presence of anti-TB IgG and anti-TB IgM in the specimen and a positive result for both IgG and IgM .

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

INVALID RESULT: Result is invalid if no colored Control line (C) is developed, regardless of any colored line in the T1 line or T2 line. Review the procedure and repeat the test with a new device. If the problem persists, stop using the kits immediately and contact the local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered as an 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.

PERFORMANCE

Sensitivity and specificity

For IgG Test: The samples from susceptible subjects were tested by the TB IgG/IgM Rapid Test and by a commercial TB IgG EIA Test. The IgG results for TB IgG/IgM Rapid Test are: Relative Sensitivity: 87.20%, Relative Specificity: 97.20%, Overall Agreement: 95.60%

For IgM Test: The samples from susceptible subjects were tested by the TB IgG/IgM Rapid Test and by a commercial TB IgM EIA Test. The IgM results for TB IgG/IgM Rapid Test are: Relative Sensitivity: 83.50%, Relative Specificity: 98.00%, Overall Agreement: 95.10%

Interference

No interference was observed in the interference study of TB IgG/IgM rapid test tested with laboratory strains of common infectious diseases.

Accuracy

All results of each 10 of three batches of TB IgG/IgM rapid tests were positive with high color uniformity when tested with National Accuracy References.

LIMITATIONS OF TEST

1. The TB IgG/IgM Rapid Test Cassette is limited to the qualitative detection of anti-TB IgG and anti-TB IgM in human whole blood, serum or plasma. It also recognizes antibodies of M. bovis and M.africanum.
2. The test is a qualitative screening assay and is not for determining quantitative concentration of TB antibodies.There is no meaning attributed to linen color intensity or width.
3. An IgG positive response may be detected in BCG vaccinated personnel.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative test result does not preclude the possibility of exposure to or infection with M.TB.
5. A negative result can occur if the quantity of the antibodies to M.TB present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
6. 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.

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Index of Symbols

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃ 30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

Manufacturer:

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