



TB Quick Test

A Rapid Immunochromatographic Test for Detection of Antibodies to
Mycobacterium tuberculosis in human Serum

Intended use

The TB Quick test is a single use, immunochromatographic test for the detection of antibodies to *Mycobacterium tuberculosis* in human serum.

Summary and explanation

Tuberculosis (TB) is a major cause of morbidity and mortality worldwide, resulting in the greatest number of deaths due to a single infectious agent. It is estimated that more than 8 million new TB cases are detected each year and about 3 million deaths are attributed to TB annually [1-3]. For the last decade, the growing global burden of TB has been increasingly linked to human immunodeficiency virus (HIV) infection [3, 4]. In HIV co-infection, TB progresses rapidly to active disease. TB is a leading cause of death among people living with HIV [4, 5].

Timely diagnosis is crucial to TB control, as it provides early initiation of therapy and limits further spread of infection. Several diagnostic methods are currently available including sputum smear microscopy, sputum culture and chest X-ray. But these have severe 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 are neither cost effective nor easy to use [6].

Serological methods constitute an attractive alternative, since TB serodiagnosis is simple, inexpensive, relatively non-invasive, and it does not depend on detection of mycobacteria [7]. None of the existing TB tests alone is sufficient to diagnose disease [6]. Therefore, new TB diagnostic algorithms are being developed, in which serological assays may play an important role (see performance characteristics below). The Cypress Diagnostics TB Quick test is a rapid immunochromatographic test for antibody detection that is highly accurate, safe, simple, and easy to perform.

Principle

The Cypress Diagnostics TB Quick test is based on the immunochromatographic (lateral-flow) technology. The test employs a cocktail of three specially selected recombinant *M. tuberculosis* proteins that are bound to the membrane solid phase. Gold particles conjugated with protein have

been used as a detection system. TB Quick test can be used with serum. Once a test sample is applied to the SAMPLE area (S) it flows laterally through the membrane strip. When it reaches the conjugate pad, antibodies, if present, bind to protein-gold conjugate and then the migrating immune complex binds to the antigens on the solid phase in the TEST area (T) producing a purple line. In the absence of antibodies there is no line in the TEST area. The sample continues to migrate along the membrane and produces a purple line in the CONTROL area (C) demonstrating that the test procedure is performed properly and the reagents are functioning.

Reagents

Reagents provided:

Each kit contains items to perform 20 tests:

- TB Quick test devices - 20.
- Instruction leaflet - 1.

Additional materials required but not provided:

- Timer
- Micropipette for transferring 100 µl sample

Storage and stability

The Cypress Diagnostics TB Quick test should be stored at 2-30°C in the original sealed pouch. The kit is stable until the date imprinted on the box label and/or pouch.

NOTE: Do not use expired test kits. Do not freeze test kits.

Precautions

1. The test is designed FOR *IN VITRO* DIAGNOSTIC USE only. For PROFESSIONAL USE only. Use the test only in accordance with instructions supplied with the kit.
2. Handle all specimens as recommended for any potentially infectious human serum.
3. Use suitable protective clothing (gloves, lab coat, safety glasses) when handling the kit or samples before performing the assay. Avoid any contact with hands, eyes, nose or mouth during specimen collection and testing.
4. Do not pipette any material by mouth. Do not smoke, eat or drink in areas where specimens or kit material are kept.
5. After the completion of assay, dispose of materials carefully as biohazardous waste.
6. Do not use the test kit if the pouch is damaged or the seal is broken.

Specimen collection

The Cypress Diagnostics TB Quick test can be performed on human serum.

Patient samples perform best when tested immediately after collection. Specimens should be refrigerated at 2-8°C immediately following collection and can be used within up to 3 days. If testing within 3 days is not possible, the specimens should be frozen (-20°C or colder) until use. Avoid repeated freezing and thawing. Samples containing precipitate may yield inconsistent test results. Such samples should be clarified prior to assaying. The use of hemolytic, lipaemic or bacterially contaminated samples should be avoided. Erroneous result may occur.

Test procedure

1. Remove the required number of TB Quick test devices from their wrappers and place on a flat surface area.
2. If test samples are refrigerated, remove them from the refrigerator and allow coming to room temperature.
3. Label test units with patient names and/or identification numbers.
4. Add **100 µl** of specimen onto the **SAMPLE** area (S) with a micropipette.
5. As the test begins to work, you will see purple color move across the result window in the center of the test device.
6. Read results at **15 minutes** after the addition of sample.

Quality Control

A purple colored line should always appear in CONTROL area if the test is performed correctly and the device is working properly. It serves as an internal test procedural control.

Interpretation of test results

NEGATIVE :

Only one purple colored line in the CONTROL area (C), with no colored line in the TEST area indicates a negative result. A negative result at 15 minutes indicates that there is no detectable antibody in the sample.



POSITIVE

Two purple lines, one in the TEST area (T) and one in the CONTROL area (C) indicate a positive result. Depending on the TB antibody concentration, the intensity of the test line may vary.

A positive result will not change once it has been established at 15 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after 30 minutes.



INCONCLUSIVE

A purple line should always appear in the CONTROL area, no matter if the TEST LINE develops or not. If there is no distinct line in the CONTROL area, the test is inconclusive. It is

recommended that the test be repeated with a new device.

Limitations

The TB Quick test procedure and the interpretation of the results must be followed closely. As this is a test designed for detecting antibodies against *M. tuberculosis* only in human serum, no testing with other body fluids should be used.

Although the TB Quick test is very accurate in detecting antibodies to TB, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained.

For a positive result obtained with TB Quick test, it is recommended that other TB diagnostic tests, such as sputum smear microscopy, culture and/or PCR-based methods, be performed along with a clinical evaluation of the patient. Rapid testing alone should not be used to diagnose TB even if the antibodies are found. A negative result does not preclude a possibility of infection with *M. tuberculosis*.

Expected results

The TB Quick test is a qualitative test for the detection of antibodies to *M. tuberculosis* in human serum. The expected test result is positive if detectable specific antibodies are present in the sample. In the absence of antibodies, the expected test result is negative.

Performance characteristics

To analyse the performance characteristic of the Cypress Diagnostics' TB Quick test, a study with 258 positive and 58 negative clinical samples was carried out. Results are given in the table below:

Subject	N	Positive	Sensitivity	Specificity
Healthy adults	58	3/58		94,8 %
Total Patients	258	22/258	85,3 %	
Pulmonary TB	224	188/224	83,9 %	
Treated				
group A (≤ 1 month)	55	44/55	80,0 %	
group B (2-3 months)	61	52/61	85,2 %	
group C (4-6 months)	31	26/31	83,9 %	
group D (7-12 months)	44	39/44	88,6 %	
group E (≥ 12 months)	33	27/33	81,8 %	
Extrapulmonary TB	34	32/34	94,1 %	

Sensitivity: 85,3%

Specificity: 94,8%

In a comparison of the Cypress Diagnostics' TB Quick test versus a leading commercial ELISA test, results gave a sensitivity of 98,2 % and a specificity of 99,7 %.

	TB Quick test		Total	
	+	-		
Commercial ELISA	+	112	2	114
	-	1	350	351
	Total	113	352	465

References

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Langdorp, 06.2006