

For the rapid detection of Mycobacterium tuberculosis infection in whole blood or serum samples.

INTENDED USE

The ACCUCARE Rapid TB Test is an in vitro, qualitative immunochromatographic screening assay for the detection of Mycobacterium tuberculosis infection in whole blood or serum.

PRINCIPLE

The Accucare Rapid TB Test utilizes a unique indirect solid-phase composite antigen immunoassay technology for the qualitative detection of M. Tuberculosis antibodies in human whole blood, serum or plasma. The antigen composite is a combination of recombinant proteins and fractionated Mycobacterium components. In the test procedure, 5 ul of serum, plasma or whole blood is spotted on the sample pad. Then the TB Test Buffer is added to the sample pad. As the serum antibody moves along the test strip by capillary action, it binds with Protein G-Colloidal Gold and the conjugate continues to migrate along the membrane.

The Test Line is visible only when the gold conjugate bound Mycobacterium specific antibodies in the serum are captured by the Mycobacterium composite antigen in the Test Line area. The Control Line will produce a colored band regardless of the presence of M. tuberculosis antibodies in the sample. Therefore, the presence of two colored bands, one at the Test Line and the other at the Control Line, indicates a positive result, while the absence of a colored band in the test area indicates a negative result.

KIT COMPONENT

1. TB Rapid Test Cassettes
2. Product insert sheet
3. TB Test Buffer in dispenser vial
4. Disposable 5 ul micropipettes

MATERIALS REQUIRED BUT NOT SUPPLIED:

Timer, gloves and lancets if using whole blood from finger stick

WARNINGS AND PRECAUTIONS

1. This test is for in-vitro diagnostic use by professionals only.
2. Prior to use, ensure that the product has not expired by verifying that the date of use is prior to the expiration date on desiccant vial or pouch.
3. Follow proper handling and disposal procedures such as those recommended because patient specimens are potentially infectious.
4. Do not pipette any specimen by mouth.
5. Avoid cross-contamination of specimens by using a new pipette or dropper for each specimen.
6. After completion of the test autoclave all materials or immerse them in bleach solution (hypochlorite).

SPECIMEN COLLECTION AND HANDLING

1. Use fresh specimens. Make sure test cassettes and TB Test Buffer are at room temperature before using.
2. Handle and dispose of specimens as if they were infectious and capable of transmitting infection. Avoid contact with skin, inhalation or ingestion.

ASSAY PROCEDURE

Using the included disposable 5 ul pipette, add approximately 5 ul serum or whole blood to the sample port (See step 1.) of the test cassette. With moderate finger pressure squeeze the pipette near the mid section. Insert the open end of the pipette in to the specimen and draw up the specimen to the calibrated line by releasing pressure. Touch the lower (open) end of the pipette to the upper area of the test cassette sample pad and transfer the specimen to the test cassette sample pad by applying pinch pressure to the middle section of the pipette. Add 100 ul (4-5 drops) of the TB Test Buffer to the Buffer Port (See step 2) of the cassette. Read the test result after 15 minutes and not longer than 20 minutes. If solution does not flow up the membrane, add 1 or 2 more drops of Buffer Solution.

INTERPRETATION OF RESULTS

Positive Result

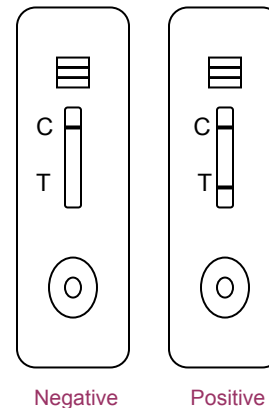
Two colored lines appear in the result window - one in the Control Line area and one in the Test Line area. This indicates active M. tuberculosis infection. The test result can be read as soon as a distinctive pink-purple line appears in the Test Line area. In most strong positive cases, the Test Line appears before the Control Line. The Test line may appear after the Control Line in some weak positive cases, and the Control Line may become darker than the Test Line.

Negative Result

Only one colored line appears in the results window, in the Control Line area, with no distinctive colored line in the Test Line area. This indicates that no active M. tuberculosis infection was detected.

Invalid Result

A distinct colored line should always appear in the Control Line area. The test is invalid if no Control Line appears.



TEST PERFORMANCE

The Rapid TB Test is highly specific for M. tuberculosis infection. Sensitivity and specificity of the test was generally greater than 80% for active TB. The test does not show positive results with BCG/PPD positive, and TB negative sera. The test also shows negative results with M. bovis infection.

SUMMARY OF CLINICAL TEST RESULTS

Specimen no/Origin	Sensitivity	Specificity
111-Mexico	64%	98%
100-Mexico	70%	100%
85-Russia	78%	91%
341-East Europe	89%	95%
321- Estonia Group 1	88%	97%
164-Estonia Group 2	93%	95%
73-Miami	92%	93%
200-Russia	86%	92%
95-Russia	85%	94%
19-Estonia	90%	89%
33-India (all positive)	91%	N/A
73-East Europe	72%	95%

STABILITY AND STORAGE

The Rapid TB Test should be stored at 15-25°C. Unopened test cassettes are stable until the expiration date when stored at 15-25°C.

BIBLIOGRAPHY

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