

AccuTest™ TB-Antibody Band

INTENDED USE

TB-Antibody Band is an in vitro, qualitative immunochromatographic assay for the detection of Mycobacterium tuberculosis infection in whole blood, serum or plasma.

PRINCIPLE

TB-Antibody Band utilizes an indirect solid-phase 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, 5µl 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 test serum-antibody and gold-conjugate (detector), followed by the TB Test Buffer moves by capillary action along the membrane strip, visualization of the test line will occur only when the gold-conjugate bound Mycobacterium specific antibodies in the serum are captured by the solid phase antigen in the test area. The control line will generate 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 window indicates a negative result.

MATERIALS PROVIDED

1. Test Devices
2. **Test Buffer**, in dispenser vial
3. Disposable 5 µl Micropipettes.
4. Product Insert

Materials Required But Not Supplied

1. Timer and Gloves

2. Pipettes, suitable to transfer 5 ul specimen

PRECAUTIONS

1. This test is for *in-vitro* diagnostic use by professionals only.
2. Do not pipette any material by mouth. Do not smoke, eat or drink in areas where specimens or kits are handled.
3. Individuals performing the test should wear protective clothing such as laboratory coats and disposable gloves while collecting and testing samples and thoroughly wash hands afterwards.
4. All spills should be wiped up thoroughly with household bleach or other suitable disinfectant.
5. Treat all materials in the test as if they were infectious. Dispose of all specimens and used assay materials as if they contained infectious agents. Preferred methods are autoclaving for 60 minutes at 121° or incineration.
6. Avoid any contact of hands with eyes and nose during specimen collection and testing.
7. Prior to use, ensure that the product has not expired by verifying that the date of use is prior to the expiration date on the foil pouch.
8. The foil pouch containing the test cassette must remain completely sealed before use. Do not use if the foil pouch seal is not intact.
9. Follow proper handling and disposal procedures because blood specimens are potentially infectious.
10. Avoid cross-contamination of specimens by using a new pipette or dropper for each specimen

STABILITY AND STORAGE

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

SPECIMEN COLLECTION AND HANDLING

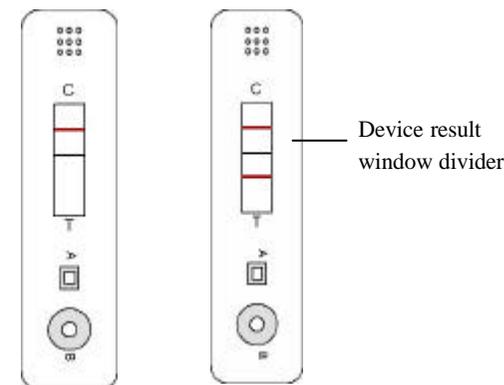
1. Use fresh specimens. Test specimens immediately after collection. Make sure test

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.

ASSAY PROCEDURE

1. Using the included disposable 5 µl pipette, add approximately 5 µl serum, plasma or whole blood to the **sample port A of the test device**. 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 by releasing pressure. Touch the lower (open) end of the pipette to the upper area of the test cassette sample pad by applying pinch pressure to the middle section of the pipette.
2. Add 4-5 drops (110µl) of the Test Buffer to the **lower area of the sample pad port B**.
3. Read the test result within 15 minutes and not longer than 20 minutes. If solution does not flow up the membrane, add 1 or 2 drops more of buffer solution.



Only one colored line appears in the Results Window.

Negative Result

Two colored lines appear in the Results Window.

Positive Result

1. Positive Result

Two colored lines appear in the results window, one in the control area and one in the test 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 area. In most strong positive cases, the test line will appear before the control line. With very strong positive specimens the control line may be lighter than the test line. With some weak positive cases, the test line may appear after the control line, and the control line may become darker than the test line.

2. Negative Result

Only one colored line in the results window, in the control area, with no distinctive colored line in the test area. This indicates that no active M. tuberculosis infection was detected.

3. Invalid Result

A distinct colored line should always appear in the control area. The test is invalid if no line forms in the control area.

PERFORMANCE CHARACTERISTICS

TB-Antibody Band is highly specific for M. tuberculosis complex 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 NON-CONFIDENTIAL CLINICAL RESULTS

Specimen amount / the origin	achieved Sensitivity	achieved Specificity
111 Mexico	64%	98%
100 Mexico	70%	100%
845 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	91%	-
73 East Europe	72%	95%

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