Abstract

Erythra has manufactured a diagnostic test for TB. The test is based on quantitative determination of Mycobacterium *tuberculosis* antigens in erythrocytes cytoplasm. In effect, the test can help in the following:

- 1. Identify exposure which means that it can be used instead of Tuberculin Skin Test.
- 2. Diagnose latent infection
- 3. Inform about the severity of infection (case prognosis)
- 4. Support physician in treatment management. Simply, by determining the initial concentration of the antigens and then tracking antigens concentrations every 7-10 days. If the antigens concentration is decreasing the antibiotic is effective. Once the antigen concentration starts to increase, this indicates that the organism has developed resistance to the administered antibiotic. Physician should change to another antibiotic.

Test Protocol

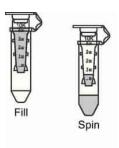
Sampling:

Collect blood on any anticoagulant and separate red blood cells (RBC)

Identify Exposure to replace Tuberculin Skin Test:

In semi-quantitative approach, take 20 ul RBC in 80 ul lysis buffer (1:5). Distilled water can be used.

Remove hemoglobin using spin filters (50K MW) using 500ul of hemolysate. Follow the protocol of spin filter.



Amicon Ultra-0.5 mL Centrifugal Filters for DNA and Protein Purification and Concentration

Diagnose Latent infection:

In semi-quantitative approach, take 10 ul RBC in 490 ul lysis buffer (1:50). Distilled water can be used.

Diagnose active TB:

In semi-quantitative approach, take 10 ul RBC in 990 ul lysis buffer (1:100). Distilled water can be used. If positive repeat the test more dilution until it is negative, say 1:200, 1:300, 1:400, 1:500. I have not seen positive case above 1:500.

Run the test:

- 1. Use 30-50 ul from diluted hemolysate and add to Lateral Flow Cassette
- 2. Read result after 5 30 minutes, visually.

Result Interpreatation

The test is positive if the TEST-LINE signal appears.