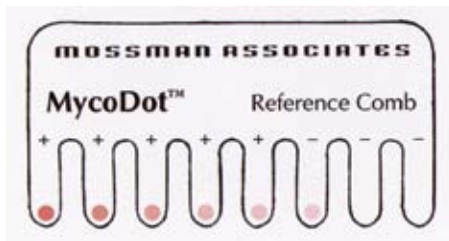
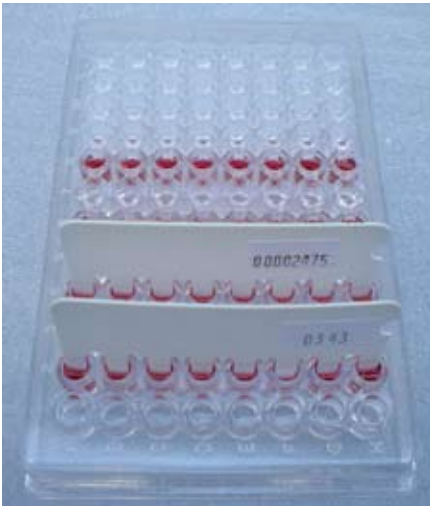


# MycoDot™

## A 20 Minute Serological Test for TB

*Front-line diagnostic test which can be used on patients suspected of TB*



- **Rapid – 20 minutes**
- **Reliable – High Specificity**
- **Kosheio Approved (Japan's FDA)**
- **Permanent Record**
- **Low Cost – Cheaper than X-ray or Culture**



**MOSSMAN ASSOCIATES**  
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## Introduction and Principle

MycoDot™ provides a simple, reliable, rapid (about 20 minutes), and cost-effective test that detects anti-mycobacterial antibodies in serum or whole blood. Patients with active tuberculosis (TB) have a significantly higher antibody titer than infected and/or healthy individuals. The MycoDot test will only read positive for individuals with active mycobacterial disease, while tuberculin test positive and/or BCG-vaccinated non-diseased individuals will be negative by MycoDot. The test may be used as a front-line diagnostic aid in the diagnosis of suspected tuberculosis cases, both pulmonary and extrapulmonary.

MycoDot detects anti-mycobacterial antibodies in whole blood or serum. If the specific antibody is detected in the specimen, colloidal gold particles will specifically aggregate

to the antigen spot on the test comb to give a colored dot, indicative of a positive reaction.

## Product Description

MycoDot™ Kit for 96 Tests (Contents: 12 combs with 8 tests each, 2 microtiter plates, 1 dropper bottle of Signal Generating Reagent (SGR), 1 dropper bottle of sample diluent, 1 bottle of 5-X concrete rinse buffer, 1 bottle each of positive and negative control, 1 reference comb, 1 rinse tray, package insert.)

## Performance Characteristics

In clinical trials, MycoDot showed a high sensitivity of 70% and specificity of 95–100%. High specificity bestows great confidence on a positive diagnosis.

## MycoDot's 9 Easy Steps



1. Add 160  $\mu$ l (4 drops if reagent is provided in a dropper bottle) of Sample Diluent to the first row of wells on a microtiter plate.



2. Add 160  $\mu$ l (4 drops if reagent is provided in a dropper bottle) of Signal Generating Reagent (SGR) to the second row of wells on a microtiter plate.



3. Add 40  $\mu$ l of serum (70  $\mu$ l of whole blood) to wells with diluent. Pipette back and forth to mix thoroughly.



4. Label combs to match the samples. Incubate for 6 minutes in the diluted samples, rocking the combs back and forth.



5. Remove comb from wells, and allow to drain on to a paper towel.



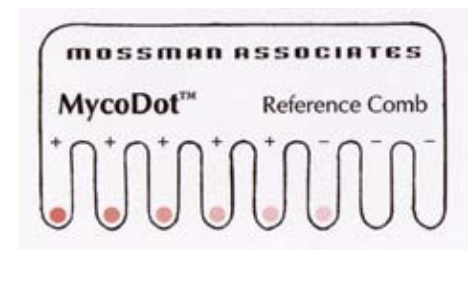
6. Dilute the Rinse Buffer 5-fold in a tray and wash comb. Allow to drain as in Step 5.



7. Incubate the combs for 10 minutes in the SGR, rocking the combs back and forth.



8. Repeat steps 5 and 6.



9. Read results by comparison to the reference comb provided.