

**A-15: A rapid serological test for diagnosis of tuberculosis:  
preliminary evaluation of a new commercial kit using lipoarabinomannan  
as the antigen**

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Tuberculosis is still a major health problem in developing countries as well as in Sri Lanka (Incidence 40 new cases / 100,000 population / year). Majority (95%) of these infections involve the lung. Early detection of patients is important for control and treatment of tuberculosis. At present bacteriological diagnosis of tuberculosis is carried out by direct smear examination and culture. The direct smear is insensitive and the culture takes 4-8 weeks. Therefore many patients are treated on clinical and radiological findings which may lead to inadvertent therapy. This may be overcome by using a rapid diagnostic method. Many immunological techniques using different mycobacterial antigens have been evaluated to determine a specific antibody response in patients and the results have not been satisfactory.

Lipoarabinomannan, a carbohydrate containing antigen of the cell wall of *M tuberculosis* has been found to be responsible for high specific antibodies in tuberculous sera. A new commercial kit using lipoarabinomannan as the antigen is produced by Genelabs Diagnostics, Singapore. This test kit has been mostly evaluated in non-endemic countries. The objective of the present study is to evaluate the test in a BCG vaccinated, endemic country.

Fresh serum from 24 patients who had acid fast bacilli positive sputum and 22 blood donors were tested by the test kit using lipoarabinomannan as the antigen. In the test lipoarabinomannan is coated on plastic combs. The serum samples were reacted with the antigen in a microtitre plate. If M tuberculosis specific antibody is detected in the serum colloidal gold particles will specifically aggregate to the antigen spot to give a coloured dot on the comb which indicates a positive reaction. The test requires only 20 min.

18 out of 24 acid fast positive patients were positive and 18 out of 22 blood donors were negative by the test. The sensitivity and specificity of the test were 75% and 82% respectively. The positive predictive value was 0.81 and the negative predictive value was 0.75.

In Sri Lanka as well as many South-east Asian countries tuberculin test positive and/or BCG vaccinated non-diseased persons are present. This has been a limiting factor in the evaluation of many immunodiagnostic techniques as cross reacting antibodies were detected in these groups.

The present test shows acceptable levels of specificity and sensitivity. It is a rapid test with a reasonable cost (Rs.135.00 per specimen).