

EVALUATION OF CLINICAL USEFULNESS OF ELISPOT USING ROP-ESAT6-CFP10 ANTIGEN

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Background/Aims: Mantoux tuberculin skin test and interferon gamma release assay (IGRA) are used to diagnose latent tuberculosis (TB) infection. Although IGRA is more sensitive and specific than skin test, it is costly. Novel Mycobacterium tuberculosis specific antigen, ROP-ESAT6-CFP10, using recombinant overlapping peptide (ROP) technique was developed. ROP consists of peptides, joined into a single molecule linked by enzyme cleavage sites, and these overlapping peptides cover the target amino acid sequence. With this ROP technique, M. tuberculosis specific antigen can be produced in a short period of time with easier quality control, which are more economic to manufacture. We evaluated the performance of ELISpot using newly developed ROP-ESAT6-CFP10.

Methods: Patients who were diagnosed as pulmonary tuberculosis within one year period were enrolled in the study. Enrolled patients were “AFB culture positive” or “AFB stain positive and TB-PCR positive”. Healthy candidates without any respiratory symptoms with normal chest x-ray were also enrolled. Blood samples from the study subjects were tested with QuantiFERON-TB Gold (Qiagen, Germantown, Maryland), T-SPOT.TB (Oxford Immunotec, Oxford, UK) as manufacture’s instruction. In addition, instead of using ESAT6 and CFP10 antigen, ROP-ESAT6-CFP10 were used as TB-specific antigen with T-SPOT.TB assay. Agreement with between assays, sensitivity and specificity were evaluated. **Results:** Ten pulmonary TB patients and seventeen healthy candidates were enrolled in the study. The kappa between ROP-ESAT6-CFP10 and T-SPOT.TB was 0.743. The kappa between ROP-ESAT6-CFP10 and QuantiFERON-TB Gold was 0.545. Sensitivity was 90%, 80%, and 60% in ROP-ESAT6-CFP10, T-SPOT.TB, and QuantiFERON-TB Gold, respectively. Specificity of these assays were 100%. **Conclusions:** ELISpot using newly developed ROP-ESAT6-CFP10 showed very good agreement with T-SPOT.TB and moderate agreement with QuantiFERON-TB Gold.

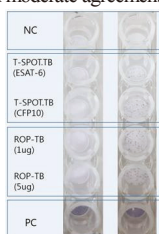


table 1. T-SPOT.TB & ROP-TB comparison results

		T-SPOT.TB	
		negative	positive
ROP-TB	negative	17	1
	positive	2	7

table 2. QuantiFERON TB & ROP-TB comparison result

		QuantiFERON TB	
		negative	positive
ROP-TB	negative	17	1
	positive	4	5

table 3. T-SPOT.TB & QuantiFERON TB comparison result

		QuantiFERON TB	
		negative	positive
T-SPOT.TB	negative	19	0
	positive	2	6

table 4. ROP-TB result

		TB state		total
		normal	TB patient	
ROP-TB	negative	17	1	18
	positive	0	9	9
total		17	10	27

table 5. T-SPOT.TB result

		TB state		total
		normal	TB patient	
T-SPOT.TB	negative	17	2	19
	positive	0	8	8
total		17	10	27

table 6. T-SPOT.TB result

		TB state		total
		normal	TB patient	
QuantiFERON TB	negative	17	4	21
	positive	0	6	6
total		17	10	27