



TB-IGRA

Diagnostic Kit for Mycobacterium Tuberculosis Correlative IFN- γ Release Assay

Tuberculosis, is a common, and in many cases lethal, infectious disease caused by various strains of mycobacteria, usually Mycobacterium tuberculosis. Tuberculosis typically attacks the lungs but can also affect other parts of the body. It is spread through the air when people who have an active TB infection cough, sneeze, or otherwise transmit their saliva through the air. Most infections are asymptomatic and latent, but about one in ten latent infections eventually progresses to active disease which, if left untreated, kills more than 50% of those so infected.

Wantai TB-IGRA is an enzyme-linked immunosorbent assay for quantitative detection of Interferon Gamma (IFN- γ) that respond to in-vitro stimulation by Mycobacterium tuberculosis antigens in human whole blood. It is intended for use as an aid in the diagnosis of tuberculosis (TB) infection (both latent tuberculosis infection and active tuberculosis disease).

IGRA measure a person's immune reactivity to M. tuberculosis. T lymphocytes from most persons that have been infected with M. tuberculosis will release interferon gamma (IFN- γ) when mixed with antigens (substances that can produce an immune response) derived from M. tuberculosis. Interferon Gamma Release Assay (IGRA) is whole-blood test that can aid in diagnosing Mycobacterium tuberculosis infection, including both latent tuberculosis infection (LTBI) and tuberculosis (TB) disease.

Performance characteristics

■ Total 1228 samples were tested in parallel to QuantiFERON-TB. The positive coincidence rate between the two kits was 94.3%, the negative coincidence rate was 83.0%, the total coincidence rate was 89.0%.

Whole blood sample		WANTAI			Total
		+	-	IND	
QFT	+	680	41	0	721
	-	82	411	2	495
	IND	4	6	2	12
Total		766	458	4	1228

■ Wantai TB-IGRA test results for BCG vaccine inoculation sample, parallel to QuantiFERON-TB. the positive coincidence rate was 100%, the negative coincidence rate was 88.0%, the total coincidence rate was 93%.

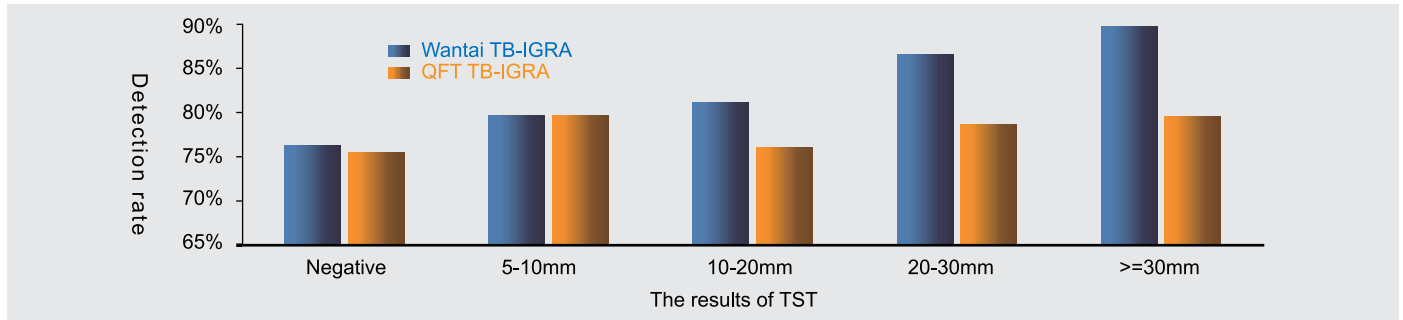
BCG vaccine inoculation sample		QFT		Total
		+	-	
WANTAI	+	115	18	133
	-	0	132	132
Total		115	150	265

Total 265 samples contain 121 active TB samples, 91 LTBI samples and 53 healthy individuals samples.



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Wantai TB-IGRA test results for TST samples. Parallel to QuantiFERON-TB



Wantai TB-IGRA comparison with PCR

Clinically confirmed samples		PCR		Total
		+	-	
WANTAI	+	111	55	166
	-	7	8	15
Total		118	67	181

NOTE: WANTAI TB-IGRA sensitivity is 92%.

Quantitative detection of Interferon Gamma (IFN- γ)

