



WANTAI TB-IGRA

Diagnostic Kit for T Cell Infected with Mycobacterium Tuberculosis

*Developing Scientifically
Focusing on the Health*

- Effective diagnostic ELISA for latent and active TB infection
- No interference from BCG vaccine
- State-of-the-art, comparable to other commercially available methods

What is TB-IGRA?

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 tenth of latent infections eventually progress to active disease which, if left untreated, kills more than 50% of those infected individuals.

Interferon Gamma Release Assay (IGRA) is a whole-blood test that can aid in diagnosing *Mycobacterium tuberculosis* infection, including both latent tuberculosis infection (LTBI) and tuberculosis (TB) disease. The test measures 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*.

Analytical sensitivity

The analytical sensitivity of WANTAI TB-IGRA was evaluated on 3 consecutive production lots of the kits using dilutions of the kit's reference standard for IFN- γ . The results show that the **analytical sensitivity of the kit is $\leq 3.0\text{pg/ml}$** .



Comparison Studies

comparison with QuantiFERON-TB Gold (QFT) on clinical samples

Total of 1228 clinical samples were tested in parallel to QuantiFERON-TB Gold (QFT).

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

**Positive accordance rate vs. QFT : 94.3%,
Negative accordance rate vs. QFT : 83.0%,
Overall accordance rate vs. QFT : 89.0%.**

comparison with QuantiFERON-TB Gold (QFT) on samples from BCG vaccinated individuals

Total of 265 samples including 121 active TB samples, LTBI91 samples and 53 healthy specimens were tested. The results show that Wantai TB-IGRA has high specificity with no interference from BCG vaccine.

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

**Positive accordance rate vs. QFT : 100%,
Negative accordance rate vs. QFT : 88.0%,
Overall accordance rate vs. QFT : 93.0%.**

comparison with PCR

181 TB specimens were tested with Wantai TB-IGRA and PCR. The sensitivity of WANTAI TB-IGRA was 92%.

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

Comparison with traditional TB testing methods

In a comparative study, 70 pulmonary tuberculosis (PTB) specimens, 33 extrapulmonary tuberculosis (EPTB) specimens and 30 healthy specimens were tested by Wantai TB-IGRA, TST, antibody ELISA, and smear and culture. The results show that the performance of WANTAI TB-IGRA is superior compared to other traditional TB testing methods.

Specimen Classification	Sample No.	Positive Detection Rate				
		TB-IGRA	TST (PPD)	TB-Ab	Sputum smear	Bacteria culture
PTB	70	97.1%	67.1%	61.4%	25.7%	58.6%
EPTB	33	93.9%	54.6%	36.4%	-	-
Healthy	30	6.7%	16.7%	13.3%	10.0%	13.3%

Specificity

To evaluate the specificity of the kit, total of 210 healthy specimens were tested. The results show that the specificity of WANTAI TB-IGRA is 94.8%.

Total	Detected Positive	Specificity
n=210	11	94.8%

Sensitivity

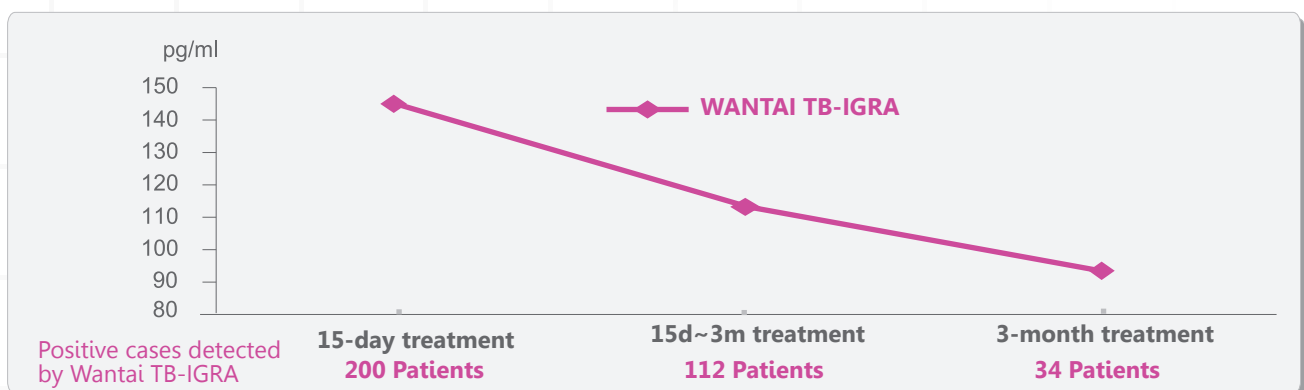
PTB and EPTB specimens were tested with WANTAI TB-IGRA, QFT and bacteriological tests. The results demonstrate the excellent sensitivity of Wantai TB-IGRA, which is comparable to that of QFT.

Specimen Classification	Total	Bacteriological Positive*	WANTAI TB-IRGA (+)	QFT (+)
PTB	721	444	591	564
EPTB	35	5	28	29
Tuberculosis with other diseases	30	9	18	17
Total	786	458	637	610
Sensitivity		58.3%	81.0%	77.6%

*Bacteriological positive is one or both positive of bacteria culture and sputum smear.

Application in TB treatment

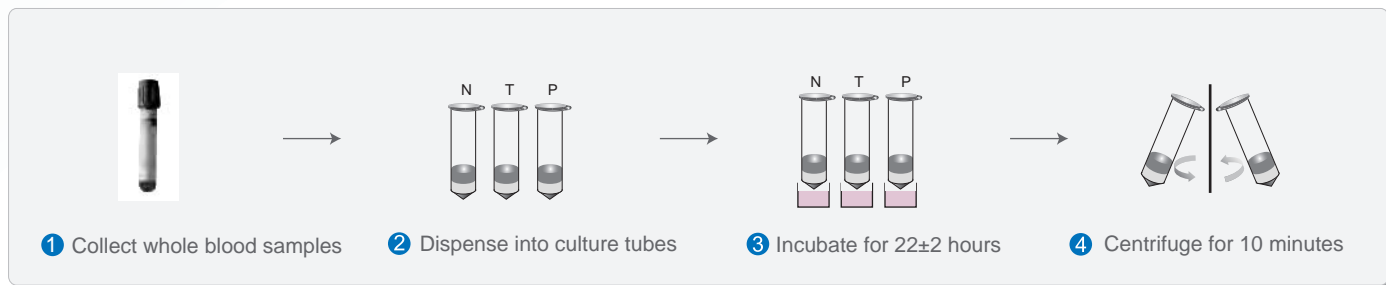
The concentration of IFN- γ was monitored in 200 TB patients for up to 3 months after initiation of treatment. The IFN- γ concentrations decreased with treatment which demonstrates the applications of WANTAI TB-IGRA as a treatment monitoring, and drug dosage control tool.



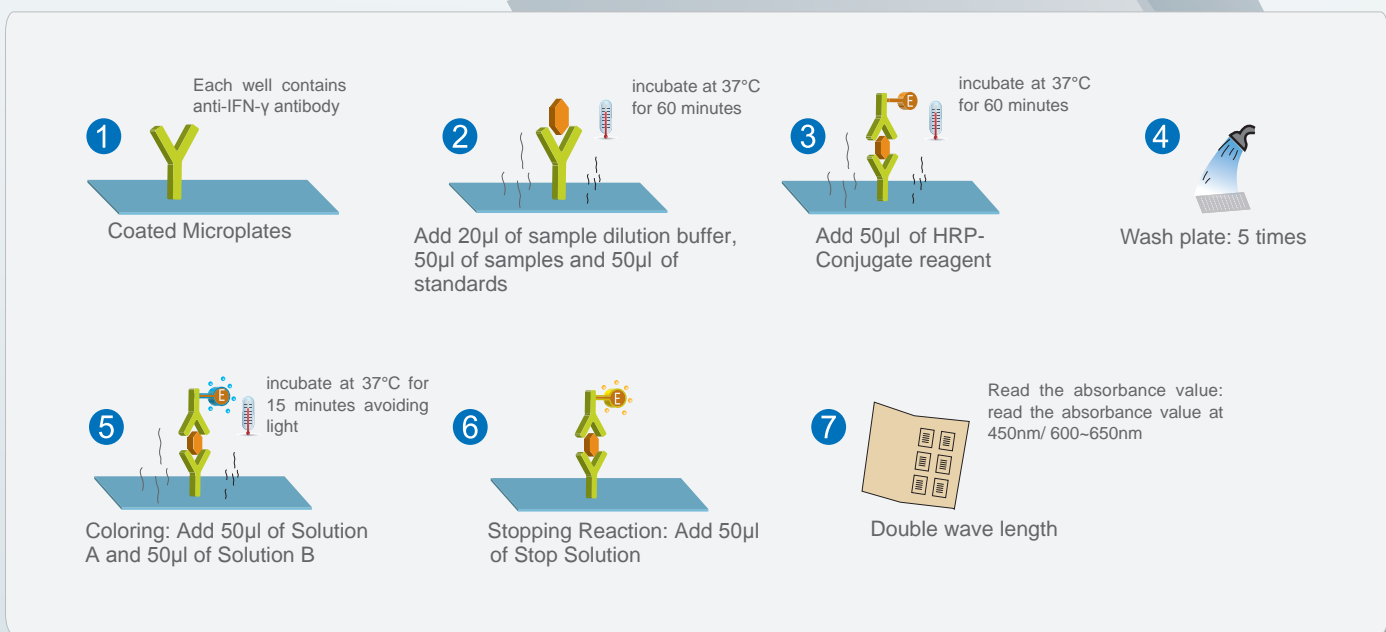
Procedures

Quantitative detection of Interferon Gamma (IFN- γ)

A: Sample Preparation



B: Testing Procedures



Ordering Info

Cat.	Product	Specimen	Pack size
WT-1196	WANTAI TB-IGRA	Whole Blood	28T/kit