2. 100 samples of healthy individuals were selected (no contact history, disease history nor family history) to evaluate specificity:

Healthy individuals	Negative fluorescence test result	Specificity
100	97	97.0%

The specificity of this kit for detecting healthy individuals was 97.0%.

3. Agreement rate with ELISA kit

A total of 1015 tuberculosis patients and non tuberculosis patients were selected to compare the agreement rate of the fluorescent kit and ELISA kit:

Test result	Fluorescence kit	ELISA kit	Pos/Neg agreement rate
Positive	450	489	92.0%
Negative	501	526	95.3%
Total	951	1015	93.7%

The positive agreement rate between the fluorescent kit and ELISA kit was 92.0%, the negative agreement rate was 95.3%, and the total agreement rate was 93.7%.

4. Repeatability

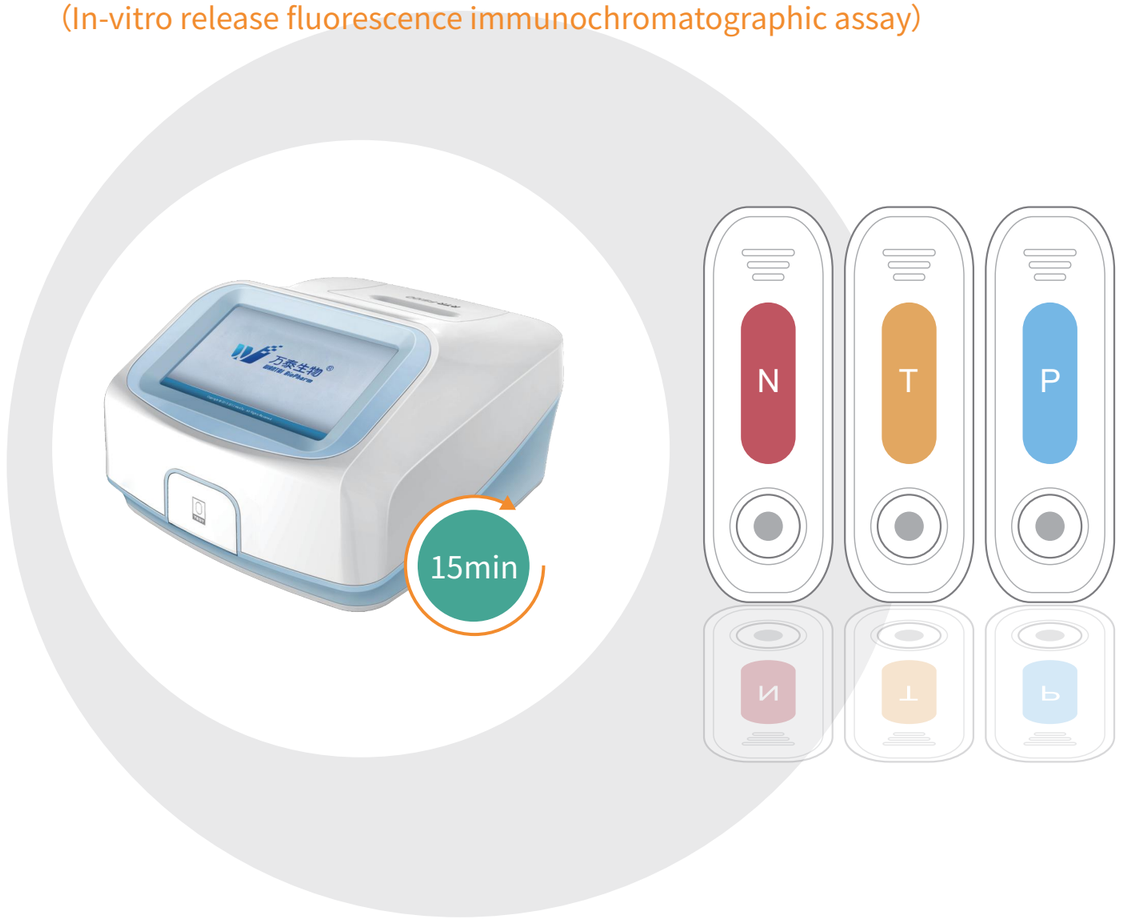
Six lots of N, T and P culture tubes were used to culture fresh blood of MTB carriers in parallel, and the within and between lot differences of the T, (T-N) and (P-N) tubes were calculated:

Kit lot #	N tube result	P tube result	T tube within-lot CV (%)	(T-N) within-lot CV (%)	(P-N) within-lot CV (%)
Lot 1	All lower than 25pg/mL	All higher than 400pg/mL	2.05	3.65	6.79
Lot 2			4.40	4.78	5.28
Lot 3			5.32	5.68	5.44
Lot 4			5.12	7.01	6.33
Lot 5			3.65	7.31	5.78
Lot 6			4.52	6.89	5.92
Between-lot CV (%)			4.44	5.89	5.92

According to the above test results, the within-lot coefficient of variation of T-tube was below 6.0%, and the between-lot coefficient of variation was 4.44%; The within-lot coefficient of variation of T-N was below 7.5% and the between-lot coefficient of variation was 5.89%; The within-lot coefficient of variation of p-n is below 7.0%, and the between-lot coefficient of variation is 5.92%. Besides this, the kit has good repeatability.

Tuberculosis Interferon Gamma release Assay (TB-IGRA)

Mycobacterium tuberculosis specific cellular immune response detection kit (In-vitro release fluorescence immunochromatographic assay)



Convenient Accurate Rapid

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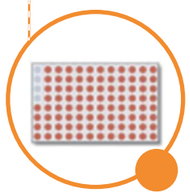
Beijing WANTAI Biological Pharmacy Enterprise Co., Ltd.

IGRA initiates the POCT era

ELISA Platform
Year 2012

Classic Methodology
Outstanding Performance



Chemiluminescence
Year 2017

Full Automation
Accurate Results

POCT Platform
Year 2018

Calibration Unnecessary
Plug and Use Right Away

Platforms of three major methodologies to fulfill the requirements of different customers

- Strong market share: Present in more than 700 clinical institutions
- High demand: Tested millions of Chinese patients
- Superior performance: Sufficient clinical validation
- Approved by professionals: Hundreds of clinical articles available

1 Easy To Use

Does not need complicated steps such as lymphocyte separation, washing, counting and CO2 culture

2 Fast Detection

Add the sample and get results in 15 minutes

3 Calibration unnecessary

Own standard curve, eliminating repeated calibration and reducing errors

4 Plug and Use Right Away

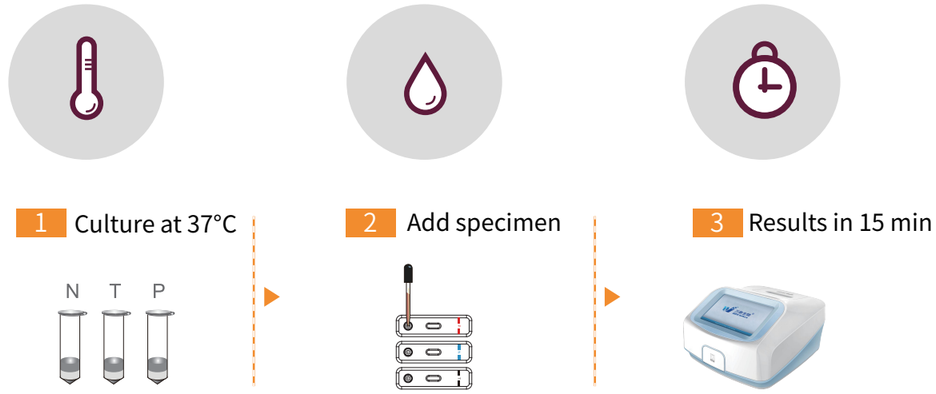
Small equipment, so professional training is not required

5 Remarkable Performance

Wide detection range from 3 to 400pg/ml, with high clinical sample agreement

POCT Features

The convenience of operating a POCT platform



Product Performance

1. 112 samples of clinically confirmed tuberculosis patients were cultured and tested, and the sensitivity was evaluated as follows:

Clinical diagnosis	Sample size	Positive fluorescence result	Sensitivity
Pulmonary TB	83	82	98.8%
Lymphatic TB	5	5	100%
Renal TB	7	7	100%
Pelvic TB	2	2	100%
Lumbar TB	4	4	100%
Other Extrapulmonary TB	11	10	90.9%
Total	112	110	98.2%

The sensitivity of this kit to tuberculosis patients was 98.2%

The data comes from performance analysis evaluation reports

Mycobacterium tuberculosis specific cellular immune response detection kit

In vitro release fluorescence immunochromatographic assay