# TB-IGRA

Tuberculosis continues to be one of the top 10 causes of death globally. The infectious disease, which is spread from person to person through the air, can be detected using Beijing Wantai's diagnostic products.

## 10600000

Total TB incidence (2022)

#### 7465430

TB new and relapse cases (2022)

#### 1300000

TB deaths (2022)

## Tuberculosis - A Global Burden

Tuberculosis (TB) is an infectious disease caused by various strains of mycobacteria, usually Mycobacterium Tuberculosis, which is spread from person to person through the air when an infected person coughs, sneezes or otherwise transmits saliva through the air.

While the disease typically attacks the lungs, it can also affect other parts of the body. However, not everyone infected with TB bacteria becomes sick. As a result, two TB-related conditions exist: latent TB infection and TB disease.

Persons with latent TB infection do not feel sick and do not have any symptoms. They are infected with M. tuberculosis, but do not have TB disease. Overall, without treatment, about 5 to 10% of infected persons will develop TB disease at some time in their lives. About half of those people who develop TB will do so within the first two years of infection. For persons whose immune systems are weak, especially those with HIV infection, the risk of developing TB disease is considerably higher than for persons with normal immune systems.

## **Diagnosis of Latent Tuberculosis Infection (LTBI)**

There is no gold standard test for LTBI. Indeed, the low tissue bacterial burden associated with LTBI works against any diagnostic strategy focused on the identification of the bacteria or its components. The diagnosis of LTBI is rather indirect and relies on evidence of a cellular immune response to mycobacterial antigens. The most commonly used tests for LTBI diagnosis are the intradermal tuberculin test (TST) and IGRA. Persons who have received BCG (either as a vaccine or for cancer therapy) and persons from groups that historically have poor rates of return for TST reading, are preferred for IGRAs testing.

## Wantai's TB-IGRA Solutions

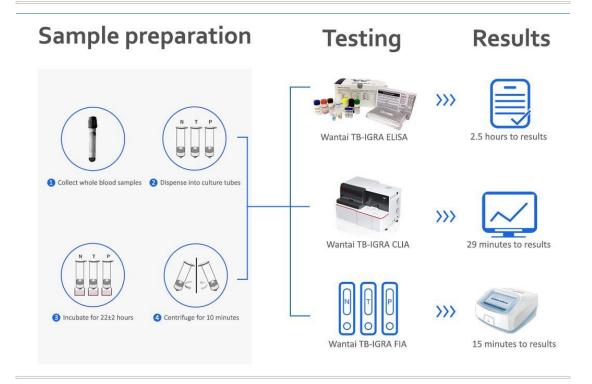
Wantai's TB-IGRAs (Interferon Gamma Release Assay) are intended for use as an aid in the diagnosis of TB infection including both latent Tuberculosis infection and Tuberculosis disease.

## How does IGRA work?

TB-IGRA measures a person's immune reactivity to Mycobacterium Tuberculosis. If a person is infected with M. Tuberculosis, his or her T-lymphocytes will release Interferon Gamma (IFN- $\gamma$ ) when mixed in-vitro with antigens derived from M. Tuberculosis. Wantai's TB-IGRAs are quantitative or semi-quantitative tests for detection of IFN- $\gamma$  released by the T-cells that have responded to in-vitro stimulation by Mycobacterium Tuberculosis antigens in human blood samples.

## Wantai's TB-IGRA Workflow

The intuitive, end-to-end process ensures improved turnaround time, optimal cost management and straightforward integration in any laboratory workflow.



#### Single-tube blood collection:

- 1. Uses a single blood collection tube containing lithium heparin as the anticoagulant.
- 2. Ensures a simplified rapid blood collection process
- 3. Enhances patient satisfaction
- 4. Increased time flexibility at the blood draw site

#### Standard centrifugation and automatic process:

Standardized results optimal harmonization between urgent, specialty and routine tests.

#### Wantai CLIA immunoassay analyzers

- 1. Wantai CLIA immunoassay analyzers are designed for both specialty and routine tests to help your laboratory handle multiple patients and tests simultaneously with minimal user intervention.
- 2. Reduced turnaround time
- 3. Optimal cost management

## Recommendations

Wantai TB-IGRA ELISA is included in the Stop TB Partnership Manual on selection and use of interferon-gamma release assays (IGRAs) for testing for TB infection and in the WHO's policy statement on the use of alternative interferon-gamma release assays for the diagnosis of TB infection.

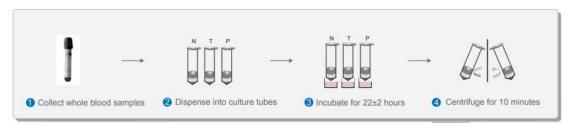
## 1、TB IGRA ELISA

#### Intended Use

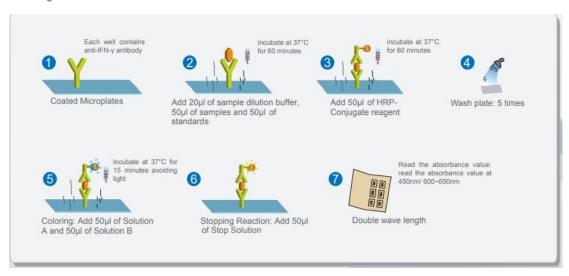
Wantai's TB-IGRA ELISA is intended for use as an aid in the diagnosis of TB infection including both latent Tuberculosis infection and Tuberculosis disease. The test is a quantitative ELISA for detection of Interferon Gamma (IFN-γ) that responds to in-vitro stimulation by Mycobacterium Tuberculosis antigens in human blood samples.

#### Procedure

#### 1. Sample Preparation



#### 2. Testing



## Specifications

Catalog No.: WT-1196

Number of tests : 28 tests per kit Storage temperature:  $2^{\circ}$ C ~  $8^{\circ}$ C

Sensitivity: Comparable to both QFT-GIT (86.4% vs 83.2%) and T-Spot (87.7% vs 88.7%)

Specificity: Comparable to both GFT-GIT(85.9% vs 88.7%) and T-Spot (81.6% vs 91.9%)(1)

#### Recommendations

Wantai TB-IGRA ELISA is included in the Stop TB Partnership Manual on selection and use of interferon-gamma release assays (IGRAs) for testing for TB infection and in the WHO's policy statement on the use of alternative interferon-gamma release assays for the diagnosis of TB infection.