



QuantiFERON®-TB Gold Plus



A new way to see tuberculosis

Meet the next evolution in TB detection.

Sample to Insight

We can build a world free from TB

One quarter of the world's population is infected with *Mycobacterium tuberculosis*, the bacteria that causes TB (1).

Individuals carrying TB infection may show no symptoms, but they are at risk for developing contagious and potentially fatal active TB disease.

Although TB infection is treatable and curable, 1.5 million people die from TB disease each year (1).



You can help end the TB epidemic

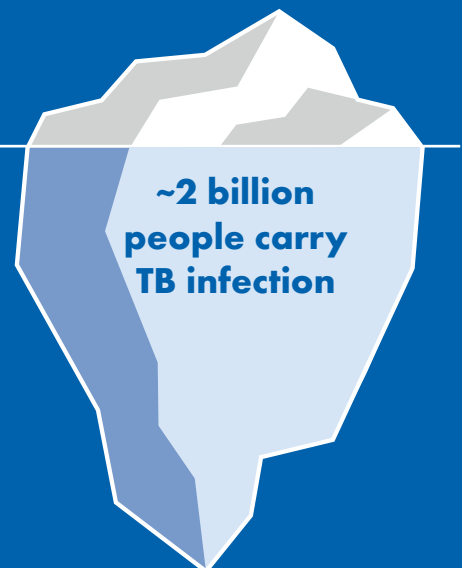
Active TB infection is just the tip of the iceberg. To end the cycle of TB transmission and disease progression, we must test and treat latent TB infection as well as active TB disease (2).

Today's TB

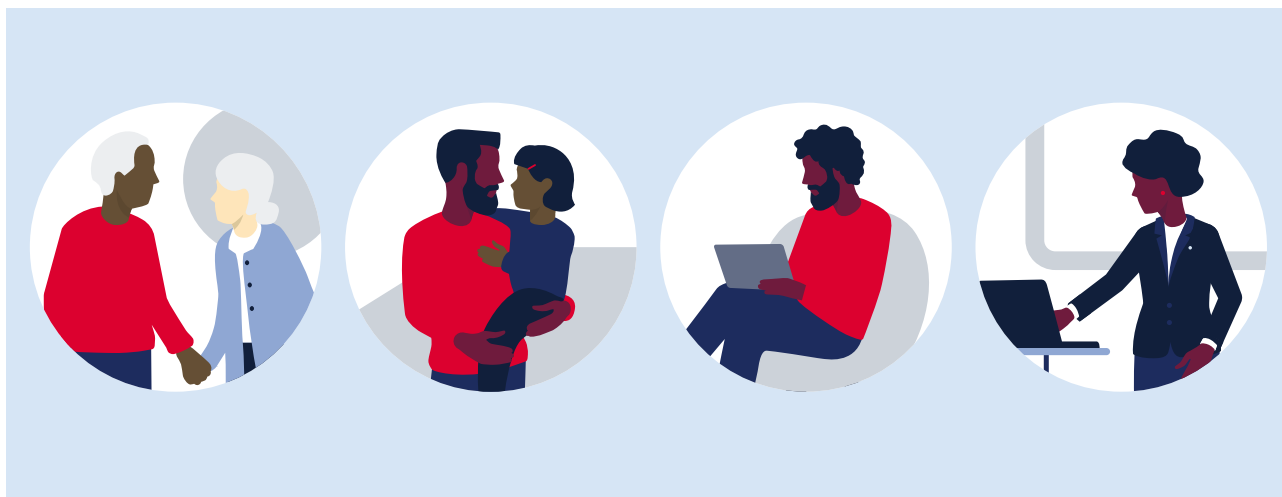
- 10 million active cases globally (1)

Tomorrow's TB

- ~2 billion people infected with TB (1)
- Silent carriers
- 5-10% will develop active TB disease



Today, we can do better for people living with TB infection



The WHO recommends testing and treatment for those at risk of TB

Individuals at increased risk should be prioritized for testing and treatment (3).

Table 1. Individuals at increased risk (3)

Increased risk for TB infection	Increased risk for TB progression
Close contacts of active TB cases	Individuals living with HIV
Healthcare workers	Persons receiving TNF- α inhibitors
Migrants from high TB-burden countries	Persons with diabetes mellitus
Persons in congregate settings	Persons with chronic renal failure
Persons in correctional facilities	Persons receiving corticosteroids
Persons in long-term care facilities	Organ transplant recipients
Persons who abuse drugs or alcohol	Persons recently infected with <i>M. tuberculosis</i>

Table 2. Relative risk for active TB (4, 5)

Risk group	Fold risk
HIV/AIDS	50–170
Transplant recipients	20–74
Hemodialysis	10–25
Recent TB infection	15
Abnormal chest X-ray	6–19
TNF- α inhibitors	10
Diabetes	2–5

TB blood tests (IGRA) can be used for screening all at-risk populations, regardless of the local TB burden or country income.

QuantiFERON-TB Gold Plus is the modern solution for TB screening

QuantiFERON-TB Gold Plus (QFT®-Plus) is the industry-leading blood test for TB screening. QFT-Plus is optimized with innovative tuberculosis-specific antigens that elicit both CD8 and CD4 T-cell responses – enabling a more comprehensive assessment of cell-mediated immune response to TB infection (5).

QFT-Plus provides:

- Single-visit screening
- Accurate and reproducible results
- Convenient and objective lab-based testing
- Innovative CD8 T-cell technology
- Flexible blood collection and scalable laboratory workflows

Reduce the disease's
impact by increasing your
ability to detect it



Focused on efficiency, accuracy, and moving the world of science and health forward



Simplicity

- One visit to the provider
- >97% specificity, reducing false positive results
- >94% sensitivity helping identify those at risk
- Unaffected by the BCG vaccine and most non-TB mycobacteria

Optimized workflow

- Whole blood samples are used to generate a single qualitative result, indicating the immune response to *Mycobacterium tuberculosis*
- Fast turnaround time
- Objective processing and results interpretation

Cost-effective testing

- Low false positive rate to reduce unnecessary follow up including chest X-rays, laboratory investigations and preventive treatment
- Single-visit testing to streamline care and reduces costs
- Results sent directly to providers

A giant step toward eradicating TB with just one test, one visit and one clear result

The QFT-Plus test uses a peptide cocktail simulating *M. tuberculosis* proteins to stimulate cells in heparinized whole blood. Detection of interferon- γ (IFN- γ) by enzyme-linked immunosorbent assay (ELISA) is used to identify in vitro responses to these peptide antigens that are associated with *M. tuberculosis* infection.

Mitogen – positive control Low response may indicate inability to generate IFN- γ
Nil – negative control Adjusts for background IFN- γ
TB1 – primarily detects CD4 T-cell response
TB2 – optimized for detection of CD4 and CD8 T-cell responses

Figure 1.
QFT-Plus Blood Collection Tubes.

Requires just 4 ml of whole blood – 1 ml in each of the four tubes

- Unique blood collection tubes enable immediate exposure of blood lymphocytes to highly-specific TB antigens
- Option of drawing blood into a standard sodium- or lithium-heparin tube
- Fastest and easiest IGRA available, with no tedious lymphocyte isolation, subjective cell counting, diluting, or culturing
- Easily scalable for high-throughput testing laboratories

Results interpretation

QFT-Plus assay results are interpreted objectively using optional QuantiFERON-TB Gold Plus analysis software.

QFT-Plus positive	QFT-Plus negative	QFT-Plus indeterminate
<i>M. tuberculosis</i> infection is likely	<i>M. tuberculosis</i> infection is NOT likely	Likelihood of <i>M. tuberculosis</i> infection cannot be determined
- Nil ≤ 8.0 ; and - TB1 and/or TB2 minus Nil ≥ 0.35 and $\geq 25\%$ of Nil	- Nil ≤ 8.0 , Mitogen minus Nil ≥ 0.5 ; and - TB1 and TB2 minus Nil < 0.35 or ≥ 0.35 and $< 25\%$ of Nil	- Nil > 8.0 ; or - Nil ≤ 8.0 and TB1 and TB2 < 0.35 or ≥ 0.35 and $< 25\%$ of Nil and Mitogen minus Nil < 0.5

Figure 2.
Interpretation of results. All values are IU/ml IFN- γ . Indeterminate results may relate to the immune status of the individual being tested, or may be related to technical factors (e.g., incomplete ELISA plate washing). **Important:** Diagnosing or excluding tuberculosis disease and assessing the probability of latent TB infection requires a combination of epidemiological, historical, medical, and diagnostic findings that should be taken into account when interpreting QFT-Plus results (5).

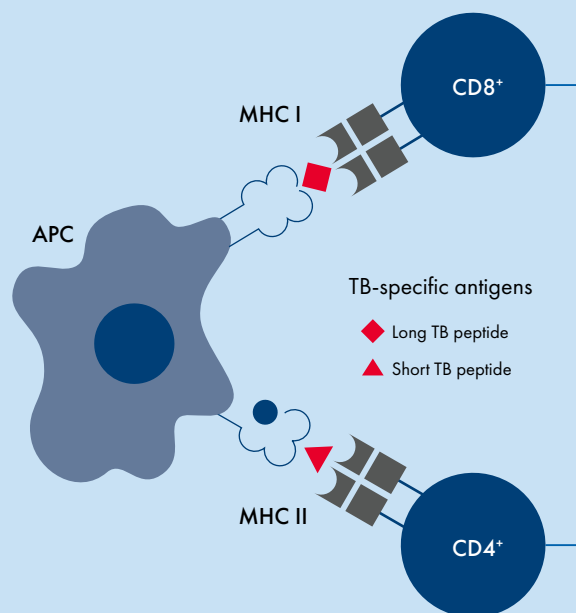
A passion for progress meets a need for TB patients everywhere

QFT-Plus leads the industry with innovative CD8 technology

During *M. tuberculosis* infection, CD4 T cells play a critical role in immunological control through their secretion of the cytokine IFN- γ . Evidence now also supports a role for CD8 T cells in host defense against *M. tuberculosis*.

TB-specific CD8 T cells have been:

- Detected more frequently in those with active TB disease vs latent infection (10, 11)
- Associated with recent exposure to TB (12)
- Detectable in active TB subjects with HIV co-infection and in young children (13-15)

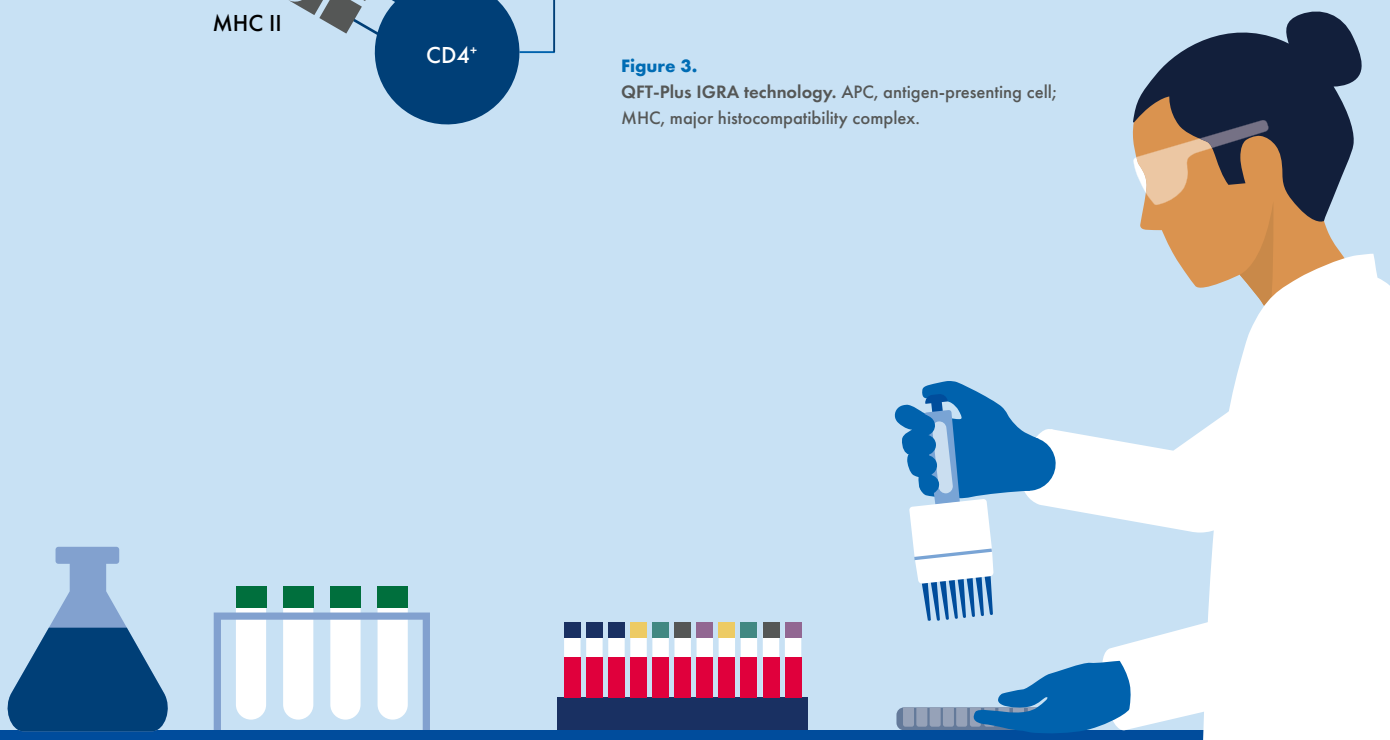


CD8 T cells produce IFN- γ and other soluble factors to (7-9):

- **Suppress *M. tuberculosis* growth**
- **Kill infected cells**
- **Lyse intracellular mycobacteria**

Figure 3.

QFT-Plus IGRA technology. APC, antigen-presenting cell; MHC, major histocompatibility complex.



The QFT-Plus difference

See TB before it shows itself

>97%

specificity

>94%

sensitivity



Positively accurate

QuantIFERON-TB Gold Plus is the patient-centered, more affordable way to test for TB infection – producing more accurate results than the century-old TST.

TST challenges	QFT-Plus solutions
Specificity is as low as 59% in BCG-vaccinated patients (16)	>97% specific, nearly eliminating false positive results and providing peace of mind for patients and physicians
Low sensitivity can cause missed true positives, putting contacts at risk (17)	>94% sensitivity enables truly infected patients to be identified and to receive appropriate antibiotic therapy
Cross-reaction with the BCG vaccine and other environmental mycobacteria cause false positive results (6)	Unaffected by the BCG vaccine and most non-TB mycobacteria, reducing unnecessary antibiotic treatments

Patient-centered and cost-effective

QFT-Plus removes the costly burden that inaccurate TB screening results place on your practice and patients.

TST challenges	QFT-Plus solutions
High false positive rate causes unnecessary additional testing and costly treatment (17)	Low false positive rate reduces the cost and burden of unnecessary antibiotic treatment
High program costs result from second visits, unnecessary X-rays, and treatment	QFT-Plus is consistently shown to be more cost effective in screening situations (18, 19)
A return visit is required to read the TST reaction	Results can be sent directly to the physician, eliminating return visits for patients who test negative and encouraging follow-up for patients who test positive



Continuously dedicated to
making **improvements in life**
possible

From a century-old skin test to a faster, modern-day, fully-optimized blood test

QFT-Plus offers a scalable workflow made for today

QFT-Plus employs standard phlebotomy procedures using whole blood to make sample collection easy and fast. Sample incubation can occur on-site or at the testing laboratory, providing your practice with complete flexibility and convenience.

It's the fastest and easiest IGRA available, with no tedious lymphocyte isolation, subjective cell counting, diluting, or culturing. **Results can be available using QFT-Plus analysis software within 24 hours, with no second patient visit required.**

Choose from industry-leading flexible blood collection options

Option 1: Direct Draw

Collect 1 ml of whole blood directly into each of the four QFT-Plus blood collection tubes and hold at room temperature for up to 16 hours prior to incubation.

Option 2: Single Sodium- or Lithium-Heparin Tube

Draw at least 5 ml of blood into a single blood collection tube containing sodium- or lithium-heparin as the anticoagulant. Blood collected into a single tube may be stored at room temperature or refrigerated, allowing up to 53 hours prior to sample incubation.

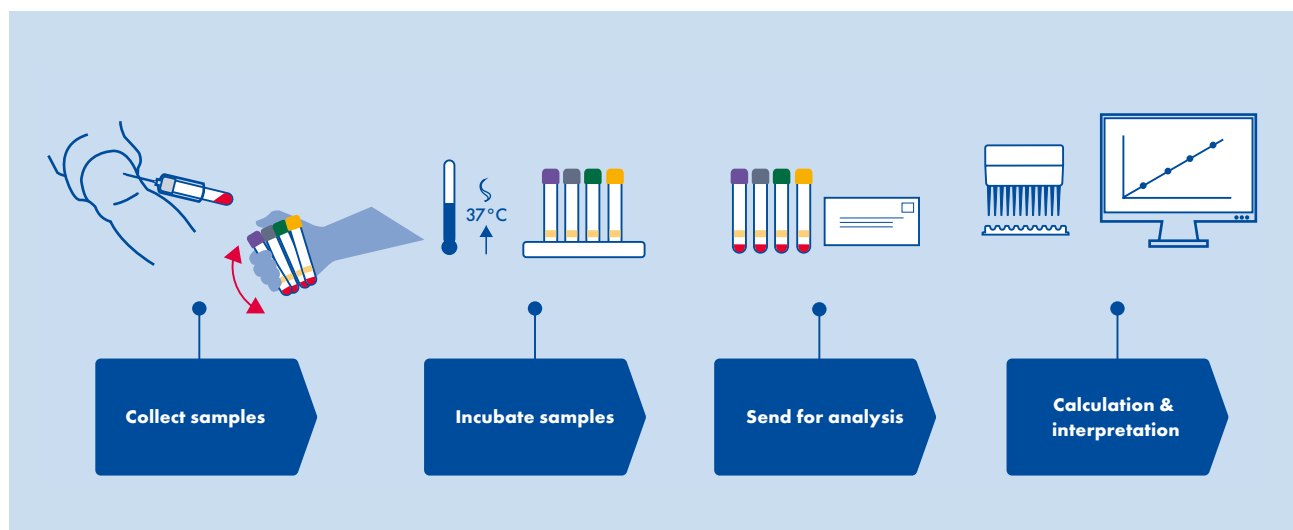


Figure 4.
Streamlined QFT-Plus workflow, from patient sample to diagnostic insight.

Choose the most tested and trusted IGRA available

QuantiFERON technology has been the subject of over 1500 clinical and scientific studies. QFT-Plus provides a comprehensive view of the immune response to TB infection – and the convenience of a single patient visit.

To learn more, contact your QIAGEN sales representative, or visit www.qiagen.com/end-TB.

Ordering Information

Product	Contents	Cat. no.
QuantiFERON-TB Gold Plus 2 Plate Kit ELISA	Microplate Strips; IFN- γ Standard, lyophilized; Green Diluent; Conjugate 100x Concentrate, lyophilized; Wash Buffer 20x Concentrate; Enzyme Substrate Solution; Enzyme Stopping Solution	622120
QFT-Plus Single Patient Pack (10 tests)	10 QFT-Plus Blood Collection Tubes packs, each including: Nil, TB1, TB2, and Mitogen tubes	622222
QFT-Plus Blood Collection Tubes (200)	QFT-Plus Blood Collection Tubes: Nil, TB1, TB2, and Mitogen tubes (50 each)	622526

Product availability may vary from country to country. To discover the full range of QuantiFERON-TB Gold Plus products for your country visit www.QIAGEN.com or contact your local sales representative.

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