



Screen for TB with confidence

QuantiFERON®-TB Gold Plus
– the most accurate test
for TB infection

Sample to Insight

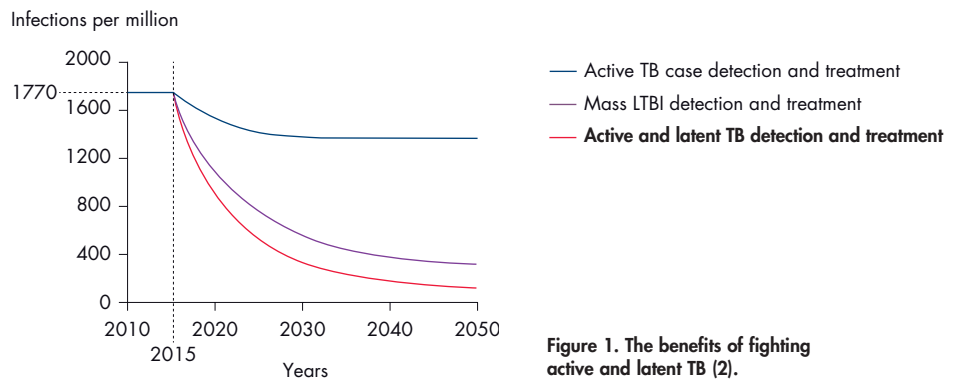


TB is a preventable disease

Tuberculosis (TB) is a contagious and deadly disease that is still prevalent today. One third of the world's population is believed to be infected with *Mycobacterium tuberculosis* (MTB), the pathogen that causes TB (1). Individuals with latent TB infection (LTBI) show no symptoms, but are at risk for developing the contagious and potentially fatal active TB disease.



The World Health Organization (WHO) acknowledges that to fight TB effectively, the accurate identification and treatment of **LTBI as well as active TB disease** are vital (1).



Together we can defeat TB

Addressing the vast reservoir of latent TB infections through targeted LTBI testing and treatment can substantially reduce the number of people who develop active TB and can prevent further spread of the disease (1).

Those at greatest risk should be prioritized for TB screening (3–9):

People exposed to TB	Individuals living in congregate settings	Immunocompromised individuals
<ul style="list-style-type: none"> Healthcare workers Migrants Contacts of persons known or suspected to have active TB 	<ul style="list-style-type: none"> Students Prison inmates Elderly Military personnel 	<ul style="list-style-type: none"> Persons living with HIV/AIDs Young children Individuals receiving immunosuppressive therapies

A test that accurately identifies TB infection is critical to reducing the global TB burden.

QuantiFERON-TB Gold Plus (QFT®-Plus) – the modern alternative to the tuberculin skin test

QuantiFERON technology is the simpler, more affordable way to test for TB infection that produces more accurate results than the century-old tuberculin skin test (TST).

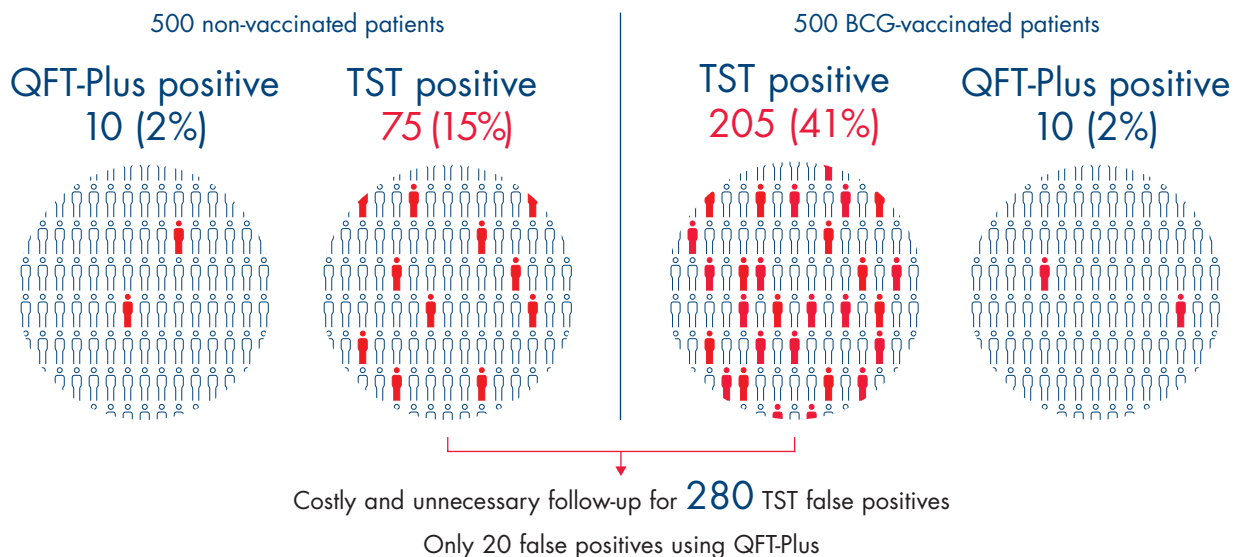
QFT-Plus is a highly-specific and controlled blood test to aid in the diagnosis of infection with MTB. QFT-Plus uses an interferon-gamma release assay (IGRA) to provide quantitative measurement of the T-cell immune response to MTB. **Unlike the TST, QFT-Plus is not affected by the Bacille-Calmette Guérin (BCG) vaccination (4, 10, 11).**

Table 1. QFT-Plus offers clear benefits over the tuberculin skin test (TST)

	QFT-Plus (4, 10)		TST (10, 12)	
Single visit assay?	YES	Requires only one patient visit	NO	Requires two patient visits
High sensitivity?	YES	95% sensitivity – accurately identify TB-infected patients	NO	70% sensitivity – more missed diagnoses
High specificity? (13)	YES	98% specificity – less unnecessary follow-up and treatment	NO	Variable; 59% in BCG-vaccinated populations – false positives result in unnecessary and costly follow-up
Objective results?	YES	Objective and controlled laboratory assay	NO	Subjective measurement of skin induration
Effective in BCG-vaccinated patients?	YES	Unaffected by BCG vaccination	NO	Results affected by BCG vaccination
Most cost effective? (14, 15)	YES	More cost effective than TST in multiple screening situations	NO	High program costs due to second visits and false positives

False positive results can be a costly burden on your TB screening program and on your patients. QFT-Plus produces fewer false positive results than the tuberculin skin test, meaning less unnecessary follow-up testing and treatment.

For **1000 uninfected** patients screened, assuming a 50% BCG vaccination rate (3, 4, 13):



Shine a light on latent TB infection in your patient population with QFT-Plus.

QuantiFERON-TB Gold Plus is the most accurate test for TB infection

QFT-Plus is an improved version of the industry-leading IGRA for TB detection, QuantiFERON-TB Gold. It is optimized with innovative tuberculosis-specific antigens that elicit both CD8⁺ and CD4⁺ T-cell responses.

Choose the most tested and trusted IGRA available

QuantiFERON technology has been the subject of over 1100 clinical and scientific studies, and maintains the highest accuracy of any test for TB infection. QFT-Plus provides the convenience of a single patient visit with electronic reporting, quantitative results and unparalleled accuracy.

The QFT-Plus advantage – four tubes, one clear result

QFT-Plus uses unique blood collection tubes that enable immediate exposure of blood lymphocytes to highly specific TB antigens or to test controls coated on the inner surface of the tubes (Figure 2).

QFT-Plus requires just 4 ml of whole blood – 1 ml in each of the 4 tubes. QFT-Plus also provides the option of drawing into a standard lithium heparin tube and transferring to the QFT-Plus tubes.

QFT-Plus is the fastest and easiest IGRA available, with no tedious lymphocyte isolation, subjective cell counting, diluting or culturing.

QFT-Plus is easily automatable and scalable for high-throughput testing laboratories.



Mitogen – Positive Control.
Confirms baseline immune status

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 2. QFT-Plus blood collection tubes.

QFT-Plus uses the same principle, test procedures, and reliable technology that you trust, but is now – enabling a more accurate assessment of cell-mediated immune response to TB infection (1).



Advancing the science of TB testing with innovative CD8⁺ T-cell technology

CD8⁺ T-cells have been shown to play an important role in MTB immunity (16–18). QFT-Plus now measures the cell-mediated immune response to MTB infection from both CD4⁺ and CD8⁺ T-cells. The new TB1 tube primarily detects CD4⁺ responses, while TB2 is optimized for both CD4⁺ and CD8⁺ responses.

QFT-Plus: unparalleled accuracy (4)

98%
specificity

95%
sensitivity

This innovative QFT-Plus assay provides the most accurate TB test on the market, producing less than 2% indeterminate results in both low- and high-risk cohorts.

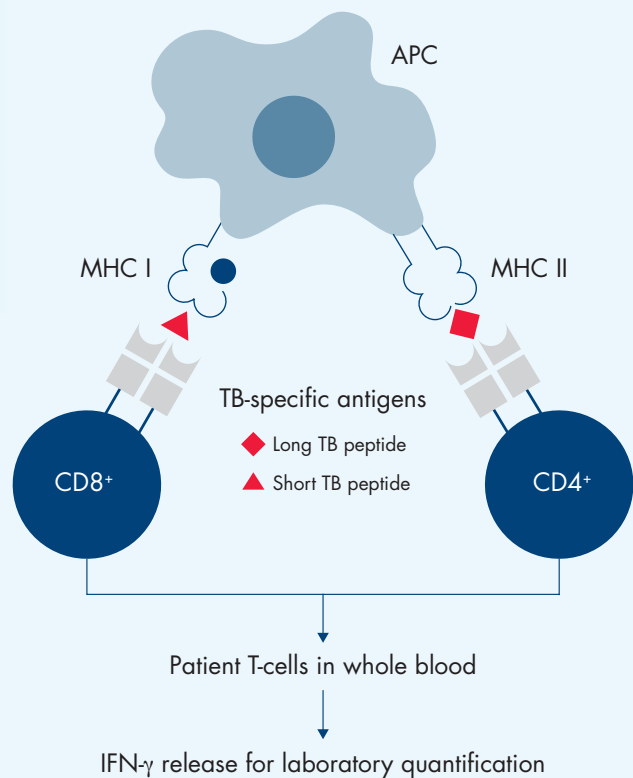


Figure 3. QFT-Plus IGRA technology. APC = antigen-presenting cell; MHC = major histocompatibility complex.

Choose QFT-Plus for accurate and convenient TB testing

QFT-Plus employs standard phlebotomy procedures using whole blood to make sample collection simple and fast. Sample incubation can occur on-site or at the testing laboratory, providing your practice with complete flexibility and convenience. Results can be available in as little as 24 hours, with no second patient visit required.

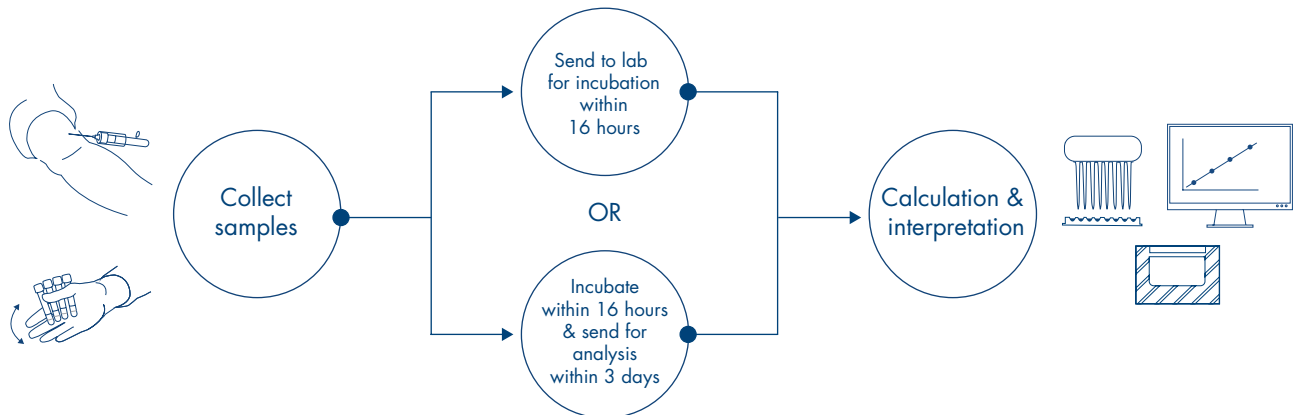
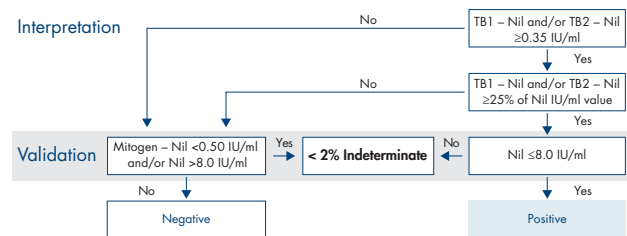


Figure 4. QFT-Plus provides a simple and rapid TB screening workflow. QFT-Plus tubes have the same phlebotomy practice and handling process as QuantiFERON-TB Gold.

QFT-Plus – an objective and controlled laboratory assay

The QFT-Plus assay produces quantitative results that are interpreted objectively using QuantiFERON software. The cut-offs for positive and negative QFT-Plus results are unchanged compared to QuantiFERON-TB Gold.

Figure 5. Interpretation of QFT-Plus results. Note: Positive results by TB1, TB2 or both (nil corrected) are considered positive. QFT-Plus is an indirect test for *M. tuberculosis* infection and is intended for use in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations.



QFT-Plus interpretation software is freely available at www.QuantiFERON.com. QFT-Plus can be automated on the Dynex DS2® or DSX® platforms. Please contact your local QuantiFERON representative for further information.

Provide your patients with accurate and objective TB testing in the convenience of a single visit.

Improving detection of TB infection with QFT-Plus

QFT-Plus offers robust and reliable results, and improved performance in high-risk groups (18). The overall QFT-Plus test sensitivity in a high-risk cohort was found to be >95%, while only 1% of tests from this cohort yielded indeterminate results (4).

A large, independent multicenter study sought to evaluate the clinical performance of QFT-Plus in various cohorts. The authors of the study concluded (19):

The data suggest that “QFT-Plus does indeed offer improved sensitivity”

“[The] difference between TB2 and TB1 was higher in smear-positive [pulmonary tuberculosis] compared to smear-negative patients”

“The increased IFN- γ release by combined stimulation of CD4⁺ and CD8⁺ T-cells observed in the newly added antigen tube (TB2) might be advantageous for improving the assay’s accuracy in patients with low CD4⁺ T-cell counts”

In summary, the findings support that QFT-Plus offers improved sensitivity, better accuracy in patients with low CD4⁺ T-cell counts, and the potential for additional valuable information in the difference between the TB1 and TB2 values.

Potential for additional clinical insights

TB-specific CD8⁺ T-cells that produce IFN- γ may also provide additional clinical insights. CD8⁺ T-cells have been:

- More frequently detected in patients with active TB compared to latent TB infection (20, 21)
- Associated with recent exposure to TB (22)
- Detectable in active TB patients with HIV co-infection and in young children (19, 23, 24)
- Observed to decline when patients are exposed to antituberculosis treatment (25)

Clinicians may also glean additional clinical information by looking at the discordance and delta between TB1 and TB2 tubes (Figure 6).

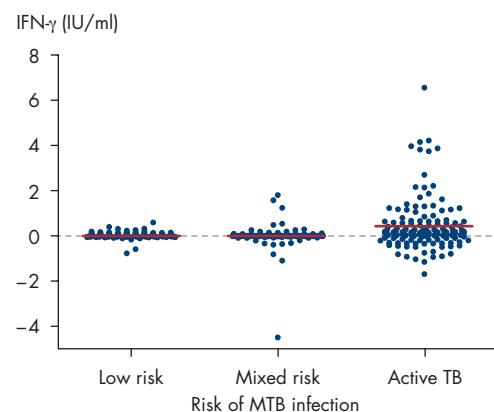


Figure 6. Observed difference between TB1 and TB2 values (nil subtracted), with cohorts stratified by risk.

Choose the proven TB test that has been trusted for over a decade.

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 Blood Collection Tubes Single Patient Pack (10 preps)*	10 QFT-Plus Blood Collection Tubes pack, 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

* Not all product configurations are available in every country. Please refer to QIAGEN customer care (details on www.qiagen.com) for more information on what configurations are available for ordering. For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at www.qiagen.com or can be requested from QIAGEN Technical Services or your local distributor.

Ask your QIAGEN sales representative, or go to www.QuantiFERON.com/Plus for more information.

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QuantiFERON-TB Gold Plus is CE marked for use in Europe. QuantiFERON-TB Gold Plus (QFT-Plus) is an in vitro diagnostic aid for detection of *Mycobacterium tuberculosis* infection (including disease) and is intended for use in conjunction with risk assessment, radiography and other medical and diagnostic evaluations. QFT-Plus results alone cannot distinguish active TB disease from latent infection. QFT-Plus Package Inserts, available in multiple languages, as well as up-to-date licensing information and product-specific disclaimers can be found at www.QuantiFERON.com.

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