QIAGEN

When accuracy matters

QuantiFERON®-TB Gold by QIAGEN

The most accurate test for TB infection

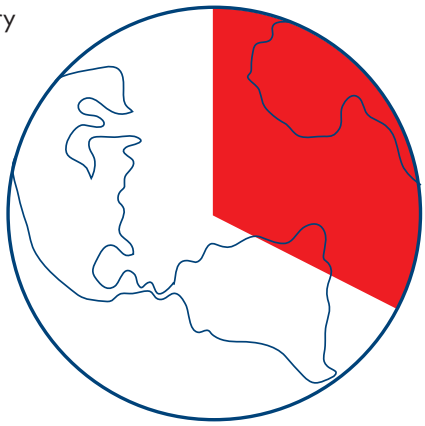
Sample to Insight

TB is one of the deadliest infectious diseases, but it can be prevented

Tuberculosis (TB) is a contagious infection responsible for more deaths annually than any other infectious disease, including HIV/AIDS. One third of the world's population is believed to be infected with *Mycobacterium tuberculosis*, the pathogen that causes TB (1). Individuals with latent TB infection (LTBI) show no symptoms. They may carry the infection for months or even years, and they are at risk for developing active and contagious 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).

Unfortunately, outdated TB testing methods that are still commonly in use, such as the tuberculin skin test (TST), are not always sufficient to accurately identify true TB infection. This is especially true in high-risk populations such as the immunosuppressed, and in groups where the limitations of the TST are well-recognized, such as BCG-vaccinated individuals (2–3).



1/3 of the world is infected with latent TB

Together we can defeat TB

A test that accurately identifies TB infection is critical to reducing the global TB burden. Moreover, in times of increasing global migration, international borders are not sufficient to prevent the spread of TB. Prioritizing and testing those at greatest risk for infection is essential to preventing TB transmission (Table 1).

Table 1. The WHO recommends LTBI testing and treatment for populations at the highest risk (1)

Those most vulnerable to TB progression	Other prioritized at-risk populations
Contacts of pulmonary TB cases	Healthcare workers
People living with HIV	Prisoners
Patients initiating TNF-α treatment	Immigrants
Patients receiving dialysis	Individuals in congregate settings
Organ or hematologic transplantation patients	Illicit drug users

Newer TB blood tests, known as Interferon-Gamma Release Assays (IGRAs), address the limitations of the century-old tuberculin skin test (TST) and are finding widespread acceptance in the market. IGRAs detect TB infection by measuring the release of interferon-gamma (IFN-γ) from patient T cells after stimulation of a whole blood sample with highly specific TB antigens.

The US Centers for Disease Control (CDC) guidelines recommend the use of IGRAs in all situations in which the TST was historically used to detect TB infection. Moreover, IGRAs are the preferred test for persons who are BCG-vaccinated or are unlikely to return for TST reading (4).

Trust QuantiFERON-TB Gold

QuantiFERON-TB Gold (QFT®) is the most clinically tested and proven IGRA available (5). More than 30 million QFT tests have been sold across 130+ countries, including more than 7 million in 2015. Trust the only blood test for TB infection that offers:

- The most accurate and reproducible results for TB infection
- The confidence of more than 1200 clinical and scientific studies
- Convenient and objective ELISA technology
- Single visit testing

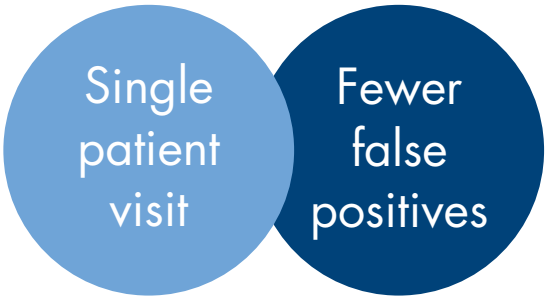
For detection of TB infection, accuracy matters

QFT is a simple, fresh blood test that produces more accurate results than the century-old skin test.

Unlike the TST, QFT is **not** affected by Bacille Calmette-Guérin (BCG) vaccination.

TST Challenges	QFT Solutions
Specificity as low as 59% in BCG-vaccinated patients (6)	>99% specific, nearly eliminating false positives and providing peace of mind for patients and physicians
Low sensitivity can cause missed true positives, putting contacts at risk (7)	Higher sensitivity than the TST, enabling truly infected patients to be identified and to receive appropriate antibiotic therapy
False positives from cross-reaction with the BCG vaccine and other environmental mycobacteria (2)	Unaffected by the BCG vaccine and most non-TB mycobacteria, reducing unnecessary antibiotic treatments

QFT is the simple, cost-effective solution for TB infection screening

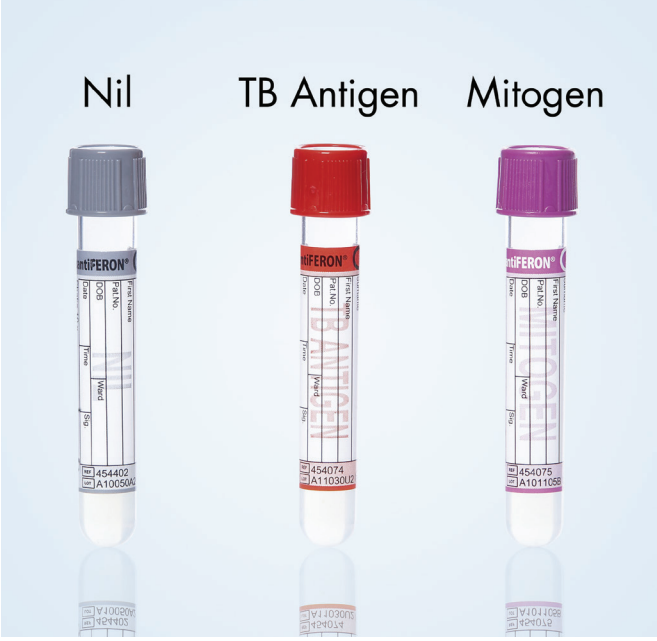


TST Challenges	QFT Solutions
High false positive rate causes unnecessary additional testing and costly treatment (6)	Low false positive rate reduces the cost and burden of unnecessary antibiotic treatment
High program costs from second visits, unnecessary x-rays and treatment (8–9)	Consistently shown to be more cost-effective in screening situations
Requires return visit to read the TST reaction	Results are sent directly to the physician, eliminating return visits for patients who test negative and encouraging follow-up for patients who test positive

You can lift the costly burden that inaccurate TB screening results place on your practice and on your patients. QFT produces fewer false positive results than the tuberculin skin test. QFT is also widely covered by Medicare, Medicaid and private insurance.

Modern and objective lab results using QFT technology

QFT is the industry-leading IGRA for TB detection. QFT uses unique blood collection tubes that enable immediate exposure of viable blood lymphocytes to highly specific TB antigens and test controls coated on the inner surface of the tubes. Antigen exposure produces a quantifiable immune response to aid in the diagnosis of TB infection.



The QFT advantage – three tubes, one clear result

Nil – negative control to adjust for background IFN-γ

TB Antigen – to detect the $CD4^+$ T cell responses to TB antigens

Mitogen – positive control to confirm baseline immune status

QFT is the fastest and easiest IGRA on the market:

- Requires only 3 ml of whole blood – 1 ml in each tube
- Optimized for speed and ease-of-use – no tedious lymphocyte isolation, subjective cell counting, diluting or culturing
- Results determined by objective ELISA analysis, rather than subjective counting of spots

Choose QFT for a flexible, convenient workflow

QFT employs whole blood collection to make T cell incubation simple and fast. After blood collection, the sample must be incubated, which can occur on-site or at the testing laboratory, providing your practice with complete flexibility and convenience.

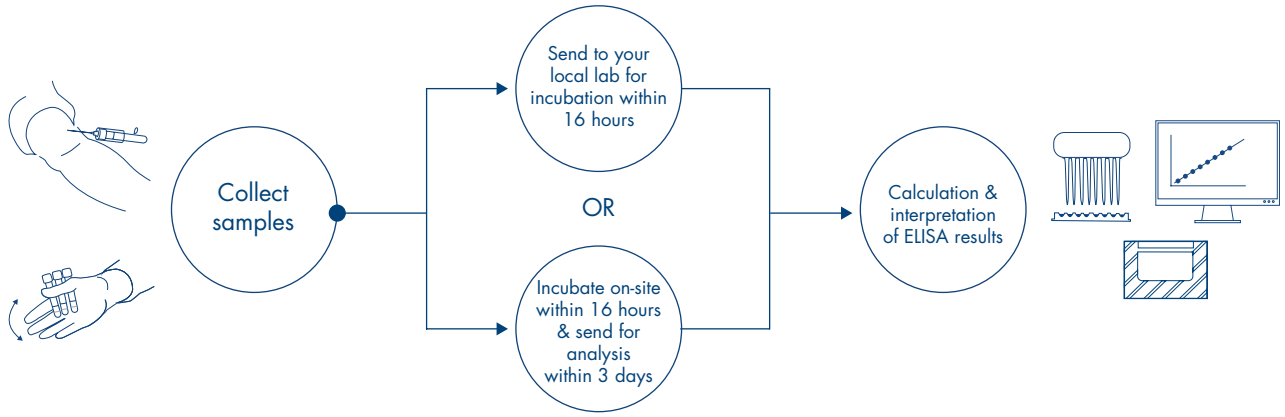


Figure 1. QFT provides a simple and rapid TB screening workflow.

The key to eradication is prevention – prevent TB in your community with QuantiFERON-TB Gold.

Improve your TB testing today –
Contact customer care at 1-800-426-8157 (USA) or visit **www.qiagen.com/shop**.

Not in the USA?
To find your local sales representative visit **www.qiagen.com/Goto/Customer-Care-Contact**.

References:

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QFT is approved by the US FDA. QFT is CE marked.

QFT is approved by FDA as an in vitro diagnostic aid for detection of *Mycobacterium tuberculosis* infection. It uses a peptide cocktail simulating ESAT-6, CFP-10, and TB7.7(p4) proteins to stimulate cells in heparinized whole blood.

Detection of IFN-γ by ELISA is used to identify in vitro responses to these peptide antigens that are associated with *M. tuberculosis* infection. QFT is an indirect test for *M. tuberculosis* infection (including disease) and is intended for use in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations.

The performance of the USA format of the QFT test has not been extensively evaluated with specimens from individuals who have impaired or altered immune functions, such as those who have HIV infection or AIDS, those who have transplantation managed with immunosuppressive treatment or others who receive immunosuppressive drugs, or those with other clinical conditions such as chronic renal failure or hematological disorders.

Up-to-date licensing information and product-specific disclaimers can be found at **www.QuantiFERON.com**.

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