



TB OR NOT TB?

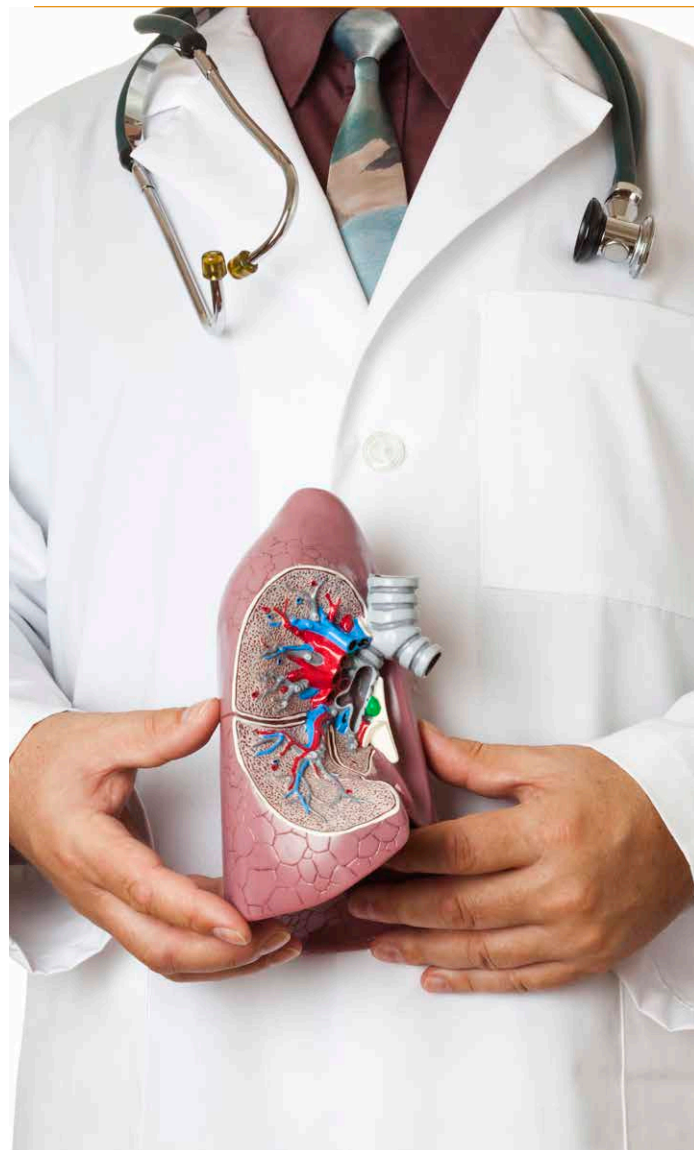
Now the **right test** — Now the **right result**

Now Available: **QuantiFERON®-TB Gold Plus**
Latest evolution of QuantiFERON® technology for tuberculosis (TB) infection evaluations

Selecting the Replacement Standard

QuantiFERON®-TB Gold Plus (QFT®-Plus) is the fourth generation in QuantiFERON-TB testing technology.¹ This single blood specimen collection is recommended by the Centers for Disease Control and Prevention (CDC) for use in certain situations in which a tuberculin skin test (TST) is appropriate.² Interferon Gamma Release Assays (IGRAs), such as QFT-Plus, are a modern alternative to the more than 100-year-old TST. QFT-Plus offers improved performance and is preferred in individuals who have received Bacille Calmette-Guérin (BCG) vaccination or who may not be in compliance for return visits to have a TST read.²

- QFT has been shown to be more accurate than the TST in identifying people who may have latent tuberculosis (TB) infection.³
- QFT has been shown to be more reliable than the TST in identifying those who may progress to active TB.⁴ QFT-Plus is >97% specific,¹ nearly eliminating false-positive readings; and false positive rates for TST have been published as low as 3% in non-BCG-vaccinated populations⁵ and as high as 65% when using a 10-mm induration as the cutoff in BCG- vaccinated populations.⁶
- QFT-Plus offers >94% sensitivity, decreasing false negatives.¹



Improving Upon Technology Limitations

QFT-Plus leads the industry with the new innovative CD8 cell technology.

- QFT-Plus is the latest IGRA technology for TB infection. This new assay adds an additional antigen that targets CD8⁺ T cells to provide clear objective results. During *M. tuberculosis* infection, CD4 T cells play a critical role in immunological control through secretions of the cytokine IFN- γ . Evidence now also supports a role for CD8⁺ T cells in host defense against *M. tuberculosis*. CD8⁺ T cells produce IFN- γ and other soluble factors.¹
- Moreover, research indicates that TB-specific CD8⁺ T cells that produce IFN- γ have been¹:
 - More frequently detected in those with TB disease (active) vs. TB infection¹ (latent);
 - Associated with recent exposure to TB¹;
 - Detectable in active TB patients with HIV co-infection and young children who have TB.¹

Advantages of QFT®-Plus

TST Challenges

Requires multiple office visits to inject and read the TST reaction⁷

Higher false-positive rate (than QFT-Plus)

Higher false-negative rate (than QFT-Plus)

Subjective result

May be affected by previous BCG vaccinations

May boost subsequent TST test results

TST approved for use to aid in the evaluation of TB

QFT Offers Improvements

One office visit for single blood draw

>97% specific, nearly eliminating false positives¹

>94% sensitivity, decreasing false negatives¹

Produces an objective result

Unaffected by previous BCG vaccinations⁸

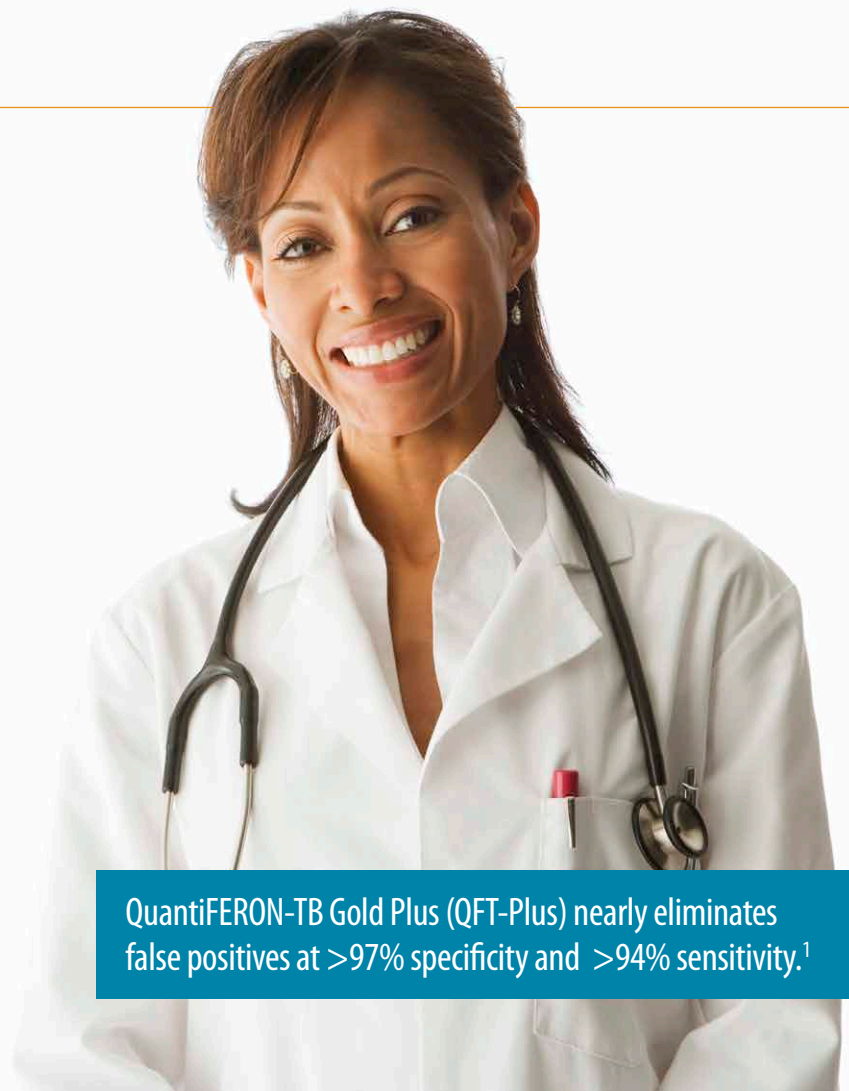
Does not boost subsequent QFT-Plus test results and less affected by prior TST⁸

QFT-Plus is an approved alternative for use where TST is appropriate.²
QFT-Plus is also preferred in individuals who have received BCG vaccination or who may not be in compliance for return visits to have a TST read.

AT RISK

The CDC states that individuals at increased risk for *M. tuberculosis* infection include:²

- ▶ Those with close contact with persons known or suspected to have active tuberculosis
- ▶ Foreign-born persons from areas with a high incidence of active tuberculosis
- ▶ Visitors to areas with a high prevalence of active tuberculosis
- ▶ Residents and employees of congregate settings whose clients are at increased risk for active tuberculosis (correctional facilities, long-term care facilities, and homeless shelters)
- ▶ Health care workers who serve clients at increased risk for active tuberculosis
- ▶ Populations defined locally with increased risk of *M. tuberculosis* infection



QuantiFERON-TB Gold Plus (QFT-Plus) nearly eliminates false positives at >97% specificity and >94% sensitivity.¹



Test Name	Test No.
QuantIFERON®-TB Gold Plus	182879
QuantIFERON®-TB Gold Plus (Client Incubated)	182893

References

1. QuantiFERON®-TB Gold Plus (QFT®-Plus) Package Insert. Germantown, MD: Qiagen; 2017.
2. Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report. *MMWR*. 2010;59(No. RR-5):2-3.
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4. Diel R, Loddenkemper R, Niemann S, Meywald-Walter K, Nienhaus A. A negative and positive predictive value of a whole-blood interferon- γ -release assay for developing active tuberculosis. *Am J Respir Crit Care Med*. 2011;183:88-95.
5. Pai M, Zwerling A, Menzies D. Systematic review: T-cell-based assays for the diagnosis of latent tuberculosis infection: An update. *Ann Intern Med*. 2008;149(3):177-184.
6. Mori T, Sakatani M, Yamagishi F, et al. Specific detection of tuberculosis infection. *Am J Respir Crit Care Med*. 2004;170:59-64.
7. Andersen P, Munk ME, Pollock JM, Doherty TM. Specific immune-based diagnosis of tuberculosis. *Lancet*. 2000;356:1099-1104.
8. National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention. TB Elimination Interferon-Gamma Release Assays (IGRAs) – Blood Tests for TB Infection. – United States, CS22784C-G, Nov 2011;(1-3).

For more information, including client-incubated test information, ask your LabCorp representative, or visit www.labcorp.com/testmenu.



www.LabCorp.com