

TB or Not TB?

TUBERCULOSIS (TB) INFECTION EVALUATIONS



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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-y. Evidence now also supports a role for CD8+ T cells in host defense against *M. tuberculosis*. CD8+ T cells produce IFN-y and other soluble factors.¹
- Moreover, research indicates that TB-specific CD8+ T cells that produce IFN-y 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



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Advantages of QFT®-Plus

TST Challenges	QFT Offers Improvements
Requires multiple office visits to inject and read the TST reaction ⁷	One office visit for single blood draw
Higher false-positive rate (than QFT-Plus)	>97% specific, nearly eliminating false positives ¹
Higher false-negative rate (than QFT-Plus)	>94% sensitivity, decreasing false negatives ¹
Subjective result	Produces an objective result
May be affected by previous BCG vaccinations	Unaffected by previous BCG vaccinations ⁸
May boost subsequent TST test results	Does not boost subsequent QFT-Plus test results and less affected by prior $TST^{\mathtt{S}}$
TST approved for use to aid in the evaluation of TB	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





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.
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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
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- 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)
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