

QuantiFERON®

TB Gold In-Tube

Test Code 905108

CPT* 86480



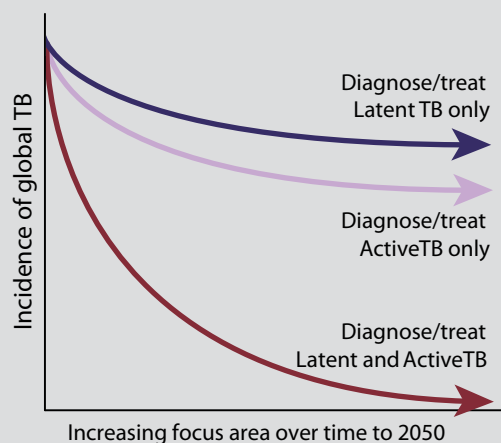
Identifying TB Infection is Essential

Tuberculosis (TB) remains a significant threat to humanity. At least one billion people are thought to be infected. A person who is infected with *Mycobacterium tuberculosis*, but who shows no symptoms and is not sick with the disease, is regarded as having latent TB infection (LTBI). Although not everyone who becomes infected with TB bacteria develops active TB disease, individuals with LTBI and a compromised immune system are more likely to progress to active TB. According to the CDC, certain communities remain at higher risk for TB infection¹, including:

- Healthcare workers
- The elderly
- Immigrants
- Homeless
- Inmates
- Military personnel
- People taking certain medications (i.e., TNF-blocker medications)
- People with a weakened immune system
- Public health officials working with TB control

Approximately 1 in 10 people with LTBI will progress to active TB (CDC Fact Sheet: The Difference Between Latent TB Infection and Active TB Disease). The key to controlling TB is accurately and efficiently identifying the 1 in 10. Global organizations are beginning to acknowledge that to fight TB effectively, identifying and treating LTBI - as well as active TB disease - are vital.

Importance of treating TB infection



Theoretical graph of how treating latent and active TB together can overcome global TB burden. Model supported by data from Dye & Williams (J R Soc Interface 2008).



Supply #24522
QuantiFERON TB
Collection Kit

High Altitude (>3350 ft)
Order Supply #24579

CDC Statement:²

An Interferon Gamma Release Assay (IGRA) or a Tuberculin Skin Test (TST) may be used without preference to test recent contacts of persons known or suspected to have active tuberculosis with special considerations for follow-up testing. IGRAs offer the possibility of detecting *M. tuberculosis* infection with greater specificity than with a TST.

Why is QuantiFERON® TB Gold so accurate?

QuantiFERON® (QFT) contains TB mycobacterial proteins which are not found in the BCG vaccine. Because of this highly specific composition, QFT overcomes most of the shortcomings of the TST, with the added benefit of providing a laboratory-based, objective result.

- QFT is more accurate than TST in identifying people who will progress to active TB disease.²
- QFT is >99% specific, greatly reducing false-positive readings (false positives by TST range from 3% to 65% of all persons tested, dependent upon the population).²
- TST can result in false-negative readings due to the tendency towards under reading of positive tuberculin test reactions (up to 33% with 10-mm induration).³

A cost-effective replacement for the skin test

When evaluating the impact of a test on TB screening programs, sensitivity and specificity are familiar parameters. How they interact with prevalence to influence negative and positive predictive values and overall test accuracy is important to understanding the clinical significance of a test.

QFT's increased accuracy has significant and tangible benefits for TB control programs—better outcomes for patients, more confidence in correctly identifying TB infection, and significant cost savings through fewer false-positive results. Studies show that switching to QFT provides significant program cost advantages.^{4,5}

"The underreading of a positive tuberculin test reaction has significant public health implications, and may present a more important medical concern than overreading such reactions."

Kendig, et al. Chest 1998

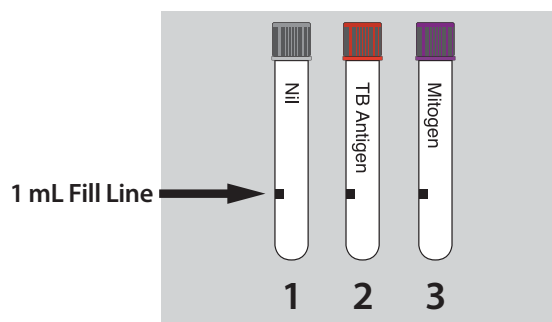
References:

1. CDC. "Questions and Answers about TB" <www.cdc.gov/tb>.
2. CDC. "Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium Tuberculosis Infection" 2010. MMWR. 2010; 59(RR05): 1-25.
3. Kendig, E.L. et al. "Underreading of the Tuberculin Skin Test Reaction" Chest. 1998; 113:1175-1177.
4. de Perio, M.A. et al. "Cost-effectiveness of Interferon Gamma Release Assays vs Tuberculin Skin Tests in Health Care Workers" Archives of Internal Medicine. 2009; 169:179-187.
5. Abdalhamid, B. et al. "Utilization of the QuantiFERON-TB Gold Test in a 2-step Process with the Tuberculin Skin Test to Evaluate Healthcare Workers for Latent Tuberculosis" Journal of Clinical Microbiology. August 2010; Vol. 48, No. 8: 2955-2956.

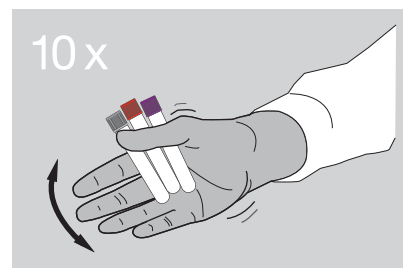
*The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.

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Blood Collection



Collect 0.8 - 1.2 mL of blood into Nil, Antigen, and Mitogen tubes. **Tubes must be collected in this order.**



Shake tubes ten (10) times just firmly enough to ensure the entire inner surface of each tube is coated with blood. **Tubes must be shaken up and down.** Do not shake any other way.

Transport samples directly to Sonora Quest Laboratories at room temperature for incubation and specimen processing. Samples must be received by the lab within 12 hours of collection and incubated within 16 hours of collection.

If outside of the Phoenix Metropolitan area, only collect Monday - Friday after 11:00 AM.

Cost-effective analysis of QFT vs. TST is available upon request.