

# Pocket Guide

QuantiFERON<sup>®</sup>-TB Gold

## Negative and positive predictive value of a whole-blood IGRA for developing active TB - an update

Study Authors: Diel R, Loddenkemper R, Niemann S, Meywald-Walter K, Nienhaus A

*Am J Respir Crit Care Med.*  
2011 Jan 1;183(1):88-95



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

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- $\gamma$  by ELISA is used to identify *in vitro* responses to these peptide antigens that are associated with *M. tuberculosis* infection.

FDA approval notes that 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.

QFT Package Inserts, available in up to 25 different languages, can be found at [www.cellestis.com](http://www.cellestis.com).

**The key purpose of diagnosing latent tuberculosis (TB) infection is to identify who is at risk of progressing to active TB disease.**

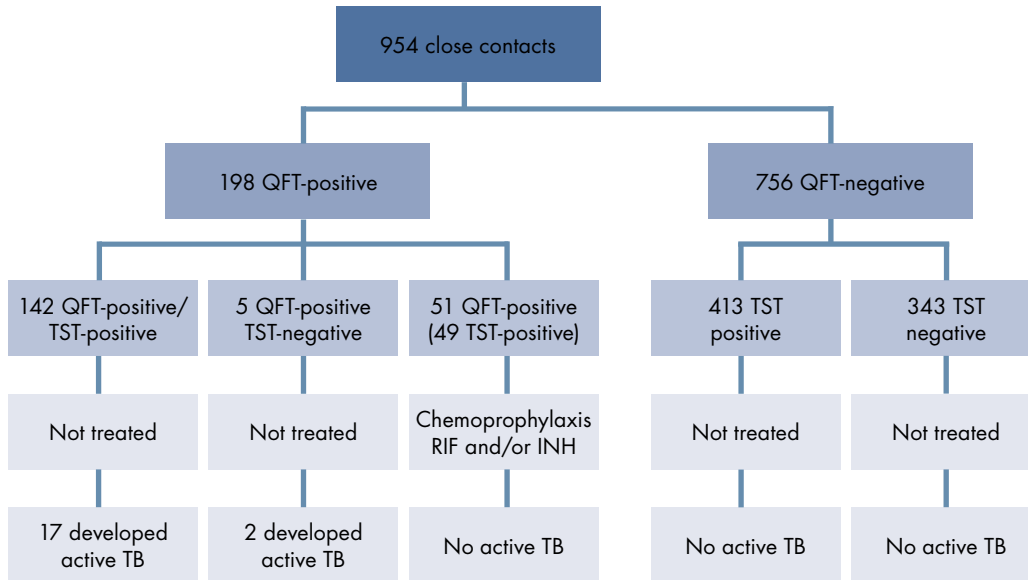
Diel R, Loddenkemper R, Niemann S, Meywald-Walter K, Nienhaus A (AJRCCM, 2011 Jan 1;183(1):88-95) have provided the most comprehensive study to date comparing QuantiFERON®-TB Gold (QFT®) and the tuberculin skin test (TST) on the ability to predict progression to active TB.

This analysis followed 1,414 close TB contacts, 954 of whom had results for both QFT and TST, for > 3.5 years.

The results demonstrate **QFT's superiority** over the 100+-year-old TST in detecting **progression to active TB**.

The following Pocket Guide provides an in-depth interpretation of the results of this study.

## Contact Investigation Results – Summary



Mean follow-up >3.5 yr; TST cut-off >5mm

### QFT-positive contacts

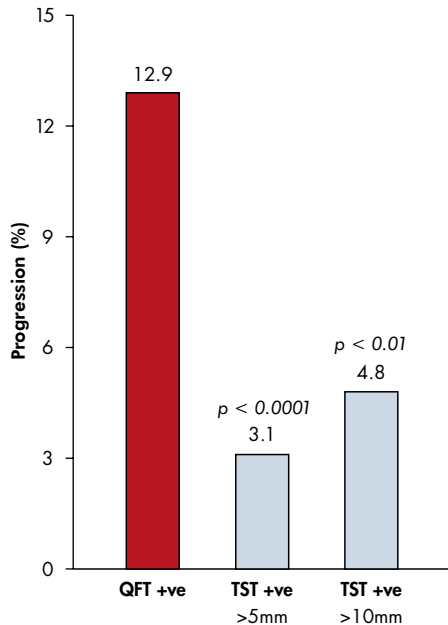
- All 19 untreated contacts who progressed to active TB were QFT-positive.
- TST missed progression
  - 11% missed @ >5mm
  - 47% missed @ >10mm

### QFT-negative contacts

- 55% of QFT-negative were TST-positive
- No progression to active TB at 3.5 years
- In this study, QFT demonstrated 100% negative predictive value (NPV)

## Contact Investigation Results

### Rates of Progression to Active TB



A significantly higher rate of progression to active TB was observed in QFT-positive close contacts than in TST-positive close contacts (either >5mm or >10mm cut-off).

**“The progression rate of 28.6% (6/21) for QFT-positive children was significantly higher than 10.3% (13/126) for adults ( $p = 0.03$ ).”**

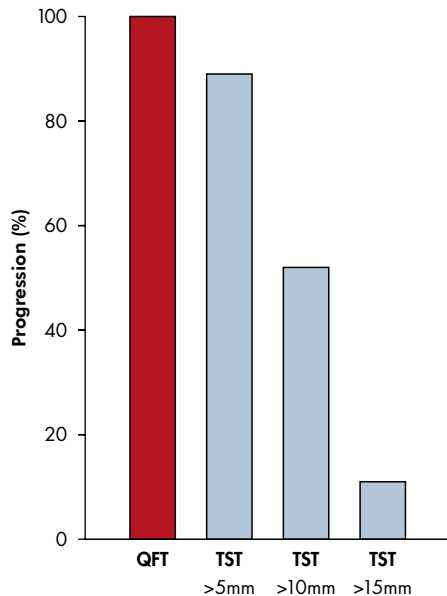
**– Study authors**

**“Notably, positive TST results were strongly associated with a history of BCG vaccination...”**

**– Study authors**

## Contact Investigation Results

### Sensitivity for Progression to Active TB



- QFT identified 100% (19/19) of contacts who progressed to active TB
- TST @ >5mm cut-off missed 11% (2/19)
- TST @ >10mm cut-off missed 47% (9/19)

**“More importantly, use of a >10mm cut off [TST alone] would only have identified ten of the 19 (53%) persons who progressed to active TB.”**  
- Study authors

**“The use of a >15mm cut off [TST alone] would have limited the success of the screening to only two individuals of the 19 (11%) who progressed”**  
- Study authors

## Contact Investigation Results

Number of contacts developing active TB who were detected by each test.

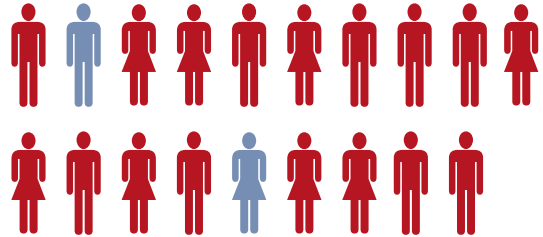
### QFT

QFT identified all 19 contacts who progressed to active TB.



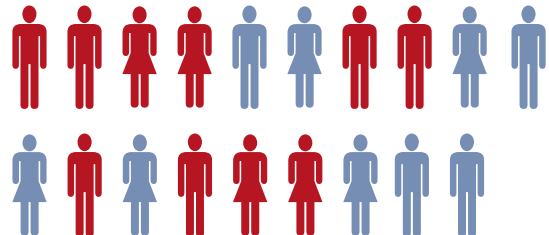
### TST >5mm

TST @ >5mm cut-off **missed 2 contacts** of 19 who progressed to active TB.



### TST >10mm

TST @ >10mm cut-off **missed 9 contacts** of 19 who progressed to active TB.



## Key Consideration

- QFT demonstrated 100% NPV in this study
  - No contacts who tested QFT-negative developed TB
- TB control program cost likely reduced by treating those who really need it
- Recommendations and Guidelines suggest QFT can be used as a replacement for the TST
  - US: Centers for Disease Control & Prevention
  - Japan: *Kekkaku* 2010

Be confident with QuantiFERON-TB Gold.

**“Results suggest that QFT is more reliable than the TST for identifying those who will soon progress to active TB, especially in children.”**

**- Study authors**





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