



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
- The US Centers for Disease Control and Prevention (CDC) suggests that QFT can be used as a replacement for the TST

“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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QuantiFERON®-TB Gold demonstrates 100% negative predicted value

Diel Study: 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 the 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.

QFT Package Inserts, available in up to 25 different languages, can be found at:

www.QuantiFERON.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 a comprehensive study comparing 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. Among these 954 individuals, 106 were children (<16 years old) and 848 were adults.

The following pocket guide provides an in-depth interpretation of the results of this study.

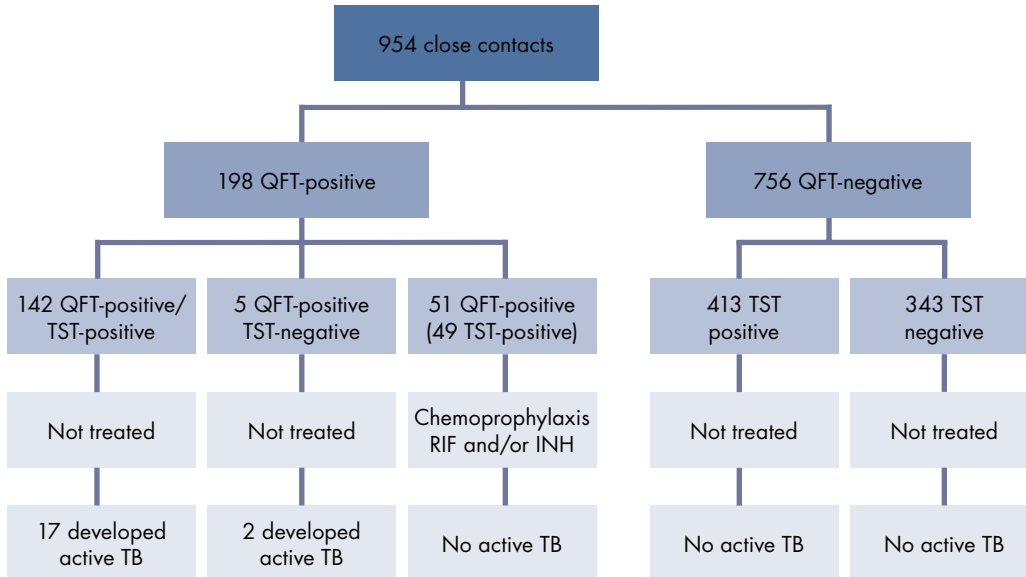
Contact Investigation Results

QFT-positive contacts

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

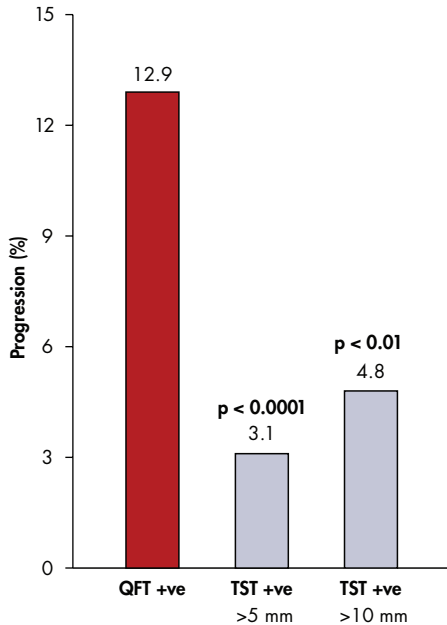
QFT-negative contacts

- 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)



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

Rates of Progression to Active TB

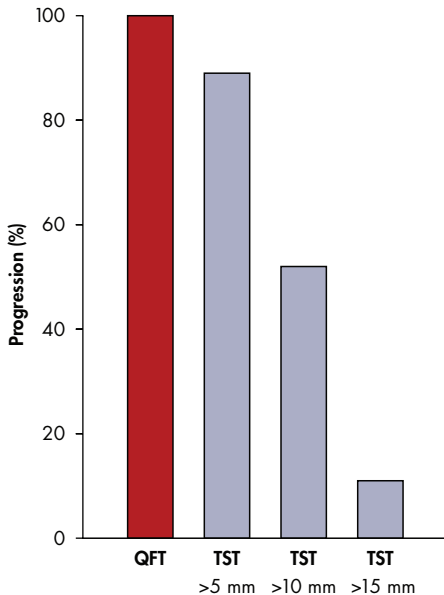


“The progression rate of 28.6% (6/21) for QFT-positive children was significantly higher than 10.3% (13/126) for adults (p = 0.03).”
– Study authors

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

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

Sensitivity for Progression to Active TB



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

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

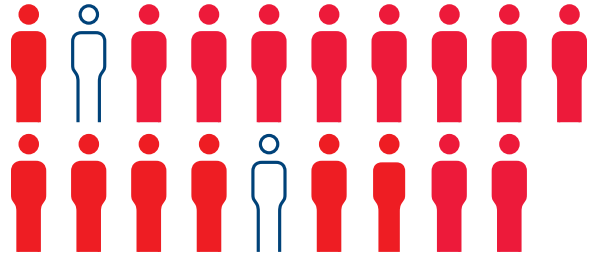
“ The use of a >15 mm cut off [TST alone] would have limited the success of the screening to only two individuals of the 19 (11%) who progressed.”
– Study authors

Summary of Contact Investigation Results

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

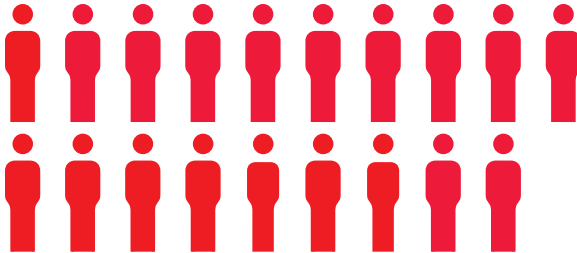
TST
>5mm

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



QFT

QFT identified all 19 contacts who progressed to active TB.



TST
>10mm

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

