



QuantiFERON®-TB Gold (QFT®)



Tuberculosis Screening with QuantiFERON **Lunch and Learn**

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Disclaimer

QuantiFERON®-TB Gold (QFT®) is CE marked. QFT is approved by the US FDA.

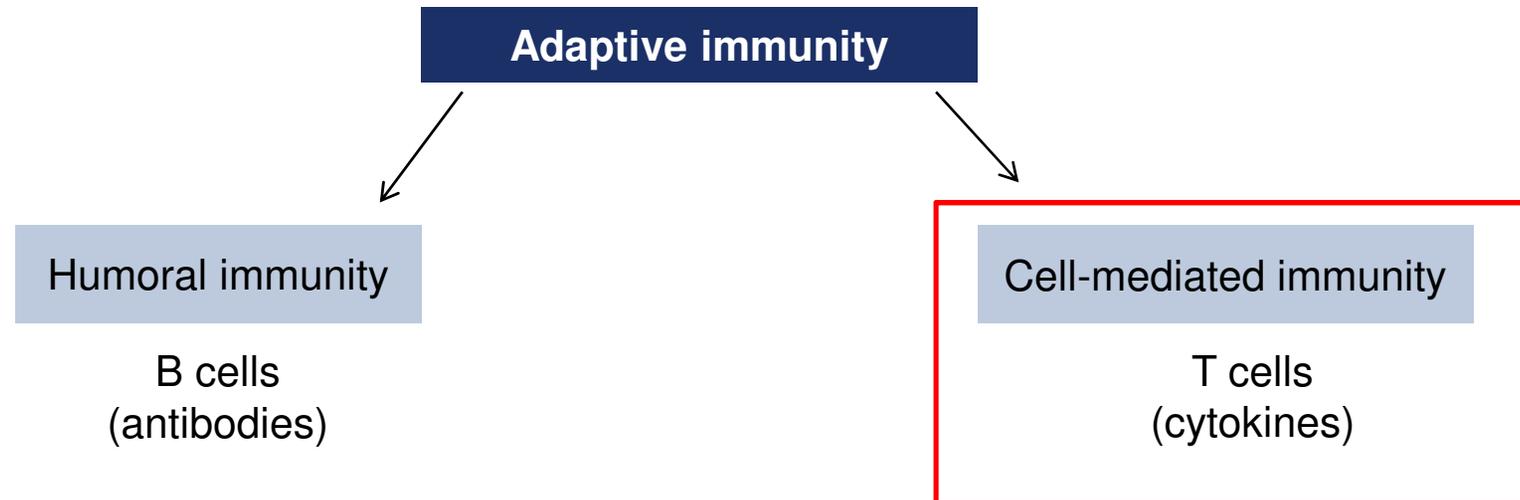
QFT is approved by the FDA as an *in vitro* diagnostic aid for detection of *Mycobacterium tuberculosis* infection. It uses a peptide cocktail simulating ESAT-6, CFP-10 and TB7.7(p4) proteins to stimulate cells in heparinized whole blood. Detection of IFN- γ by ELISA is used to identify *in vitro* responses to these peptide antigens that are associated with *M. tuberculosis* infection. 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.QuantiFERON.com.

Immunological basis of QFT

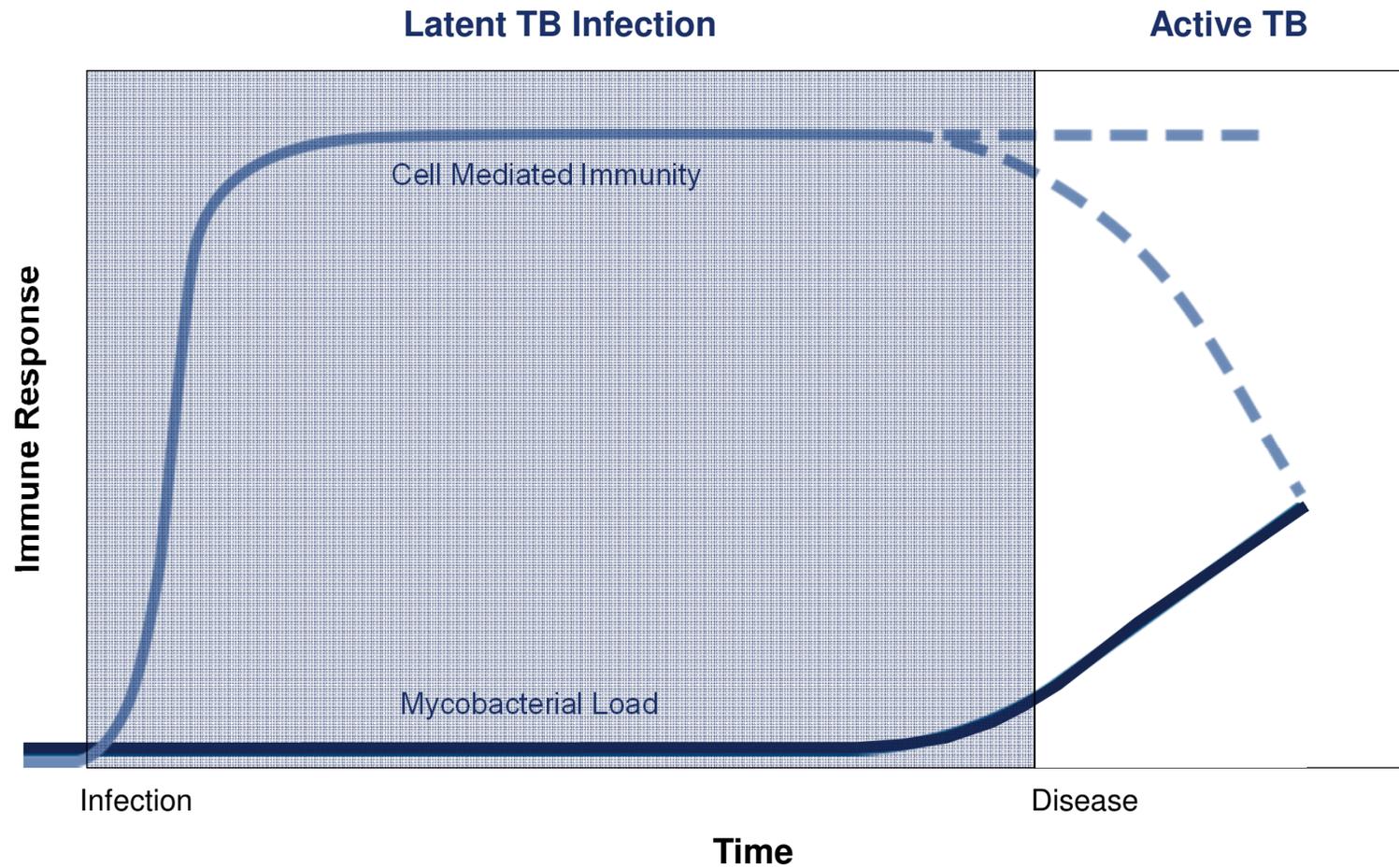


Modern TB diagnostics measure IFN- γ



- IFN- γ is a marker of cell-mediated immunity (CMI)
- T cells produce IFN- γ when activated in response to antigen
 - Secreted, measurable, stable
 - Absent from normal circulation
- QFT stimulates CD4⁺ T cells
- Extensive literature showing importance of IFN- γ in TB infection

Measuring CMI is the key for a diagnostic test for LTBI



Summary

- QFT assay QuantiFERON-TB Gold (QFT) - whole blood indirect test to screen for tuberculosis (TB) infection
 - Detects a cell-mediated immune response (CMI) to TB infection by measuring the IFN- γ from cell-mediated immune response to *M. tuberculosis* from CD4⁺ T cells
 - QFT contains TB specific antigens which make it highly specific for TB infection
 - Does not differentiate between latent TB infection and active disease

- QuantiFERON-TB Gold has significant advantages over TST in LTBI screening:
 - More specific
 - More accurate
 - Does not cross-react with BCG-vaccination and most non-tuberculous (environmental) mycobacteria
 - Requires single visit
 - Not subject to human interpretation

 QFT is a modern and effective method for TB testing



QFT System Overview

QFT Step-by-Step Test Procedure

Interpretation of QFT Results

QFT Performance Characteristics

QFT on Automated Platforms

QFT blood collection tubes



QFT ELISA*



Quantiferon supplies needed at the draw site

- Quantiferon Tubes
 - Nil, TB Antigen, and Mitogen tubes
- Incubator
 - 37°C ± 1°C
- Centrifuge
 - Available via the Texas TB Control Program

*Enzyme-Linked Immunosorbent Assay

3 blood collection tubes

- **Nil** (Grey cap)
 - Negative control
 - Adjusts for background noise or non-specific IFN- γ in blood samples

- **TB Antigen** (Red cap)
 - Contains highly specific TB antigens: ESAT-6, CFP-10, TB7.7(p4)

- **Mitogen** (Purple cap)
 - Positive control
 - May indicate:
 - Decreased patient immune status, or
 - Incorrect blood handling & incubation



QFT Results

- Provides a qualitative result, which needs to be interpreted in conjunction with other clinical evaluations:

| Result | Interpretation |
|---------------|---|
| Positive | TB infection is likely |
| Negative | TB infection is unlikely |
| Indeterminate | Results are indeterminate for TB Antigen responsiveness |

- A quantitative result is also provided as additional information on your report.



QFT System Overview

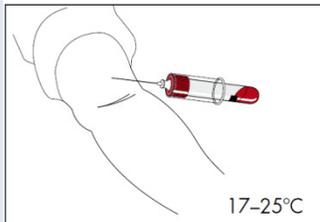
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Interpretation of QFT Results

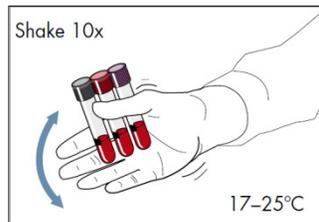
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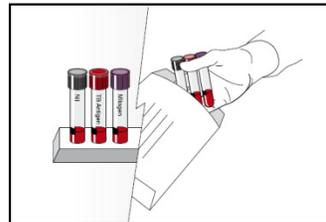
Quick guide



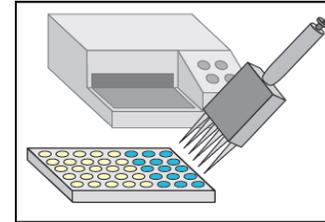
**Step 1.
Blood Collection**



**Step 2.
Mixing of
Tubes**



**Step 3.
Incubation**



**Step 4.
ELISA***

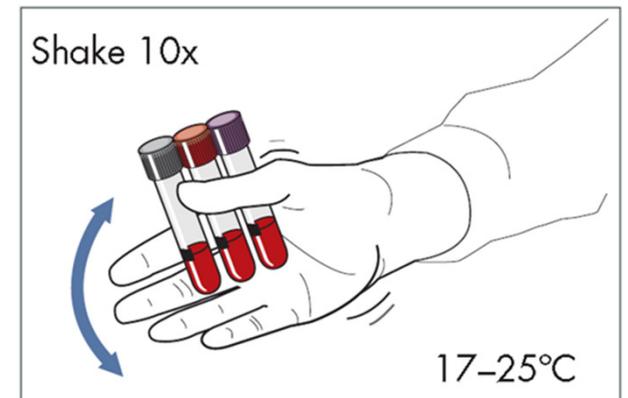
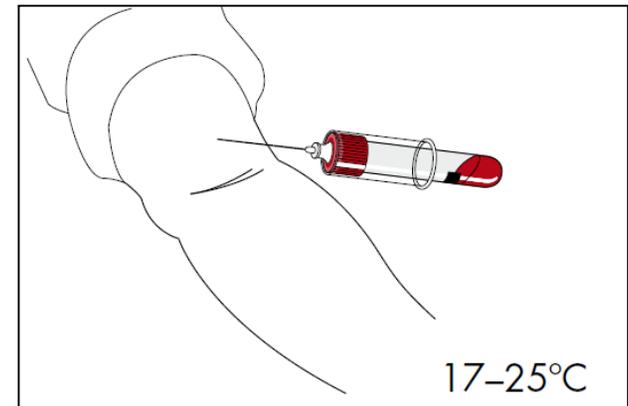


**Step 5.
Calculation
of Results***

* Both of these steps performed in laboratory and can be automated

Blood collection into QFT tubes

- Tubes should be between 17°C-25°C at the time of blood filling
- Collect 1 ml by venipuncture into each tube as shown
 - If a “butterfly needle” is used to collect blood, a “purge” tube should be used to fill tubing with blood and prevent tube underfill
- Hold tube on needle for 2 to 3 seconds after flow ceases as QFT tubes fill relatively slowly
- Take all three tubes and shake firmly up and down 10 times
- Hemolysis is expected and will not interfere with the test



 Standard blood handling precautions apply

QFT Blood Collection Tips and Information

- QFT tubes use vacuum to draw blood and fills slowly wait extra 2-3 seconds
- Standard QFT blood collection tubes are validated to fill with 0.8 ml and 1.2 ml of blood
- Black mark on tube side indicates 1 ml fill volume
- If level of blood not close to the black mark, obtain another blood sample into a new tube
- Prior to incubation, maintain the tubes at room temperature (22°C ± 5°C)
- Do not refrigerate or freeze the blood samples
- Bi-monthly live webinar trainings are available





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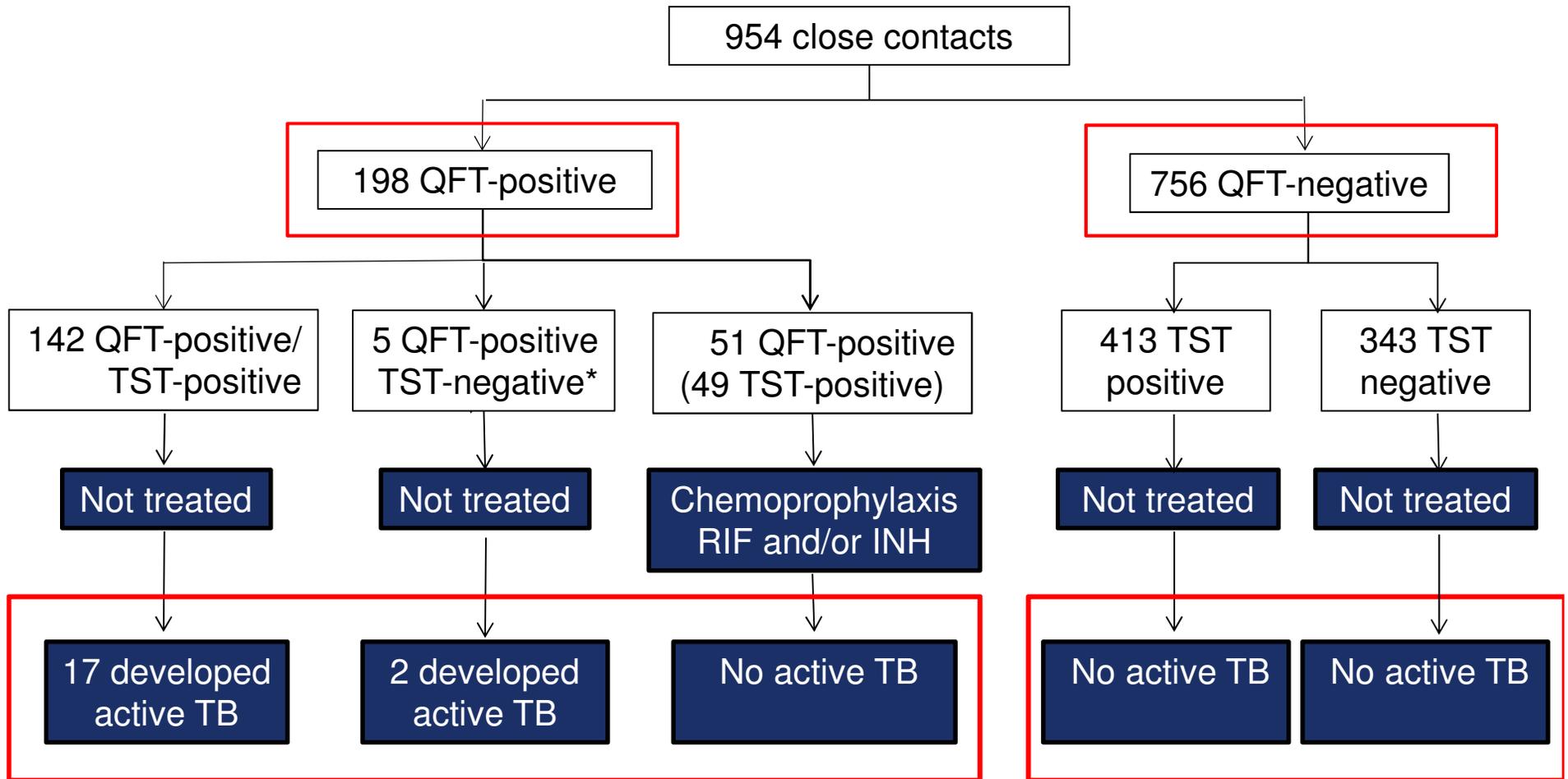
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Predictive value of QFT– Diel et al (1)



1. Diel, R., et al. (2011) *Am J Respir Crit Care Med* 183, 88.

Guidelines for TB screening in the US



CDC guidelines (1)



MMWRTM

Morbidity and Mortality Weekly Report

www.cdc.gov/mmwr

Recommendations and Reports

June 25, 2010 / Vol. 59 / No. RR-5

Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection – United States, 2010

1. Centers for Disease Control and Prevention (2010) MMWR 59:RR-5

CDC guidelines (1)

- IGRAs may be used in place of (and not in addition to) TST in all situations in which CDC recommends TST

- IGRA is preferred:
 - For testing persons from groups that historically have poor rates of return for TST reading.

 - For testing persons who have received BCG

- Of critical importance is the ability for a test to predict risk for subsequent active disease (remember PPV!)



QuantiFERON in Contact Investigations

Qiagen Team Contact Information

If you are interested in using the TBoss services for your next contact investigation please contact:

For general QuantiFERON Information and Support:

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