

QuantiFERON-TB Gold Plus

Effective Date: November 6, 2018

QuantiFERON-TB (QFT-TB) testing provides an assessment of cell-mediated immunity to peptide antigens derived from *Mycobacterium tuberculosis* (MTB). T lymphocytes from patients with active or latent tuberculosis infection will secrete interferon gamma (IFN γ) when stimulated in vitro by those antigenic peptides. The QFT-TB test system measures mycobacterium-specific IFN γ release as an endpoint for determining exposure to MTB.

Commencing on November 6, 2018, Beaumont Laboratory will transition from performing QFT-TB testing using the QFT-TB Gold assay, to the more recently FDA-Cleared QFT-TB Gold Plus assay.

Specimen Collection Requirements:

- QFT-TB Gold plus requires collection of blood using **4 QFT-TB-specific tubes**. Collection kits are distributed to approved sites by the Special Testing section of Beaumont Laboratory Royal Oak.
- Collection tubes must be collected in the following order according to cap color provided in each kit:

<u>Cap Color</u>	<u>Tube Designation</u>
Gray	Nil
Green	TB1
Yellow	TB2
Purple	Mitogen

- QFT-TB Gold Plus **does not** require any change to specimen collection procedure and handling, compared to the prior assay version (QFT-TB Gold).

TB1 and TB2 Tubes:

- QFT-TB Gold (old version of assay), in part requires specimen collection into a tube that harbors peptides derived from *M. tuberculosis*, designated as “TB Antigen”. In contrast, QFT-TB Gold Plus (new version of assay) requires specimen collection into two tubes designated as TB1 and TB2, both of which contain MTB-specific peptides. Differences in their properties are noted below:
 - **TB1:** Peptides are derived from MTB antigens ESAT-6 and CFP-10- these primarily stimulate MTB-specific CD4+ memory T cells. Most immunocompetent individuals previously exposed to MTB will secrete IFN γ upon in vitro stimulation with these peptides. TB1 is similar to the TB Antigen tube in QFT-TB Gold.
 - **TB2:** Contains longer and shorter peptides derived from MTB antigens ESAT-6 and CFP-10. These peptides can stimulate MTB-specific CD4+ and CD8+ memory T cells. Inclusion of peptides capable of stimulating CD8+ memory T cells may be beneficial towards assessing cell-mediated immunity to MTB in immunocompromised patients.

For additional information, access the Laboratory Test Directory at:

<http://beaumontlaboratory.com/test-lab-directory>

Date submitted: October 22, 2018

Submitted By: Gabriel Maine, PhD - Technical Director, Royal Oak Special Testing Laboratory
Elizabeth Sykes, MD - Medical Director, Royal Oak Special Testing Laboratory