

# Laboratory News

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## New Test Offering in Marshfield for Tuberculosis (TB) Screening

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Starting **March 4th, 2024**, the MCHS Microbiology and Molecular Pathology laboratory in Marshfield will be performing the Interferon-Gamma release assays (IGRA) blood test that measures and compares the amount of interferon-gamma (IFN- $\gamma$ ) released by blood cells in response to antigens using the QuantiFERON-TB Gold Plus (QFT®-Plus) assay.

This testing is currently sent to a reference laboratory that performs the T-SPOT.TB Interferon-Gamma release assay. The results from the QuantiFERON®-TB Gold Plus are comparable to the T-SPOT.TB assay.<sup>1,2.</sup>

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### QuantiFERON-TB Gold Plus (QFT®-Plus) Assay

QuantiFERON-TB Gold Plus (QFT®-Plus) is a whole-blood test measuring the cell-mediated immune response to 2 M. tuberculosis complex antigens (ESAT-6, and CFP-10) through quantification of IFN-gamma levels in plasma.

Approved by the US Food and Drug Administration (FDA) and endorsed by the WHO, QFT-Plus can aid in diagnosing tuberculosis infection and active TB disease. QFT-Plus is the fourth generation of the QuantiFERON TB test and detects IFN-gamma response from both CD4+ and CD8+ T-cells, providing a broader picture of the immune response than its predecessors.

## Test Details

### Specimen Collection

#### Lithium Heparin (Green Top Tube) ONLY (SAME AS FOR T-SPOT.TB)

6 mL (5 mL min) of whole blood by venipuncture directly into a lithium heparin tube.

- ONLY lithium heparin tubes are acceptable.
- Tubes with less than 5 mL of blood will not be accepted.
- Tubes should have the DATE and TIME of collection.
- After collection, thoroughly mix the specimen by slowly inverting the tube at least 10 times to dissolve the heparin. Inversion should be performed slowly enough to ensure the airspace reaches the opposite end of the tube each time.
- Allow the blood drawn into the lithium-heparin tube to remain at room temperature between 15 minutes to 3 hours after blood collection.
- After a minimum of 15 minutes at room temperature, refrigerate the specimen within three hours of collection and transport it to the MCHS Microbiology and Molecular Pathology laboratory in Marshfield.
- Send the specimen to the MCHS Microbiology and Molecular Pathology laboratory in Marshfield the same day it is collected.
- Specimens can be collected ONLY MONDAY through THURSDAY for the required timely processing of specimens.

### Transport Temperature & Stability

- Room Temperature: 3 hours
- Refrigerated: 48 hours
- Storage/Transport Temperature: Refrigerated

### Rejection Criteria

- Sodium heparin (green-top) tubes
- Lithium heparin tubes with less than 5 mL of blood
- Tube without DATE and TIME of collection
- QuantiFERON(R)-TB Gold Plus, 4 tube collection tubes
- Incubated specimens
- Specimens received frozen

### Other

- **Performed:** Monday through Friday (Note: specimens can be collected ONLY MONDAY through THURSDAY as noted above)
- **CPT Code:** 86480
- **Test Code:** QGOLD

## Results

Submitted blood samples will be aliquoted into four assay tubes by the Laboratory. Interferon-gamma release is measured for specimens from each of the four assay tubes.

A **qualitative result** (Negative, Positive, or Indeterminate) is based on the interpretation of the four assay tube values:

- **NIL:** This value represents nonspecific reactivity produced by the patient specimen.
- **MITOGEN minus NIL** (MITOGEN-NIL): This value serves as the positive control for the patient specimen, demonstrating successful lymphocyte activity.
- **TB1 minus NIL** (TB1-NIL): This tube specifically detects CD4+ lymphocyte reactivity, specifically stimulated by the TB1 antigens.
- **TB2 minus NIL** (TB2-NIL): This tube detects both CD4+ and CD8+ lymphocyte reactivity stimulated by TB2 antigens.

## References

1. Zhang L, Yang Z, Bao X, Ma H, Ge Q, Zhang Y, Cao Q, Gao M, Liu X. Comparison of diagnostic accuracy of QuantiFERON-TB Gold Plus and T-SPOT.TB in the diagnosis of active tuberculosis in febrile patients. *J Evid Based Med*. 2022 Jun;15(2):97-105. doi: 10.1111/jebm.12477. Epub 2022 Jun 28. PMID: 35762517; PMCID: PMC9540107.
2. Zhang Y, Zhou G, Shi W, Shi W, Hu M, Kong D, Long R, He J, Chen N. Comparing the diagnostic performance of QuantiFERON-TB Gold Plus with QFT-GIT, T-SPOT.TB and TST: a systematic review and meta-analysis. *BMC Infect Dis*. 2023 Jan 20;23(1):40. doi: 10.1186/s12879-023-08008-2. PMID: 36670347; PMCID: PMC9862551.

## Questions

Please call Marshfield Labs Customer Service at 1-800-222-5835 with questions.