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**Lab Dept:** Serology

**Test Name:** QUANTIFERON-TB GOLD

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***General Information***

**Lab Order Codes:** QFR

**Synonyms:** QFT; QFT-G

**CPT Codes:** 86480 – Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response

**Test Includes:** Quantiferon-TB reported as negative, positive, or indeterminate.

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***Logistics***

**Test Indications:** Used as an aid in diagnosing *Mycobacterium tuberculosis* infection, including latent tuberculosis infection (LTBI) and tuberculosis (TB) disease. QFT-G can be used in all circumstances in which the tuberculin skin test is currently used, including contact investigations, evaluation of recent immigrants who have had BCG vaccination and TB screening of health workers and others undergoing serial evaluation for *M. tuberculosis*. However, caution should be used when testing certain populations because of limited data in the use of QFT-G.

**Lab Testing Sections:** Serology - Sendouts

**Referred to:** Mayo Medical Laboratories (MML Code: QFT4)

**Phone Numbers:** MIN Lab: 612-813-6280

STP Lab: 651-220-6550

**Test Availability:** Daily, 24 hours

**Turnaround Time:** 2 – 4 days, performed Monday - Friday

**Special Instructions:** Special kits are required for specimen collection. Please contact the lab for kit. Following specific collection instructions included with kit.

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***Specimen***

**Specimen Type:** Whole blood

**Container:** Quantiferon (QFT)-TB Gold Plus Collection Kit (available from Lab). Lab orders kits from Mayo (Mayo Supply T794).

**Draw Volume:** 4 mL blood (1 mL per each collection tube in kit). Note: Minimum is 1 mL per tube.

**Processed Volume:** Same as Draw Volume

**Collection:** Routine venipuncture

Follow instructions from the kit. The tubes are slow to fill. If using a butterfly needle to collect, draw a waste tube first, then fill the 3 tubes.

**Specific collection info for kit:**

- Collect 1 mL blood into each of the four QFT collection tubes. Tubes should be 17-25 degrees C at the time of collection.
- Use of a butterfly needle is not recommended. If a butterfly needle is used for collection, a discard tube must be collected prior to collecting the QFT tubes.
- All three tubes must be collected on each patient
- Fill each tube to black 1 mL fill line
- **Tubes fill slowly**; keep each tube on the needle for 2-3 seconds after the tube appears to have filled completely.
- These tubes are manufactured to draw 1 mL of blood and perform optimally within the range of 0.8 – 1.2 mL, if under or overfilled it may lead to. If the level of blood is outside the BLACK INDICATOR LINE, another blood specimen should be collected.
- Immediately after filling tubes, shake them 10 times just firmly enough to ensure the entire inner surface of the tube is coated with blood, to solubilize antigens on tube walls. Over-energetic shaking may cause gel disruption and could lead to aberrant results. Thorough mixing is required to ensure complete integration of the tube's contents into the blood.
- Label each tube appropriately. The label should be placed below the colored Quantiferon band so back window and black marks are visible on all four collection tubes.
- Send specimens to the lab.
- Maintain tubes at room temp until incubation. Do not refrigerate or freeze.
- Incubation of the 4 tubes must be started within 16 hours of collection.

**Special Processing:** Lab Staff: Do Not centrifuge. Specimens should remain as whole blood in original collection tubes.

Incubation: Sendout/Evening shift will batch specimens in the incubator Monday-Friday @1800. Incubate tubes upright @ 37 C. Batched specimens should be removed 16-24 hrs after start time.

Weekend & Nights (after 1800): For specimens rec'd after 1800, incubate specimens immediately. Document incubation start time on incubator & notify Sendout staff as to when specimens should be removed & centrifuged.

Processing after Incubation: Centrifuge tubes for 15 minutes at 3000 RCF.

**Note: Hemolyzed specimens are unacceptable.**

Placed all 4 tubes together back in the QTB transport bag. Store & ship tubes at refrigerated temperatures. Specimens are stable for 28 days at refrigerated temperatures. Forward promptly.

**Patient Preparation:** None

**Sample Rejection:** Mislabeled or unlabeled specimens; insufficient volume or tubes overfilled; specimens other than those collected and processed according to instructions in the QuantiFERON collection kit; hemolysis

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### ***Interpretive***

**Reference Range:**

Negative (negative, positive, or Indeterminate).

Note: A positive result indicates that *Mycobacterium tuberculosis* infection is likely. However, positive reactivity to proteins present in other mycobacteria such as *Mycobacterium kansasii*, *Mycobacterium szulgai*, and *Mycobacterium marinum* may cause false-positive results.

A positive QuantiFERON-TB Gold Plus result should be followed by further medical and diagnostic evaluation for tuberculosis disease (eg, acid-fast bacilli smear and culture, chest x-ray).

QuantiFERON-TB Gold Plus is usually negative in individuals vaccinated with *Mycobacterium bovis* BCG.

Note: Tuberculosis Antigen IU/mL value is reported (TB Ab IU/mL Value). This information may be required for certain CDC reporting forms (eg, Form I-693).

**Critical Values:**

N/A

**Limitations:**

- Blood samples must be processed within 16 hours after collection while white blood cells are still viable.
- A negative QuantiFERON-TB Gold result does not preclude the possibility of *Mycobacterium tuberculosis* infection or tuberculosis disease. False negative results can be due to the stage of infection (eg., specimen obtained prior to development of cellular immune response), co-morbid conditions that affect immune functions, or other individual immunological factors. Additionally, heterophile antibodies or nonspecific interferon-gamma (INF-gamma) production from other inflammatory conditions may mask specific responses to ESAT-6 or CFP-10 peptides.
- A delay in incubation may cause false-negative or indeterminate results, and other technical parameters may affect the ability to detect INF-gamma response.
- A positive QFT-Plus should not be the sole or definitive basis for determining infection with *M tuberculosis*. Positive results should be followed by further medical evaluation for active tuberculosis disease (eg, acid-fast bacilli smear and culture, chest X-ray).
- While ESAT-6 and CFP-6 are absent from all bacilli Calmett-Guerin (BCG) strains and from most known nontuberculous mycobacteria, it is possible that a positive QFT-Plus result may be due to infection with *M kansasii*, *M szulgai*, or *M marinum*. If such infections are suspected, alternative tests should be performed.
- The effect of lymphocyte count on reliability is unknown. Lymphocyte counts may vary from person to person. The minimum number required for a reliable result has not been established and may also be variable.

- The predictive value of a negative AFT-Plus result in immunosuppressed patients has not been determined.

**Methodology:** Enzyme-Linked Immunosorbent Assay ELISA

**References:** [Mayo Medical Laboratories](#) February 2018

Centers for Disease Control Fact Sheet:  
<http://www.cdc.gov/nchstp/tb>

**Updates:**  
4/27/2009: Moved from Abbott Northwestern Hospital to MML.  
11/30/2010: Reporting of Tuberculosis Antigen Value in IU/mL added.  
11/3/2011: Moved from MML to Fairview University Medical Center.  
11/21/2012: Moved from Fairview University to Mayo Medical Labs (MML).  
2/13/2018: Updated to QFR-TB Gold Plus 4-tube assay at MML.