Lab Dept: Serology

Test Name: QUANTIFERON-TB GOLD PLUS

General Information

Lab Order Codes:	QFTB
Synonyms:	QFT; QFT-G; QFT-Plus
CPT Codes:	86480 – Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response
Test Includes:	QuantiFERON-TB reported as negative, positive, or indeterminate.

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:	Chemistry (Performed on the St. Paul campus)
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Usually Daily, 24 hours
Turnaround Time:	2-5 Days; Testing performed Monday/Wednesday/Friday
Special Instructions:	Special kits are required for specimen collection. Please contact the lab for kit. Following specific collection instructions included with kit.

Specimen

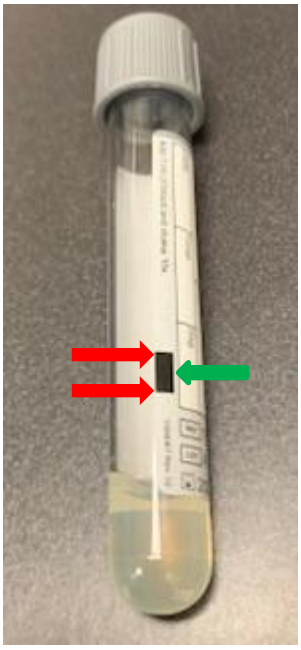
Specimen Type:	Whole blood

Container: Quantiferon (QFT)-TB Gold Plus 4 Tube Collection Kit (available from Lab).

Note: Unlike routine blood collection tubes, the tube color does not indicate anticoagulant.

Draw Volume: 4 mL blood (1 mL per collection tube in kit).

Note: Fill tubes to center of black indicator line. Over or under filled tubes will be rejected.



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 4 tubes.

Specific collection information 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 four 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 dissolve 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 St. Paul lab to arrive within 16 hours from collection.
- Maintain tubes at room temperature 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. Send immediately to St. Paul Lab by routine courier, or STAT courier if needed to maintain 16 hour stability. **Incubation:** Upon receipt in St. Paul Lab invert tubes 10x before incubation. Incubate tubes upright @ 37 C. Specimens will be removed 16-24 hrs after start time. Document incubation start time on incubator. Chemistry staff will check incubator at the start of each shift, removing samples after 16 hours and before 24 hours incubation. **Processing after Incubation:** Centrifuge tubes for 15 minutes at 3000 RCF. Note: Hemolyzed specimens are unacceptable. Placed all 4 centrifuged tubes together in the Liaison XL fridge, in the QuantiFERON rack. Specimens are stable for 28 days at refrigerated temperatures.
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; hemolyisis; failure to follow temperature or processing requirements.

Interpretive

Reference Range:	Reference Value: **Negative; *M. tuberculosis* infection NOT likely** Possible values: 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 mariunum* 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.
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 inderterminate results, and other technical parameters may affect the ability to detect INFN-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.

Methodology: Chemiluminescence immunoassay (CLIA)

Updates: 8/30/2022 Initial Document