Lab Dept: Serology

Test Name: QUANTIFERON-TB GOLD

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.

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: QFT3)
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.

Specimen

Specimen Type:	Whole blood
Container:	Quantiferon (QFT) Collection Kit (available from Lab). Lab orders kits from Fairview.

Draw Volume: 3 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 3 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 not close to 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.
● Label each tube appropriately and return tubes and label tabs to bag for transport to the laboratory.

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. Placed all 3 tubes together back in the QTB transport bag. Store & ship tubes 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; hemolyisis

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 mariunum* may cause false-positive results. A positive QuantiFERON-TB Gold 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 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 12 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. Falsely 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. ● A positive QuantiFERON-TB Gold result may not indicate infection with *Mycobacterium tuberculosis*; false positives do occur. ● 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. ●A false-negative QuantiFERON-TB Gold result can be caused by incorrect blood specimen draw or improper handling of the specimen affecting lymphocyte function. Blood must be incubated with stimulation antigens within 16 hours of draw. Delay in incubation may cause false-negative or indeterminate results. ●QuantiFERON-TB Gold has been evaluated with specimens from patients with culture-confirmed active tuberculosis and from apparently healthy adults with and without identified risk factors for *Mycobacterium tuberculosis* infection. ●The performance of QuantiFERON-TB Gold has not been evaluated in specimens from: Indivduals with impaired or altered immune functions (HIV infections, transplant patients, those receiving immunosuppressive drugs such as corticosteroids) and those with other clinical conditions (ef, diabetes, hematological disorders), individuals younger than 17 years old, pregnant women
Methodology:	Enzyme-Linked Immunosorbent Assay ELISA

References:

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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 Tuberulosis Antigen Value in IU/mL added.
11/3/2011: Moved from MML to Fairvew University Medical Center.
11/21/2012: Moved from Fairview University to Mayo Medical Labs (MML).