Florida HEALTH
Bureau of Public Health Laboratories

Test Menu

TOPIC	DESCRIPTION
Test Name	QuantiFERON-TB Gold Plus
Other Name (s)	QFT-Plus, Interferon-Gamma Release Assay (IGRA)
Analyte(s)	*Mycobacterium tuberculosis*
Test Code	0470
Lab location	Jacksonville ONLY for the TB Program
Department	Serology
Pre-Approval Required	Yes, not orderable for routine patient testing
Additional Required Forms	QFT-TB TESTING SPECIMEN SUBMISSION FORM
Specimen Source	Heparinized Whole blood
Special Specimen Preparation	The acceptable range of the room during **specimen collection is 17-25°C**. Whole blood may be collected into 4 QFT-Plus tubes or in a single lithium-heparin tube. Follow specimen hold times below: A. Direct draw into **QFT-Plus tubes** – 4 (Nil gray cap, TB1 green cap, TB2 yellow cap, and Mitogen purple cap). 1. Collect 1 mL directly into each of the QFT-Plus tubes. 2. After collection, the blood needs to be thoroughly mixed with the antigens in the inner wall of the blood collection tubes. 3. Send to laboratory within 16 hours of collection for incubation. B. Blood collection into a **single lithium-heparin tube** then transfer to QFT-Plus tubes. 1. Store at 17-25°C up to 12hrs or 2-8°C up to 48 hrs. 2. Send to laboratory within these time constraints for transfer into 4 QFT-Plus tubes and incubation. CALL Jacksonville lab for training on specimen collection, handling and shipping.
Minimum Volume	0.8-1.2 ml (black mark on side of QFT-Plus tubes) or 5 mL (lithium-heparin tube)
Storage Conditions	1. The QFT-TB TESTING SPECIMEN SUBMISSION FORM needs to be filled out and included in the shipment for each patient specimen collected. 2. QFT-Plus tubes need to be kept at 17-25°C and received in the testing laboratory no more than 16 hours after collection. 3. Single tube Lithium-heparin specimens need to be shipped at 2-8°C and received no more than 48 hrs after collection.
Collection Media	QFT-Plus tubes, Lithium-heparin tube
Specimen Labeling	Specimen must be labeled with at least two unique patient identifiers, Ex: Name and DOB. **Electronic lab order preferred, HMS, Etc.** **Information on the specimen must match the requisition.**
Packaging and Shipping Instructions and Handling	**-QFT-Plus tubes** need to **be kept at 17-25°C** and received in the testing laboratory **no more than 16 hours after collection**. -Single tube **Lithium-heparin** specimens need to **be shipped at 2-8°C** and received **no more than 48 hrs after collection**
Test Methodology	IFN-Gamma (IFN-g) detection by chemiluminescence immunoassay (CLIA)
Turnaround Time	N/A
Result Indicator	Positive, Negative, or Indeterminate Reported IU/mL values: Nil, TB1 Ag, TB2 Ag, Mitogen Reported calculated IU/mL values: Mitogen minus Nil, TB1 minus Nil, TB2 minus Nil Positive: Criteria for Positive: When Nil is ≤ 8.0 and TB1-Nil or TB2-Nil are ≥0.35 and ≥25% of Nil value. Negative: Criteria for Negative: **1.** When Nil ≤ 8.0 and TB1 minus Nil or TB2 minus Nil <0.35 and Mit minus Nil ≥0.50; **OR** 2. When Nil ≤ 8.0 and TB1 minus Nil or TB2 minus Nil ≥0.35 and <25% of Nil value and Mit minus Nil ≥0.50. Indeterminate: Criteria for Indeterminate: 1. When Nil >8.0 ; **OR** 2. When Nil ≤8.0 and TB1 minus Nil or TB2 minus Nil <0.35 and Mit minus Nil <0.50; **OR** 3. When Nil ≤8.0 and TB1 minus Nil or TB2 minus Nil ≥0.35 and <25% of Nil value and Mit minus Nil <0.50.
Unsatisfactory Specimen	Specimens not stored or shipped within temperature and time specifications. QFT-Plus tubes with blood not within allowable volume (black marks on tube side). Grossly hemolyzed, icteric or lipemic samples, heat-inactivated or samples containing particulate matter or obvious microbial contamination should not be tested.
Interferences and Limitations	1. Combine only results from tubes collected from the patient in the same sampling session. 2. Inaccurate or indeterminate results may occur if strict adherence to the LIAISON QuantiFERON –TB Gold Plus assay and QuantiFERON-TB Gold Plus Blood Collection tube instructions is not exercised. 3. A negative result does not preclude the possibility of *M. tuberculosis* infection or tuberculosis disease: false negative results can be due to the stage of infection (e.g. specimen obtained prior to the development of cellular immune response), co-morbid conditions that affect immune functions, incorrect handling of the blood collection tubes following venipuncture, incorrect performance of the assay, or other immunological variables. 4. A positive result should not be the sole or definitive basis for determining infection with *M. tuberculosis*. Incorrect performance of the assay may cause false-positive responses. 5. Patients routinely exposed to animals or animal serum products can be prone to interference due to heterophilic antibodies and their results should be evaluated with care. 6. While ESAT-6 and CFP-10 are absent from all BCG strains and from most known nontuberculous mycobacteria, it is possible that a positive result may be due to infection by *M. kansasii, M. szulgai,* or *M. marinum*. If such infections are suspected, alternative testing should be considered. 7. The performance characteristics of the test in the following groups of individuals has not been extensively evaluated: persons <18 years, pregnant women, those with impaired or altered immune functions or other clinical conditions (HIV, transplant recipient, hematological disorders, malignancies, diabetes, chronic renal failure).
Additional Information & Notes	Limited testing for CDC funded TB testing program. **Not orderable for routine patient testing.**
Reference Range	N/A
Reference Lab	None
Reflex testing	None