LABORATORY ALLIANCE of Central New York, LLC

QuantiFERON - TB Gold Plus (QTF4) Assay

Effective June 1, 2021, Laboratory Alliance of Central New York will offer the QuantiFERON -TB Gold Plus (QTF4) assay. It will be performed locally at our Operations Center laboratory. The assay is an interferon-γ (IFN-y) release assay performed on the Diasorin Liaison XL platform using Qiagen antigen-coated tubes.

The QFT4 assay is an indirect screening assay that detects IFN-y cytokine release by $CD4^+$ and $CD8^+$ cells when a patient's blood is incubated with tuberculosis (TB) antigens (ESAT-6 and CFP-10). The assay results are not affected by previous Bacillus Calmette and Guérin (BCG) vaccinations. This assay should not be used as the sole basis for diagnosing active or latent TB infection and results must be interpreted in conjunction with risk assessment, radiography and other medical and diagnostic evaluations.

Clinical performance characteristics of the Diasorin QuantiFERON gold plus assay:

Performance Measure	Estimate of Performance	95% Confidence Interval
Specificity	96.9% (279/288)	(94.2 - 98.3%)
Sensitivity (cumulative)	84.4% (130/154)	(77.9 - 89.3%)

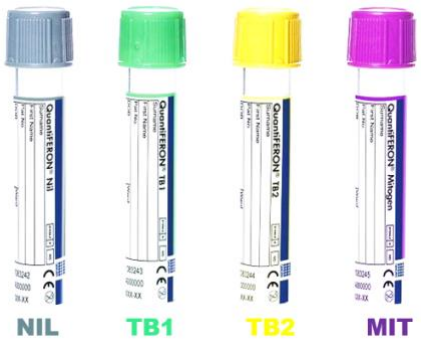
Test Interpretation:

Positive: IFN-y response to *Mycobacterium tuberculosis* antigens, suggesting infection with *M. tuberculosis*. For patients at low risk for infection, a second test or repeat test should be considered. Prior infection with *M. kansasii, M. szulgai and M. marinum* may lead to false positive results.

Negative: No IFN-y response to *Mycobacterium tuberculosis* antigens and infection with *M. tuberculosis* is unlikely. For patients at high risk for infection, a second test should be considered.

Indeterminate: Indeterminate results can result from either a poor response to positive control mitogen, which may be secondary to low lymphocyte count, decreased lymphocyte activity or immunosuppression, or from a high background (nil) response, which may be secondary to heterophile antibody effects or circulating IFN-y in the patient's blood.

Assay Details

Test Code	QFT4
Method	Chemiluminescence immunoassay
Specimen Requirements	Collection – Four (4) QTF4 tubes  Volume: **1 mL (0.8-1.2 mL) in each tube** **Immediately** after filling the tubes, shake ten (10) times just firmly enough to make sure the entire inner surface of the tube is coated with blood.
Specimen Collection	Patients may have their blood specimen collected at any of our 11 Patient Service Centers. For driving directions see our map at www.laboratoryalliance.com
Storage and Transport	Specimens should be transported and stored at 18-25°C and received by the Chemistry Department within 15 hours of collection, Monday through Thursday
Stability	15 hours at room temperature (18- 25°C)
Unacceptable Conditions	Blood samples received in the Chemistry Department after 15 hours of specimen collection; specimens refrigerated or exposed to excessive heat; over- or under-filled tubes; submission in any tubes other than the 4 specific collection tubes. All 4 tubes must be submitted.
Schedule of Testing	Monday through Friday
Turn Around Time	3 days
CPT Code	86480
Billing Code	1010590

Questions regarding this test may be directed to Chemistry and Referral Testing Manager Bodhraj Acharya, Ph.D. at 315-410-7028 or bodhrajacharya@lacny.com.

Reference:

"American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children." *Clinical Infectious Diseases*, Volume 64, Issue 2, 15 January 2017, Pages e1–e33.