LABORATORY ALLIANCE of Central New York, LLC

Important Update - August 2010

QuantiFERON®-TB Gold In-Tube Test

The Microbiology Department of Laboratory Alliance of Central New York, LLC, offers the in-house performance of the QuantiFERON®-TB Gold test by the "In-Tube Method" which uses 3 mycobacterial proteins for increased sensitivity. The QuantiFERON®-TB Gold In-Tube test is an *in-vitro* diagnostic test intended as an aid in the detection of infection caused by *Mycobacterium tuberculosis*. Importantly, the recent 2010 guidelines published by the CDC in MMWR recommend the preferred use of the QuantiFERON®-TB In-Tube test over the traditional Tuberculin Skin Test (TST) to screen individuals with subclinical infection or exposure to *M. tuberculosis* and particularly encourage the use of the QuantiFERON®-TB assay in BCG vaccinated individuals or those patients who are not likely to return for follow up reading of their TST.

Clinical Significance:

The immune response to infection with *M. tuberculosis* is predominantly a Cell Mediated Immune (CMI) response that results in sensitization of T-cell lymphocytes specific to *M. tuberculosis* antigens. Gamma interferon (IFN) is a protein produced by sensitized T-cells (primarily CD4+ but also CD8+) upon stimulation with their specific antigen. The QuantiFERON®-TB Gold In-Tube assay detects CMI responses to tuberculosis infection by measuring IFN produced in whole blood after incubation with synthetic peptides of the *M. tuberculosis* antigens ESAT-6, CFP-10, and TB7.7. These TB specific proteins, which are secreted by *M. tuberculosis,* stimulate a robust and detectable CMI response in infected people. They have been demonstrated to be both specific for *M. tuberculosis* infection, unaffected by BCG vaccination status and most non-tuberculous mycobacteria.

Response to either ESAT-6, CFP-10, or TBT7.7 antigen indicates infection. The antigens are small proteins (<10Kd) with a limited number of epitopes, so although the majority of TB infected individuals respond to all three antigens, many infected individuals may respond to only one. Unlike skin testing, there is no stratification of the diagnostic-cut-off based on patient history, BCG vaccination status or risk factors, and thus the answer is a simple yes/no to TB infection. **The QuantiFERON®-TB Gold In-Tube test is intended for use only with blood specimens collected into 3 special tubes for this test.** The specimens must be collected Monday through Friday by 2:00 p.m. and received in the Microbiology Department by 5:00 p.m. to initiate T-cell activation. These activated specimens are tested on Wednesday and Thursday.

The QuantiFERON®-TB Gold In-Tube test has been evaluated for use with immunocompetent healthy adults with and without identifiable risk factors for latent TB infection (LTBI). QuantiFERON®-TB Gold has also been evaluated in individuals with culture-proven TB disease.

IMPORTANT:

QuantiFERON-TB Gold In-Tube Test can be used for people who are being tested for TB infection, with the following limitations. The test has not been evaluated for use in children (<17 years), infants, pregnant women, immunocompromised individuals (including HIV positive individuals), or people with certain clinical conditions predisposing immunosuppression (i.e. diabetes, silicosis, cancers, organ transplants), or those taking immunosuppressive medication.

Clinicians should use clinical judgment in interpretation of test results, particularly when excluding TB infection as a diagnosis.

Test Code:	QFTB
Method:	Lymphocyte activation followed by EIA.
Specimen Collection:	**Central New York-based patients MUST have their blood specimen collected at any of our Patient Service Centers in Onondaga County:** For driving directions: See our map at www.laboratoryalliance.com **All other interested parties outside of Onondaga County, must contact the V.P. of Business Development & Marketing at (315) 461-3036.** It is preferable that the patient's blood be collected before 2:00 p.m. Monday through Friday in order for the specimens to be received in the Microbiology department by 5:00 p.m.
Schedule of Testing:	T-cell stimulation: Monday through Friday EIA analysis: Wednesday and Thursday **Note:** *Specimens initially testing positive may be repeated in duplicate during the next scheduled day of testing.*
CPT Code:	86480
Billing Code:	3010253
For More Information:	If you have any questions or concerns regarding this laboratory service, please contact Mr. Russell Rawling, Microbiology Manager, at 315-410-7060.

References:

1. Mazurek, G.H. et al. Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis Infection - United States, 2010. MMWR, June 25, 2010. p. 1-25.
2. Huebner R.E., et al. The tuberculin skin test. Clin Infect Dis, 1993. 17:968-75.
3. Andersen, P., et al. Specific immune-based diagnosis of tuberculosis. Lancet, 2000. 356:1099-1104.
4. Chapman, A.L. et al. Rapid detection of active and latent tuberculosis infection in HIV-positive individuals by enumeration of Mycobacterium tuberculosis-specific T cells. AIDS, 2002. 16:2285-93. 5. Munk, M.E. et al. Use of ESAT-6 and CFP-10 antigens for diagnosis of extrapulmonary tuberculosis. J. Infect. Dis, 2001. 183:175-6.

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