

MEMORANDUM

TO: All Regional Medical Laboratory Clients

FROM: Gerald C. Miller, Ph. D., Chief of Microbiology and Immunology

SUBJECT: QuantiFERON-TB GOLD TESTING AVAILABILITY

DATE: February 27, 2014

Regional Medical Laboratory is now collecting and processing specimens at our Patient Service Centers for the QuantiFERON-TB GOLD assay, an alternative to the TB (PPD) skin test. QuantiFERON -TB GOLD, an indirect test for *Mycobacterium tuberculosis* infection, is based on the measurement of the cell-mediated immune response to selected *M. tuberculosis* antigens. The TB Gold assay, an Interferon Gamma Release Assay (IGRA), has improved specificity, no reader bias, and results are not affected by prior BCG vaccination or booster phenomenon (i.e. increased sensitivity on subsequent tests leading to false-positives). It is also more convenient to the patients, as it requires only one patient visit.

This test is intended for use in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations. The QuantiFERON-TB GOLD Assay is not currently validated for patients 12 years and younger.

RML TEST CODE: **5587325** CPT CODE: **86480**

Results Reporting:

Tests	Results Flag	Units
Quantiferon	Detected	
Nil	≤ 8.0*	IU/mL
Mitogen	≥ 0.5**	IU/mL
TB Ag	≥ 0.35***	IU/mL

*The Nil tube value is used to determine if the patient has a preexisting immune response and must be ≤ 8.0 IU/mL for the test to be valid.

**The Mitogen control tube is used to assure that the patient has a competent immune status and must have a reading of ≥ 0.5 IU/mL greater than the value of the Nil tube.

***For a test to be considered positive, the TB antigen tube value minus the Nil tube value must be ≥ 0.35 IU/mL.

Please feel free to contact Gerald C. Miller, Ph.D. at 918-744-2553, if you have any questions about the assay. However, please visit the RML website for more information regarding the interpretation of the QuantiFERON TB Gold assay.