

June 12, 2014

**IMPORTANT NOTICE: QuantiFERON<sup>®</sup>-TB GOLD IN-TUBE REPORT MODIFICATION**

Dear Valued Client,

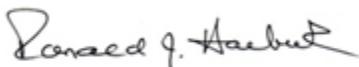
We have recently modified the QuantiFERON<sup>®</sup>-TB Gold In-Tube (QFT-GIT) test report to include numerical values for interferon gamma in unstimulated, mitogen stimulated and TB antigen stimulated samples, in addition to the qualitative interpretation of the test result. A sample report is attached for your reference.

The QFT-GIT test is based on the measurement of a cell mediated response to Mycobacterium tuberculosis-specific antigens (ESAT-6, CFP-10 and TB7.7). Whole blood is stimulated with these antigens for 16-24 hours, following which interferon gamma is measured in the plasma using ELISA methodology. Controls include unstimulated cells (Nil control) and phytohemagglutinin stimulated cells (Mitogen control). A test is considered positive when interferon gamma released in response to TB antigens is significantly greater than the Nil control (TB-Nil), and the Mitogen control has a robust interferon gamma response. The QFT result is indeterminate if the Nil control is high (>0.8 IU/mL) or the mitogen control is low (< 0.5 IU/mL). Although the test is reported qualitatively, interferon gamma levels for the individual test conditions are also reported as recommended by the Centers for Disease Control and Prevention.

The QFT-GIT detects infections due to *M. tuberculosis* complex (*M. tuberculosis*, *M. bovis* and *M. africanum*). BCG strains and nontuberculous mycobacteria with the exception of *M. marinum*, *M. kansasii*, *M. szulgai* and *M. flavescens* do not express ESAT-6, CFP-10 and TB7.7 proteins. Therefore, patients either vaccinated with BCG or infected with most nontuberculous mycobacterial strains should test negative.

QFT-GIT results should always be interpreted in conjunction with clinical and other relevant laboratory findings.

Please contact our client services team at 800.550.6227, Option 6, if you have any questions or if you would like to receive a copy of a recently published article on this topic written by Drs. Belknap and Daley.



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