National Jewish Health®

Advanced Diagnostic Laboratories

September 23, 2014

IMPORTANT NOTICE: T-SPOT.*TB* REPORT MODIFICATION

Dear Valued Client,

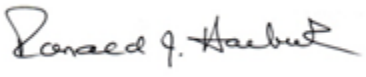
We have recently modified the T-SPOT.*TB* test report to include numerical values for interferon gamma spot-forming units (SFU) in unstimulated, mitogen stimulated and TB antigen stimulated samples, in addition to the qualitative interpretation of the test result. A sample report is attached for your reference.

The T-SPOT.*TB* test is based on the measurement of a cell mediated response to Mycobacterium tuberculosis-specific antigens (ESAT-6 and CFP-10) Peripheral blood mononuclear cells are separated from whole blood and incubated in plates coated with anti-interferon gamma antibodies with these antigens for 16-24 hours. .Following incubation, interferon gamma producing cells are detected using a second anti-interferon gamma antibody, an enzyme linked conjugate and substrate. Controls include unstimulated cells (Nil control) and phytohemagglutinin stimulated cells (Mitogen control). A test is considered positive or borderline when interferon gamma SFU produced in response to either of the TB antigens is significantly greater than the Nil control (TB-Nil; positive = > 8 SFU, borderline = 5, 6 or 7 SFU), and the Mitogen control has a robust interferon gamma response. The T-Spot.*TB* result is indeterminate if the Nil control is high (>10 SFU) or the mitogen control is low (< 20 SFU). Although the test is reported qualitatively, interferon gamma SFU for the individual test conditions are also reported as recommended by the Centers for Disease Control and Prevention.

The T-Spot.*TB* 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. gordonae* do not express ESAT-6 and CFP-10 proteins. Therefore, patients either vaccinated with BCG or infected with most nontuberculous mycobacterial strains should test negative.

T-Spot.*TB* 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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