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Title: Sensitivity of the QuantiFERON-TB Gold test in culture-verified NTM disease and TB in a Danish setting

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Body: Introduction: Previous studies have suggested that the QuantiFERON®-TB Gold (QTF) test can be used to discriminate between tuberculosis (TB) and non-tuberculous mycobacterial (NTM) disease. The QFT-test has a higher specificity and sensitivity for infection with mycobacterium tuberculosis (MTB) compared to the tuberculin skin test, but only few studies have included a large number of patients on a nation-wide basis. Methods: We have studied 12000 QTF-tests obtained between 2009-2011 from a Danish national database. Results of mycobacterial cultures were available for 300 patients. Performance of the QTF-test in the group of patients with active TB and NTM disease was evaluated. Results: 202 patients had positive culture for M. tuberculosis complex (MTC) and a QFT done. We found 165 positive, 29 negative and 8 indeterminate results, resulting in a sensitivity of 81,7 %. In total 98 patients had culture verified NTM infection (species known to share the ESAT6 and CFP10 antigens were excluded, n=6). We found 15 positive, 68 negative and 9 indeterminate results. The causative microorganisms of NTM pulmonary disease were: M. avium (52%), M. gordonae (17%), M. Cellatum (7%), M. Malmoense (6%), M. xenopi (4%), M. intracellulare (4%), M. kansasii (4%). Conclusion: The sensitivity of the QFT-test in Denmark, a low-burden TB setting; corresponds well with earlier findings. In a large population of patients with NTM we found a specificity of 74% for infection and a relatively high indeterminate rate. The impact of prior BCG vaccination, MTB exposure and immunodeficiency on specificity and indeterminate rate in the NTM group will be further explored.