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Performance of the immunochromatographic BD MGIT TBc identification test for the differentiation of *Mycobacterium tuberculosis* complex from non-tuberculous mycobacteria: a seven-year experience

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Background: Rapid diagnosis of patients with active tuberculosis is of major importance for the control of the disease, including treatment initiation and patient isolation. Fast and accurate differentiation between *Mycobacterium tuberculosis complex* (MTBC) from nontuberculous mycobacteria (NTM) is essential, as it allows the implementation of appropriate therapy and prevents inappropriate drug susceptibility testing. The BD MGIT TBc Identification Test (TBc ID, Becton-Dickinson) is an immunochromatographic test that uses monoclonal antibody to detect the MPB64 protein, which is specifically secreted by the MTBC during growth into the liquid culture medium. It is rapid (requires 15 minutes) and does not require laboratory equipment; the reagent cost is 15.8 € per test. The purpose of the study is the evaluation of TBc ID test for differentiation of MTBC strains from NTM.

Material/methods: A total of 200 clinical mycobacterial isolates recovered from different patients in MGIT960 tubes during a 7-year period, 11/2009-10/2016, were studied. The assay was performed according to the manufacturer's instructions. We performed it directly in the positive for mycobacteria MGIT960 tubes as preliminary screening identification test and subsequently applied the appropriate molecular identification methods Genotype MTBDRplus, Genotype Mycobacterium CM and AS, and Genotype MTBC (Hain-Lifescience) to validate the identification.

Results: Of the 200 strains, 141 were identified as MTBC [134 *M. tuberculosis* (MTB), 2 *Mycobacterium bovis* and 5 *M. bovis* BCG and the remaining 59 as: *Mycobacterium avium* (15), *Mycobacterium gordonae* (8), *Mycobacterium intracellulare* (8), *Mycobacterium lentiflavum* (7), *Mycobacterium fortuitum* (8), *Mycobacterium chelonae* (4), *Mycobacterium kansasii* (4), *Mycobacterium simiae* (3) and *Mycobacterium abscessus* (2). The TBc ID test gave a positive result for all MTB strains (134) and all *M. bovis* (2) but gave negative results for all 5 *M. bovis* BCG strains and for all NTM. It should be noted that *M. bovis* BCG strains were recovered from two urine specimens, from a biopsy spine specimen and from a gastric fluid specimen of patients after intravesical BCG therapy for bladder carcinoma. The fifth *M. bovis* BCG strain was recovered from a lymph node biopsy of an infant who suffered with BCG lymphadenitis after BCG vaccination. The sensitivity, specificity, positive and negative predictive values of the method were 96.5, 100, 100, and 92.2%, respectively.

Conclusions: The BD MGIT TBc Identification test is simple, rapid, and easy to perform and interpret and does not require sample preparation or instrumentation. During a 7-year period, it proved to be highly sensitive and specific, enabling the accurate, fast and relatively costly identification of MTBC in the daily laboratory practice.