Performance of the immunochromatographic BD MGIT Tbc Identification Test for the differentiation of Mycobacterium tuberculosis complex from non-tuberculous mycobacteria: a seven years’ experience.

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Figure 1. Ziehl-Neelsen stain of M. tuberculosis complex and M. intracellulare strain grown in the MGIT960 tubes (600x). Which picture correlates to each species?

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 form NTM.

RESULTS

Of the 200 strains:
- 141 were identified as MTBC: 134 M. tuberculosis (MTB), 2 M. bovis and 5 M. bovis BCG
- The remaining 59 strains were NTM: 15 M. avium, 8 M. gordonae, 10 M. intracellulare, 7 M. lentiflavum, 8 M. fortuitum, 4 M. chelonae, 4 M. kansasii, and 3 M. simiae

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.

Four M. bovis BCG strains were recovered from:
- two urine specimens
- a biopsy spine specimen
- a gastric fluid specimen
- 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. Carefully examination of medical records help to correct the choice of identification methods.

CONCLUSIONS

The BD MGIT Tbc Identification test is simple, rapid, and easy to perform and interpret and does not require sample preparation or instrument. 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.

References
1. Diagnostic Microbiology and Infectious Disease 46(4): 290-301.
3. BD diagnostic Systems 2009 BD MGIT Tbc ID identification test package insert BD document LI08517 (01)

Table 1. Distribution of mycobacterial strains according to different clinical specimens and comparison of identification results with the results of TBc ID

![Figure 2. Results of the TBc ID for M. tuberculosis and M. avium strains grown in MGIT960 tubes. Positive result is indicated by the development of two purple bands, one in the control zone (C) and another in the test zone (T). Negative result is indicated by the development of one band, only in the test zone (T).](Image 54x597 to 230x738)

Table 2. Performance of TBc ID assay compared with identification results. PPV: Positive Predictive Value, NPV: Negative Predictive Value

![Figure 3. Suggested Algorithm for identification of mycobacterial strains studied (A), hypothetical algorithm without the use of TBc ID assay (B).](Image 298x597 to 473x738)

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MATERIALS AND 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, 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.

![Figure 4. Algorithm for identification of mycobacterial strains studied (A), hypothetical algorithm without the use of TBc ID assay (B).](Image 519x584 to 899x727)