EP0653

Performance of the immunochromatographic BD MGIT TBc Identification Test for the differentiation of *Mycobacterium tuberculosis* complex from non tuberculous mycobacteria: a seven years' experience.

Kontos F., Kalogeras G., Vourli S. Pournaras S.
Laboratory of Clinical Microbiology, Attikon Hospital, University of Athens,, Greece
Contact information: Fanourios Kontos, Tel, +30 210 5831900; Email: fankon@gmail.com

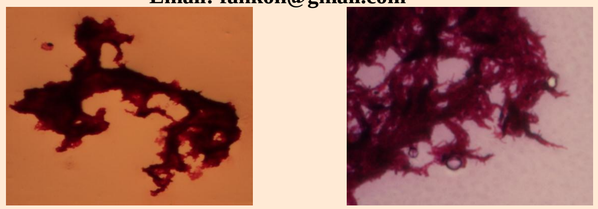

Figure 1. Ziehl-Neelsen stain of *M. tuberculosis complex* and *M. intracellulare* strain grown in the MIGT960 tubes (6000x). **Which picture correlates to each species**?

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.

References
1. Diagnostic Microbiology and Infectious Disease 46(4): 299-301.\
2. BioMed Research International Vol 2014 ID 398108
3. BD diagnostic Systems 2009. BD MGIT TBc ID identification test package insert BD document L8085917 (01)

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 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).

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

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 the correct choice of identification methods

CONCLUTIONS

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.

Species		Respiratory specimens	Extrapulmonary specimens				Total	Number of positive TBc ID results
		sputum	Pus/ abscesses	Urine	Sterile fluids	Stool		
MTBC (n=141)	*M. tuberculosis*	108	14	3	8	1	134	134
	M. bovis		1		1		2	2
	M. bovis BCG	1	2	2			5	0
NTM (n=59)	*M. avium*	15					15	0
	M. gordonae	8					8	0
	M. intracellulare	10					10	0
	M. lentiflavum	7					7	0
	M. fortuitum	8					8	0
	M. chelonae	4					4	0
	M. kansasii	4					4	0
	M. simiae	3					3	0
	Total	168	17	5	9	1	200	136

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

Identification	TBc ID result		Performance	%
	Negative	Positive	Sensitivity	96.5
MTBC	5	136	Specificity	100
NTM	59	0	PPV	100
			NPV	92.2

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

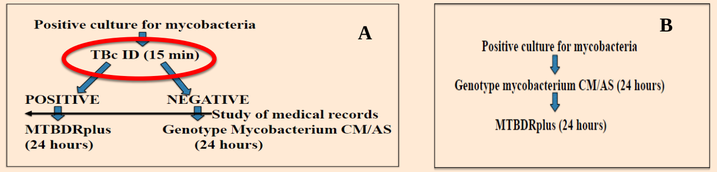

Figure 3. Suggested Algorithm for identification of mycobacterial strains studied (A), hypothetical algorithm without the use of TBc ID assay (B).

- With the use of TBc ID assay we are able to have an identification result 24 hours (one working day) earlier. This is very important for the correct treatment of the patient.
- By using TBc ID we spend 200X 15.8 € (TBc ID) + 141X61.5€ (MTBDRplus) + (59+10)X59.04 € (59 Genotype CM + 10 AS) = **15905,26 €**
- Without using TBc ID we will spend (200+10) X59.04 € (200Genotype CM +10 AS) +141X61.5€ (MTBDRplus)= **21070 €**
- **With the use of TBc ID we spend 21070 € - 15905,26 € = 5164,76 less €.**