ISSN: 2755-0141

Japan Journal of Clinical & Medical Research

SCIENTIFIC Research and Community

Review Article

Open Access

Laboratory evaluation of Capilia TB-Neo and BD MGITTM TBc ID antigen test to identify *Mycobacterium tuberculosis* complex from BD MGIT Positive Cultures

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ABSTRACT

Rapid identification of Mycobacterium Tuberculosis Complex (MTBC) from cultures is essential for TB control. Capilia TB-Neo and BD TBc antigen tests were evaluated on 64 MGIT-positive cultures. Both showed high concordance (96.8%), with Capilia detecting two additional MTBC-positive cases confirmed by line probe assay, indicating slightly superior performance.

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Received: August 22, 2025; **Accepted:** September 02, 2025; **Published:** September 09, 2025

Keywords: Mycobacterium Tuberculosis, Non-Tuberculous Mycobacteria, Antigen, Immuno-Chromatographic Tests

Laboratory diagnosis is key for the control of Tuberculosis (TB) and drug-resistance. Improvement in laboratory processes is critical to obtain lab results rapidly and accurately [1,2]. The introduction of Immuno-Chromatographic Tests (ICT) has improved the identification of Mycobacterium Tuberculosis Complex (MTBC) from liquid cultures. These tests generally detect the MPT64 secreted antigen [2-4]. The ICT tests provide rapid detection of MTBC which helps to reduce turnaround time of results for further laboratory processing. The currently available MPT64 antigen tests for detecting MTBC in cultures include (but not limited to) BD TBc, Capilia TB-Neo and SD Bioline [5]. However, Capilia TB-Neo and SD Bioline are WHO-recommended (World Health Organization) ICT tests for MTBC identification in liquid cultures [5]. We conducted a study to assess the level of agreement between the Capilia TB Neo and BD MGITTM TBc ID Becton Dickinson Diagnostic Instrument Systems, Sparks, MD, USA) antigen tests to identify MTBC from BD MGIT positive cultures.

In our laboratory, the BD TBc was validated for use, in this evaluation we compared the concordance of these two tests for the qualitative identification of positive cultures as MTBC. A total of 64 anonymized random prospective BD MGIT 960 positive cultures were included based on availability of kit for evaluation. Prior to testing, the Ziehl-Neelson smear microscopy was performed on cultures that flagged positive on the Becton, Dickinson© (BD) MGIT instrument (BD©, USA) to confirm the presence of acid-fast bacilli. The two antigen tests, Capilia TB-Neo and the BD TBc were performed in parallel, on all 64 MGIT positive cultures in accordance with the manufacturer's instructions [6,7]. Further confirmatory testing was performed using the molecular Line probe assay (LPA) CM (Hain Lifescience GmbH, Nehren, Germany).

Acid-fast bacilli were observed in all 64 MGIT positive cultures. The six AFB negative samples were visually consistent with the presence of contamination by a non-tuberculous mycobacterial organism. Of the 64 MGIT positive cultures, 45 were identified as MTBC on both BD TBc and Capilia TB-Neo. This indicated a 100% agreement between the two tests for cultures that were MTBC positive. The remaining 19 cultures were negative for MTBC by BD TBc while only 17 were negative for MTBC by Capilia TB-Neo. There was 89.5% concordance for true negatives amongst the two tests. The remaining 2 (11%) cultures showed discordant results of negative for MTBC by BD TBc and MTBC by Capilia TB-Neo. Overall agreement between the two tests was 96.8%. Table 1 displays summary of the results for the concordance between the two methods compared. Full data is displayed in appendix A.

Table 1: Concordance Between BD MGIT TBc and Capilia TB-Neo

		BD MGIT TBc ID		
		POS	NEG	Total
CAPILIA TB-NEO	POS	45	2	*47*
	NEG	0	17	*17*
	Total	*45*	*19*	*64*

Discordant results were resolved using the Line Probe Assay (Hain Lifescience, Nehren, Germany) for common mycobacteria data. The two (11%) isolates detected by Capilia TB-Neo as MTBC were confirmed by the Line probe-assay with one a mix of MTBC and Mycobacterium malmoense and therefore a false negative by the BD MGIT TBc ID. In conclusion Capilia TB-Neo showed slightly better performance to the BD MGITTM TBc ID

test in this evaluation by correctly identifying an additional 2 isolates. The correct identification is critical as it impacts on patient management and also determines additional testing downstream such as genotypic or phenotypic drug susceptibility testing to inform appropriate patient management [8].

Acknowledgements
The authors would like to thank the laboratory staff (NICD-CTB) for their assistance with this study. The study was funded through Wits Health Consortium for the performance of work with the Centre for Tuberculosis and WHO TB Supranational Reference Laboratory Network at the NICD-NHLS in South Africa.

Author Contributions
Mamello Motsei, formal analysis, Methodology, Validation, Visualization, Writing – original draft, Writing – review and editing | Minty van der Meulen, Methodology, Validation, Writing- review, Supervision | Shaheed Valley Omar, formal analysis, Validation, Visualization, Writing – review and editing, Conceptualization, Supervision

Declaration of Competing Interests
The authors declare no known conflict of interest.

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APPENDIX A: Raw Study Data

EPISODE	ZN Microscpy	BD AG TEST	CAPILLIA AG	Line-Probe Assay (Hain CM)
JC00998921	AFB - POSITIVE	POS	POS	
PE01463907	AFB - POSITIVE	POS	POS	
PS01208090	AFB - POSITIVE	POS	POS	
RE00250588	AFB - POSITIVE	POS	POS	
ST03015666	AFB - POSITIVE	POS	POS	
T00790861	AFB - POSITIVE	POS	POS	
TD03187714	AFB - POSITIVE	POS	POS	
TD03201247	AFB - POSITIVE	POS	POS	
TD03206530	AFB - POSITIVE	POS	POS	
TD03210614	AFB - POSITIVE	POS	POS	
TD03215455	AFB - POSITIVE	POS	POS	
TD03216696	AFB - POSITIVE	POS	POS	
TD03219239	AFB - POSITIVE	POS	POS	
U00232684	AFB - POSITIVE	POS	POS	
UH01448440	AFB - POSITIVE	POS	POS	
UH01455353	AFB - POSITIVE	POS	POS	
VG00566219	AFB - POSITIVE	POS	POS	
XD02778992	AFB - POSITIVE	POS	POS	
XD02843381	AFB - POSITIVE	POS	POS	
XD02871625	AFB - POSITIVE	POS	POS	
XD02912330	AFB - POSITIVE	POS	POS	
XD03049171	AFB - POSITIVE	POS	POS	
XG00608082	AFB - POSITIVE	POS	POS	
XK01093119	AFB - POSITIVE	POS	POS	

XN00766727	AFB - POSITIVE	POS	POS	
YA00056849	AFB - POSITIVE	POS	POS	
YA00084602	AFB - POSITIVE	POS	POS	
YA00156847	AFB - POSITIVE	POS	POS	
YA00190164	AFB - POSITIVE	POS	POS	
YA00190165	AFB - POSITIVE	POS	POS	
YA00191271	AFB - POSITIVE	POS	POS	
YA00191283	AFB - POSITIVE	POS	POS	
YA00191809	AFB - POSITIVE	POS	POS	
YA00192146	AFB - POSITIVE	POS	POS	
YA00192898	AFB - POSITIVE	POS	POS	
YA00193405	AFB - POSITIVE	POS	POS	
YA00193407	AFB - POSITIVE	POS	POS	
YA00193408	AFB - POSITIVE	POS	POS	
YA00194362	AFB - POSITIVE	POS	POS	
YA00194365	AFB - POSITIVE	POS	POS	
YA00195002	AFB - POSITIVE	POS	POS	
YA00195440	AFB - POSITIVE	POS	POS	
YA00202292	AFB - POSITIVE	POS	POS	
YA00204088	AFB - POSITIVE	POS	POS	
YA00204117	AFB - POSITIVE	POS	POS	
XG00575939	AFB - POSITIVE	NEG	NEG	Mycobacterial species
XN00746182	AFB - POSITIVE	NEG	NEG	Mycobacterial species
XN00746182	AFB - POSITIVE	NEG	NEG	Mycobacterial species
YA00135757	AFB - POSITIVE	NEG	NEG	Mycobacterium chelonae
YA00146234	AFB - POSITIVE	NEG	NEG	Mycobacterium fortuitum
YA00173310	AFB - POSITIVE	NEG	NEG	Mycobacterium species
YA00173311	AFB - POSITIVE	NEG	NEG	Mycobacterium malmoense
YA00173823	AFB - POSITIVE	NEG	NEG	Mycobacterium tuberculosis complex and Mycobacterium abscessus
YA00176224	AFB - POSITIVE	NEG	NEG	Mycobacterium tuberculosis complex and Mycobacterium intracellulare
YA00188808	AFB - NEGATIVE	NEG	NEG	contaminating Non-mycobacterial organism
YA00188809	AFB - NEGATIVE	NEG	NEG	contaminating Non-mycobacterial organism
YA00190912	AFB - POSITIVE	NEG	POS	Mycobacterium tuberculosis complex and Mycobacterium malmoense
YA00191253	AFB - POSITIVE	NEG	NEG	Mycobacterium intracellulare
YA00191281	AFB - POSITIVE	NEG	NEG	Mixed Non-tuberculosis Mycobacteria
YA00192249	AFB - NEGATIVE	NEG	NEG	contaminating Non-mycobacterial organism
YA00192753	AFB - NEGATIVE	NEG	NEG	contaminating Non-mycobacterial organism
YA00193107	AFB - NEGATIVE	NEG	NEG	contaminating Non-mycobacterial organism
YA00193139	AFB - NEGATIVE	NEG	NEG	contaminating Non-mycobacterial organism
YA00194127	AFB - POSITIVE	NEG	POS	Mycobacterium tuberculosis complex