CAPILIA TB-NEO: A NEW TOOL FOR RAPID DISTINGUISH BETWEEN TUBERCULOUS AND NON-TUBERCULOUS MYCOBACTERIA

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1 INTRODUCTION AND PURPOSE

Tuberculosis remains one of the leading infectious causes of death worldwide. In 2012, 8.6 million people developed tuberculosis and 1.3 million died from the disease (WHO). Improving the laboratory diagnostic capacity is a crucial component of tuberculosis control. Additionally, there is an increasing number of clinical isolates of non-tuberculous mycobacteria (NTM) in many countries and growing awareness of their ability to cause disease. The ability to rapidly distinguish between *Mycobacterium tuberculosis* complex (MTBc) and NTM is critical in clinical practice. Here we evaluated of an immunochromatographic assay to rapid distinguish between MTBc and NTM.

2 MATERIAL AND METHODS

Mycobacterial culture: 145 clinical samples from 128 patients were considered for the study. The samples were decontaminated by the N-acetyl-L-cysteine-sodium hydroxide and inoculated in Middlebrook 7H9 broth medium (BBL® MGIT®) for 42 days at 37ºC or in modified Middlebrook 7H9 broth with CO2 (BACTEC® MYCO/F-Sputa). Some samples are also inoculated in Lowenstein Jensen medium for 60 days. ***Mycobacterial identification:*** The positive cultures were examined by Kinyoun's stain to confirm acid-fast bacilli. To determine the species of the isolates, AccuProbe® and GenoType Mycobacterium CM® and AS® assays were used according to manufacturer's instructions. MTBc real-time PCR based on 16S-rRNA amplification was the identification method for some isolates. ***Capilia TB-Neo:*** For Capilia TB-Neo® assay, 100 µl of positive culture was placed onto specimen area test and results were available 15 min after, with a positive result indicated by a purple-reddish line. ***Assessment of discordant results:*** The assessment of discordant results was made using GenoType Mycobacterium MTBC® assay, according to manufacturer's instructions.

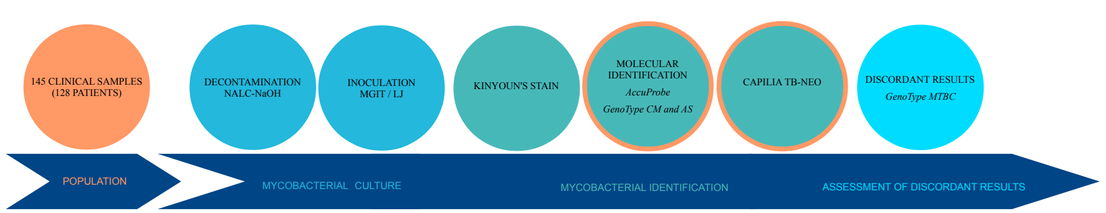

Figure 1. *Study design*

3 RESULTS

Of the 101 positive cultures with MTBc molecular identification, 98 were correctly identified by the Capilia TB-Neo® . The test failed to detect three cultures. Of the three discordant isolates one was identified as *M. bovis* BCG and two were identified as *M. tuberculosis*.

Additionally, we did not observe cross-reaction with any of the 22 NTM and 12 other microorganisms. There was no color reaction observed in MTBc reading area in the 10 negative cultures also tested. These results correspond to a **sensitivity of 97%**, a **specificity of 100%**, as well as, a **positive predictive value of 100%** and a **negative predictive value of 96%** of the Capilia TB-Neo® assay for the identification of the MTBc.

Table 1. *Performance of Capilia TB-Neo to distinguish between MTBc and NTM.*

Strain	Total	Capilia (+)	Capilia (-)
* MTBc	101	98	3
* NTM (2) *Mycobacterium spp.* (4) *Mycobacterium intracelullare* (1) *Mycobacterium avium* (2) *Mycobacterium kansasii* (5) *Mycobacterium fortuitum* (3) *Mycobacterium gordonae* (3) *Mycobacterium chelonae* (1) *Mycobacterium peregrinum*	22	0	22

* Routine molecular identification methods were used as reference method.

Table 2. *Performance of Capilia TB-Neo in negative cultures and other bacterias isolates.*

Strain	Total	Capilia (+)	Capilia (-)
Negative cultures	10	0	10
Other microorganisms (3) *Nocardia spp.* (1) *Klebsiela pneumoniae* (3) *Pseudomonas aeruginosa* (1) *Escherichia coli* (1) *Staphylococcus aureus* (2) *Candida albicans* (1) *Proteus mirabilis*	12	0	12

4 CONCLUSION

IC assay failed to detect one *M. bovis* BCG and two *M. tuberculosis* strains. As previously reported for some BCG strains, such as substrains of the Pauster strain, the *mpb64* gene is delected. False negative results for *M. tuberculosis* due to mutations in *mpb64* gene have been also reported. Although, this study confirmed that the Capilia TB-Neo®, a less expensive assay, is fast and easy to perform with high sensitivity (97%) and specificity (100%) and thus useful in rapid differentiation of MTBc from NTM, which is essential for clinical practices and tuberculosis control.