

Clinical Evaluation of ELITechGroup Biomedical Systems Aerospray® BK *series 2* Stainer (TB Stainer) compared to Hand Staining of TB samples at Bichat Hospital

Grall N.^{1,2,3}, Pierre-Audigier C.³, Milhau M.⁴, Mullen K.⁴, Andreumont A. ^{1,2,3}

¹INSERM, IAME, UMR 1137, F-75018 Paris, France, ² Univ Paris Diderot, IAME, UMR 1137, Sorbonne Paris Cité, F-75018 Paris, France, ³ AP-HP, Hôpital Bichat, Laboratoire de Microbiologie, F-75018 Paris, France, ⁴ ELITech Group

INTRODUCTION

Staining clinical samples with Ziehl-Neelsen stain is an essential part of *Mycobacterium tuberculosis* screening. Indeed this manual staining method is rapid, economic, and useful to detect acid-fast bacilli (AFB) and guide empiric therapy decisions. It is however time consuming and laborious. In this study, we aimed to evaluate the Aerospray® TB *series 2* Stainer (ELITechGroup Inc., www.elitechgroup.com), designed to automate the Ziehl-Neelsen staining process and thus to lower the labor and avoid direct exposure to toxic fumes, with the consistence and complete traceability granted by an automated method.

METHODS

104 clinical samples suspected of containing AFB (88 respiratory samples (70 sputums, 5 broncho-alveolar lavages and 13 bronchial aspirations), 4 gastric aspirates, 4 nodes, 3 aortas, 2 cutaneous, 2 urines and 1 stool) were included in the study. Samples were prepared by smearing it directly onto a microscope slide, as thinly and evenly as possible. Slides were made in duplicate, one slide stained with traditional manual method (Quick-TB, RAL Diagnostics) and its duplicate stained with the Aerospray® TB *series 2* Stainer using ELITechGroup Inc. stains. The slides were then examined microscopically and rated. The rating result of each slide was compared to its respective duplicate.

RESULTS

There was a high correlation between the two staining methods with 99% agreement. Indeed, 64 of the 104 samples (61.5%) were rated as AFB negative and 39 (37.5%) were rated as AFB positive with both staining methods. One sample (0.96%) was rated as positive (rare) when stained manually, but negative when stained with the Aerospray® TB *series 2* Stainer. Of the 40 positive samples, 26 (65%) rated exactly the same with both staining methods, 10 (25%) had a higher positivity rating when stained with the Aerospray® TB *series 2* Stainer and 4 (10%) had a lower positivity rating when stained with the Aerospray® TB *series 2* Stainer.

		Number of slides stained with Aerospray® TB <i>series 2</i> Stainer					
Number of slides stained with manual method	Slide Rating	Negative	Rare	1+	2+	3+	Total
	Negative	64	0	0	0	0	64
	Rare	1	2	2	0	2	7
	1+	0	2	14	3	1	20
	2+	0	0	1	9	2	12
	3+	0	0	0	0	1	1
	Total	65	4	17	12	6	104

CONCLUSION

Despite some minor discrepancies in slide ratings, there was an excellent correlation between the manual and automated staining methods. These results demonstrated that Aerospray® TB *series 2* Stainer is a good alternative to manual Ziehl-Neelsen staining. Moreover Aerospray® TB *series 2* Stainer allows a safety workflow and his staining flexibility enables users to do adjustments to fit their reading habits.