

# 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.<sup>1,2,3</sup>, Pierre-Audigier C.<sup>3</sup>, Milhau M.<sup>4</sup>, Mullen K.<sup>4</sup>, Andremont A.<sup>1,2,3</sup>

<sup>1</sup>INSERM, IAME, UMR 1137, F-75018 Paris, France, <sup>2</sup>Univ Paris Diderot, IAME, UMR 1137, Sorbonne Paris Cité, F-75018 Paris, France, <sup>3</sup>AP-HP, Hôpital Bichat, Laboratoire de Microbiologie, F-75018 Paris, France, <sup>4</sup>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 series 2 Stainer					Total
		Negative	Rare	1+	2+	3+	
Number of slides stained with manual method	Slide Rating						
	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.