

# 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>, 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

† Both authors contributed equally to the manuscript

**Background:** 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](http://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.

**Materials/methods:** 59 clinical samples suspected of containing AFB (46 respiratory samples (42 sputum, 2 broncho-alveolar lavage and 2 bronchial aspiration), 4 gastric tubing, 3 node, 3 aorta, 2 cutaneous, 1 urine 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 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 method with 97.7% agreement. Indeed, 40 of the 59 samples (67.8%) were rated as AFB negative and 18 (30.5%) were rated as AFB positive with both staining methods. One sample (1.7%) was rated as positive (rare) when stained manually, but negative when stained with the Aerospray® TB series 2 Stainer. Of the 19 positive samples, 9 (47.4%) rated exactly the same with both staining methods, 7 (36.8%) had a higher positivity rating when stained with the Aerospray® TB series 2 Stainer and 3 (15.8%) had a lower positivity rating when stained with the Aerospray® TB series 2 Stainer.

**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.

**Key words:** acid-fast bacilli, Ziehl-Neelsen staining, laboratory automation

		Number of slides stained with Aerospray® TB series 2 Stainer					
		Slide Rating	Negative	rare	1+	2+	3+
Number of slides stained with manual method	Negative	40	0	0	0	0	40
	rare	1	2	2	0	2	7
	1+	0	2	4	0	1	7
	2+	0	0	0	2	2	4
	3+	0	0	0	0	1	1
	Total	41	4	6	2	6	59