

MINDRAY BC-6800 BODY FLUID MODE: CELL COUNT AND DIFFERENTIAL PERFORMANCES ON CEREBROSPINAL FLUID

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INTRODUCTION

A cerebrospinal fluid (CSF) cell count is a clinical laboratory test that provides important diagnostic information in various pathological conditions. High white blood cell (WBC) counts in CSF samples ($>5 \times 10^6$ cells/L in adults, $>7 \times 10^6$ cells/L in children, $>27 \times 10^6$ cells/L in neonates) are often observed in meningitis, encephalitis and other neurological disorders. BC-6800 is able to perform Body Fluid analysis in a dedicated module (BF); it provides the following parameters: total nucleated cells (TC-BF), leukocytes (WBC-BF), polymorphonuclear (PMN# and %) and mononuclear cells (MN# and %). Aim of this study is to evaluate the application of BC-6800-BF in analysis of CSF, according to CLSI document H56-A, 2006 (1).

MATERIALS AND METHODS

Total cell count (TC) and differential of 80 CSF samples (range 0 to 3356×10^6 cells/L), collected in sterile tubes without additives, were simultaneously assessed by BC-6800-BF and optical microscopy (OM) performed both in Nageotte chamber and cytopsin. Diagnostic performance was evaluated with receiver operating characteristics (ROC) curves analysis. Statistical analysis was done with Analyse-it software version 3.80. The verification protocol included limit of blank (LoB), limit of detection (LoD) and functional sensitivity (limit of quantitation, LoQ) according to CLSI document EP17-A2 (2), Carry Over according to CLSI H56-A (1) and Linearity according to CLSI document EP06-A (3).

RESULTS

TC-BF and differential count in PMN and MN showed respectively: Pearson's correlation of 0.99, 0.84 and 0.83 ($p < 0.0001$); Passing and Bablok regression $y = 0.93x + 0.07$, $y = 0.95x - 3.80$, $y = 0.92x + 10.26$ and Bias of -18.1, -7.0 and 6.5 (Table 1 and Figure 1, Figure 2, Figure 3)

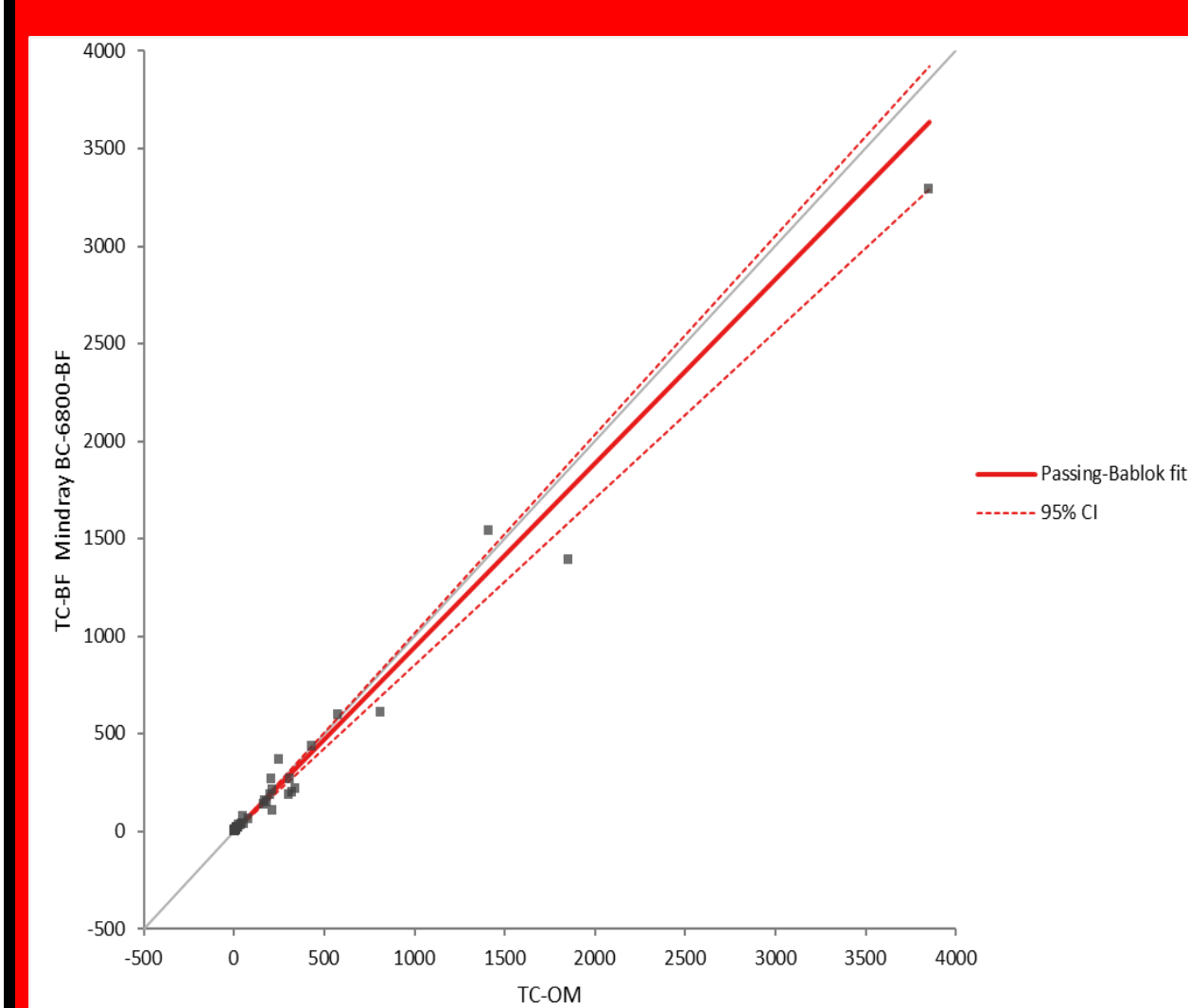


Figure 1: Passing Bablok regression for Total nucleated cells count

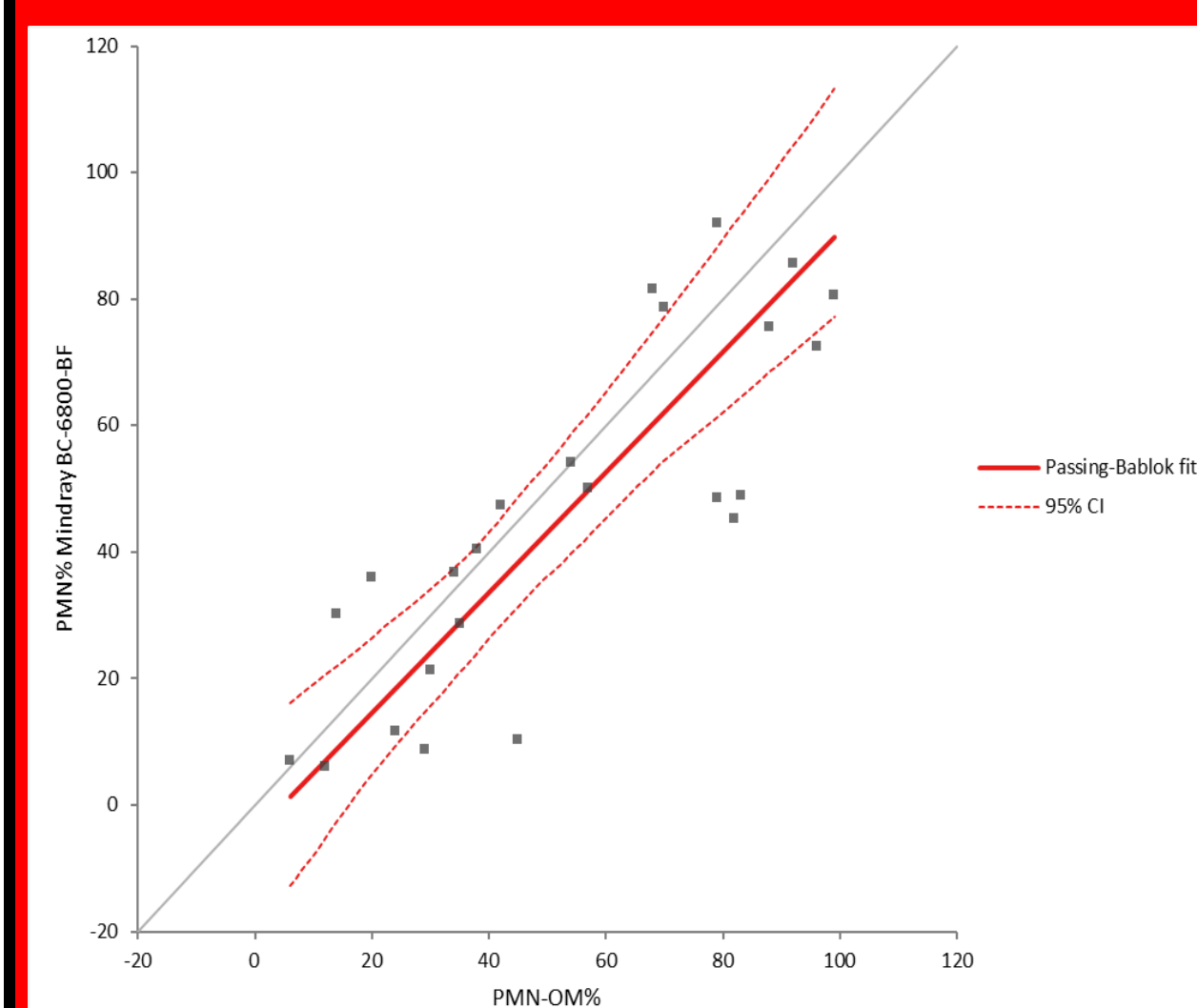


Figure 2: Passing Bablok regression for Polymorphonuclear cells count

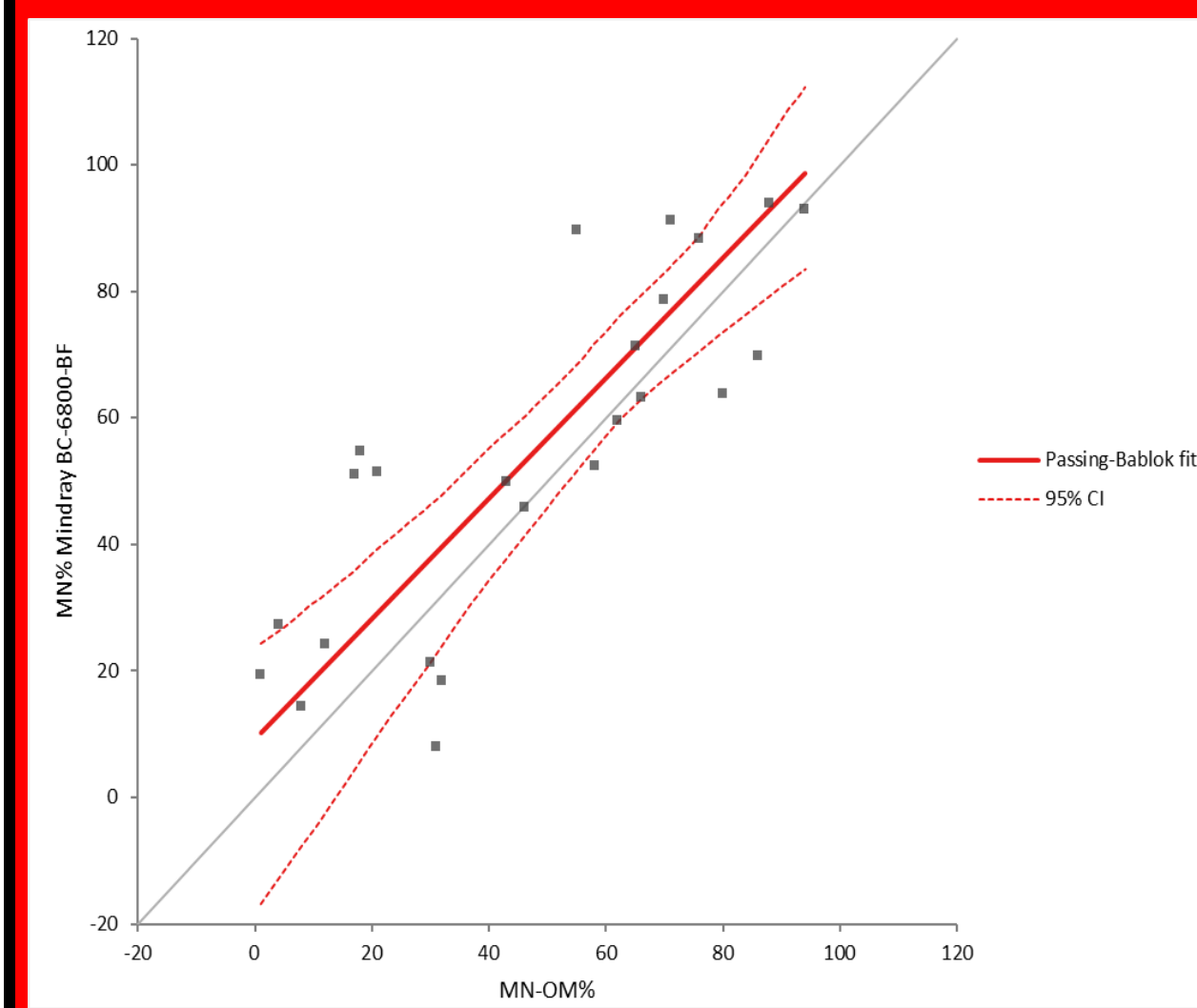


Figure 3: Passing Bablok regression for Mononucleated Cells Count

Table 1: Pearson's correlation, Passing Bablok regression and Bland Altman Bias for TC, PMN and MN

	Pearson correlation (r) (p value)	Passing-Bablok regression (CI 95% Slope and Intercept)	Bias Altman-Bland (CI 95%)
TC-BF	0.99	$y = 0.93x + 0.07$	-18.1
PMN-BF	0.84	$y = 0.95x - 3.80$	-7.0
MN-BF	0,83	$y = 0.92x + 10.26$	6.5

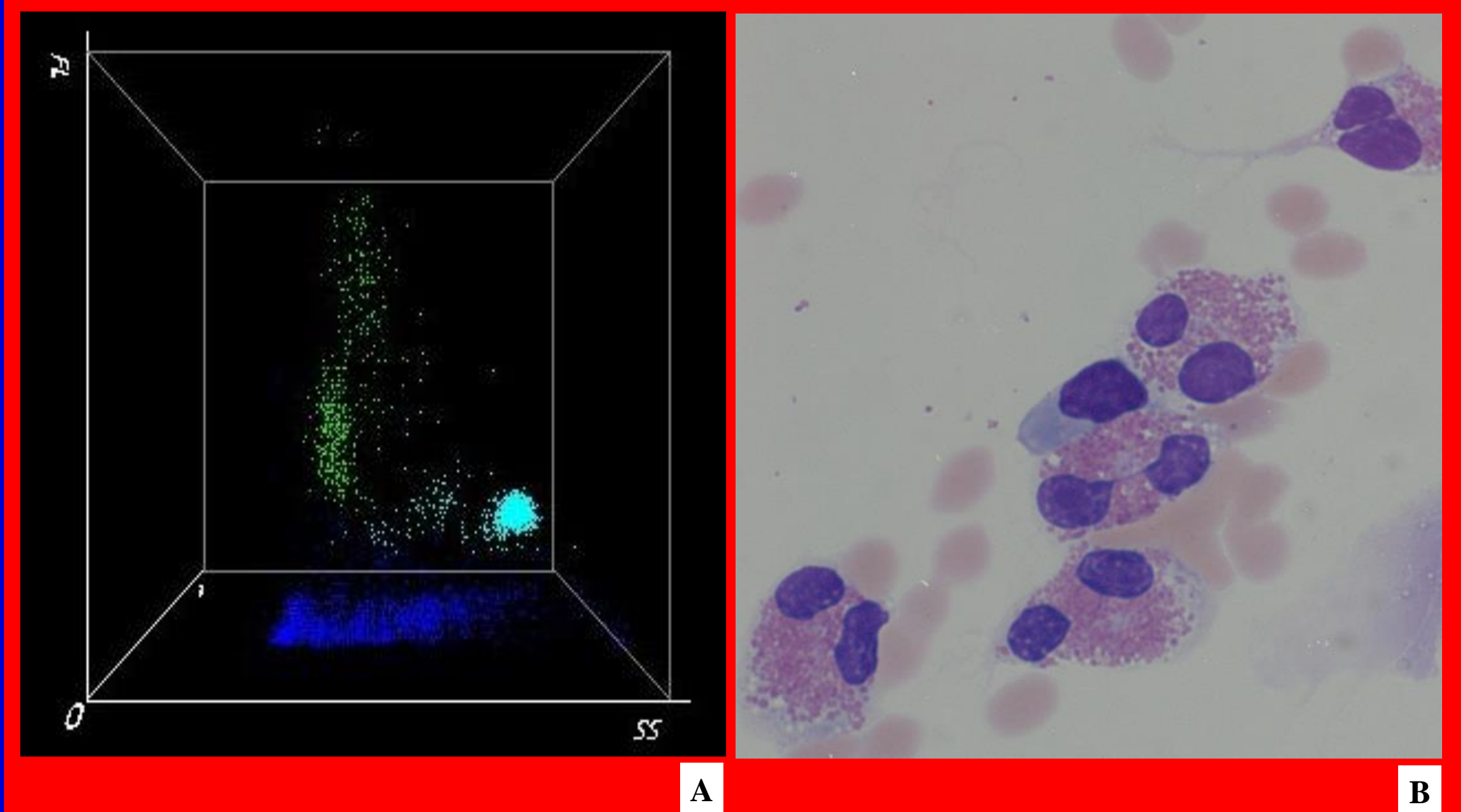


Figure 4: (A) DIFF Scattergram with the presence of the cluster of eosinophil (light blue area), confirmed in optical microscopy (OM) (B)
Mindray BC-6800-BF: TC-BF: 608×10^6 cells/L; PMN: 72.6%; MN: 27.4%, EO-BF: 402×10^6 cells/L
OM: neutrophils 1%; lymphocytes 4%; eosinophil 95% and OM-TC 811×10^6 cells/L.

The area under curve (AUC) of TC- BF, PMN% and MN% were 0.98, 0.99 and 0.99 ($p < 0.0001$) respectively. As for TC-BF at the cellularity cut-off of 5×10^6 cells/L, we obtained a diagnostic agreement of 95%, whereas for PMN% and MN% it was 90% at the cut-off of 50% (Table 2)

Table 2: ROC Analysis of different BC-6800-BF parameters in CSF sample

	AUC (CI 95%) p-value	CUT-OFF	Diagnostic Agreement
TC	0.98	5×10^6 cell/L	95%
MN%	0.99	50%	90%
PMN%	0,99	50%	90%

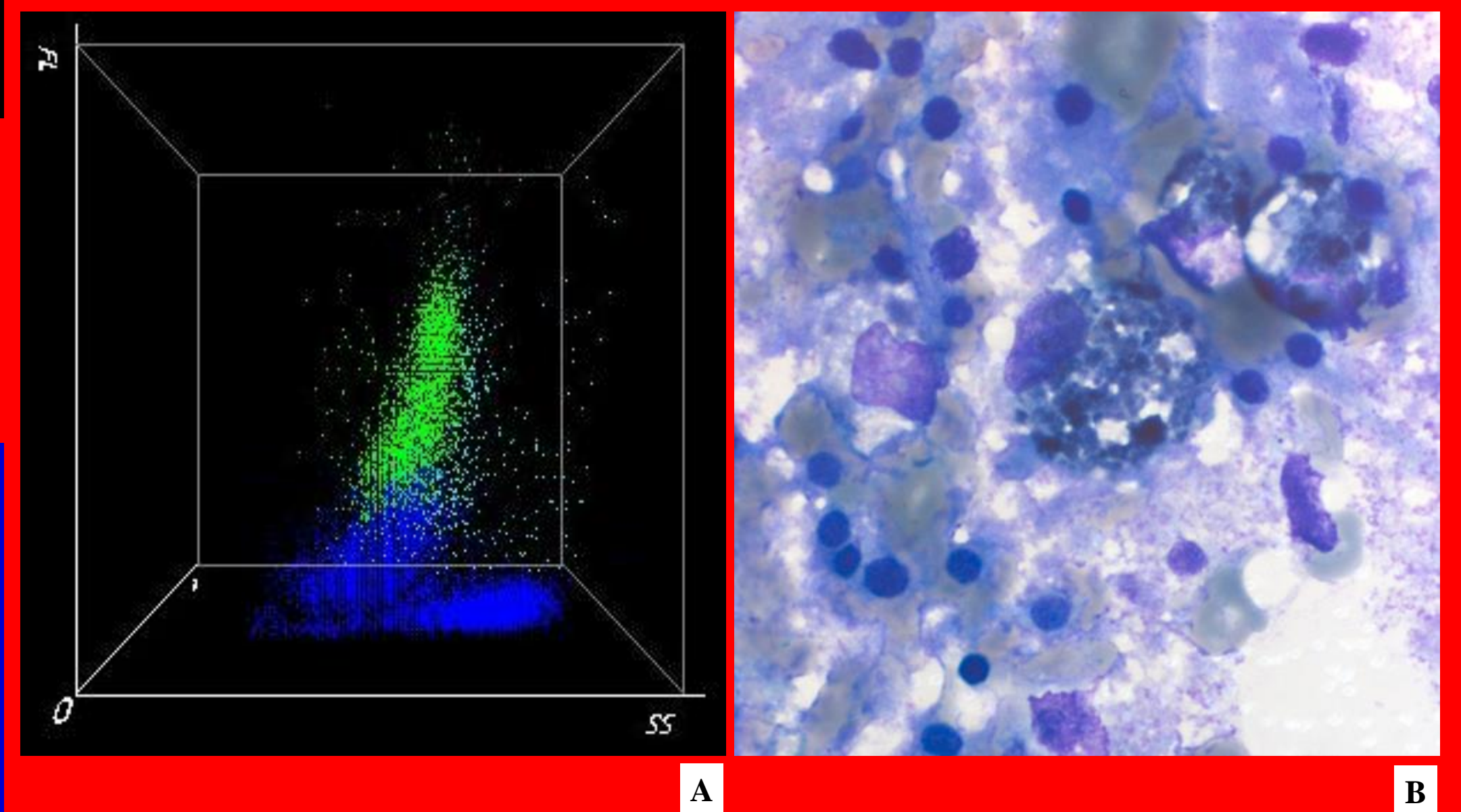


Figure 5: (A) Abnormal DIFF Scattergram due to the presence of ghost. (B) Morphological analysis with OM reveals the presence of siderophages macrophages
Mindray BC-6800-BF: 1542×10^6 cells/L; PMN: 11.7%; MN: 88.3%
OM: neutrophils 24%; lymphocytes 6%; monocytes 21%; macrophages 49% and OM-TC 1413×10^6 cells/L.

TC-BF's LoB, LoD and LoQ were respectively of 0×10^6 cells/L 3×10^6 cell/L 8×10^6 cells/L, with an excellent Linearity ($r^2 = 1.0$), and a negligible carry-over.

CONCLUSIONS

The results obtained by our study show the utility of the BC-6800-BF in automated cell count and differentiation of CFS. BC-6800-BF offers fast cytometric analysis of CSF samples in clinically relevant concentration ranges, thus replacing the counting chamber and microscopic differentiation process in the majority of samples that needs such analysis, except for samples displaying abnormal cell counts or abnormal DIFF scattergram as showed in Figure 5 and Figure 6

REFERENCES

- 1) Body Fluid Analysis for Cellular Composition; approved guidelines. CLSI H56-A 2006
- 2) Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; approved guideline - second edition. CLSI document EP17-A2. 2012
- 3) Evaluation of the linearity of quantitative measurement procedures: a statistical approach; approved guideline. CLSI document EP-06A 2003