

# Human Peripheral Blood Leukopak Collections from Healthy Donors: Impact of Donor Demographics on Leukopak Quality and Product Consistency between Multiple Collection Sites

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## INTRODUCTION

Leukopak is a blood-derived product obtained from leukapheresis, a specialized apheresis procedure that allows donors to directly donate white blood cells (WBC) through a special apheresis device<sup>1</sup>.

Allogeneic treatments have a high potential in clinical development. However, allogeneic product manufacturing presents several challenges, including high-quality and reliable starting materials.

Leukopak is a source of peripheral blood mononuclear cells used as starting material in personalized medicine, immunotherapy, and gene and cell therapies, notably in the production of CAR-T therapies<sup>2</sup>.

## AIM

To assess the consistency of Leukopaks collected from healthy donors in blood centers and to identify donor demographic factors that affect the product's quality and collection efficiency.

## METHODS

Leukapheresis for Leukopaks obtention was conducted in healthy donors using the Spectra Optia® apheresis system in three blood centers (Rostock, Erfurt and Berlin) operated by Haema AG in Germany (a Grifols partner) between January 2021 and July 2023.



**FIGURE 1.** Leukopak specifications: Total Volume, Anticoagulant, Leukocyte and Monocyte concentration.

Leukopaks' quality parameters included total volume, WBC yield, cell viability and the percentage of WBC subsets (flow cytometry). Factors influencing collection efficiency, BMI/age/total blood volume and WBC yields were compared by linear regression. Quality parameters were evaluated among centers using one-way ANOVA. Leukopak specifications are shown in **Figure 1**.

## RESULTS

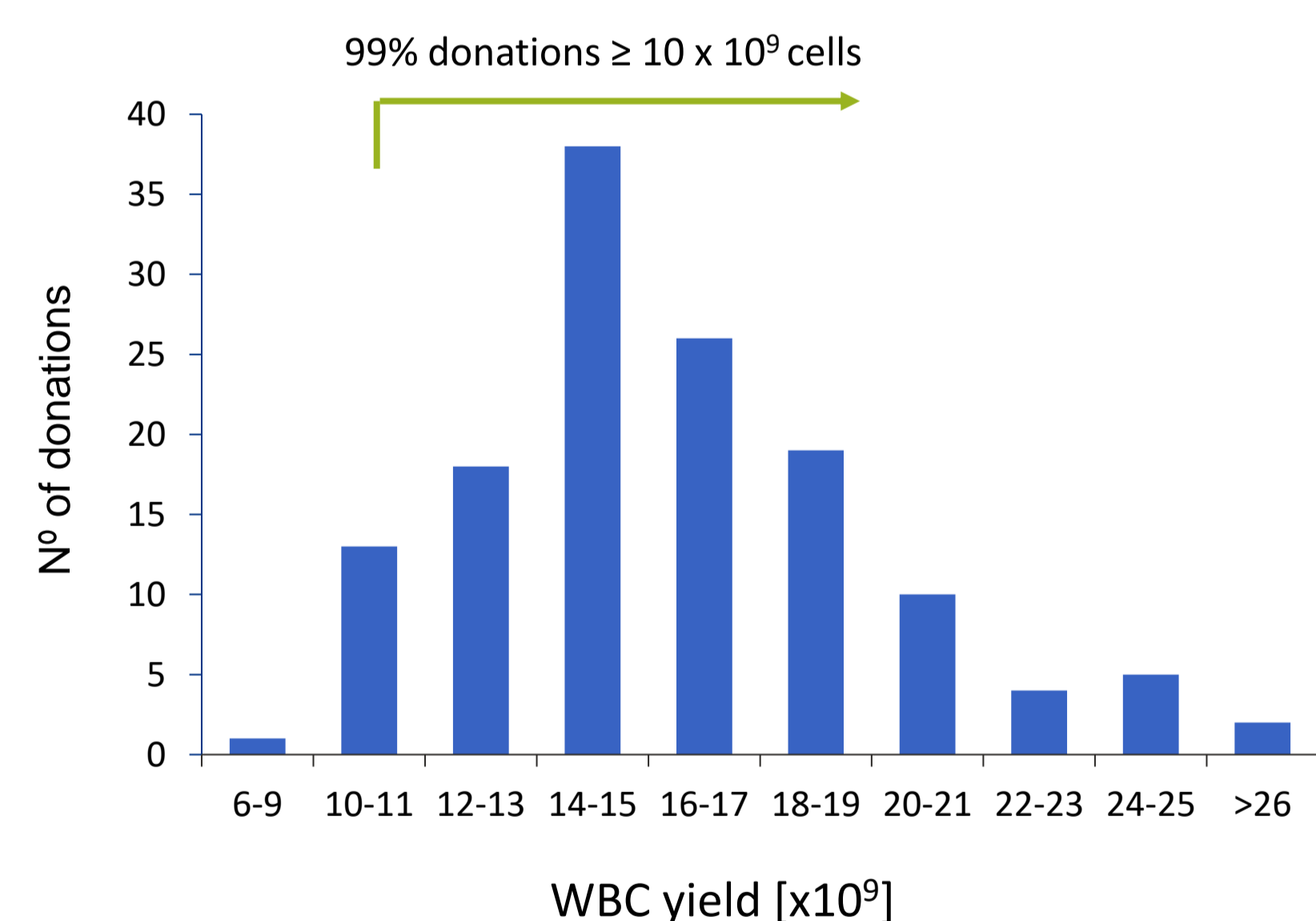
A total of 137 Leukopaks were obtained from 83 donors, mostly males (96%), and aged between 20-61 years. Donors with high body mass index (BMI) > 25 kg/m<sup>2</sup>, were selected to obtain a higher WBC yield. Demographic data are shown in **Table 1**.

**TABLE 1.** Donor demographic characteristics and process parameters.

Parameter	Value
Number of leukapheresis, n	137
Number of donors, n	83
Sex, male, %	96.5
Age, years	35.4 (7.1)
Weight, kg	101.6 (12.8)
Height, m	1.8 (0.1)
Body mass index, kg/m <sup>2</sup>	30.1 (4.2)
Total blood volume, ml	6168.4 (563.7)

Data are reported as mean (SD).

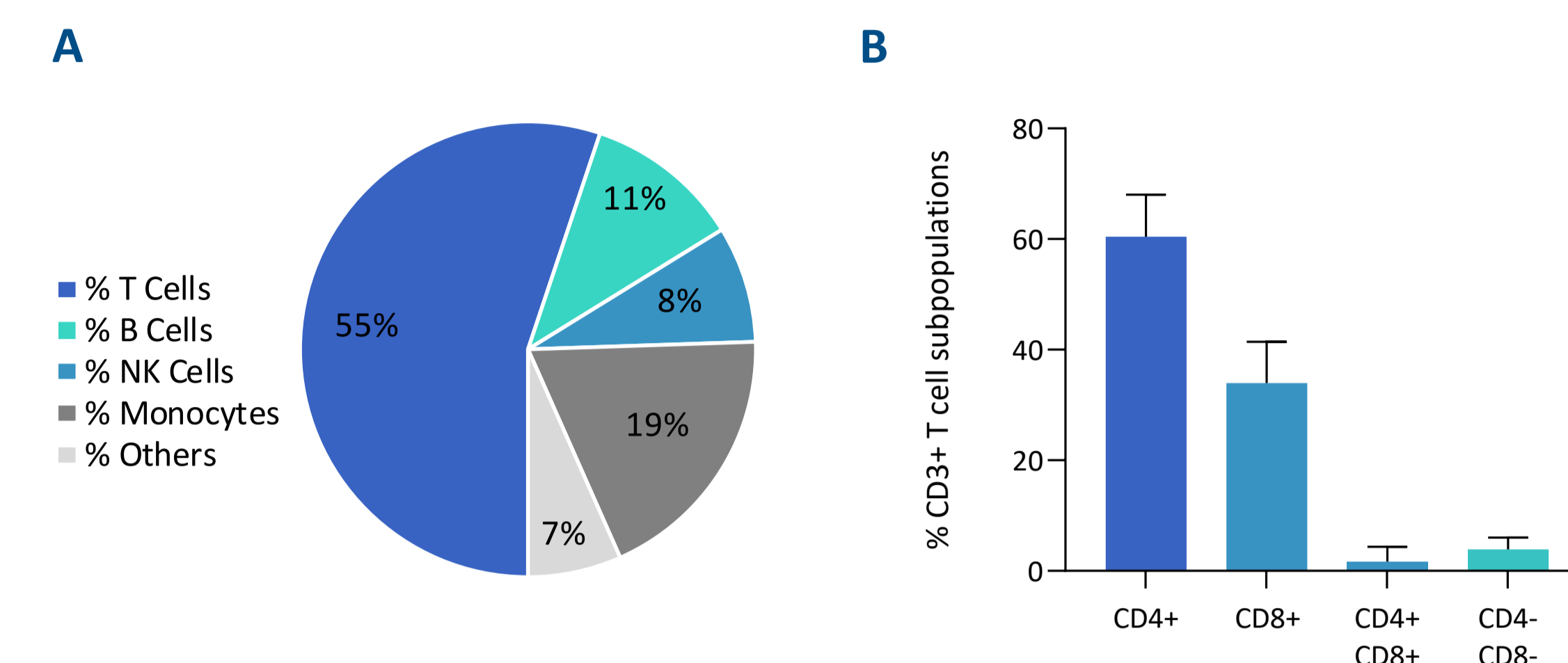
Mean (SD) Leukopak volume was 177 (8.7) ml, and the median (range) WBC yield was 15.9 x 10<sup>9</sup> (6-37 x 10<sup>9</sup>) WBC per Leukopak (**Figure 2**). Notably, 99.3% of donations exceeded 10 x 10<sup>9</sup> WBC and the cell viability 24h post-collection was 99 (0.7) %, proving Leukopak consistency.



**FIGURE 2.** Distribution of WBC yields across donors. Most of values clustered near the mean (16 x 10<sup>9</sup> cells).

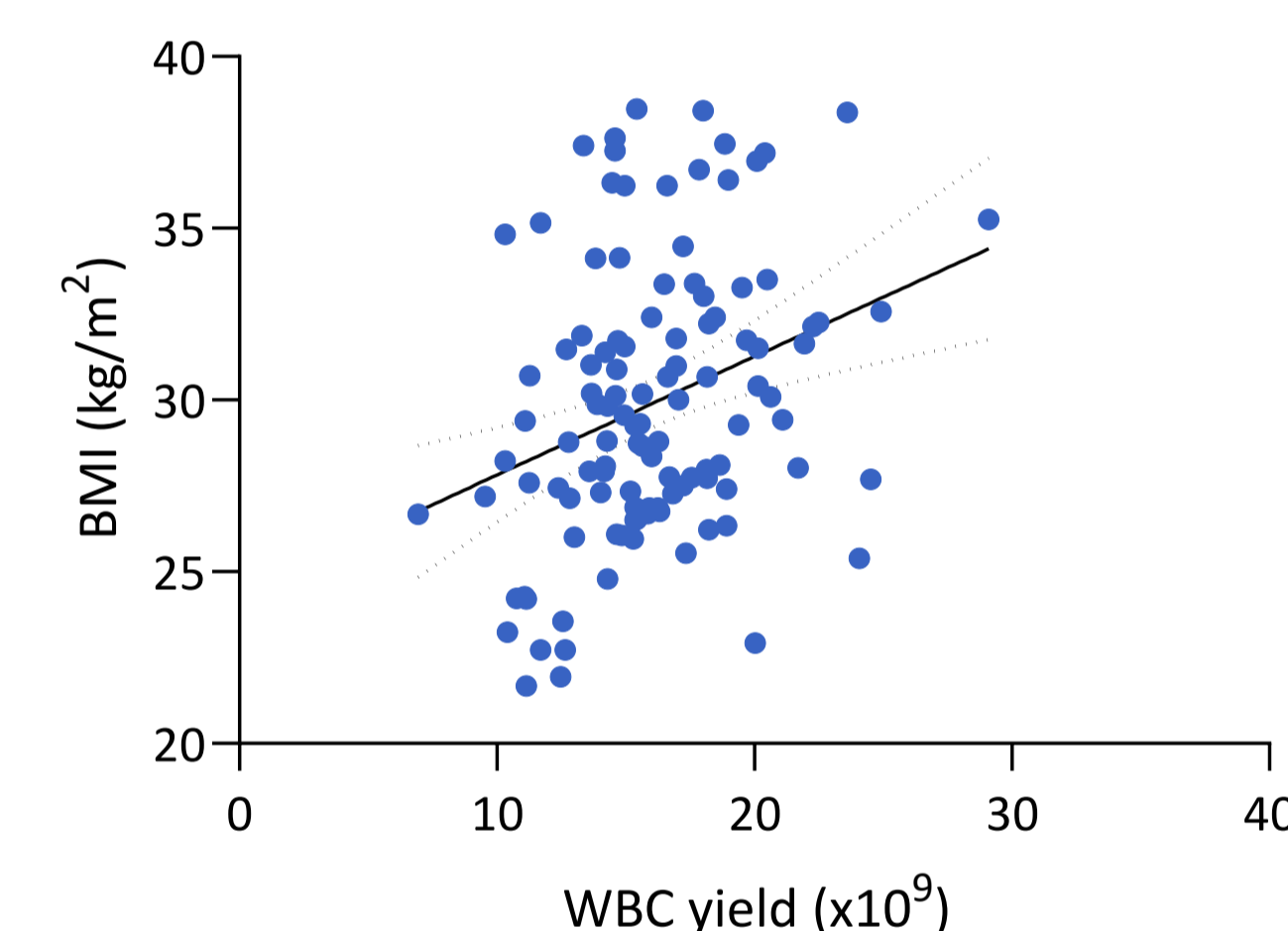
The distribution of WBC subset and CD3+ T cells showed the expected frequencies for a healthy donor population (**Figure 3**).

Additionally, immunophenotyping analysis of several donations from the same donor showed consistency of immune cell subsets over time.



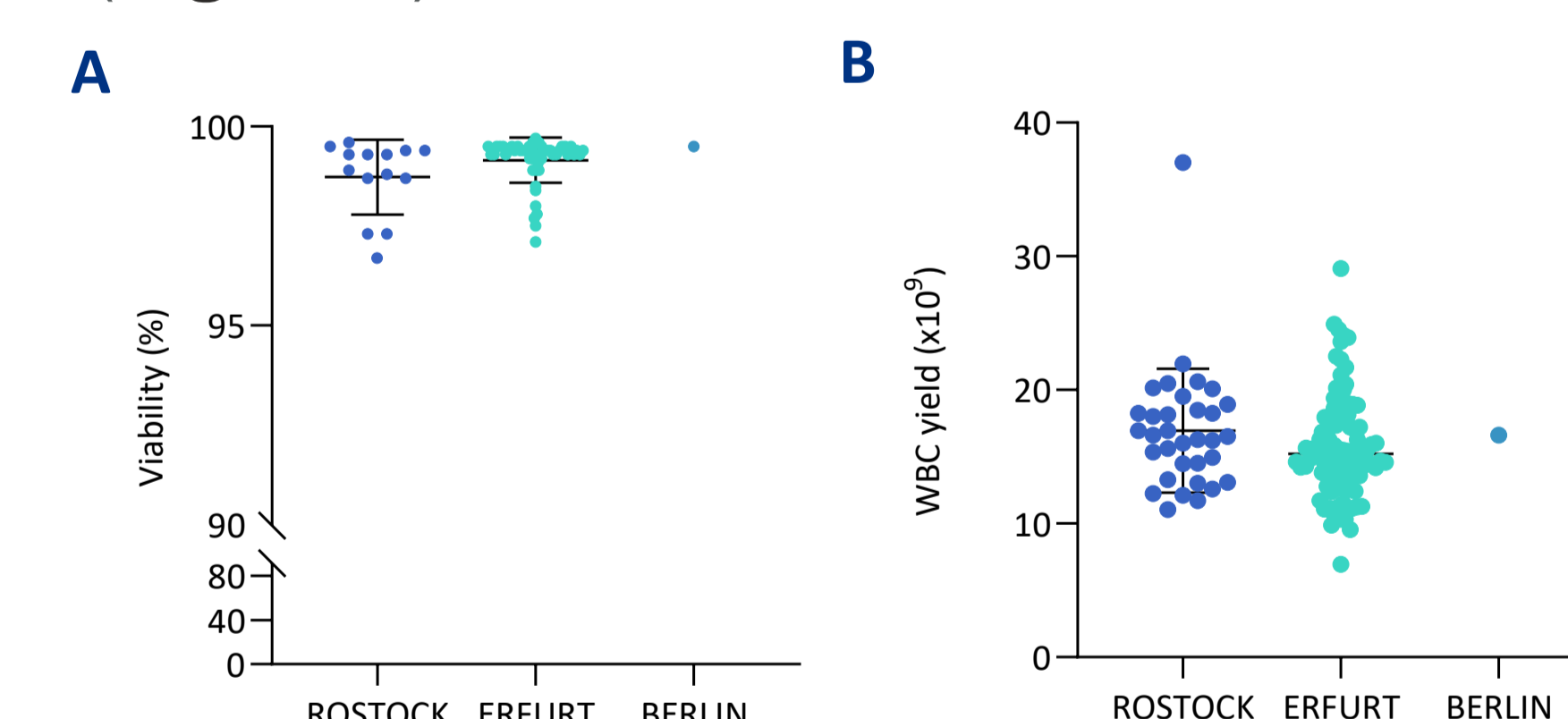
**FIGURE 3.** Distribution of WBC subsets. (A) Percentage of T cells, B cells, NK cells, Monocytes and others, n=133. (B) CD3+ T cell subpopulations frequencies from flow cytometry data (CD4+, CD8+, CD4+CD8+ and CD4-CD8- T cells). Results are expressed as mean (SD), n=66.

WBC yield significantly correlated with donor's BMI (r=0.3115, p=0.0007) (**Figure 4**).



**FIGURE 4.** Correlation between WBC yield and BMI (r=0.3115, p=0.0007).

No statistically significant differences in both WBC yield and cell viability were observed among the collection centers (**Figure 5**).



**FIGURE 5.** Comparison of quality parameters across the donation centers. (A) Cell viability (%) and (B) WBC yield (x10<sup>9</sup>).

## CONCLUSIONS

- Leukopaks collected by Haema ensured a collection efficiency of  $\geq 10 \times 10^9$  WBCs in 99% of donations, with a mean of  $16 \times 10^9$  WBCs and a very high post-collection viability.
- Product consistency between multiple collections sites was confirmed.

