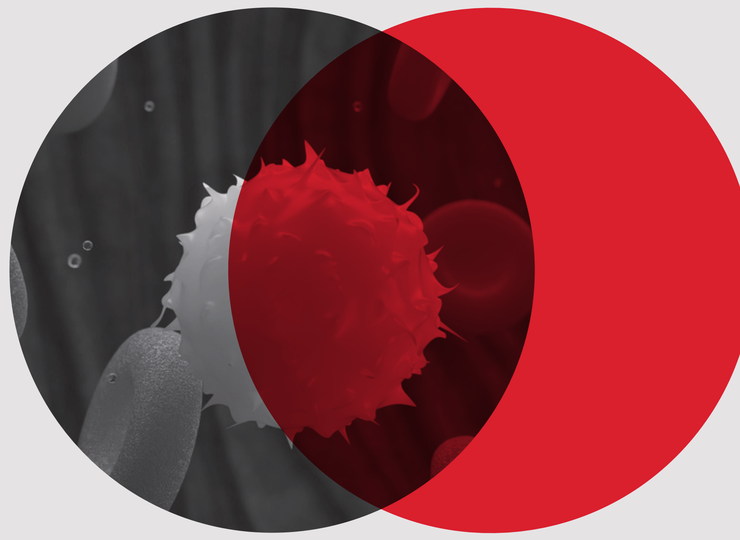
Comparison of EQA variation between two Sysmex instruments over a four-year period



Elinor Cobbin[1]

[1] Royal College of Pathologists of Australasia Quality Assurance Programs, St Leonards, Sydney NSW 2065, Australia

Introduction

White blood cell (WBC) count is a fundamental parameter in routine haematology testing. WBC count provides diverse information to clinicians, from diagnosis of infection or malignancy to treatment monitoring in chemotherapy, it has broad application in practice. Flow cytometry is one of the most widely utilised methods for counting WBCs in haematology automation. Sysmex instrument groups XN and XN-L use flow cytometry with a semi-conductor laser to enumerate WBCs in blood and body fluids.

Although these instruments are grouped and assessed separately, both instrument classes utilise the same reagents, QC material and analytical principle for most parameters in a Full Blood Count (FBC)[1–3]. Accordingly, there should be a good correlation between the two instruments. Several comparison studies have reported excellent correlations between the two analysers using whole blood[3–6]. However, comparison data on stabilised materials is limited. This study used stabilised whole blood samples to compare WBC results from external quality assurance (EQA) surveys between the Sysmex XN and XN-L instrument classes.

Method

The RCPAQAP FBC program consists of 12 surveys per year with two samples per survey. The EQA samples used are a stabilised whole blood product. For this study, WBC results from survey samples between 2018–2021 were included for the XN and XN-L instruments. RCPAQAP in-house software was used to calculate the median, mean, SD, and CV for each survey sample. The survey sample median and CV results were then assessed using three WBC target levels, ('Low' = WBC< 5 x109/L, 'Medium' = WBC 5–10 x109/L and 'High' = WBC >10 x109/L) where the targets are derived from the 'all results' medians for the sample. The difference between XN and XN-L WBC results was assessed using t-test on the CVs, and the medians were used to assess the magnitude of any differences found.

Results

The comparison of the two instruments at all three levels indicated less variation in the XN group results compared to the XN-L group over the four-year period. As shown in table 1, the CVs for the XN-L group were on average 1.9, 1.8, and 2.1% higher for the low, medium, and high groups, respectively. This difference was statistically significant, with a p-value of <0.01 for all groups. Although the difference in median results for the two instrument groups was statistically significant, the average difference was small in magnitude and not deemed clinically significant to patient outcomes. When the survey results for two samples were graphed on a Youden plot, a dual population becomes evident, as shown in Figure 2.

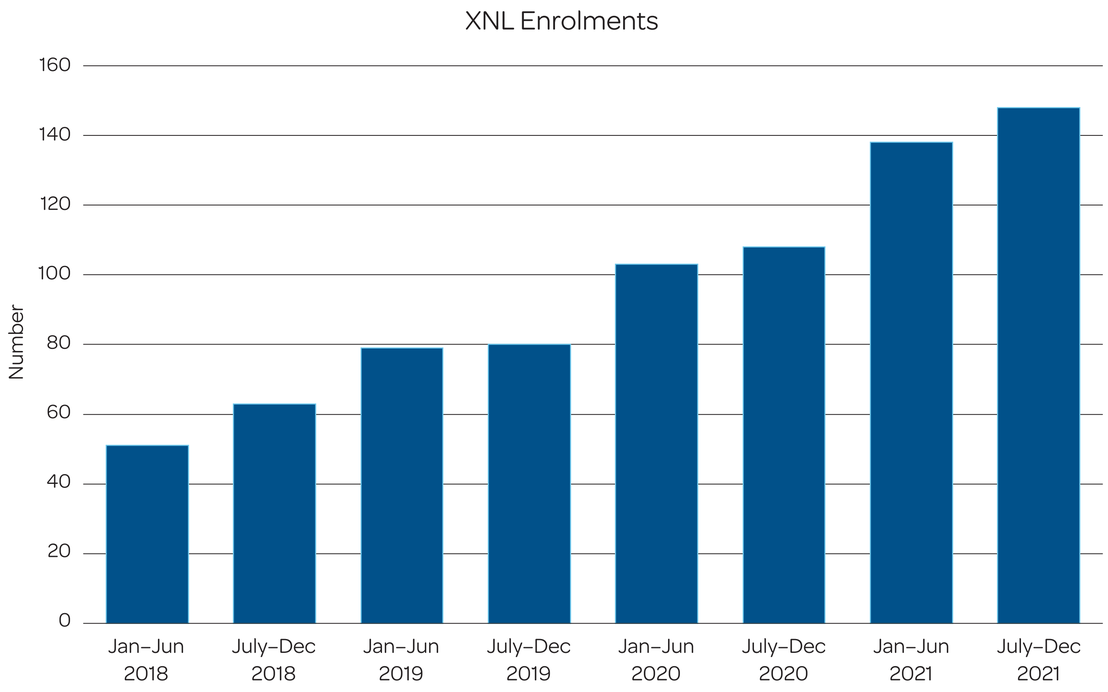


Figure 1. The number of participant enrolments for the Sysmex XN-L instrument group in the FBC program from 2018 to 2021

Discussion

From 2018–2021 there was a steady increase in enrolments for the Sysmex XN-L instrument in the RCPAQAP Full Blood Count program, as shown in Figure 1.

With this increase in returned results, a variation in reporting for WBC became evident through higher CVs compared to the XN Sysmex instrument class.

Highlighted in Figure 2 is a dual population in the WBC results for XN-L users, which does not exist in the XN group. The samples used are a stabilised product. Consequently, matrix effects were considered a potential causal factor. In this instance, it was ruled out because there was no dual population in the comparative Sysmex XN instruments, which have been well established as correlating with the XN-L instrument FBC results[3–6].

One key difference between the two instruments is the presence of a secondary QC mode on the XN-L instruments. Participants are instructed to report through the XN control mode instead of the XN-L control mode. When surveying participants in August 2021, we noted that the group reporting in the second population of results was running the EQA material through the alternate XN QC mode and consequently determined this to be the most likely causal factor. Despite ongoing commentary in our reports and emails advising of the need to run our stabilised samples in the XN mode, we have anecdotal evidence that the practice continues.

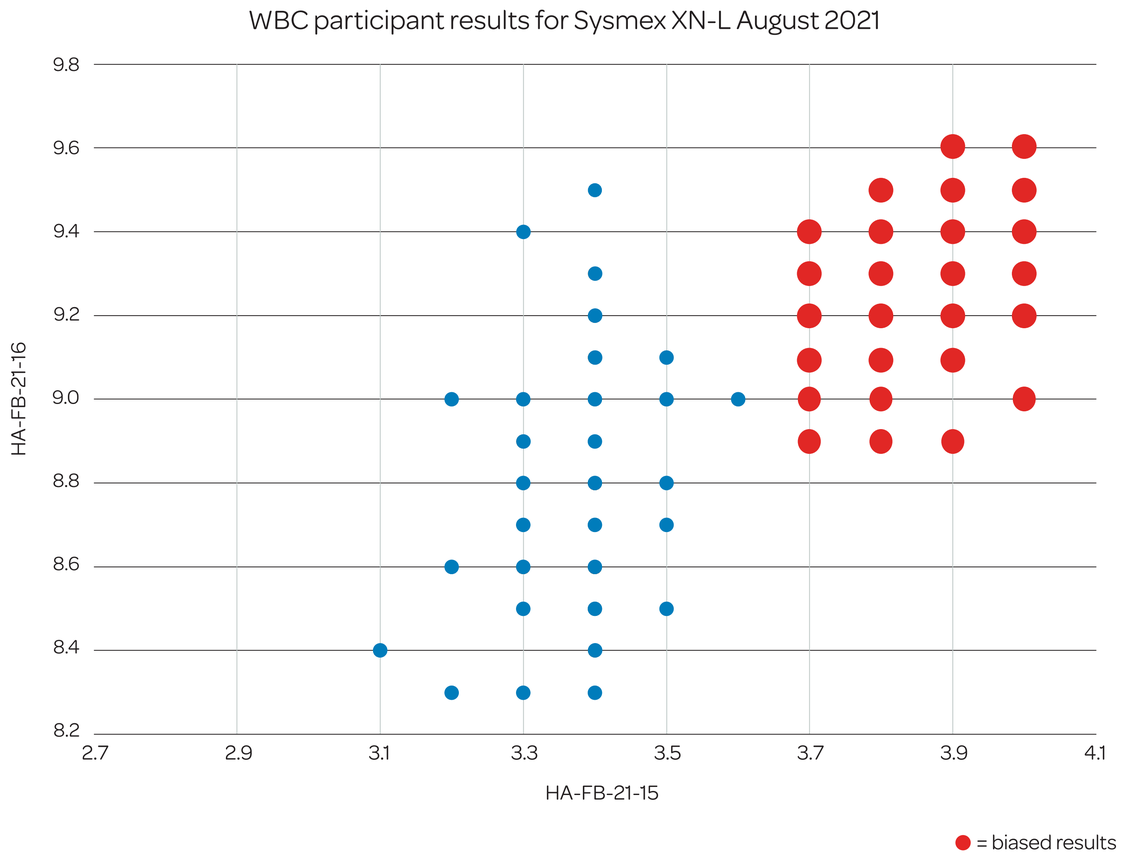


Figure 2. The dual population of WBC results from the August FBC survey 2021

Table 1. Average difference in results between the XN-L and XN instruments
**p-value <0.01, *p-value <0.05

	Average Difference	
	Median (x10^9/L)	CV (%)
Low	-0.03*	1.9**
Medium	-0.04*	1.8**
High	-0.19*	2.1**

Conclusion

The two instruments assessed in this study showed a statistically significant difference in EQA reporting for WCC which is likely due to sample processing differences between the instruments, including the presence of a secondary QC mode on the XN-L instrument. While, ideally, EQA samples should be treated the same as patient samples, there are scenarios where alternate modes are required in order to adjust for the stabilisation of the material. EQA participants are encouraged to check sample handling instructions on a regular basis.

References:

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