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Evaluating the Performance of the New Sysmex XR-Series Haematology Analyser: A Comparative Study with the Sysmex XN-Series

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Abstract: The objective of this study was to assess the performance characteristics of the new automated haematology analyser from Sysmex Corporation, the Sysmex XR-Series, compare its performance to the Sysmex XN-Series through method comparison, and compare our results to previously published literature. Analytical performance of the new Sysmex XR-20 consisting of precision, bias, and total error, a method comparison with the Sysmex XN-2000, and the flagging performance evaluation were conducted on a Sysmex XR-20 analyser in the AZ Sint-Lucas Hospital (Bruges, Belgium) several months before its launch in Europe. We conclude that the Sysmex XR-Series is an excellent successor to the Sysmex XN-Series for routine haematology analysis. Analytical performance and flagging efficiency are comparable to the Sysmex XN-analyser.

Keywords: haematology analyser; Sysmex; XR-20

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1. Introduction

The Sysmex XR-Series is the new successor to the automated haematology analyser Sysmex XN-Series from Sysmex Corporation, launched in Europe in July 2023. The performance of Sysmex XN has already been extensively studied and shows excellent results in terms of reliability for determining haematological parameters [1–3]. Most features of this new haematology analyser are comparable to the Sysmex XN-Series. The most important improvements include the ability to view 3D scatterplots in the Integrating Processing Unit (IPU) software, enhanced separation between eosinophils and neutrophils in the white cell differential (WDF) channel, and improved blast/abnormal lymphocytes flagging in the WDF channel. Furthermore, throughput increases slightly from 100 to 110 samples per hour. The software now includes new features such as a planned shutdown in the daily maintenance and an automated backup. Except for the Lysercell WDF reagent, all other reagents remain the same as for Sysmex XN. The measuring channels on Sysmex XR also remain unchanged. An impedance channel for the measurement of red blood cell parameters and platelets (PLT-I) is available. Other analysing channels include a white cell nucleated (WNR) channel for the measurement of white blood cells (WBCs), basophils, and nucleated red blood cells (NRBCs), a WDF channel for WBC differentiation, a white pathological and precursor (WPC) channel to distinguish reactive lymphocytes from blasts, a fluorescent platelet (PLT-F) channel for recounting of unreliable platelet counts obtained from the impedance channel, and a reticulocyte (RET) channel for measurement of reticulocytes and immature platelet fraction (IPF). As mentioned above, the WDF channel has an improved blast/abnormal lymphocyte flagging, making the detection of potential

malignant or reactive cells more sensitive. When such flagging is produced, the sample will be analysed in the WPC channel. Several studies already showed the benefits of using both channels in distinguishing malignant or reactive lymphocytes prior to performing a blood smear [4,5]. Also, in cases of WBC counts lower than 0.5×10^9/L, the low WBC mode with prolonged WBC count is available to ensure accurate counts [2]. The new Sysmex XR-series can, similar to the XN-series, include a body fluid (BF) mode for cell counts and (partial) WBC differentiation in several body fluids [2,6]. The Sysmex-XR series incorporates the Extended Processing Unit (EPU), which provides enhanced computational capabilities for analysing scatterplots and detection of abnormalities with greater precision to optimize workflow and improve result interpretation. Within the EPU, automated decision rules are applied to results, incorporating both predefined system algorithms and customizable rules tailored to individual laboratory preferences. These rules are partly based on Q-flags, which indicate potential abnormalities or technical issues [7,8]. The dimensions of the Sysmex XR-analyser are nearly identical to the XN-Series. Recently, two studies on the performance of the new XR were published: one study on the performance in whole blood mode and one study examining the BF mode [6,8].

Several months before its launch, the Sysmex XR-20 was evaluated in the laboratory of the AZ Sint-Lucas hospital in Bruges, Belgium. Hereby, we aimed to evaluate the performance characteristics of this new haematology analyser, conducted a method comparison with the Sysmex XN-Series, and compared our results with the recent published paper by Fujimaki et al. [8].

2. Materials and Methods

The evaluation of the Sysmex XR-20 (Sysmex Corporation, Kobe, Japan) was conducted in the laboratory of the AZ Sint-Lucas Hospital in Bruges, Belgium, through an analytical performance experiment and method comparison with our two routine haematology analysers (Sysmex XN-2000). The XR-20 analyser was installed and calibrated by the manufacturer, and IPU settings were set equal to the routine haematology analysers. The XN analysers are connected to the IPU software version 22.16, and the XR analyser to version 02.16. The XR-20 analyser was not connected to an automated slide-maker and -stainer, in contrast to our routine haematology analysers.

2.1. Analytical Performance

Within-run imprecision was assessed by analysing a normal and pathological patient sample (with low absolute WBC, red blood cell (RBC), and platelet (PLT) counts) 10 and 6 consecutive times, respectively. Between-run imprecision, bias, and total error were assessed by analysing level 1 and 2 of Sysmex XN Check quality control material on 6 different days. Results were compared to Ricos desirable criteria, Ricos minimal criteria, the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) desirable 2022 criteria, and/or manufacturer's criteria [9,10]. The following parameters were evaluated: RBC count, haematocrit (HCT), haemoglobin (HGB), mean corpuscular volume (MCV), mean corpuscular haemoglobin (MCH), mean corpuscular haemoglobin concentration (MCHC), red blood cell distribution width–CV (RDW-CV), absolute reticulocyte (RET) count, impedance platelet count (PLT-I), mean platelet volume (MPV), WBC count, absolute basophil count, absolute eosinophil count, absolute lymphocyte count, absolute monocyte count, absolute neutrophil count, and immature granulocyte (IG) count.

2.2. Method Comparison

In total, 388 residual fresh K2EDTA-anticoagulated patient samples (Sarstedt, Nümbrecht, Germany) previously analysed during routine practice on one of the Sysmex XN-

2000 analysers were analysed according to the manufacturer's instructions within 2 h after collection, on the Sysmex XR-analyser by a dedicated technologist. All samples with sufficient sample volume were included, encompassing both normal and pathological samples. Pathological samples included samples from patients with sepsis, bacterial or viral infections, patients receiving chemotherapy and patients diagnosed with or under follow-up for haematological malignancies. Sysmex XN Check quality controls level 1 and 2 were performed daily prior to analysing the samples. In total, 388 samples were analysed for Complete Blood Count (CBC), 319 samples for WBC differential, and 105 samples for reticulocyte count. Method comparison was performed by conducting Passing–Bablok regression analysis and Bland–Altman plots, and by calculation of Spearman's correlation coefficients (R), version 12.0 (Medcalc® statistical software, Ostend, Belgium). The statistical methods were chosen because they are suitable for non-normally distributed data, robust, and not sensitive to outliers. Confidence intervals for slopes and intercepts were calculated to test the hypotheses. A significant deviation was considered present if the respective confidence interval did not include 1 for the slope or 0 for the intercept. Correlation was assumed to be acceptable if $R > 0.975$.

The following parameters were evaluated: RBC count, HCT, HGB, MCV, MCH, MCHC, RDW-CV, absolute RET count, reticulocyte haemoglobin equivalent (Ret-He), absolute NRBC count, PLT-I, fluorescent platelet count (PLT-F), optical platelet count (PLT-O), MPV, WBC count, absolute basophil count, absolute eosinophil count, absolute lymphocyte count, absolute monocyte count, absolute neutrophil count, and IG count.

2.3. Flagging Performance

Flaggings generated by both analysers were compared and analysed using kappa statistics and global concordance calculations (level of agreement between XR and XN). Kappa values > 0.8 indicate very good association, values 0.6–0.8 good association and values 0.4–0.6 moderate association. Global concordance is considered excellent if >0.9. Global concordance was calculated by summing the true negative and true positive samples and dividing this number by the total number of samples. The WBC flaggings included in this study were: "Blast/Abn Lympho?", "Abn Lympho?", "Blasts?", "Atypical Lympho?", "WBC Abn Scattergram", "IG Present", "Left shift?". The RBC flaggings included were: "Turbidity/HGB Interf?", "RET Abn Scattergram", "Fragments?", "HGB Defect?", "Iron Deficiency?", "RBC Abn Scattergram", "Dimorphic population", "NRBC Present". The PLT flaggings included were: "PLT Clumps?", and "PLT Abn Distribution". For XN-2000, analysis in PLT-F and/or WPC channel was triggered through the EPU (Extended IPU) workflow, whereas the XR-analyser was not connected to EPU, and all channels were analysed in one run. The "Blast/Abn Lympho?" flagging was assessed through a retrospective in silico simulation since all measurement channels were activated on the XR-20 analyser. The Chi-squared test was used to compare the number of flaggings for "Abn Lympho?" and "Blasts?" from the WPC-reflex test after the initial "Blast/Abn Lympho?" flagging in the WDF channel. p values < 0.05 are considered statistically significant. Also, all samples that generated flaggings on XN were microscopically reviewed during routine analysis. Samples flagged by the XR-20 but analyser not by XN-2000 were not microscopically reviewed due to the absence of automatic smear preparation for these samples.

3. Results

Results of the within-run imprecision experiment are shown in Table 1. Most of the parameters showed acceptable imprecision for both samples tested according to Ricos desirable criteria. RET count (normal patient sample), MCHC (pathological patient sample), and eosinophil count (normal and pathological patient sample) did not fulfil the Ricos

desirable criteria but were compliant with the Ricos minimal criteria. Only basophil count (pathological patient sample) and monocyte count (pathological patient sample) did not fulfil the provided desirable or minimal criteria, but these parameters had low absolute counts, which typically results in higher coefficients of variation (CVs). These parameters were acceptable compared to manufacturer's criteria. CVs for IG count are not interpretable, given very low counts measured.

Table 1. Within-run imprecision analysis. Results that are higher than the provided criterium are marked bold.

Parameter	Normal Patient Sample (n = 10)		Pathological Patient Sample (n = 6)		Criterium (% CV)
	Mean	CV	Mean	CV	
RBC count ($\times 10^{12}$/L)	5.35	0.39%	3.19	0.67%	1.60 (Ricos Desirable) [9]
HCT (%)	45.7	0.39%	28.0	0.61%	1.35 (Ricos Desirable) [9]
HGB (g/dL)	15.0	0.32%	9.4	0.59%	1.43 (Ricos Desirable) [9]
MCV (fL)	85.3	0.09%	87.9	0.34%	0.70 (Ricos Desirable) [9]
MCH (pg)	28.0	0.30%	29.3	0.67%	0.70 (Ricos Desirable) [9]
MCHC (g/dL)	32.8	0.28%	33.6	0.64%	0.80 (Ricos Minimal) [9]
RDW-CV (%)	13.9	0.38%	13.8	0.65%	1.80 (Ricos Desirable) [9]
RET count ($\times 10^{9}$/L)	0.10	5.68%	0.10	2.56%	8,25 (Ricos Minimal) [9]
PLT-I ($\times 10^{9}$/L)	242	0.81%	93	1.06%	2.15 (Ricos Desirable) [9]
MPV (fL)	10.9	0.90%	13.1	1.35%	3.80 (EFLM Desirable 2022) [10]
WBC count ($\times 10^{9}$/L)	6.61	1.33%	2.64	1.41%	5.73 (Ricos Desirable) [9]
Basophil count (/µL)	0.08	6.28%	0.01	**37.3%**	21.0 (Ricos Minimal) [9]
Eosinophil count (/µL)	0.06	12.2%	0.02	15.6%	15.7 (Ricos Minimal) [9]
Lymphocyte count (/µL)	1.32	2.65%	0.84	4.05%	5.10 (Ricos Desirable) [9]
Monocyte count (/µL)	0.69	2.65%	0.28	**13.8%**	13.3 (Ricos Minimal) [9]
Neutrophil count (/µL)	4.44	1.54%	1.43	5.24%	8.55 (Ricos Desirable) [9]

Results of the analytical performance evaluation (between-run, bias, and total error) are shown in Table 2. MCH level 2, MCHC level 1 and 2, and RDW-CV level 2 showed slightly higher CVs when compared to Ricos minimal criteria, but all results were well below the manufacturer's specifications for imprecision.

Table 2. Between-run imprecision experiment, performed with Sysmex quality control material. * Ricos desirable ** Ricos minimal [9]. Results that are higher than the provided criterium are marked in bold.

Parameter	Criterium			Level 1				Level 2			
	% CV	Bias%	TE%	Mean	% CV	Bias%	TE%	Mean	% CV	Bias%	TE%
RBC count ($\times 10^{12}$/L)	** 2.40	** 2.65	** 6.61	2.6	1.90	−0.49	3.63	4.4	1.31	2.52	4.67
HCT (%)	** 2.02	** 2.61	* 5.95	18.2	2.00	−2.00	5.29	35.8	1.73	2.70	5.56
HGB (g/dL)	** 2.14	** 2.76	** 6.29	5.9	1.96	**−3.28**	**6.51**	12.0	2.02	1.94	5.27
MCV (fL)	** 1.05	** 1.89	** 3.63	69.1	0.79	−1.43	2.73	82.1	0.85	0.09	1.49
MCH (pg)	** 1.05	** 2.02	** 3.75	22.4	**1.73**	**−2.73**	**5.58**	27.5	**1.40**	−0.57	2.88
MCHC (g/dL)	** 0.80	** 0.60	** 1.91	32.4	**1.35**	**−1.31**	**3.54**	33.6	**1.11**	**−0.68**	**2.51**
RDW-CV (%)	** 2.62	** 2.51	** 6.84	19.9	2.47	**3.72**	**7.79**	**16.9**	**6.47**	**−12.13**	**22.81**
RET count ($\times 10^{9}$/L)	* 5.50	* 7.80	* 16.80	0.14	3.35	−4.42	9.94	0.10	5.34	0.01	8.83
PLT-I ($\times 10^{9}$/L)	** 6.82	** 8.89	** 20.2	93	2.75	0.31	4.84	259	1.67	3.19	5.94
WBC ($\times 10^{9}$/L)	* 5.73	* 9.19	* 15.5	2.90	3.36	−3.58	9.12	7.0	1.84	−1.26	4.30
Basophil count (/µL)	* 14.0	* 15.4	* 38.5	0.14	6.49	−1.02	11.73	0.34	2.77	0.84	5.42
Eosinophil count (/µL)	* 10.5	* 19.8	* 37.1	0.28	8.14	−3.94	17.37	0.75	8.41	3.33	17.21
Lymphocyte count (/µL)	** 7.65	** 13.8	** 26.4	1.08	5.21	−6.09	14.68	2.23	2.71	−1.83	6.30
Monocyte count (/µL)	* 8.90	* 13.2	* 27.9	0.26	8.31	4.00	17.71	0.63	5.04	−4.33	12.65
Neutrophil count (/µL)	* 8.55	* 9.25	* 23.3	1.16	2.75	−2.98	7.52	3.07	2.77	−1.51	6.09
IG count (/µL)	/	/	/	0.30	4.51	−3.69	11.12	0.78	4.22	0.90	7.86

HCT level 2, HGB level 1, MCH level 1, MCHC level 1 and 2, and RDW-CV level 1 and 2 showed slightly higher values for bias compared to the provided criteria. HGB level 1, MCH level 1, MCHC level 1 and 2, and RDW-CV level 1 and 2 showed slightly

higher values for total error compared to the provided criteria. Since all provided criteria are sharp, results were accepted.

Results of method comparison are shown in Table 3. On both instruments, a few outliers were observed for several parameters, but these results were included in the method comparison experiment, since no underlying causes were found and there was insufficient time for reanalysis. Overall, the results are excellent. Most parameters showed acceptable correlation coefficients (R > 0.975). Absolute RET count (R = 0.42) and NRBC count (R = 0.62) showed the poorest results, possibly explained by the low absolute counts of the parameters in the majority of samples, where even a small difference can lead to a large percentage variation. Slope and intercept were calculated from Passing–Bablok regression analysis. Slope and/or intercept showed a statistically significant difference for a few parameters (Table 3), but these differences were not found to be clinically relevant. Bias was calculated from the Bland–Altman plot with its 95% confidence interval (CI). For PLT-F and PLT-O, observed bias was higher than the acceptable limit for total error (Ricos desirable criterium). However, only 18 samples were included for PLT-F, due to limited reflex testing on XN.

Table 3. Method comparison haematology parameters. Spearman's correlation coefficient was calculated. Results indicated in bold are <0.975. Intercept and slope were calculated from Passing–Bablok regression and bias was calculated from the Bland–Altman plot. Results in bold indicate a statistically significant difference.

Parameter	N	Correlation Coefficient (r) (95% CI)	Intercept (95% CI)	Slope (95% CI)	Bias (95% CI)
RBC count ($\times 10^{12}$/L)	388	0.979 (0.974 to 0.982)	0.00 (−0.05 to 0.05)	**1.02 (1.01 to 1.03)**	2.3 (−5.9 to 10.5)
HCT (%)	388	0.991 (0.989 to 0.993)	0.25 (−0.11 to 0.65)	1.01 (1.00 to 1.02)	2.0 (−4.4 to 8.4)
HGB (g/dL)	388	0.995 (0.993 to 0.996)	**−0.10 (−0.10 to −0.10)**	1.00 (1.00 to 1.00)	−0.1 (−6.0 to 5.9)
MCV (fL)	388	**0.971 (0.964 to 0.976)**	0.86 (−0.70 to 2.18)	0.98 (0.97 to 1.00)	−0.2 (−3.3 to 3.0)
MCH (pg)	388	**0.953 (0.943 to 0.962)**	0.25 (−0.80 to 1.10)	0.96 (0.94 to 1.00)	−2.3 (−7.1 to 2.5)
MCHC (g/dL)	388	**0.885 (0.862 to 0.905)**	−0.70 (−0.70 to 1.29)	1.00 (0.94 to 1.00)	−2.1 (−5.3 to 1.1)
RDW-CV (%)	388	0.991 (0.989 to 0.993)	**−0.10 (−0.10 to −0.10)**	1.00 (1.00 to 1.00)	−0.3 (−4.5 to 3.9)
RET count ($\times 10^{9}$/L)	105	**0.420 (0.238 to 0.574)**	−0.02 (−0.05 to 0.00)	**1.43 (1.07 to 1.90)**	0.05 (−0.31 to 0.40)
Ret-He (pg)	142	0.989 (0.984 to 0.992)	**2.39 (1.63 to 3.16)**	**0.92 (0.90 to 0.95)**	−0.1 (−4.2 to 4.1)
NRBC count ($\times 10^{9}$/L)	388	**0.621 (0.556 to 0.679)**	0.00 (0.00 to 0.00)	1.00 (0.79 to 1.00)	−0.01 (−0.17 to 0.16)
PLT-I ($\times 10^{9}$/L)	388	0.979 (0.974 to 0.983)	0.79 (−1.71 to 3.58)	**1.03 (1.02 to 1.04)**	2.7 (−13.5 to 18.9)
PLT-F ($\times 10^{9}$/L)	18	0.977 (0.937 to 0.991)	−4.01 (−12.3 to 1.64)	**0.88 (0.81 to 0.95)**	**−26.4 (−70.3 to 17.6)**
PLT-O ($\times 10^{9}$/L)	177	0.983 (0.978 to 0.988)	−2.00 (−4.36 to 1.98)	**0.87 (0.85 to 0.88)**	**−16.7 (−33.4 to 0.0)**
MPV (fL)	377	**0.940 (0.927 to 0.951)**	−0.13 (−0.49 to 0.30)	1.04 (1.00 to 1.08)	2.8 (−5.5 to 11.2)
WBC ($\times 10^{9}$/L)	388	0.987 (0.984 to 0.990)	0.01 (−0.03 to 0.05)	**0.98 (0.97 to 0.99)**	−2.3 (−23.4 to 18.7)
Basophiles (/µL)	319	**0.867 (0.836 to 0.892)**	0.00 (0.00 to 0.00)	1.00 (1.00 to 1.00)	0.00 (−0.03 to 0.04)
Eosinophils (/µL)	319	**0.966 (0.957 to 0.972)**	0.00 (0.00 to 0.00)	1.00 (1.00 to 1.00)	0.00 (−0.05 to 0.05)
Lymphocytes (/µL)	319	0.977 (0.971 to 0.981)	0.00 (−0.01 to 0.02)	0.99 (0.98 to 1.00	−0.4 (−35.2 to 34.4)
Monocytes (/µL)	319	**0.963 (0.954 to 0.970)**	**−0.01 (−0.03 to −0.01)**	1.00 (1.00 to 1.02)	3.0 (−41.4 to 35.4)
Neutrophils(/µL)	319	0.985 (0.981 to 0.988)	0.00 (−0.97 to 0.99)	**0.98 (0.97 to 0.99)**	−2.2 (−34.4 to 30.0)
IG (/µL)	319	**0.790 (0.745 to 0.828)**	0.00 (0.00 to 0.00)	0.98 (0.93 to 1.00)	−0.01 (−0.16 to 0.14)

Both analysers generate flaggings from the four different measurement channels. The XR-20 analyser flagged a total of 104 samples, while the XN-2000 analysers flagged 95 samples. Results from kappa statistics and concordance calculation are shown in Table 4. Most frequently generated flaggings in our study were "Blast/Abn Lympho?" and "IG Present" (both generated in the WDF channel), "PLT Clumps?" (generated from the WNR and/or WDF channel), and "Abn Lympho?" (generated in the WPC channel after "Blast/Abn lympho?" flagging). All RBC, PLT, and nearly all WBC flaggings showed excellent global concordance (>0.900). In total, 42 samples were reanalysed in the WPC-channel after initial flagging in the WDF-channel, with 10 samples flagged for "Blast/Abn Lympho?" on the XN but not on the XR. In 6 out of 10 samples, the flagging was removed after reflex in the WPC channel. The other four samples were microscopically reviewed, three were considered normal, and in one sample, a comment of reactive lymphocytes was

added, but there was no absolute lymphocytosis. Conversely, nine samples were flagged with "Blast/Abn Lympho?" on the XR but not on the XN, and in only one of these samples the flagging was removed in the WPC channel. Since the XR-20 was not connected to an automated slide-maker and -stainer, there were no smears made of these samples. Global concordance for this flagging was 0.949 and kappa coefficient was 0.679, indicating a good association. The "Blast/Abn Lympho?" flagging in the WDF channel showed comparable performance between the two analysers. The positivity rates were similar: 8.9% (33/369) for XN and 8.7% (32/388) for XR. The XR retained more "Blast/Abn Lympho?" flags than the XN after reanalysis in the WPC channel: in 56.3% (18/32) of cases, the XR converted samples to "Abn Lympho?", compared to 42.4% (14/33) for the XN. Additionally, in 25.0% (8/32) of cases, the XR converted samples to "Blast?", whereas the XN converted only 12.1% (4/33) of samples. In 81.3% (26/32) of samples, the flag was retained on XR after WPC reflex, whereas the flag was retained in only 54.5% (18/33) of samples on XN. However, this difference was not statistically significant using the Chi-squared test ($p = 0.377$).

Table 4. Comparison of flagging performance.

Flagging	XN-2000 (n)	XR-20 (n)	Concordance	Kappa Coefficient
Blast/Abn Lympho	33	32	0.949	0.679
Abn Lympho?	14	18	0.714	0.400
Blasts?	4	8	0.762	0.045
Atypical lympho?	1	0	0.997	0.000
WBC Abn Scattergram	16	15	0.987	0.832
IG Present	23	21	0.987	0.902
Left Shift?	16	22	0.981	0.832
Turbidity/HGB Interf?	3	1	0.995	0.498
RET Abn Scattergram	13	11	0.962	0.812
Fragments?	4	3	0.971	0.557
HGB Defect?	3	4	0.992	0.568
Iron Deficiency?	3	3	1.000	1.000
RBC Abn Distribution	2	2	1.000	1.000
Dimorphic population	2	2	1.000	1.000
NRBC Present	7	5	0.995	0.831
PLT Clumps?	20	19	0.951	0.487
PLT Abn Distribution	14	19	0.987	0.842

4. Discussion

To evaluate Sysmex' new automated haematology analyser, the Sysmex XR-20 was validated as a demo analyser in our laboratory in the AZ Sint-Lucas hospital in Bruges, Belgium. The Sysmex XR is the successor of the automated haematology analyser Sysmex XN-Series, with comparable features. The most important improvements include a slightly enhanced sample throughput, the possibility to see the 3D scatterplots in the IPU software, enhanced separation between eosinophils and neutrophils, and improved blast/abnormal lymphocyte flagging in the WDF channel due to a new Lysercell WDF II reagent.

Overall, our results for within- and between-run imprecision experiments are comparable to those recently published for the XR-analyser by Fujimaki et al. However, they only evaluated WBC, relative neutrophil count, relative lymphocyte count, relative monocyte count, and relative eosinophil count in their precision experiments [8]. The calculated CVs in our study correspond well to our provided criteria. Also, obtained CVs are comparable to previously published studies evaluating the Sysmex XN-Series [1–4,11].

Our method comparison demonstrated excellent results for most parameters. The poorest results were obtained for the absolute RET and NRBC counts, but this was due to low absolute numbers of measured reticulocytes and NRBC's. A study performed by Bruegel et al., which compared five automated haematology analysers, observed also

comparable low results in method comparison for RET and NRBC counts [12]. The study performed by Fujimaki et al. conducted a method performance for the new Sysmex XR on 7460 samples. Although our dataset was much smaller, our results for correlation coefficients, intercept and slope, and bias with its 95% CI were comparable to those obtained by this study [8].

Excellent global concordance (>0.9) was calculated for all RBC and PLT flaggings between the new Sysmex XR-20 and XN-2000 analysers. Similar to the study performed by Fujimaki et al., the most frequently generated WBC flag in our study was the "Blast/Abn Lympho?" flag. A similar global concordance was obtained (94.9% in our study compared to 91.4% obtained by Fujimaki et al.). Both studies observed comparable positivity rates for the XN- and XR-analysers: Fujimaki et al. reported 22.7% and 21.4%, respectively, whereas our study found rates of 8.7% and 8.3%, respectively [8]. The results of our study are lower as in the other study an enriched sample pool was used. The "Blast/Abn Lympho?" flag is generated in the WDF channel but can be further specified in the WPC channel into suspect flags "Blasts?" and/or "Abn Lympho?", or the initial flag can be removed [5]. The major advantage of this channel is the reduced smear rate [4,5]. Compared to Fujimaki et al., our data confirmed there was no statistically significant difference in smear reduction rate between both analysers [8]. Additionally, when combining the flags generated in the WPC channel with positional lymphocyte parameters, the discrimination between malignant and reactive lymphocytosis can be further enhanced. These findings were recently published by Chiriac et al., who explored the differentiation between blasts and abnormal lymphocytes using the new Sysmex XR-Series [13].

We conducted only microscopy as a reflex for flagged samples on the Sysmex XN, and not for each sample, so sensitivity and specificity of the Sysmex XR towards microscopy could not be evaluated. There were no samples that showed a poor separation between the eosinophils and the neutrophils (eosinophil count suspicious flagging) on the XN, so this improved feature of the XR analyser could not be evaluated during this study. Low WBC mode could not be evaluated because only two samples had WBC counts < 500/µL. The enhanced throughput was not evaluated, and a stability experiment was not conducted. Furthermore, evaluation of the body fluid channel fell outside the scope of this study.

5. Conclusions

Overall, Sysmex XR is an excellent successor to the Sysmex XN for routine haematology analysis. Analytical performance and flagging efficiency are comparable to the XN analyser.

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Abbreviations

The following abbreviations are used in this manuscript:

BF	body fluid
CVs	coefficients of variation
CBC	complete blood count
CI	confidence interval
EFLM	European Federation of Clinical Chemistry and Laboratory Medicine
EPU	Extended Processing Unit
PLT-F	fluorescent platelet
HCT	haematocrit
HGB	haemoglobin
IG	immature granulocyte
PLT-I	impedance platelet count
IPU	Integrating Processing Unit
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MPV	mean platelet volume
NRBC	nucleated red blood cell
PLT-O	optical platelet count
PLT	platelet
RBC	red blood cell
RDW-CV	red blood cell distribution width – CV
RET	reticulocyte
Ret-He	reticulocyte haemoglobin equivalent
WBC	white blood cell
WDF	white cell differential
WNR	white cell nucleated
WPC	white pathological and precursor

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