

Blood Diagnostics Reimagined



sight

OLO Evaluation Report Comparison of OLO to Other Hematology Analysers

Intended for international audience outside of the US

Summary

Sight OLO® is a quantitative multi-parameter hematology analyzer that performs complete blood count (CBC) analysis for capillary or venous whole-blood samples, using a novel sample preparation method. The analyzer is based on a machine-vision technology that combines automated fluorescence digital microscopy with computer-vision algorithms for image processing.

The following report summarizes clinical method comparison studies, which aimed to compare the performance of OLO to different comparative hematology analyzers, and to evaluate its accuracy compared to the existing methods used by local labs.

The studies were conducted in various institutes and clinical settings in different countries, while comparing OLO to multiple comparative devices that are based on different technologies: Sysmex® XN-1000 at an oncology lab, Beckman Coulter® DxH 900 at the central lab of a public hospital, Sysmex XN-2000 at the central lab of a children's hospital, Sysmex XN-1000 at the central lab of a public hospital, Siemens Advia® 2120i at the central lab of a public hospital, and Horiba ABX Pentra XL 80 at the pathology lab of a private hospital.

At each evaluating site, fresh residual K2EDTA whole blood samples were collected from patients (age of ≥ 3 months) with normal¹ and abnormal blood counts, to cover a wide clinical range across the different measurands (610 samples in total across all studies). Each sample was tested on both the comparative device and OLO, with the two scans completed within 2 hours, and no more than 8 hours from blood collection.

The samples were collected over periods of 4-6 weeks and were scanned by 2-5 operators in total at each site, thus showing the high robustness of OLO over time and over different users.

Passing Bablok regression analyses were performed between each comparative device and OLO for each measurand² (see the results below).

The results of the method comparison studies show OLO's excellent performance and equivalence to various comparative analyzers. The comparability of OLO to each analyzer was exhibited across a wide variety of patients, both normal and abnormal, while covering a wide analytical measuring range. Furthermore, in light of the high agreement shown between OLO and the comparative analyzers tested, OLO has been found suitable to a variety of clinical settings, including a children's hospital, and an oncology department characterised by patients with especially low blood counts.

OLO is CE Marked according to the IVD European directive for performing CBC tests in point of care settings. The device is also FDA 510(k) cleared for use in moderately complex settings in the United States. For full indications for use and safety information, please refer to the Quality and Compliance page at www.sightdx.com.

¹ For the purpose of these studies, normal was defined as within predefined normal count ranges and with no flags, according to the comparative device.

² Measurands which were invalidated by either OLO or the comparative device, as well as measurands outside the OLO analytical measurement range (AMR), were removed from the analysis.

OLO Performance - Results

The tables below present the correlation, slope, intercept, and bias values retrieved for each CBC measurand at each evaluation study. These comparative clinical study data and results are available upon request.

Sysmex XN-1000 at the Central Lab of a Public Hospital³

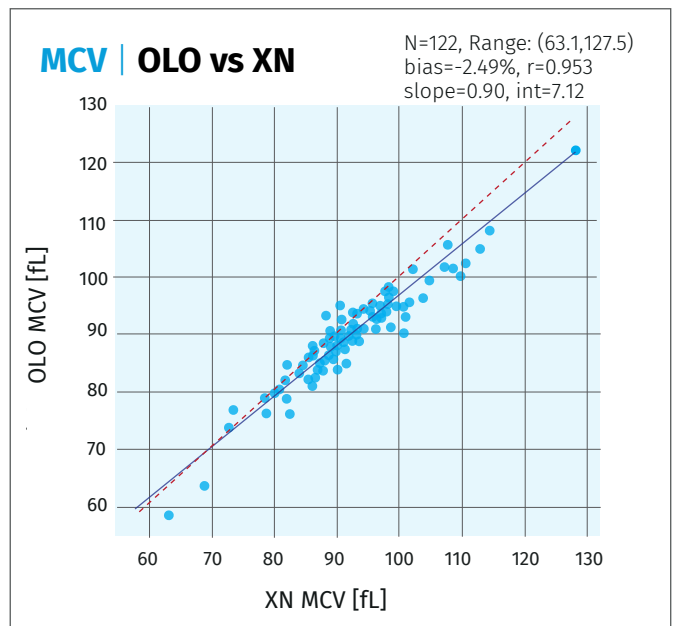
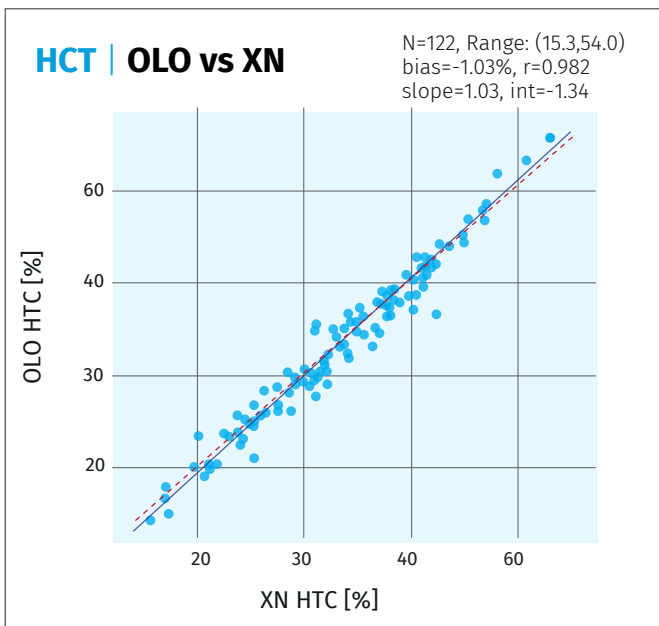
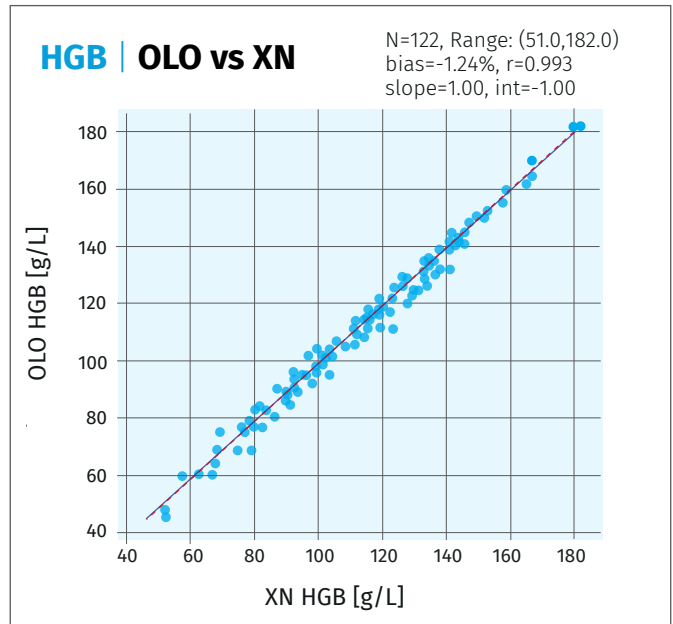
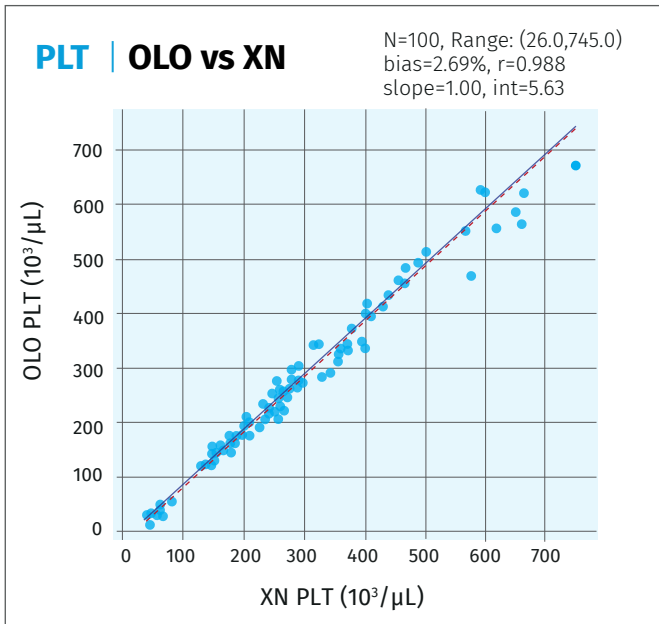
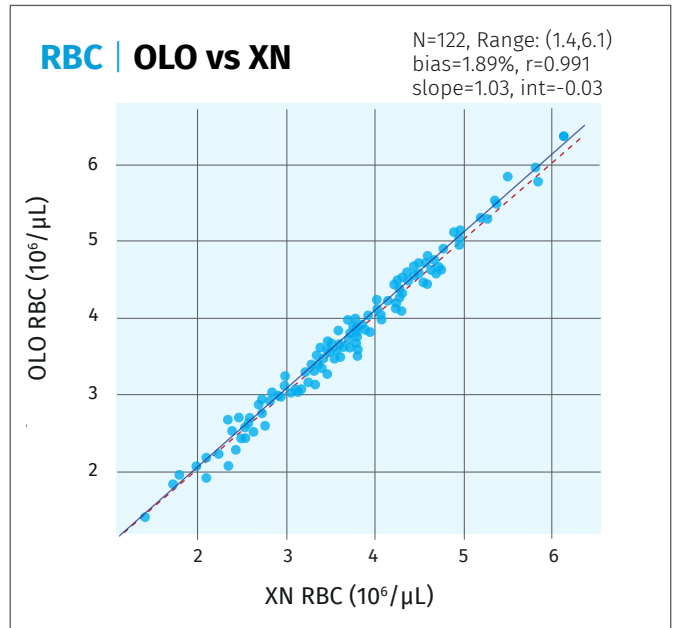
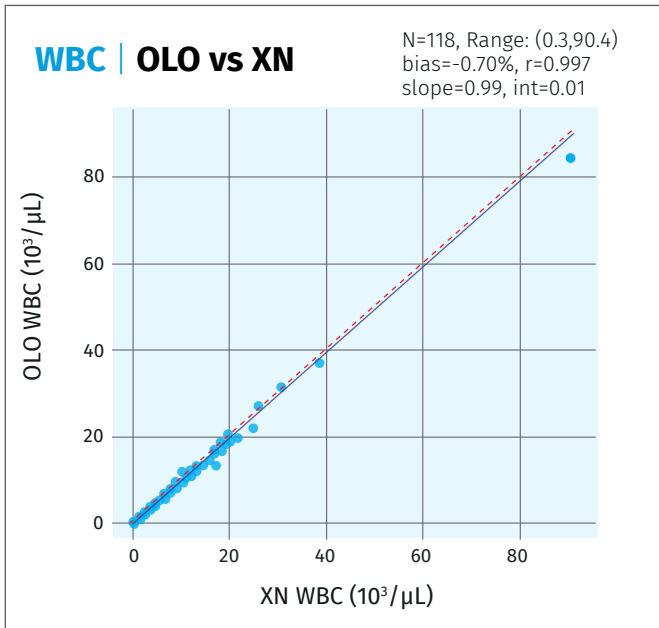
123 whole blood samples were collected from patients older than 3 months with normal and abnormal blood counts, and arrived at the hospital central lab from different hospital wards and departments.

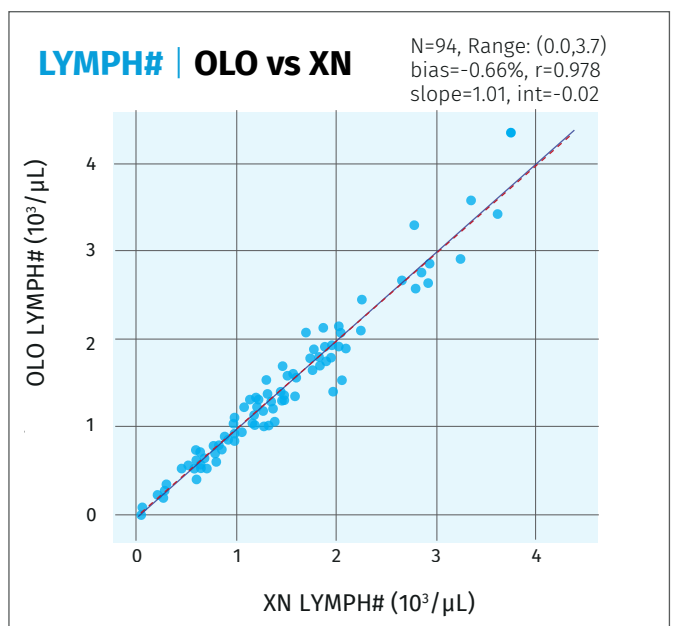
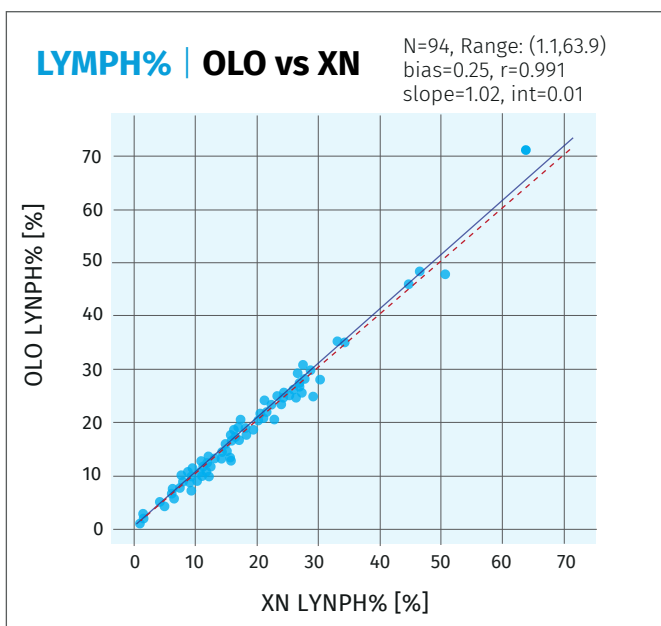
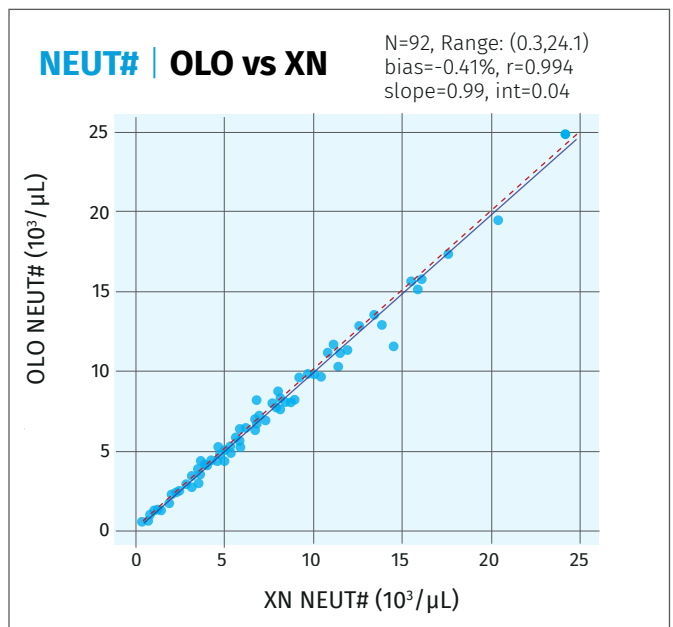
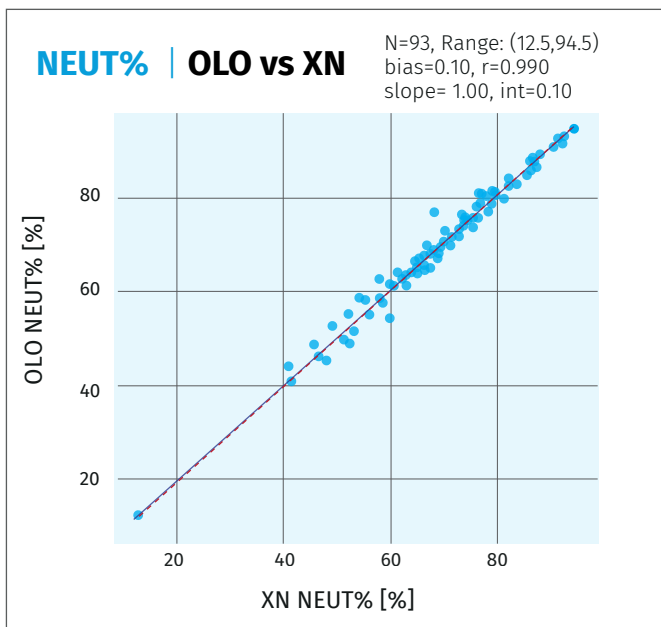
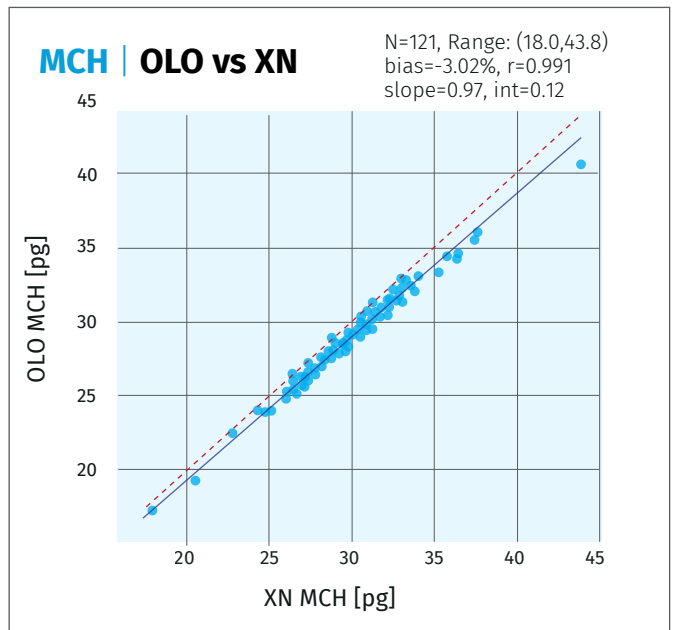
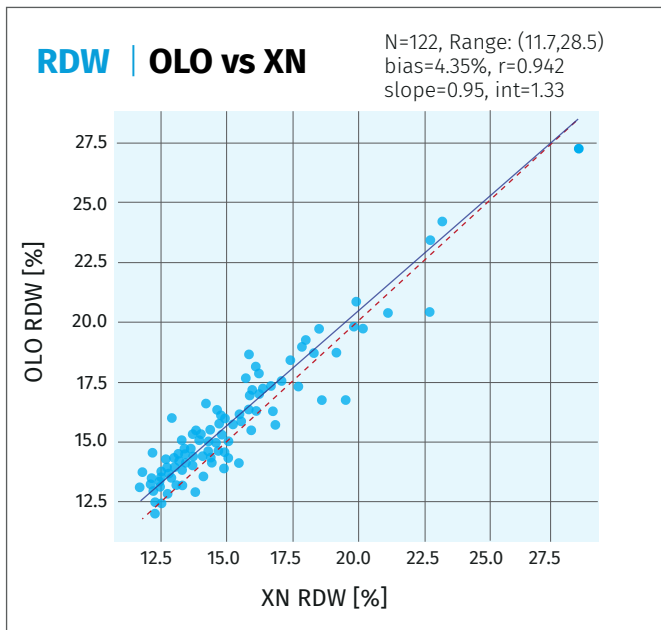
	N	Range	Correlation	Slope	Intercept	Relative Bias	Absolute Bias
WBC [$10^3/\mu\text{L}$]	118	0.3 to 90.4	0.997	0.991	0.01	-0.70	-0.04
RBC [$10^6/\mu\text{L}$]	122	1.4 to 6.1	0.991	1.027	-0.03	1.89	0.07
PLT [$10^3/\mu\text{L}$]	100	26.0 to 745.0	0.988	0.998	5.63	2.69	5.00
HGB [g/L]	122	51.0 to 182.0	0.993	1.000	-1.00	-1.24	-1.00
HCT [%]	122	15.3 to 54.0	0.982	1.033	-1.34	-1.03	-0.30
MCH [pg]	121	18.0 to 43.8	0.991	0.966	0.12	-3.02	-0.90
RDW [%]	122	11.7 to 28.5	0.942	0.951	1.33	4.35	0.60
MCV [fL]	122	63.1 to 127.5	0.953	0.897	7.12	-2.49	-2.30
NEUT# [$10^3/\mu\text{L}$]	92	0.3 to 24.1	0.994	0.987	0.04	-0.41	-0.03
LYMPH# [$10^3/\mu\text{L}$]	94	0.0 to 3.7	0.978	1.007	-0.02	-0.66	-0.01
MONO# [$10^3/\mu\text{L}$]	85	0.2 to 4.1	0.980	0.962	-0.04	-8.33	-0.07
EOS# [$10^3/\mu\text{L}$]	85	0.0 to 1.4	0.965	1.062	0.02	28.57	0.03
BASO# [$10^3/\mu\text{L}$]	89	0.0 to 0.1	0.622	1.333	-0.01	NaN	0.00

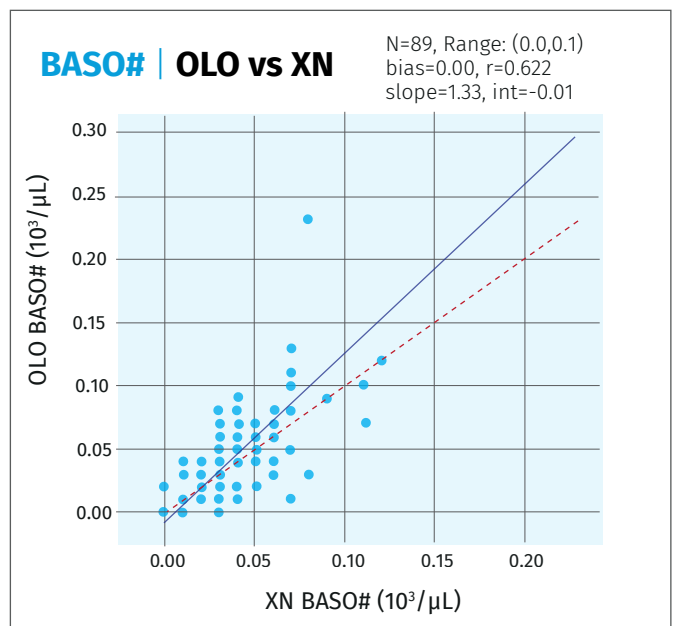
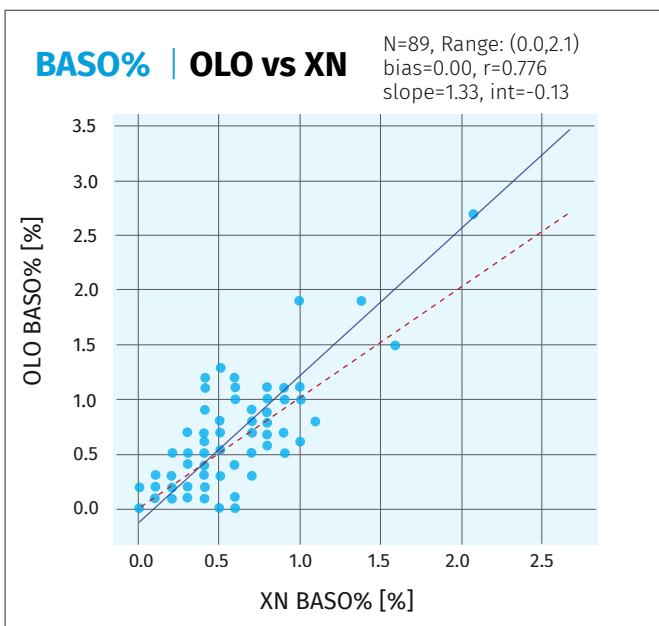
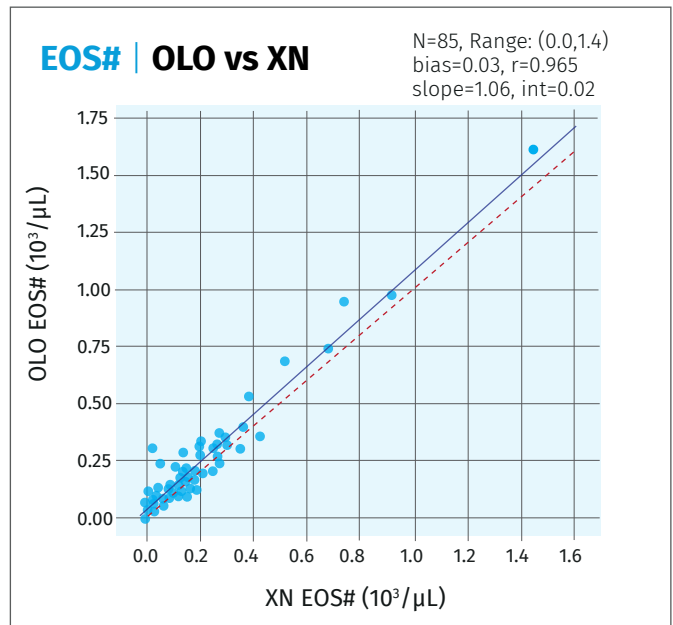
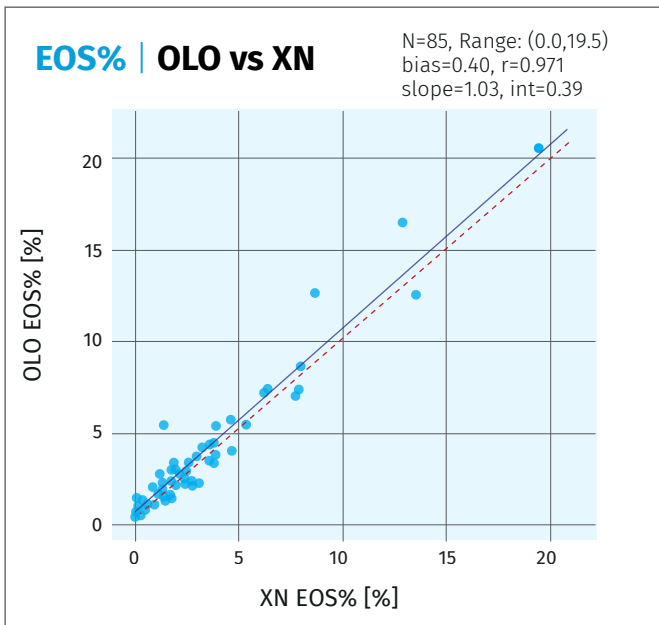
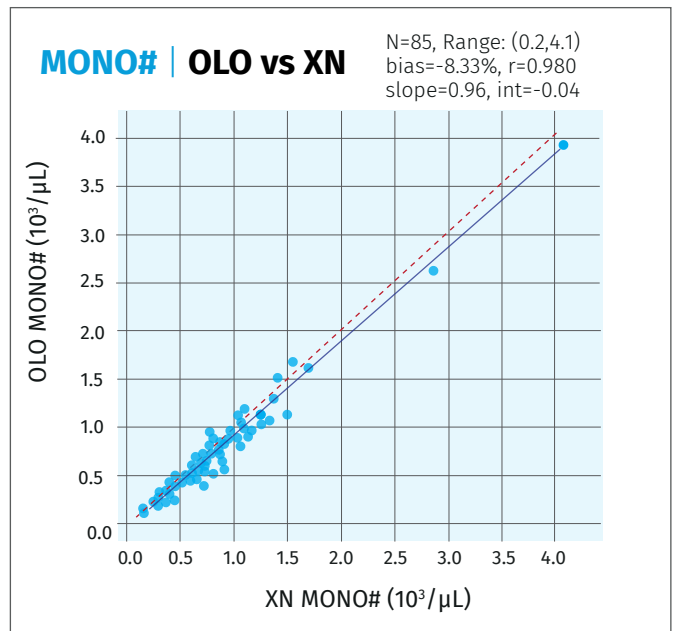
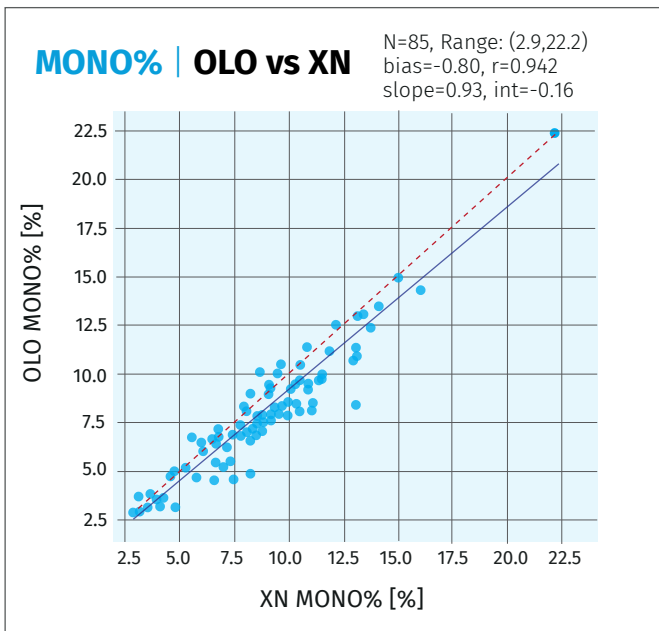
The findings are further detailed in the plots below, with the regression analysis results presented for each measurand. In each plot, Sysmex XN-1000 results are shown in the horizontal axis while OLO results are shown in the vertical axis. The correlation, best linear fit (Passing-Bablok regression) and relative bias⁴ are presented, as well as the regression (blue) line and identity (dashed red) line.

³ One major Eos outlier (> 8 SD from mean) - in which the Sysmex result obtained in the study was extremely different from the OLO result as well as from the original lab result of Sysmex - was removed from the analysis.

⁴ Relative bias is used for all measurands except Baso and Eos, where absolute bias is used.







Sysmex XN-1000 at the Oncology Lab of a Public Hospital

55 whole blood samples were collected from oncological patients older than 3 months with severely low PLT counts, and arrived at the hospital oncology lab. As the study's focus was on this low range, the results include values outside the OLO AMR⁵, thus showing its excellent performance in enumerating low PLT counts.

	N	Range	Correlation	Slope	Intercept	Relative Bias	Absolute Bias
WBC [$10^3/\mu\text{L}$]	50	0.0 to 13.6	0.998	0.970	-0.00	-3.01	-0.03
RBC [$10^6/\mu\text{L}$]	55	1.7 to 5.8	0.980	0.936	0.18	0.32	0.01
PLT [$10^3/\mu\text{L}$]	15	2.0 to 32.0	0.864	1.021	0.35	3.23	1.00
HGB [g/L]	55	53.0 to 164.0	0.971	0.926	7.67	1.30	1.00
HCT [%]	55	16.3 to 48.9	0.958	0.898	2.26	-0.45	-0.10
MCH [pg]	55	23.1 to 35.9	0.987	1.000	0.40	1.32	0.40
RDW [%]	55	10.7 to 22.4	0.919	0.978	0.93	4.07	0.60
MCV [fL]	55	78.7 to 110.2	0.934	0.934	5.48	-0.35	-0.30
NEUT# [$10^3/\mu\text{L}$]	9	1.1 to 6.2	0.988	0.981	-0.01	-2.23	-0.04
LYMPH# [$10^3/\mu\text{L}$]	11	0.6 to 2.6	0.993	0.873	0.12	-3.06	-0.06

* Due to the high rate of samples which had at least one measurand invalidated by Sysmex XN (>70% of all samples), as a second stage, Sysmex XN invalid measurands were included in the analysis:

	N	Range	Correlation	Slope	Intercept	Relative Bias	Absolute Bias
WBC [$10^3/\mu\text{L}$]	50	0.0 to 13.6	0.998	0.970	-0.00	-3.01	-0.03
RBC [$10^6/\mu\text{L}$]	55	1.7 to 5.8	0.980	0.936	0.18	0.32	0.01
PLT [$10^3/\mu\text{L}$]	51	2.0 to 40.0	0.912	0.923	3.08	16.67	2.00
HGB [g/L]	55	53.0 to 164.0	0.971	0.926	7.67	1.30	1.00
HCT [%]	55	16.3 to 48.9	0.958	0.898	2.26	-0.45	-0.10
MCH [pg]	55	23.1 to 35.9	0.987	1.000	0.40	1.32	0.40
RDW [%]	55	10.7 to 22.4	0.919	0.978	0.93	4.07	0.60
MCV [fL]	55	78.7 to 110.2	0.934	0.934	5.48	-0.35	-0.30
NEUT# [$10^3/\mu\text{L}$]	26	0.0 to 6.2	0.996	0.983	-0.00	-1.12	-0.00
LYMPH# [$10^3/\mu\text{L}$]	27	0.1 to 2.6	0.996	0.930	0.02	-1.95	-0.01

⁵ Note that the established OLO AMR for PLT is limited at the lower range by technical issues with depleting PLT from the samples used for establishing the Limit of Blank and Limit of Detection of OLO and does not reflect on the actual low PLT detection of the OLO, as shown in this analysis.

Beckman Coulter DxH 900 at the Central Lab of a Public Hospital

90 whole blood samples were collected from patients older than 3 months with normal and abnormal blood counts, and arrived at the hospital central lab from different hospital wards and departments.

	N	Range	Correlation	Slope	Intercept	Relative Bias	Absolute Bias
WBC [$10^3/\mu\text{L}$]	81	0.6 to 78.2	0.999	0.984	-0.04	-2.04	-0.12
RBC [$10^6/\mu\text{L}$]	88	2.1 to 7.3	0.993	1.038	-0.22	-1.79	-0.08
PLT [$10^3/\mu\text{L}$]	76	15.2 to 793.7	0.988	1.020	5.31	4.87	7.00
HGB [g/L]	89	62.3 to 187.0	0.995	1.013	-4.66	-2.93	-3.10
HCT [%]	88	19.1 to 57.1	0.991	1.016	-1.46	-2.58	-0.85
MCH [pg]	88	17.3 to 38.2	0.972	1.012	-0.58	-0.74	-0.22
RDW [%]	88	11.8 to 26.4	0.947	0.943	0.05	-5.37	-0.76
MCV [fL]	88	56.9 to 110.6	0.978	0.996	-0.46	-0.94	-0.88
NEUT# [$10^3/\mu\text{L}$]	81	0.1 to 38.6	0.995	0.987	0.00	-0.73	-0.01
LYMPH# [$10^3/\mu\text{L}$]	75	0.2 to 72.1	1.000	0.993	0.01	0.62	0.01
MONO# [$10^3/\mu\text{L}$]	72	0.0 to 2.8	0.938	0.857	0.00	-12.90	-0.05
EOS# [$10^3/\mu\text{L}$]	54	0.0 to 1.1	0.919	0.974	0.01	6.48	0.01
BASO# [$10^3/\mu\text{L}$]	54	0.0 to 0.3	0.543	0.543	-0.00	-49.36	-0.02

Sysmex XN-2000 at the Central Lab of a Children's Hospital

121 whole blood samples were collected from 4 different age groups of patients (25 babies: $\geq 3\text{m}$ & $< 2\text{y}$, 35 children: $\geq 2\text{y}$ & $< 12\text{y}$, 29 adolescents: $\geq 12\text{y}$ & $< 18\text{y}$, 30 transitional adolescents: $\geq 18\text{y}$ & $< 21\text{y}$, 1 adult sample and 1 samples with no age information available) with normal and abnormal blood counts, arriving at the children's hospital.

	N	Range	Correlation	Slope	Intercept	Relative Bias	Absolute Bias
WBC [$10^3/\mu\text{L}$]	116	0.3 to 63.7	0.998	0.989	-0.15	-3.17	-0.23
RBC [$10^6/\mu\text{L}$]	119	2.4 to 6.2	0.989	0.925	0.36	1.06	0.04
PLT [$10^3/\mu\text{L}$]	106	21.0 to 693.0	0.981	0.944	13.57	0.65	1.50
HGB [g/L]	120	66.0 to 172.0	0.991	0.941	5.76	-0.87	-1.00
HCT [%]	119	19.3 to 50.9	0.982	0.927	2.84	0.64	0.20
MCH [pg]	118	21.1 to 33.9	0.985	1.000	-0.60	-1.95	-0.60
RDW [%]	119	11.0 to 25.7	0.955	0.922	1.24	1.55	0.20
MCV [fL]	119	69.2 to 106.1	0.944	0.986	0.80	-0.29	-0.20
NEUT# [$10^3/\mu\text{L}$]	89	1.4 to 19.5	0.995	0.999	0.00	0.00	0.00
LYMPH# [$10^3/\mu\text{L}$]	78	0.5 to 10.4	0.993	0.955	0.01	-4.05	-0.08
MONO# [$10^3/\mu\text{L}$]	75	0.2 to 3.4	0.978	0.888	-0.04	-17.91	-0.11
EOS# [$10^3/\mu\text{L}$]	72	0.0 to 1.4	0.985	0.944	0.01	NaN	0.01
BASO# [$10^3/\mu\text{L}$]	74	0.0 to 0.2	0.781	1.000	-0.01	NaN	-0.01

Sysmex XN at a Private GP Clinic⁶

30 randomly selected whole blood samples were collected from patients older than 3 months arriving at the GP clinic, and were sent to an adjacent central lab for comparison.

	N	Range	Correlation	Relative Bias	Absolute Bias
WBC [$10^3/\mu\text{L}$]	30	2.8 to 13.9	0.980	-3.21	-0.24
RBC [$10^6/\mu\text{L}$]	30	3.6 to 5.9	0.958	0.11	0.00
PLT [$10^3/\mu\text{L}$]	30	32.0 to 468.0	0.968	1.72	4.50
HGB [g/L]	30	118.0 to 167.0	0.935	0.62	1.00
HCT [%]	30	34.5 to 49.9	0.894	0.67	0.25
MCH [pg]	30	24.0 to 33.8	0.981	0.62	0.20
RDW [%]	30	11.3 to 15.4	0.906	2.40	0.30
MCV [fL]	30	75.0 to 99.8	0.932	1.55	1.40
NEUT# [$10^3/\mu\text{L}$]	28	1.0 to 11.4	0.993	-0.34	-0.01
LYMPH# [$10^3/\mu\text{L}$]	24	0.9 to 3.4	0.925	-3.60	-0.08
MONO# [$10^3/\mu\text{L}$]	23	0.2 to 0.8	0.840	-25.53	-0.14
EOS# [$10^3/\mu\text{L}$]	24	0.0 to 0.5	0.944	0.00	0.00
BASO# [$10^3/\mu\text{L}$]	24	0.0 to 0.1	0.716	-22.50	-0.01

Horiba ABX Pentra XL 80 at the Pathology Lab of a Private Hospital⁷

92 whole blood samples were collected from patients older than 3 months with normal and abnormal blood counts, and arrived at the hospital pathology lab from different hospital wards and departments.

	N	Range	Correlation	Slope	Intercept	Relative Bias	Absolute Bias
WBC [$10^3/\mu\text{L}$]	79	1.2 to 10.0	0.990	1.009	-0.12	-1.74	-0.08
RBC [$10^6/\mu\text{L}$]	83	2.0 to 6.3	0.986	0.965	0.04	-2.36	-0.09
PLT [$10^3/\mu\text{L}$]	79	91.0 to 731.0	0.984	0.859	19.96	-6.31	-15.00
HGB [g/L]	91	58.0 to 191.0	0.990	0.956	-0.24	-4.67	-6.00
HCT [%]	83	0.2 to 0.6	0.978	0.955	-0.00	-5.29	-0.02
MCH [pg]	92	20.2 to 45.1	0.987	0.955	0.59	-2.61	-0.80
RDW [%]	92	10.4 to 18.9	0.823	1.154	-0.75	9.28	1.15
MCV [fL]	83	82.0 to 105.0	0.947	1.050	-7.05	-2.48	-2.40
NEUT# [$10^3/\mu\text{L}$]	65	0.5 to 8.3	0.989	1.038	-0.12	-0.99	-0.02
LYMPH# [$10^3/\mu\text{L}$]	53	0.6 to 2.8	0.967	1.028	-0.14	-6.96	-0.09
MONO# [$10^3/\mu\text{L}$]	53	0.0 to 0.9	0.893	0.933	-0.00	-8.33	-0.03
EOS# [$10^3/\mu\text{L}$]	50	0.0 to 1.1	0.971	1.122	-0.03	-17.29	-0.02
BASO# [$10^3/\mu\text{L}$]	51	0.0 to 0.1	0.145	5.000	-0.07	100.00	0.01

⁶ Due to the small sample size, the slope and intercept have low statistical significance and therefore are not presented.

⁷ The relatively low Baso correlation can be due to this parameter being especially susceptible to differences in measuring technologies. This is supported in other comparative studies. For example:

Meintker, L., Ringwald, J., Rauh, M., & Krause, S. W. (2013). Comparison of automated differential blood cell counts from Abbott Sapphire, Siemens Advia 120, Beckman Coulter DxH 800, and Sysmex XE-2100 in normal and pathologic samples. *American journal of clinical pathology*, 139(5), 641-650.

Siemens Advia 2120i at the Central Lab of a Public Hospital⁸

99 whole blood samples were collected from patients older than 3 months with normal and abnormal blood counts, and arrived at the hospital central lab from different hospital wards and departments.

	N	Range	Correlation	Slope	Intercept	Relative Bias	Absolute Bias
WBC [$10^3/\mu\text{L}$]	93	0.7 to 52.6	0.996	0.937	-0.00	-6.33	-0.44
RBC [$10^6/\mu\text{L}$]	98	2.4 to 6.8	0.985	1.040	-0.30	-3.38	-0.13
PLT [$10^3/\mu\text{L}$]	95	12.0 to 1144.0	0.983	0.882	14.76	-4.41	-9.00
HGB [g/L]	99	76.0 to 203.0	0.991	1.063	-12.69	-4.42	-5.00
HCT [%]	97	20.7 to 56.4	0.976	1.046	-3.56	-5.13	-1.90
MCH [pg]	98	17.7 to 35.0	0.942	1.000	-0.30	-1.07	-0.30
RDW [%]	96	12.2 to 22.0	0.928	1.378	-4.97	3.07	0.40
MCV [fL]	98	70.3 to 108.6	0.955	1.092	-9.61	-1.50	-1.25
NEUT# [$10^3/\mu\text{L}$]	91	0.1 to 19.6	0.995	0.923	0.01	-7.23	-0.34
LYMPH# [$10^3/\mu\text{L}$]	88	0.3 to 42.1	0.995	1.005	-0.04	-1.76	-0.03
MONO# [$10^3/\mu\text{L}$]	80	0.0 to 1.4	0.850	1.241	-0.01	21.37	0.08
EOS# [$10^3/\mu\text{L}$]	65	0.0 to 0.6	0.906	1.000	0.01	2.86	0.01
BASO# [$10^3/\mu\text{L}$]	65	0.0 to 3.4	0.304	1.250	-0.01	NaN	0.00

⁸ The relatively low Baso# correlation is due to 2 severe lymphocytotic samples in which the Advia reported high Baso#. When inspected by manual smear review, no Basophils were found, in agreement with OLO results. When removing these samples from the analysis, the correlation coefficient is 0.617.

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Glossary of Terms and Abbreviations

CBC	Complete Blood Count	HGB	Hemoglobin
K₂EDTA	Dipotassium Ethylenediaminetetraacetic Acid	MCH	Mean Corpuscular Hemoglobin
LYMPH%#	Lymphocyte (percentage and absolute count)	MCV	Mean Corpuscular Volume
EOS%#	Eosinophil (percentage and absolute count)	PLT	Platelets
BASO%#	Basophil (percentage and absolute count)	RBC	Red Blood Cells
MONO%#	Monocyte (percentage and absolute count)	WBC	White Blood Cells
NEUT%#	Neutrophil (percentage and absolute count)	RDW	Red Blood Cell Distribution Width
HCT	Hematocrit		

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