sight

Lab-grade accuracy from a near-patient CBC analyzer

The Current State of POC CBC Analyzers

In recent years, technological advances have made point-of-care (POC) complete blood count (CBC) analyzers increasingly prevalent and practical. POC CBC analyzers are critical because they shorten the turnaround time from sample collection to test results. This ability to process whole blood quickly and simply allows staff with various experience levels to carry out diagnostic processes[1].

However, gaps in the market for POC hematology analyzers capable of CBC tests have existed for some time[2]. POC CBC analyzers require the use of wet reagents and frequent quality control (QC) to maintain lab-grade functionality[1,2]. Other limitations in CBC POC analyzers include reduced amounts of parameters, limited flagging capabilities and narrower reportable ranges[3].

The Sight OLO® CBC Analyzer

Sight Diagnostics' OLO is a POC CBC analyzer that delivers lab-grade CBC results without the limitations of many POC devices[4]. OLO achieves its accurate results through a combination of advanced digital microscopy and an AI algorithm. OLO delivers lab-grade 19-parameter and 5-part differential CBC results within just minutes that are comparable to those delivered by other analyzers in the central laboratory[4].

A recent study in the American Journal of Hematology demonstrated a comprehensive validation of the performance of OLO CBC analyzer in comparison to a standard lab-grade analyzer[4], demonstrating its accuracy and reliability[4].

Comparable accuracy and capability to a standard lab-grade CBC analyzer[4]

To put OLO to the test, the device's accuracy, repeatability, and flagging capabilities were compared against a standard lab-grade analyzer, the Sysmex XN-Series System in a multi-center trial. The data show that OLO had excellent concordance with results from the Sysmex XN-Series.

Specifically, the study found that main measures such as: total WBC count, total RBC count, total platelet (PLT) count, hemoglobin (HGB), total lymphocyte (LYMPH #) count, and total neutrophil (NEUT #) count each had a correlation coefficient (r) greater than 0.985. This means that OLO and the Sysmex XN-Series yielded comparable accuracy. Additionally, OLO demonstrated high repeatability for most of the testing parameters.

Altogether, method comparison, repeatability, and reproducibility studies demonstrate that OLO provides CBC results that are comparable with the Sysmex XN-Series across a wide measuring range, including in highly challenging samples (e.g., atypical lymphocytes).

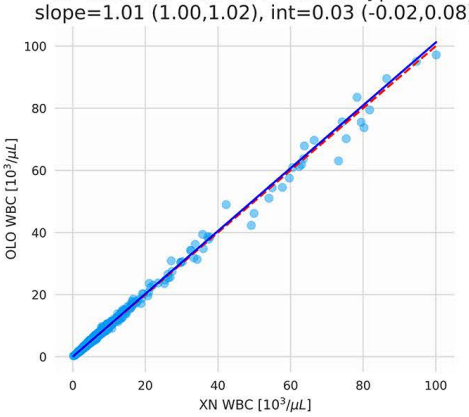
Results

Summary of the method comparison study comparing the Sight OLO and the Sysmex XN

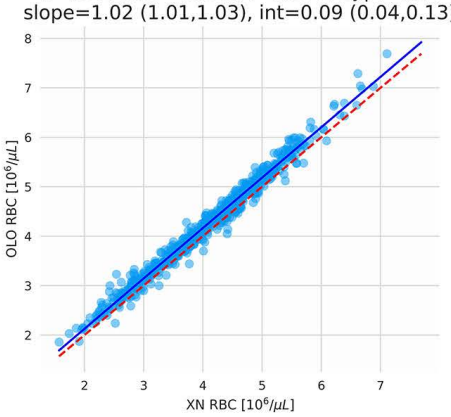
Measurand	N	Results Range	Correlation Coefficient (r)	Slope (95% CI)	Intercept (95% CI)v	Median Bias	Median Relative Bias (%)
White Blood Cell (WBC) x10³/µL	608	0.30 to 97.16	0.997	1.011 (1.003, 1.020)	0.033 (-0.016, 0.082)	0.1	1.6
Red Blood Cell (RBC) x10⁶/µL	657	1.86 to 7.69	0.991	1.019 (1.008, 1.030)	0.089 (0.043, 0.129)	0.16	4.1
Platelet Count (PLT) x10³/µL	624	22 to 985	0.985	1.006 (0.994, 1.021)	8.937 (6.103, 11.801)	10	5.2
Hemoglobin (HGB) g/dL	673	4.9 to 21.2	0.990	1.031 (1.020, 1.042)	-0.028 (-0.150, 0.104)	0.3	2.9
Hematocrit (HCT)	657	15.2 to 63.7	0.982	1.030 (1.014, 1.045)	-0.639 (-1.214, -0.044)	0.4	1.3
Mean Corpuscular Volume (MCV) fL	657	57.3 to 121.2	0.941	0.889 (0.862, 0.916)	7.489 (5.119, 9.821)	-2.3	-2.6
Red Blood Cell Distribution Width (RDW)	647	10.6 to 29.4	0.939	1.000 (0.980, 1.036)	-0.100 (-0.607, 0.171)	-0.1	-0.7
Mean Corpuscular Hemoglobin (MCH) pg	652	14.9 to 42.0	0.978	1.000 (0.986, 1.007)	-0.400 (-0.583, 0.046)	-0.4	-1.3
Mean Corpuscular Hemoglobin (MCH) pg	652	26.0 to 36.6	0.693	0.667 (0.625, 0.731)	11.567 (9.431, 12.944)	0.5	1.5
Neutrophil Percent (NEUT%)	419	0.4 to 96.4	0.989	0.994 (0.980, 1.008)	0.980 (0.051, 1.861)	0.5	0.9
Neutrophil Count (NEUT#) x10³/µL	412	0.01 to 52.59	0.995	1.023 (1.011, 1.033)	0.020 (-0.014, 0.070)	0.12	2.9
Lymphocyte Percent (LYMPH%)	423	0.9 to 99.6	0.992	1.000 (0.989, 1.013)	0.800 (0.452, 1.033)	0.8	3.3
Lymphocyte Count (LYMPH#) x10³/µL	415	0.02 to 8.44	0.987	1.025 (1.007, 1.044)	0.050 (0.022, 0.083)	0.09	5.7
MONO%	423	0.0 to 23.4	0.886	0.962 (0.910, 1.000)	-0.646 (-0.900, -0.264)	-0.9	-12.5
Monocyte Count (MONO#) x10³/µL	415	0.00 to 3.74	0.964	0.982 (0.941, 1.000)	-0.049 (-0.060, -0.027)	-0.06	-10.9
Eosinophil Percent (EOS%)	436	0.0 to 33.3	0.979	1.023 (1.000, 1.071)	0.170 (0.100, 0.200)	0.2	11.1
Eosinophil Count (EOS#) x10³/µL	427	0.00 to 4.24	0.986	1.042 (1.000, 1.094)	0.014 (0.009, 0.020)	0.02	15.0
Basophil Percent (BASO%)	438	0.0 to 3.1	0.670	1.500 (1.333, 1.667)	-0.250 (-0.300, -0.167)	0	0.0
Basophil Count (BASO#) x10³/µL	429	0.00 to 0.34	0.641	1.333 (1.200, 1.500)	-0.010 (-0.015, -0.006)	0	0.0

Results of the regression analysis between the Sight OLO and the Sysmex XN

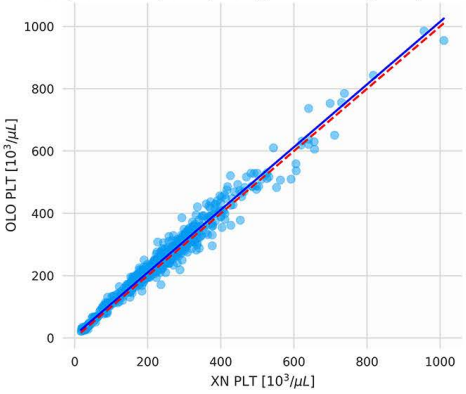
WBC OLO vs XN
N=608, bias=1.64%, r=0.997, Sy|x=0.95
slope=1.01 (1.00,1.02), int=0.03 (-0.02,0.08)



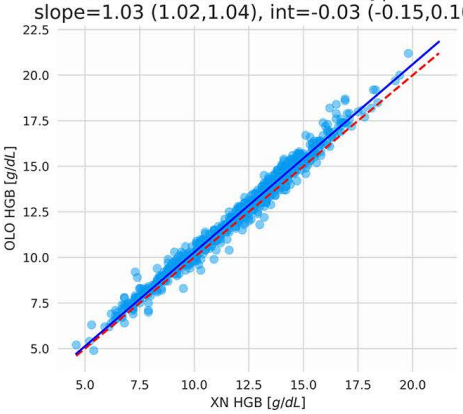
RBC OLO vs XN
N=657, bias=4.06%, r=0.991, Sy|x=0.14
slope=1.02 (1.01,1.03), int=0.09 (0.04,0.13)



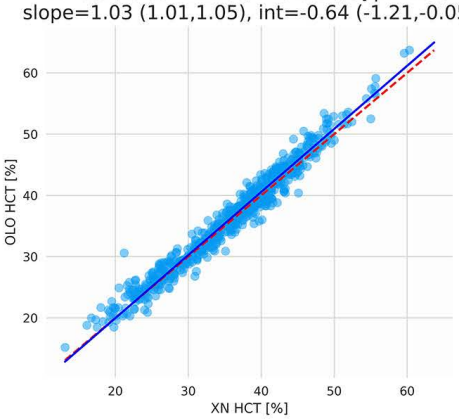
PLT OLO vs XN
N=624, bias=5.16%, r=0.985, Sy|x=22.56
slope=1.01 (0.99,1.02), int=8.94 (6.12,11.78)



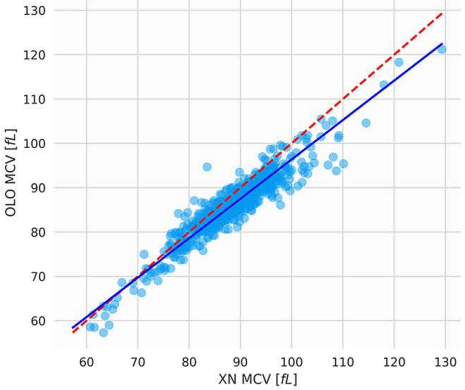
HGB OLO vs XN
N=673, bias=2.91%, r=0.990, Sy|x=0.41
slope=1.03 (1.02,1.04), int=-0.03 (-0.15,0.10)



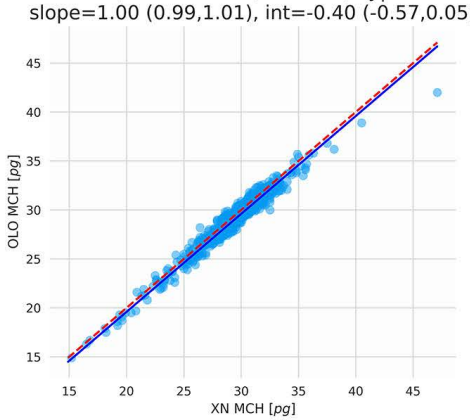
HCT OLO vs XN
N=657, bias=1.27%, r=0.982, Sy|x=1.55
slope=1.03 (1.01,1.05), int=-0.64 (-1.21,-0.05)



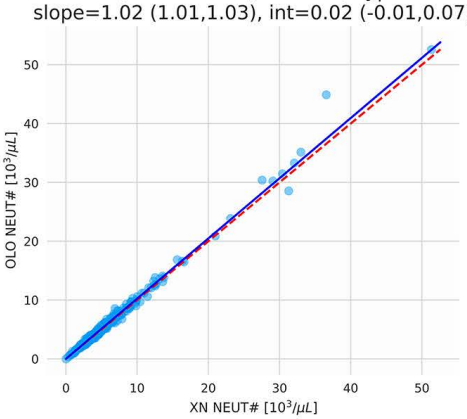
MCV OLO vs XN
N=657, bias=-2.60%, r=0.941, Sy|x=2.41
slope=0.89 (0.86,0.92), int=7.49 (5.13,9.82)



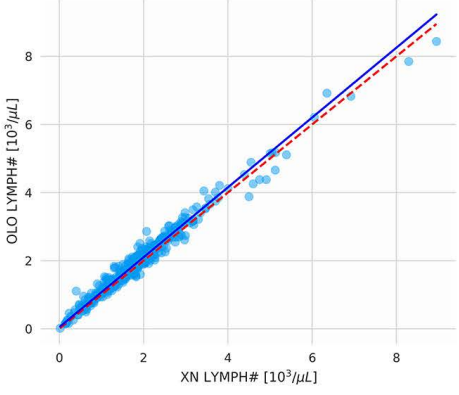
MCH OLO vs XN
N=652, bias=-1.29%, r=0.978, Sy|x=0.62
slope=1.00 (0.99,1.01), int=-0.40 (-0.57,0.05)



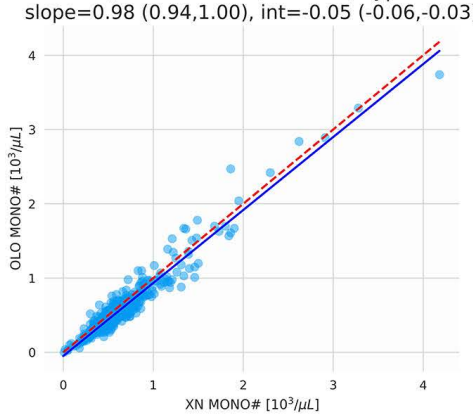
NEUT# OLO vs XN
N=412, bias=2.88%, r=0.995, Sy|x=0.51
slope=1.02 (1.01,1.03), int=0.02 (-0.01,0.07)



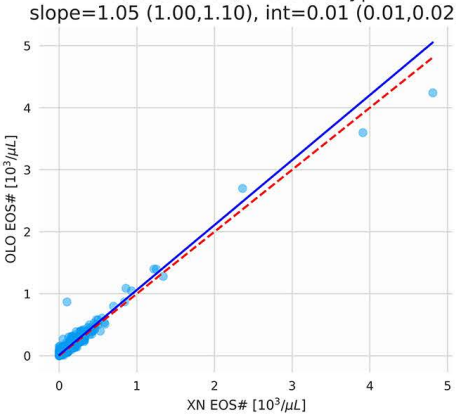
LYMPH# OLO vs XN
N=415, bias=5.65%, r=0.987, Sy|x=0.18
slope=1.03 (1.01,1.04), int=0.05 (0.02,0.08)



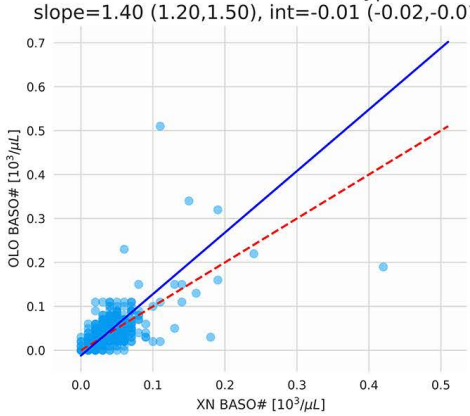
MONO# OLO vs XN
N=415, bias=-10.87%, r=0.963, Sy|x=0.11
slope=0.98 (0.94,1.00), int=-0.05 (-0.06,-0.03)



EOS# OLO vs XN
N=428, bias=0.02, r=0.980, Sy|x=0.07
slope=1.05 (1.00,1.10), int=0.01 (0.01,0.02)



BASO# OLO vs XN
N=430, bias=0.00, r=0.600, Sy|x=0.04
slope=1.40 (1.20,1.50), int=-0.01 (-0.02,-0.01)



Technology advancement and power of AI

The technological advancement made possible by a combination of digital microscopy and AI in OLO have resulted in a machine that yields accurate and reproducible CBC measures. OLO digitizes blood by capturing over 1,000 high-resolution images (over 6 gigabytes of data) per sample to perform cell counts and to flag for abnormalities based on cell morphology, powered by proprietary AI algorithms. This is all done without the need for wet reagents, routine cleaning or daily QC. OLO also simplifies the sample preparation process by providing disposable test kits that include pre-filled reagents that stain for different cellular components of blood.

The technological advancements in OLO deliver lab-grade accurate 19 parameters and 5-part differential CBC results in near-patient settings in minutes, with minimal training and maintenance requirements. The data presented in the recent publication validates OLO's accuracy and repeatability against the current industry standard, providing end-users confidence for OLO's performance.

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