sight

Sight OLO® CBC Analyzer Method Comparison Report Enumeration of Low Cell Counts (E1)

June 2021 | Doc ID: RP0250.6 | Rev: 1.0

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Introduction

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 the accumulated results from 17 clinical method comparison studies, while focusing on low counts for main CBC parameters which are especially clinically significant. These studies 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 different countries at various institutes and clinical settings, including oncology departments, an epidemic clinic and central labs of both general and pediatric hospitals. OLO was tested against multiple comparative analyzers which are based on different technologies, including different models of Sysmex XN and Beckman Coulter DxH.

At each site, whole blood venous samples were collected from patients aged 3 months and above. Each sample was scanned on both the comparative analyzer and OLO within a maximum of 8 hours from blood collection.

For each parameter, samples with low counts[1] which are particularly relevant for making clinical decisions were collected from all studies, and a Passing Bablok regression analysis was performed between OLO and the comparative analyzers[2].

The results of the method comparison studies show OLO's excellent performance in enumerating low counts, as reflected in the equivalence of OLO to various comparative analyzers. The high agreement between OLO and the comparative analyzers demonstrates OLO's compatibility to a variety of clinical settings characterized by patients with especially low blood counts.

The versatility of technologies, locations, operators and clinical settings shows the high robustness of OLO across different variables.

The advantage of OLO is especially evident as a factory-calibrated analyzer, which demonstrates equivalent performance as traditional hematology analyzers that require calibration on a regular basis.

[1] The thresholds defining the low range of each parameter can be found in the appendix.

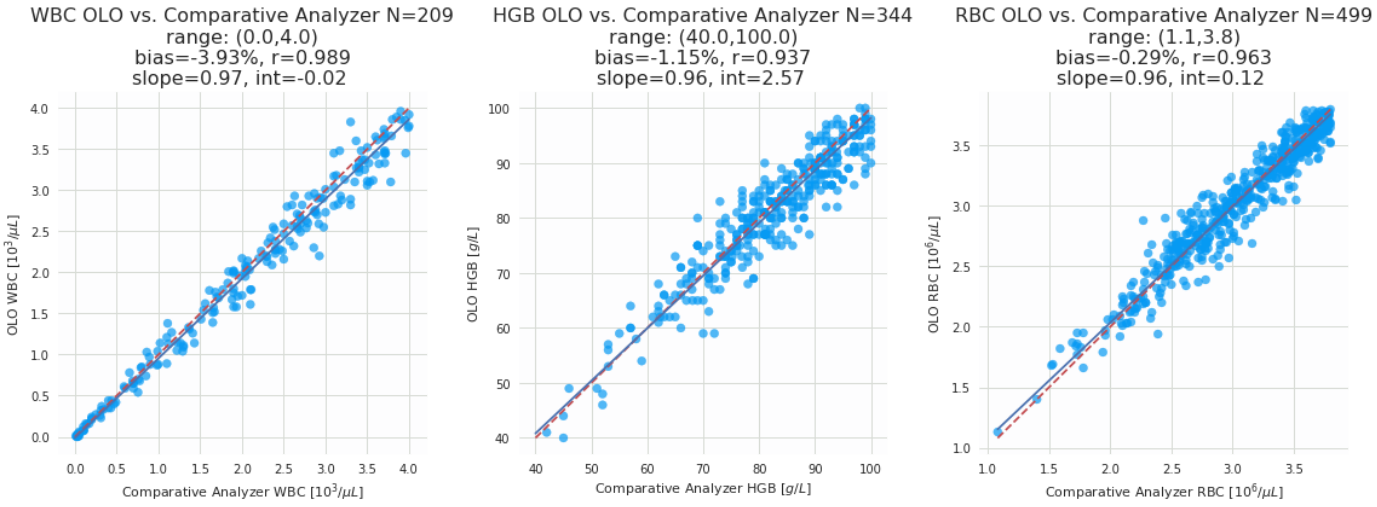
[2] Values which were invalidated by either OLO or the comparative analyzer were excluded from the analysis (whenever this information was available). 2 significant outliers were identified according to CLSI guidelines (Section 4 of CLSI EP09-A2), and were excluded from the analysis as well. The procedure included visual inspection of the Passing Bablok plots, to identify suspected outliers. For these outliers, the difference between the results of OLO vs. the comparative analyzer were compared to a threshold of 4*E (where E is the mean deviation), to determine which of these are statistically significant outliers. Both relative and absolute deviations were required to consider an outlier significant.

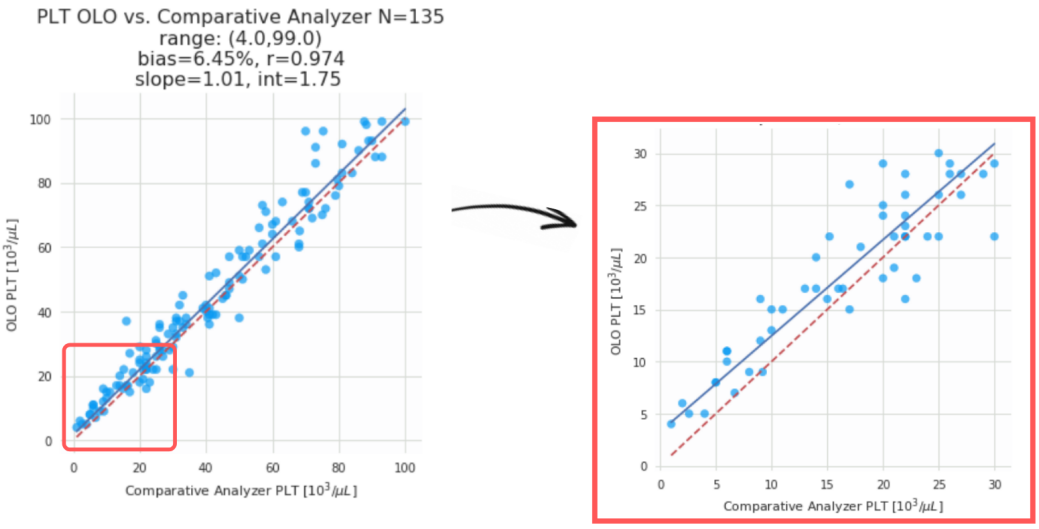
Sight OLO Performance

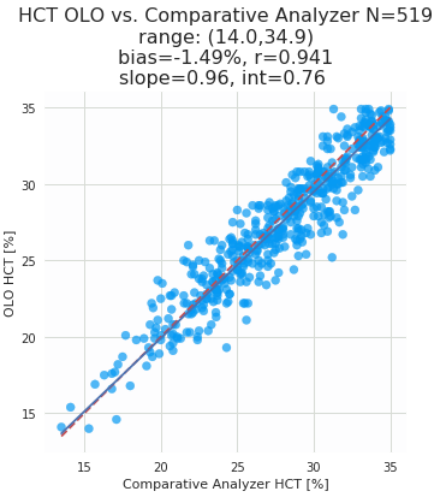
For each CBC parameter, the table below presents the correlation, slope, intercept, and bias retrieved between OLO and the comparative analyzers.

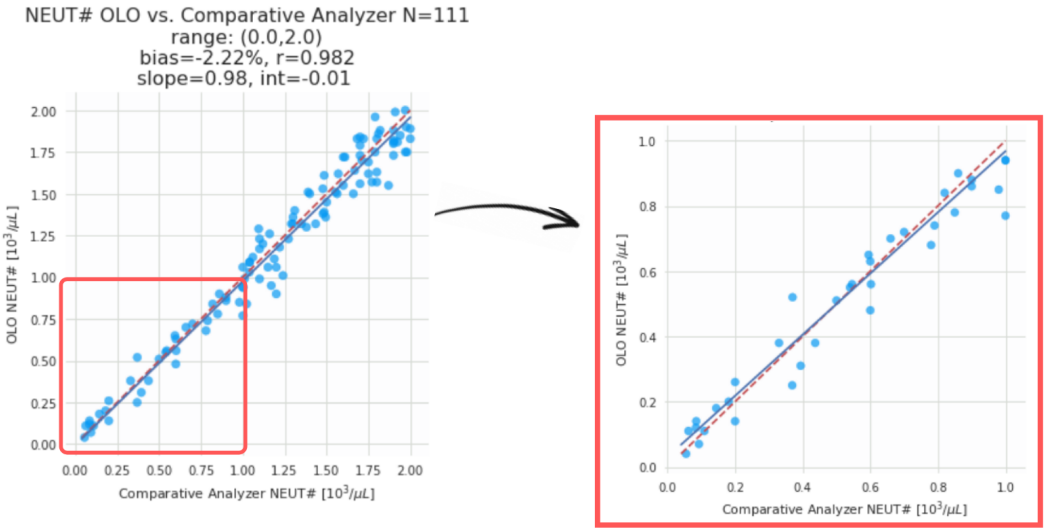
Additionally, the regression analysis results for each parameter are presented in the plots below. In each plot, the comparative analyzers' results are shown in the horizontal axis while the OLO results are shown in the vertical axis. The correlation, best linear fit (Passing-Bablok regression) and relative bias are presented, as well as the regression (blue) line and identity (dashed red) line. For PLT and NEUT#, additional zoom-in plots are presented for extremely low counts.

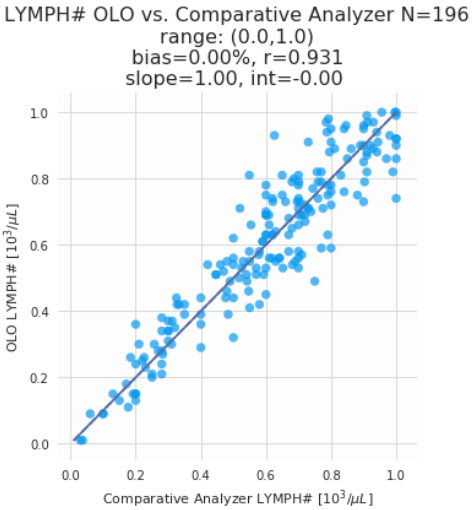
Parameter	N	Range	Correlation	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Relative Bias	Relative Bias 95% CI
WBC [×10³/µL]	209	0.0 to 4.0	0.989	0.97	(0.95, 0.99)	-0.015	(-0.030, 0.012)	-3.9	(-5.3, -2.0)
HGB [g/L]	344	40.0 to 100.0	0.937	0.96	(0.92, 1.00)	2.57	(-1.00, 6.04)	-1.2	(-2.0, -0.6)
RBC [×10⁶/µL]	499	1.1 to 3.8	0.963	0.96	(0.94, 0.98)	0.117	(0.047, 0.183)	-0.3	(-0.8, 0.0)
PLT [×10³/µL]	135	4.0 to 99.0	0.974	1.01	(0.98, 1.06)	1.7	(0.3, 3.0)	6.5	(4.4, 11.6)
HCT [%]	519	14.0 to 34.9	0.941	0.96	(0.93, 0.99)	0.76	(-0.05, 1.52)	-1.5	(-1.9, -1.2)
NEUT# [×10³/µL]	111	0.0 to 2.0	0.982	0.98	(0.94, 1.02)	-0.006	(-0.052, 0.038)	-2.2	(-4.4, 1.7)
LYMPH# [×10³/µL]	196	0.0 to 1.0	0.931	1.00	(0.96, 1.06)	0.000	(-0.029, 0.023)	0.0	(-2.5, 3.3)




PLT OLO vs. Comparative Analyzer N=135
range: (4.0,99.0)
bias=6.45%, r=0.974
slope=1.01, int=1.75
OLO PLT [10³/μL]
Comparative Analyzer PLT [10³/μL]


HCT OLO vs. Comparative Analyzer N=519
range: (14.0,34.9)
bias=-1.49%, r=0.941
slope=0.96, int=0.76
OLO HCT [%]
Comparative Analyzer HCT [%]


NEUT# OLO vs. Comparative Analyzer N=111
range: (0.0,2.0)
bias=-2.22%, r=0.982
slope=0.98, int=-0.01
OLO NEUT# [10³/μL]
Comparative Analyzer NEUT# [10³/μL]


LYMPH# OLO vs. Comparative Analyzer N=196
range: (0.0,1.0)
bias=0.00%, r=0.931
slope=1.00, int=-0.00
OLO LYMPH# [10³/μL]
Comparative Analyzer LYMPH# [10³/μL]

Appendix - Thresholds for Low Ranges

Parameter	Threshold
WBC (White Blood Cells)	≤ 4 $\times 10^3/\mu L$
PLT (Platelets)	≤ 100 $\times 10^3/\mu L$ (zoom-in of ≤ 30 $\times 10^3/\mu L$)
HGB (Hemoglobin)	≤ 100 g/L
RBC (Red Blood Cells)	≤ 3.8 $\times 10^6/\mu L$
HCT (Hematocrit)	≤ 35%
NEUT# (absolute Neutrophils)	≤ 2 $\times 10^3/\mu L$ (zoom-in of ≤ 1 $\times 10^3/\mu L$)
LYMPH# (absolute Lymphocytes)	≤ 1 $\times 10^3/\mu L$

Glossary of Terms and Abbreviations

CBC	Complete Blood Count	HGB	Hemoglobin	NEUT #	Neutrophil absolute count
WBC	White Blood Cells	RBC	Red Blood Cells	LYMPH #	Lymphocyte absolute count
PLT	Platelet Count	HCT	Hematocrit	K_2EDTA	Dipotassium Ethylenediamine tetraacetic Acid

Indications for Use[3]

Sight OLO is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening capillary or venous whole blood samples collected in K_2EDTA blood collection tubes, or fingertip samples collected using the Sight OLO test kit microcapillary tubes.

When used with Sight OLO cartridge, the Sight OLO enumerates the following CBC parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EOS%/#, and BASO%/#.

Sight OLO is indicated for use in point of care settings and in clinical laboratories to identify and classify one or more of the formed elements of blood in children 3 months and above, adolescents and adults.

Note: OLO is intended for use with K_2EDTA tubes only, but in some of the evaluating sites, K_3EDTA tubes were approved by both parties for the purpose of the study only. No clinical decisions or patient notifications were made based on the results of the studies.

[3] This document was created for the specific site. Indications for Use of the analyzer may vary between different territories. OLO should be used in accordance with the regulatory clearance in the country in which it is used. Note that in the Israeli market, OLO is restricted for lab use by qualified lab personnel. For complete Indications for Use and safety information of Sight OLO please visit www.SightDX.com.