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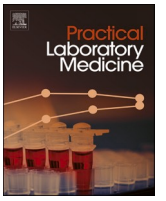

Registered Report Stage II

Complete blood count in neonatal Intensive care Unit (NICU): Performance comparison between POCT Sight OLO® and Sysmex XN-9100™ hematology analyzers

Francesca Nencini [a,1], Alessandro Bonari [a,1], Sara Ciullini Mannurita [a,1], Alessandra Mongia [a], Francesca Romano [a], Maria Garieri [b], Edda Russo [c], Silvia Sastrucci [a], Graziella Marrani [a], Martina Tonelli [a], Stefano Salti [a], Niccola Funel [d], Amedeo Amedei [c], Carlo Dani [b,*], Alessandra Fanelli [a]

[a] General Laboratory, Careggi University Hospital, Florence, Italy
[b] Division of Neonatology and Neonatal Intensive Care Unit, Careggi University Hospital, Florence, Italy
[c] Department of Experimental and Clinical Medicine, University of Florence, Italy
[d] Chemical Chemistry Laboratory, Azienda Usl Toscana Nord Ovest, Italy

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ABSTRACT

Background and aims: The use of a POCT (Point Of Care Test) could help in reducing the impact of pre-analytical errors in particular in challenging newborn samples.
The study purpose is to compare the POCT Sight OLO® hematology analyzer, validated for >3 months patients, with the reference system Sysmex XN-9100™ in Neonatal Intensive Care Unit (NICU).
Material and methods: The two analyzers were compared through Passing-Bablok regression analysis and Bland-Altman plot.
Results: We analyzed 65 blood samples, in detail 38 from adults and 27 from newborns.
The regression analysis results performed in the newborn and adult patients showed a good agreement between the two instruments. The evaluation of the Bland-Altman plots showed comparable values of bias <10 % for the most of parameters.
The evaluation of sample flags for the presence of distributional and morphological abnormalities showed a partial accordance between the two approaches, but the POCT exhibited good performance compared to the final report revised by the laboratory specialist.
Conclusions: The comparison of the two instruments demonstrated that they provide comparable blood counts, also in patients aged <3 months. The POCT allows having reliable analytical data and faster turning around time, particularly useful in NICU.

* Corresponding author. University of Florence, Department of Neurosciences, Psychology, Drug Research and Child Health, University of Florence, Florence, Italy.
E-mail address: c.dani@unifi.it (C. Dani).
[1] These authors contributed equally to the manuscript.

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List of abbreviations

CBC	Complete Blood Count
CI	Confidence Interval
HCT	Hematocrit
HGB	Hemoglobin
MCH	Mean Corpuscolar Hemoglobin
MCHC	Mean Corpuscolar Hemoglobin Concentration
MCV	Mean Corpuscolar Volume
NICU	Neonatal Intensive Care Unit
PLT	Platelets
POCT	Point Of Care Testing
RBC	Red Blood Cells
RDW	Red Blood Cell Distribution Width
WBC	White Blood Cells

1. Introduction

Blood sampling is one of the most common diagnostic methods for the treatment and assessment of pediatric diseases and pathological conditions [1]. However, for children, it can be considered the most anxiety-causing procedure experienced during their hospital stay [2]. The success of blood sampling strongly depends on the technical, psychological and pedagogical skills of nurses and laboratory assistants and on the knowledge of pre-analytical pitfalls and guidelines [3,4].

The overall process of laboratory testing can be defined according to the pre-analytical, analytical and post-analytical phases. Errors in the pre-analytical phase account for approximately 60%–70 % of all blood sampling errors [5,6].

Pre-analytical variables, related to blood collection (hemolysis, clots, low volume) and sample transport, affect the quality of laboratory tests and the presence of clots is the most frequent cause of pre-analytical errors. This is particularly true in pediatric and neonatal wards, where capillary blood sampling is usually the choice method [7–9].

POCT is a modern approach that refers to any test performed outside the laboratory, near or at the patient's site, the result of which influences patient management, supporting timely, safe and effective acute care [10,11].

Using a POCT could reduce the impact of pre-analytical errors. However, this strategy must be at the same standard as that of the central laboratory and requires the involvement of more personnel from specialties' outside the laboratory.

The Sight OLO® portable analyzer (S.D. Sight Diagnostics Ltd., Israel) provides on-site Complete Blood Count (CBC) from finger pricks or venous samples and it was validated for >3 months patients by the manufacturer.

The purpose of this study is to evaluate the use of the POCT Sight OLO® analyzer in NICU, performing a comparison with the Sysmex XN-9100™ hematology system (Sysmex Corporation, Kobe, Japan).

2. Material and methods

2.1. Study design

Sight OLO® is a novel POCT hematological platform, based on recent advances in artificial intelligence (AI) and computerized image analysis (computer vision). It provides a 19-parameter, five-part differential CBC. OLO® employs single-use test kits, a "dry" instrument and an extensive "Failsafe" self-test system to reduce overheads and simplify operation.

A method comparison study was undertaken to compare Sight OLO® with the Sysmex XN-9100™ System, the reference hematology analyzer presents at the Central Laboratory. The study design was based on the methods outlined in CLSI H20-A2, CLSI H26-A2 and CLSI EP09-A3.

Residual whole blood samples were collected from 27 newborn patients (0 days–4 months old) admitted at NICU of Careggi University Hospital (Florence, Italy) and from 38 adults (>22 years old) to have a group of samples from the Sight OLO® validated population.

Newborn samples were capillary whole blood samples, collected in 0.5 mL microtube with K2-EDTA anticoagulant (Greiner Bio-One International GmbH, Kremsmünster, Austria), while adult samples were venous whole blood samples, collected in standard K2-EDTA collection tubes (Becton Dickinson, Franklin Lakes, NJ, USA). The analysis was carried out on both analyzers within 2 h of sampling and no later than 1 h between the two instruments.

The study included both normal and pathological samples to assess Sight OLO®'s performance across the analytical measuring range and around medical decision points.

In addition, given the important pre-analytical clinical impact, non-compliant samples, verified during routine diagnostic sessions (coagulated samples or with the presence of platelet aggregates), were tested to evaluate any instrumental warning alarms.

The samples' loading and analysis on both instruments were carried out following the manufacturer's specifications, except for hemoglobin chamber loading, for which a 20 μl micropipette was used instead of the microcapillary pipette supplied with the kit, as

Table 1
Summary of the method comparison study in the newborn population.

Measurand	N	Results Range	Correlation Coefficient (r)	Slope (95 % CI)	Intercept (95 % CI)	Mean Bias (Desiderable limits for inaccuracy %; 95 % CI)
WBC x10^3/μL	17	4.26 to 19.96	0.937	0.986 (0.782, 1.109)	0.299 (-1.31, 3.047)	0.01 (11.1; −0.97, 0.74)
RBC x10^6/μL	17	3.32 to 6.96	0.894	1.3 (0.87, 1.78)	−1.44 (-3.912, 0.411)	−0.02 (2.8; −0.15, 0.26)
PLT x10^3/μL	17	47 to 368	0.889	0.803 (0.5, 0.969)	35.12 (-5.14, 93.25)	−0.07 (−7.3; −1.41, 44.93)
HGB g/dL	17	10.2 to 23.5	0.95	1.254 (1.033, 1.535)	−4.42 (-9.41, −0.895)	0.01 (2.7; −0.46, 0.71)
HCT %	17	30.5 to 64.1	0.891	1.225 (1.064, 2.04)	−8.874 (-46.69, −0.369)	0.04 (2.8; −4.65, 0.20)
MCV fL	17	84.2 to 118.7	0.836	1.019 (0.833, 1.855)	4.725 (-78.17, 23.83)	0.05 (0.8; −7.84, −2.94)
RDW %	17	14.6 to 24.2	0.861	1.104 (0.655, 1.824)	−0.211 (-13.34, 7.143)	0.1 (1.7; −2.48, 0.89)
MCH pg	17	29.1 to 40	0.963	0.869 (0.667, 1.041)	4.716 (-1.096, 11.97)	0.01 (0.7; −0.50, 0.40)
MCHC g/dL	17	30.7 to 37.3	0.249	1.5 (-0.917, 3.75)	−20.1 (-101.5, 65.31)	−0.05 (−1; 0.94, 2.60)
NEUT# x10^3/μL	14	0.92 to 11.68	0.953	0.953 (0.811, 1.105)	0.409 (-0.715, 1.793)	0.05 (−14.1; −0.75, 0.44)
LYMPH# x10^3/μL	14	1.75 to 7.21	0.913	0.783 (0.415, 1.014)	1.197 (-0.102, 2.625)	0.09 (10.8; −0.71, 0.05)
MONO# x10^3/μL	14	0.17 to 2.95	0.931	0.811 (0.587, 1.013)	0.013 (-0.36, 0.319)	−0.18 (13.3; 0.05, 0.43)
EOS# x10^3/μL	14	0.01 to 1.55	0.944	0.837 (0.741, 1.171)	0.037 (-0.112, 0.13)	−0.09 (−15; −0.04, 0.13)
BASO# x10^3/μL	14	0.00 to 0.13	nd	−0.436 (-1, 0.498)	0.0571 (-0.037, 0.115)	−1.18 (12.4; 0.04, 0.09)

BASO, basophil; CI, confidence interval; EOS, eosinophil; HCT, hematocrit; HGB, hemoglobin; LYMPH, lymphocyte; MCHC, mean corpuscular hemoglobin concentration; MCH, mean corpuscular hemoglobin; MCV, mean corpuscular volume; MONO, monocyte; NEUT, neutrophil; PLT, platelet; WBC, white blood cell; RBC, red blood cell; RDW, red blood cell distribution width.

difficulty in filling was encountered.

2.2. Statistical analysis

A Passing-Bablok regression analysis was performed for each CBC parameter, after excluding any result that was invalidated by Sight OLO® or by the reference analyzer. For each regression analysis, the slope, the intercept and the 95 % two-sided confidence interval (CI) around the slope, as well as the correlation coefficient, were calculated using Bootstrap Method. The overall bias was calculated as the values on the axis [(method A – Method B)/mean)] *vs*. the mean of the two measurements (Bland-Altman plots). The 95 % two-sided confidence interval (CI) of bias was calculated by Microsoft Excell as follow:

$x \pm Z_{\alpha/2} \times \frac{\sigma}{\sqrt{n}}$ with x as mean value, σ standard deviation, and n e number of samples analyzed. Statistical analysis was performed using the online software https://bahar.shinyapps.io/method_compare/ [12,13].

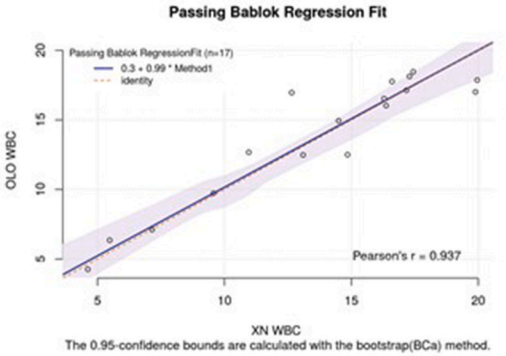
2.3. Flagging study

Like any CBC counter, also the Sight OLO® displays instrumental analytical alarms (flags) due to cell distributional and morphological abnormalities, such as blasts, immature granulocytes, nucleated RBCs, atypical lymphocytes, platelet clumps and RBC agglutination. The device reports specific messages of abnormalities. The POCT flagging capabilities were compared to Sysmex XN-9100™ System and to the final medical report, after microscopic revision of manual blood smears. The level of agreement between the analyzers and medical report was performed evaluating flag messages. Complete agreement was considered if the same comments were reported in both analyzers, partial agreement in case of incomplete accord between flags, and no agreement if the flag description was different between the two analyzers.

3. Results

3.1. Method comparison

Regarding the accuracy, the comparison between Sight OLO® and Sysmex XN-9100™ System was performed by testing a total of 65 residual whole blood clinical samples of male (52.3 %) and female (47.7 %) patients; 41.5 % of the samples were from newborn



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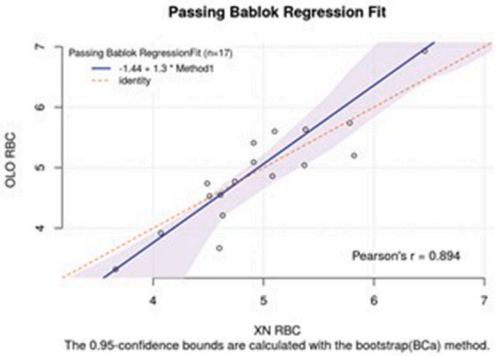

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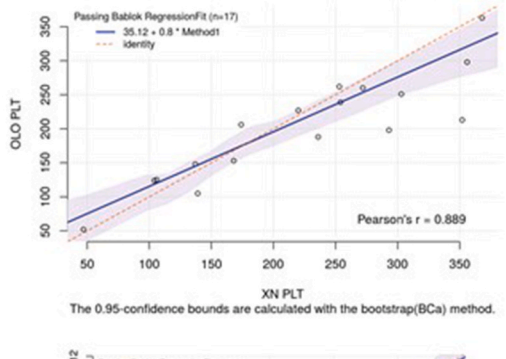

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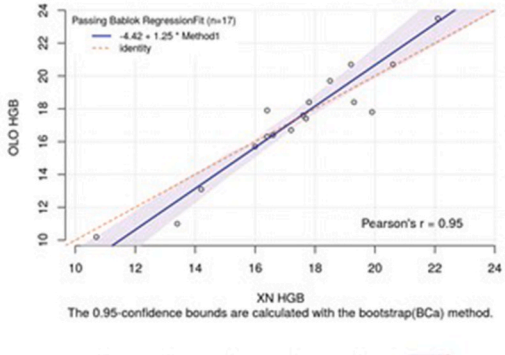

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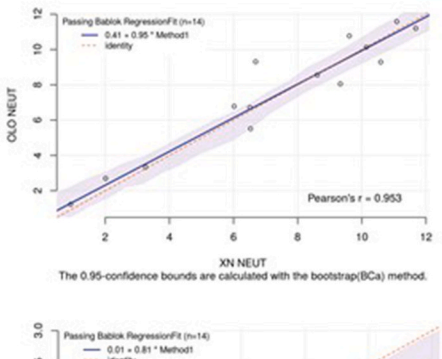

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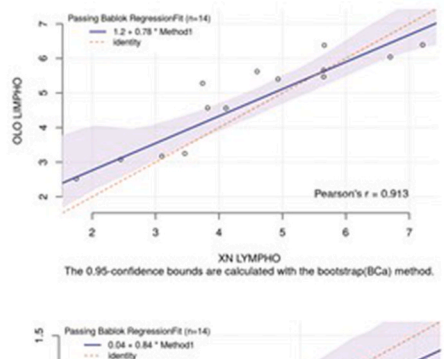

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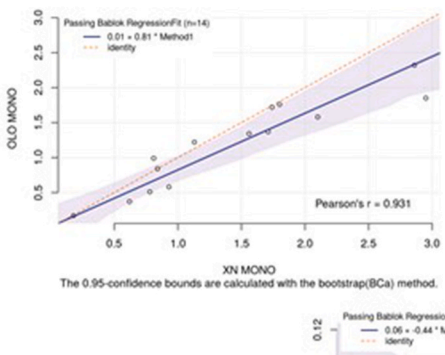

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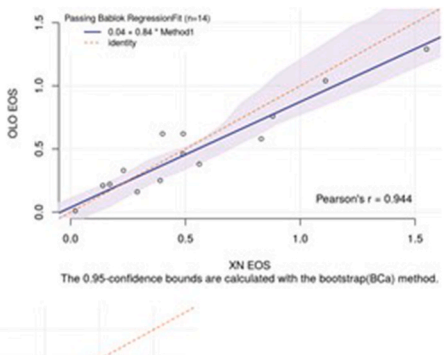
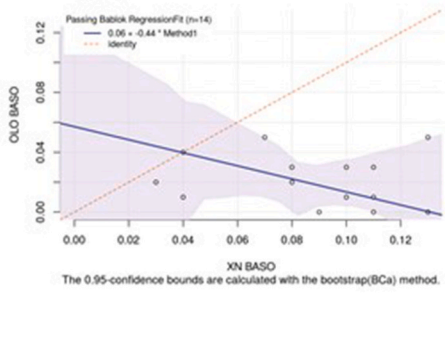


The 0.95-confidence bounds are calculated with the bootstrap(BCa) method.



The 0.95-confidence bounds are calculated with the bootstrap(BCa) method.

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Fig. 1. Regression analysis in the newborn population. Results of the method comparison study between the Sight OLO® and the Sysmex XN™ hematology analyzers. Graphs indicate Pearson correlation, slope and intercept for the main parameters. WBC: White Blood Cells, RBC: Red Blood Cells, PLT: Platelets, HGB: Hemoglobin, NEUT: Neutrophils, LYMPHO: Lymphocytes, MONO: Monocytes, EOS: Eosinophils, BASO: Basophils.

patients (**Additional file 1**).

In eight cases (five adults and three newborns), the blood count performed with the Sight OLO® instrument failed (**Additional file 1**, samples 1, 2, 9, 46, 48, 59, 61, 62).

Moreover, in the POCT analysis, none of the seven samples (all newborns, of which two failed), identified as coagulated during the pre-analytical evaluation by the laboratory staff, reported alarms suggesting the presence of clots and, therefore, they were excluded for the analysis (Table 1 Additional file 1, samples 1, 2, 3, 5, 6, 8, 11).

Furthermore, two samples, initially uncoagulated and successfully analyzed with the XN-9100™ System, were subsequently coagulated at the time of analysis using the Sight OLO® System. These samples were omitted from the study (**Additional file 1**, samples 26, 27).

In three cases of newborn samples, the leukocyte differential count was not requested, hence these data were not included in the analysis (**Additional file 1**, samples 7, 17, 25).

Summarizing, we analyzed 17 newborn patients (14 including leukocyte differential count) and 33 adult patients (**Additional file 2**).

Considering the newborn population, the regression analysis, in terms of linearity (correlation coefficient), slope and intercept of the regressions, showed a good agreement between the Sight OLO® System and the Sysmex XN-9100™ System (Fig. 1 and Table 1). We observed high correlation ($r \geq 0.90$) for the parameters WBC, HGB, MCH, neutrophils, lymphocytes, monocytes and eosinophils; moderate correlation ($0.75 < r < 0.90$) for RBC, HCT, MCV, PLT and RDW; no correlation for MCHC and basophils.

In terms of acceptability, the values relating to slope and intercept sometimes showed a slight variability, suggesting potential proportional and systematic errors. No systematic differences, neither proportional nor constant, were observed for the measurement of most parameters, except for HGB and HCT.

The agreement evaluation, carried out by the Bland-Altman test, showed values of bias <10 % for all parameters, except for monocytes and basophils (Fig. 2 and Table 1).

Similar results were obtained considering the adult population, with a better correlation, probably due to a greater sample size (Figs. 3 and 4 and Table 2). In detail, we documented: high correlation ($r \geq 0.90$) for the parameters WBC, RBC, PLT, HGB, HCT, MCV, RDW, MCH, neutrophils, lymphocytes, monocytes and eosinophils; moderate correlation ($0.75 < r < 0.90$) for MCHC and low correlation for basophils ($r = 0.559$).

Finally, no systematic differences were observed for the measurement of most parameters, except for RBC, MCHC and lymphocytes regarding the acceptability.

The agreement evaluation, carried out by the Bland-Altman test, showed values of bias <10 % for all parameters, except for lymphocytes, monocytes and basophils.

3.2. White blood cell flagging study

The OLO®'s flagging for cell distributional and morphological abnormalities was assessed for agreement with the Sysmex XN-9100™'s flagging and with the evaluation of manual blood smears (**Additional file 3**).

Considering the newborn population, the OLO®'s flagging capabilities of showed a complete or partial agreement in 65 % of samples compared to microscopic revision (Table 3), but a complete or partial agreement in 53 % of samples compared to the Sysmex XN-9100™ System.

Considering the adult population, the flagging OLO® capabilities showed a complete or partial agreement in 60.6 % of samples compared to microscopic revision (Table 4), but a complete or partial agreement in 33.3 % of samples compared to the Sysmex XN-9100™ System.

4. Discussion

The Sight OLO® offers a complete blood count in about 10 min, utilizing only 27 µl of blood sample (compared with 88 µl utilized by Sysmex XN-9100™ hematology system), providing considerable blood conservation and recording up to 500 blood count results. Furthermore, the small volume of sample that may be directly drawn from a finger prick reduces some additional overheads as well as inconveniences associated with venous phlebotomy and may mitigate the blood sampling anxiety. Running costs between the two analyzers are sensibly different (mean cost 4 euro/sample for Sysmex XN-9100™ hematology system vs 23 euro/sample for the POCT Sight OLO® analyzer) however the main purpose of a POCT instrument is the rapid and effective testing outside the laboratory, reducing the impact of pre-analytical errors in critical setting.

In accordance with the international standards ISO 15189 ("Medical Laboratories - Requirements For Quality And Competence"), every analytical process should be tracked by barcoding and validated in the central laboratory as well as near-patients' setting in medical units inside and outside the hospital since the POCT instrument can be connected to either middleware or directly to the laboratory information system.

The specific technical guidelines ISO 22870 ("Point-of-Care Testing (POCT) - Requirements For Quality And Competence") define

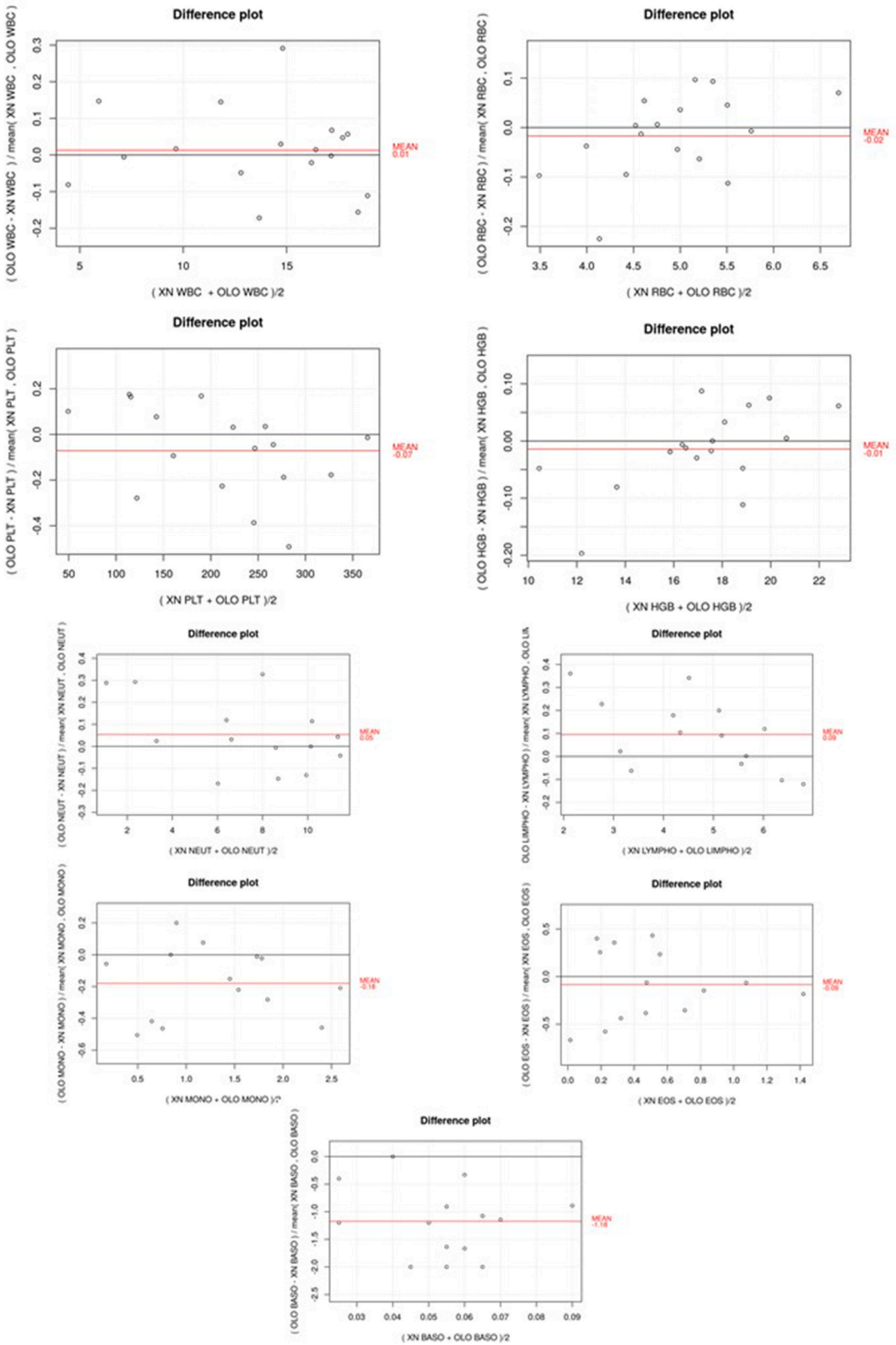

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Fig. 2. Bias plot in the newborn population. Bland Altman of the results of a method comparison study between the Sight OLO® and the Sysmex XN™ hematology analyzers for the main measurements in the newborn population.
WBC: White Blood Cells, RBC: Red Blood Cells, PLT: Platelets, HGB: Hemoglobin, NEUT: Neutrophils, LYMPHO: Lymphocytes, MONO: Monocytes, EOS: Eosinophils, BASO: Basophils.

the validation, verification phases and responsibilities that must be adopted in the POCT application and management.

Applying these guidelines, a comparison between the results of the central laboratory and POCT analyzer must be verified and documented for quality assurance requirements and in agreement with the validation data. Thus, a verification protocol should be approached and adopted by any laboratory.

The results obtained in our adult cohort confirmed previous data published in the analytical validation study by Bachar et al. [14] and, for the first time, the comparison performed in our study demonstrated that the Sight OLO® analyzer provides CBC results comparable with the Sysmex XN-9100™ in newborn patients (<3 months).

A good correlation was found for most of the WBC parameters, except for MCHC and basophils. Particularly consistent is the HGB correlation, probably due to the similar technology approach (spectrophotometry) on evaluating this parameter on the two instruments. No correlation for the basophil population could be due to the very low number of these cells and their limited typical data range. As previously explained by Bachar et al. [14], the low correlation for MCHC could be due to calculation differences based on the ratio of two highly correlated values (MCH and MCV or HGB and HCT), giving a small range of MCHC values.

In newborn samples, the regression and concordance analysis were in line with adult samples, but there was a slight worsening of the correlation, surely attributable to the small number of newborn patients.

Both in the newborn and the adult populations, neither systematic differences nor bias over 10 % were observed for the measurement of most parameters and thus we could assume the interchangeability of the two types of measurement.

The presence of proportional and systematic errors in the Passing-Bablok plot of HGB determination and, consequently, of the calculated parameter HCT in the newborn population could be explained by the wide range of results (10.2–23.5 g/dL).

RBC and MCHC values sensibly differ between the two methods probably because the Sight OLO® estimates the RBC count by a calculation from the measured parameters HGB and MCH, unlike Sysmex XN-9100™ (RBC is not a calculated parameter; MCH and MCHC are calculated from RBC, HGB and HCT). For this reason, in the adult patients, we observed the presence of proportional and systematic errors in RBC and MCHC parameters.

Proportional and systematic errors in lymphocytes' correlation in the adult subjects could be simply explained by highly dispersed values (0.1–62.4) that affected the comparison between the two methods.

The present study also evaluated Sight OLO®'s automated flagging of samples for the presence of distributional and morphological abnormalities: NRBCs, platelet aggregates, blast cells, immature granulocytes and atypical lymphocytes. Flags of the OLO® system were in partial accordance with the Sysmex XN™ system, but the POCT showed good performance compared to the final report, after revision carried out by the laboratory specialist. The partial concordance between the two analytical systems could be due to the different technology.

The analytical principle of the Sight OLO® analyzer is based on spectrophotometry and automated optical microscopy. The Sysmex XN™ instrumentation uses fluorescence flow cytometry, spectrophotometry and the resistive method with hydrodynamic focusing. Therefore, it is better to compare Sight OLO® alarms with the laboratory specialist assessment of the manual blood smears, described in the report.

In our study, the most critical step of the overall testing process was the pre-analytical phase (10 % of total processed samples). According to Tóth J. et al. [15], pre-analytical problems are the most frequent non-compliances in neonatal patients: in particular, in preterm births, the hemolysis for serum samples (approximately 46 % in newborn samples and 4 % in adult samples) and clots for whole blood samples (approximately 7 % in pediatric samples and 0.4 % in all laboratory samples).

The recognition of non-compliances occurs following a sample observation by the laboratory staff, also using a micropipette, to check the blood fluidity and viscosity and to detect any clots. This technical step is crucial and irreplaceable, even with decentralized instrumentation, such as the Sight OLO® analyzer.

5. Conclusions

The use of the Sight OLO® analyzer is aimed at all sanitary personnel, for easy-to-use and rapid testing of hematological parameters and then also feasible for emergency and critical units such as NICU, reducing the risk of non-compliance sampling associated with the time between collection and analysis.

The analytical performance of the two analyzers resulted substantially comparable and in accordance with the validation study.

Nevertheless, the sanitary personnel skilled activity remains essential for the assessment of sample compliance and for the identification of any pre-analytical problem, being the clot evaluation the most critical step, even with decentralized instrumentation.

CRediT authorship contribution statement

Francesca Nencini: Writing – original draft, Formal analysis, Data curation. **Alessandro Bonari:** Writing – review & editing, Writing – original draft, Data curation, Conceptualization. **Sara Ciullini Mannurita:** Writing – review & editing, Writing – original draft, Data curation, Conceptualization. **Alessandra Mongia:** Writing – review & editing, Data curation. **Francesca Romano:** Writing

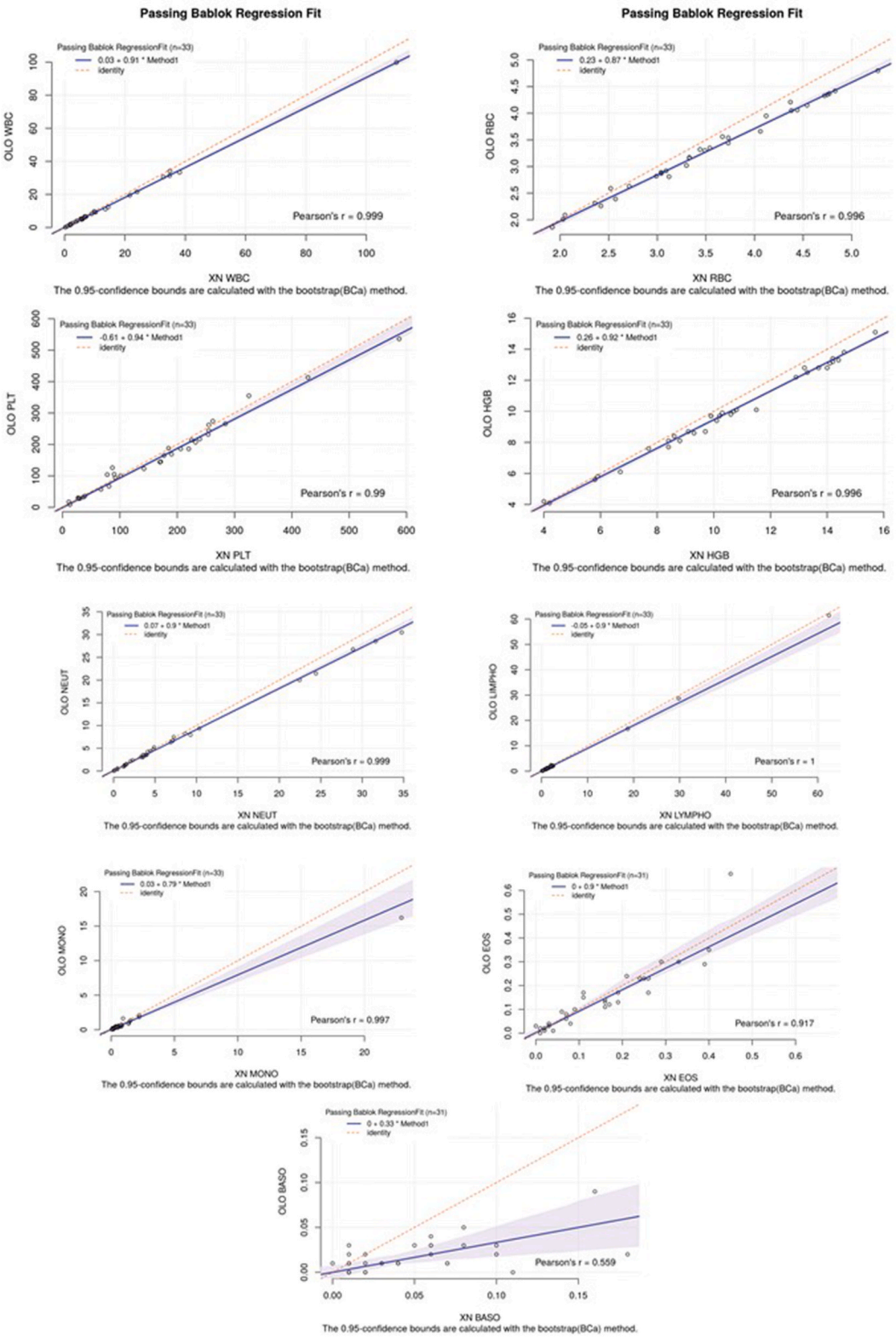
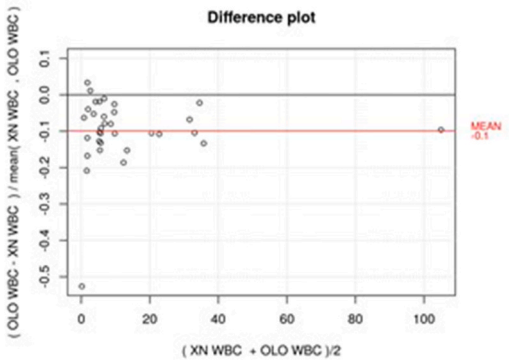
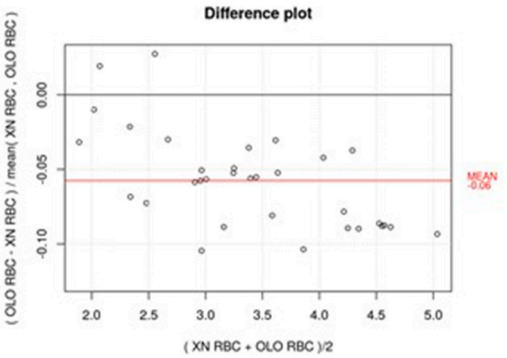
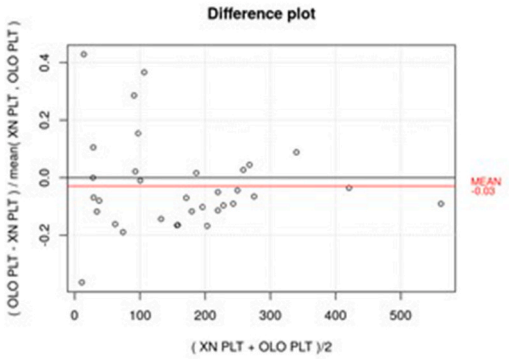
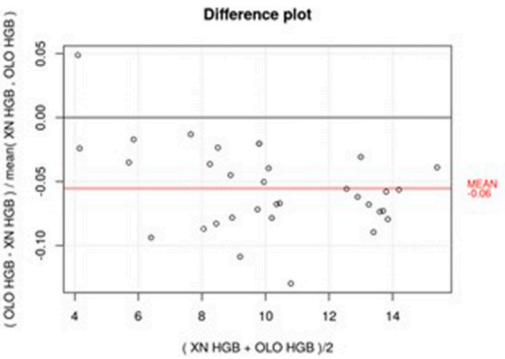


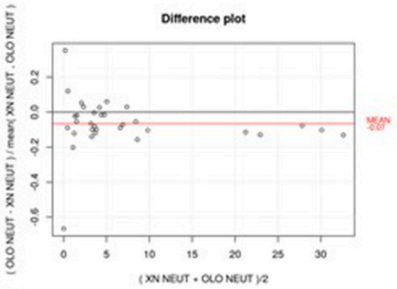
Fig. 3. Regression analysis in the adult population. Graphs indicate Pearson correlation, slope and intercept for each parameter. WBC: White Blood Cells, RBC: Red Blood Cells, PLT: Platelets, HGB: Hemoglobin, NEUT: Neutrophils, LYMPHO: Lymphocytes, MONO: Monocytes, EOS: Eosinophils, BASO: Basophils.

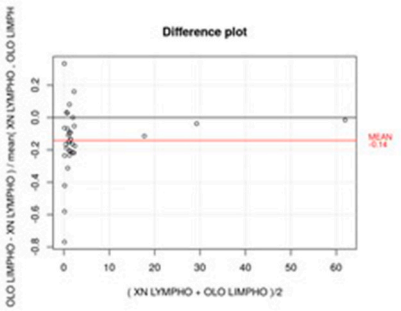


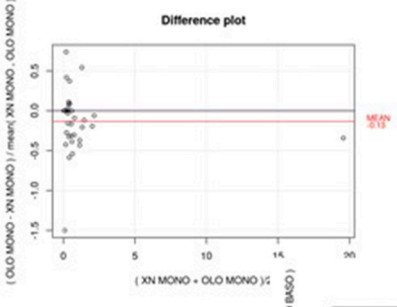


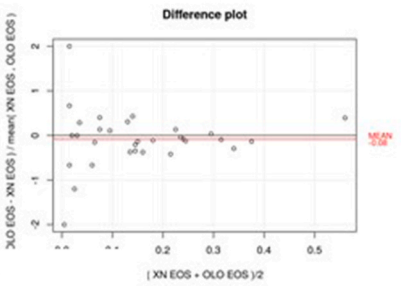












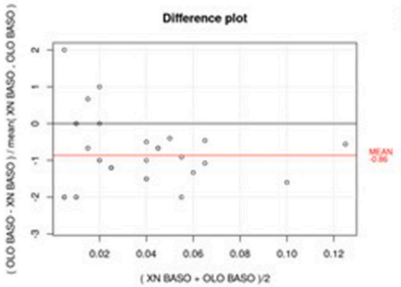


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Fig. 4. Bias plot in the adult population. Bland Altman of the results of method comparison study between the Sight OLO® and the Sysmex XN™ hematology analyzers for the main measurands in the adult population.
WBC: White Blood Cells, RBC: Red Blood Cells, PLT: Platelets, HGB: Hemoglobin, NEUT: Neutrophils, LYMPHO: Lymphocytes, MONO: Monocytes, EOS: Eosinophils, BASO: Basophils.

Table 2
Summary of the method comparison study in the adult population.

Measurand	N	Results Range	Correlation Coefficient	Slope	Intercept	Mean Bias (Desiderable limits for inaccuracy %; 95 % CI)
			(r)	(95 % CI)	(95 % CI)	
WBC $x10^3/\mu L$	33	0.14 to 110	0.999	0.91 (0.89, 0.94)	0.03 (-0.08, 0.26)	−0.1 (11.1; 0.49, 1.87)
RBC $x10^6/\mu L$	33	1.86 to 5.27	0.996	0.87 (0.85, 0.91)	0.23 (0.09, 0.32)	−0.06 (2.8; 0.16, 0.26)
PLT $x10^3/\mu L$	33	9 to 587	0.99	0.94 (0.90, 1.01)	−0.61 (-8.68 5.57)	−0.03 (−7.3; 1.60, 12.22)
HGB g/dL	33	4 to 15.7	0.996	0.92 (0.89, 0.95)	0.26 (-0.18, 0.62)	−0.06 (2.7; 0.47, 0.73)
HCT%	33	13,3 to 48.1	0.992	0.9 (0.86, 0.94)	0.78 (-0.65, 2.09)	−0.08 (2.8; 1.93, 2.88)
MCV fL	33	55 to 109	0.959	1.09 (0.87, 1.25)	−9.33 (-24.6, 11.6)	−0.02 (0.8; 0.32, 2.66)
RDW%	33	11.5 to 25.6	0.961	1.05 (0.94, 1.19)	−0.04 (-2.23, 1.63)	0.05 (2.7; −1.23, −0.48)
MCH pg	33	15.9 to 36.9	0.989	1.02 (0.94, 1.13)	−0.39 (-3.5, 1.98)	0.01 (0.7, −0.35, 0.11)
MCHC g/dL	33	24.1 to 33.5	0.809	0.72 (0.5, 0.98)	9.5 (0.46, 16.61)	0.02 (−1; −1.17, −0.22)
NEUT# $x10^3/\mu L$	33	0.01 to 34.76	0.999	0.9 (0.88, 0.94)	0.07 (-0.02, 0.12)	−0.07 (14.1; 0.30, 0.95)
LYMPH# $x10^3/\mu L$	33	0.1 to 62.4	1	0.9 (0.84, 0.97)	−0,05 (-0.1, −0,005)	−0.14 (10.8; 0.09, 0.39)
MONO# $x10^3/\mu L$	33	0.02 to 22.92	0.997	0.79 (0.69, 0.91)	0.03 (-0.03, 0,1)	−0.13 (13.3; −0.14, 0.69)
EOS# $x10^3/\mu L$	33	0.00 to 0.67	0.917	0.9 (0.8, 1.1)	0.002 (-0.01, 0,02)	−0.08 (−15; −0.01, 0.03)
BASO# $x10^3/\mu L$	33	0.00 to 0.18	0.559	0.33 (0.07, 0.5)	0 (-0.01, 0,01)	−0.86 (12.4; 0.02, 0.04)

BASO, basophil; CI, confidence interval; EOS, eosinophil; HCT, hematocrit; HGB, hemoglobin; LYMPH, lymphocyte; MCHC, mean corpuscular hemoglobin concentration; MCH, mean corpuscular hemoglobin; MCV, mean corpuscular volume; MONO, monocyte; NEUT, neutrophil; PLT, platelet; WBC, white blood cell; RBC, red blood cell; RDW, red blood cell distribution width.

Table 3
Instrumental analytical alarms (flags) concordance between Sight OLO® and Sysmex XN™ in the newborn population.

	Concordant Flags	Partial Concordant Flags	No concordant Flags
XN-9100™ vs Sight OLO®	0/17 (0 %)	9/17 (53 %)	8/17 (47 %)
XN-9100™ vs Medical report	1/17 (5.9 %)	7/17 (41.1 %)	9/17 (53 %)
Sight OLO® vs Medical report	2/17 (11.7 %)	9/17 (53 %)	6/17 (35.3 %)

Table 4
Instrumental analytical alarms (flags) concordance between Sight OLO® and Sysmex XN™ in the adult population.

	Concordant Flags	Partial Concordant Flags	No concordant Flags
XN-9100™ vs Sight OLO®	7/33 (21.2 %)	4/33 (12.1 %)	22/33 (66.7 %)
XN-9100™ vs Medical report	9/33 (27.3 %)	5/33 (15.1 %)	19/33 (57.6 %)
Sight OLO® vs Medical report	18/33 (54.5 %)	2/33 (6.1 %)	13/33 (39.4 %)

– review & editing. **Maria Garieri:** Validation, Data curation. **Edda Russo:** Writing – review & editing. **Silvia Sastrucci:** Formal analysis. **Graziella Marrani:** Formal analysis. **Martina Tonelli:** Formal analysis. **Stefano Salti:** Resources. **Niccola Funel:** Validation. **Amedeo Amedei:** Writing – review & editing, Validation. **Carlo Dani:** Supervision, Resources, Funding acquisition. **Alessandra Fanelli:** Validation, Resources, Project administration.

Declaration section

Ethics approval, consent to participate and consent for publication.

The study protocol was in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments. Data were collected retrospectively from anonymized patient using residual whole-blood clinical samples. The study have been approved by Institutional Review board Committee (CEAVC Em. 2023-083 Studio 13,725_bio). Informed consent was obtained from all the participant.

Availability of data and materials

All data on the Complete Blood Count that support the findings of this study are included within this paper and its Supplementary Information file (Additional file 2- dataset).

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.plabm.2025.e00453.

Data availability

Data will be made available on request.

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