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Performance evaluation the new automated Atellica Hema 580 hematology analyzer

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Abstract

Introduction: The Atellica Hema (Siemens Healthineers, Tarrytown, NY, USA) is a new generation multi-parameter analyzer for full blood count, 6-part differential and reticulocyte testing by impedance variation and fluorescence flow cytometry. In this study, we verified the whole blood and limited body fluid modes of the Atellica Hema 580.

Methods: We evaluated precision, linearity, carry-over, throughput and performed a method comparison to assess the performance of the Atellica Hema 580. For comparison of the Atellica Hema 580 with the Sysmex XN-1000 (Sysmex, Kobe, Japan), 140 samples from adult and pediatric patients including both normal and abnormal hematology profiles were analyzed in parallel.

Results: The Atellica Hema 580 demonstrated acceptable imprecision within the manufacturer's specifications for whole blood and body fluid modes, good linearity for high and low ranges and no significant carryover. The full blood count, differential and reticulocyte correlated well with the Sysmex XN-1000, except for mean cell hemoglobin concentration, basophil and large immature cells. The optical platelet count, reflexed in 34 samples with a platelet count <150 $\times$ 10^9/l, showed a strong correlation with the fluorescent platelet count on the Sysmex XN-1000. The morphology flagging efficiency was 92% for white blood cells, 95% for red blood cells and 87% for platelets.

Conclusion: The Atellica Hema 580 showed good analytical performance and workflow efficiency for a wide range of patient samples.

KEYWORDS
Atellica Hema, full blood count, hematology analyzer, validation

1 | INTRODUCTION

The Atellica Hema 580 (Siemens Healthineers, Tarrytown, NY, USA) is a new generation multi-parameter analyser for hematology testing. This automated system has been designed to meet the throughput, workspace and efficiency requirements of medium to high volume laboratories. Its components, which can be connected to a conveyer transport system, include analyzer modules, a compressor (external data management) and an automated slide-maker and stainer.[1]

The Atellica Hema 580 performs a full blood count (FBC), differential (DIFF) and reticulocyte (Retic) testing by impedance variation and fluorescence flow cytometry.

Platelets (PLT) are counted by impedance variation in conjunction with optical detection to increase the accuracy of the automated PLT count. Further it is possible to obtain an accurate DIFF from a low white blood cell (WBC) count using the extended counting sequence in the instrument's low WBC mode. The WBC is automatically corrected for nucleated red blood cells (NRBC) when present, thereby

reducing the manual peripheral blood smear (PBS) review rate. Lastly, the instrument can perform quantitative measurement of blood cells in synovial, serous (peritoneal, pericardial, pleural) and cerebrospinal fluids.[1]

Moreover, the Atellica Hema 580 offers advanced clinical and research parameters. This includes WBC precursor subpopulations namely, atypical lymphocytes and large immature cells (LIC) which include immature lymphocytes, immature monocytes and immature granulocytes. Reflex use of these tests in routine analysis may be of clinical value in early diagnosis and follow-up of hematological disorders. In addition, red blood cells (RBC) and Retic flags namely, microcytic red blood cells and Retic hemoglobin cellular content offer an early measure of iron deficiency.

To date, the Atellica Hema 580 analyzer has not been verified in whole blood or body fluid mode. A study was designed to evaluate the analytical performance of the Atellica Hema 580 analyzer for FBC, DIFF and Retic. The laboratory at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), Johannesburg, South Africa, which is an academic laboratory with a large volume of abnormal samples, was selected by the Hematology Technology Advisory committee of the National Health Laboratory Service as the site for verification to assess if the analyzer can meet specific requirements at a given test site. We analyzed sample precision, linearity, carry-over, throughput and performed a method comparison. This study was designed according to the Clinical Laboratory Standards Institute (CLSI) and International Council for Standardization in Hematology (ICSH) guidelines.[2–6]

2 | MATERIALS AND METHODS

2.1 | Analyzer

The Atellica Hema 580 system was installed and calibrated by the manufacturer over a five-day period at CMJAH. The system has the following dimensions: analyzer: 87 cm wide × 67 cm deep × 73 cm high; compressor: 20 cm wide × 47 cm deep × 31 cm high. The workflow was programmed by the *Data Management System* which stores up to 100 000 patient results. Laboratory staff members were trained on instrument operation, troubleshooting and maintenance procedures. Daily quality control measurements were performed. This study was approved by the Human Research Ethics Committee of the University of the Witwatersrand (M090688).

2.2 | Principles

The instrument uses impedance variation to measure RBC and PLT in the RBC/PLT chamber. The hemoglobin (Hb) is measured by spectrophotometry. The WBC is measured by impedance in three different chambers (WBC/Hb, WBC/BASO and WBC/DIFF chamber) and the WBC subpopulations of the DIFF are detected with double hydrodynamic sequential system technology. As each cell passes through the light beam, these WBC subpopulations are separated based on cell volume measured on the X-axis (forward scatter) and absorbency measured on the Y-axis (side-scatter). The instrument uses impedance variation and fluorescence flow cytometry to measure the Retic, which are subdivided according to their fluorescence intensity to represent the different stages of maturity. The instrument uses impedance variation and absorbance flow cytometry to measure the optical PLT count. The PLT measurement in the PLT-O channel utilizes the double hydrodynamic sequential system to count PLT which are distinguished from RBC based on the refractive index. The body fluid RBC and WBC are measured by impedance. The body fluid WBC is measured in two different chambers (WBC/Hb, and WBC/DIFF chamber).[1]

2.3 | Samples

The samples used included commercial controls (Siemens Healthineers, Tarrytown, NY, USA) and residual specimens referred for routine laboratory testing. These samples included both normal and abnormal hematology profiles representative of the patient population. Samples with interference namely microcytes ($n = 19$), schistocytes ($n = 7$) and PLT aggregates ($n = 2$) were included. Microtainer samples from children were also included. A total of 150 samples were selected from the workload. Aged and insufficient samples were excluded ($n = 10$). Samples were collected in K_2EDTA tubes (Vacutainer®, Becton Dickinson, Plymouth, UK) for analysis. Samples were stored at room temperature and analyzed by a dedicated technologist within 4 h of collection. This study was performed from 1 February to 30 May 2023.

2.4 | Precision

Imprecision was performed with manufacturer's control material (high, low and normal for blood samples and high and normal for body fluid, lots: AD439 and AF0123).[3,4] All levels were processed as five replicates per run over five days. The co-efficient of variation (% CV) determined from the mean and standard deviation for each level of quality control was compared to the manufacturer's and state of the art precision limits. The manufacturer's % CV for low, normal and high quality control material obtained from the Atellica Hema 580 analyzer operators guide, were employed as the first hierarchy.[1] Subsequently, the state of the art precision limits were accessed from the European Federation of Clinical Chemistry and Laboratory Medicine Biological Variation Database.[7]

2.5 | Comparison study

Method comparison studies were performed to compare the performance of the Atellica Hema 580 to the Sysmex XN-1000 (Sysmex, Kobe, Japan) for FBC, DIFF and Retic in whole blood.[5] For the DIFF, comparison with the Sysmex XN-1000 was performed. This was owing to several errors associated with the gold standard 200-cell

TABLE 1 Within and between run precision analysis for normal, abnormal high and low control material in whole blood and body fluid.

	Within-run precision control samples CV%			Acceptance criteria for within-run precision CV%			
Parameter ($n = 5$)	Abnormal Control Low	Normal control	Abnormal Control high	Siemens low	Siemens normal	Siemens high	SOTA
WBC, $\times 10^9$/l	1.43	1.08	0.72	5	2	2	6.0/2.5/1.5
RBC, $\times 10^{12}$/l	0.71	0.80	0.47	2.5	2	1.5	1.1
Hb, g/dl	0.79	0.29	0.00	1.5	1	1	0.9
Hct, l/l	0.76	0.96	0.74	2	2	1.5	1.2
PLT-I, $\times 10^9$/l	2.94	1.91	1.71	10	5	3	4.5/3.0/–
PLT-O, $\times 10^9$/l	2.90	1.08	1.20	10	5	3	4.5/3.0/–
MPV, fl	0.8	1.31	1.5	-	3	-	2.5
MCV, fl	0.25	0.41	0.51	1	1	1	0.6
MCH, pg	0.78	0.68	0.52	-	2	-	1.1
MCHC, g/dl	0.84	0.25	0.81	-	2	-	1.06
RDW, CV, %	1.44	1.23	1.82	3	3	3	2.0
WBCD, $\times 10^9$/l	2.77	1.76	0.65	5	2	2	6.0/2.5/1.5
Lymph, #, 10^9/L	5.21	2.97	2.53	-	10	6	3.5
Lymph, %	3.15	2.44	5.04	7	5	4	-
Mono, #, 10^9/L	8.84	4.14	4.79	-	20	12	8.5
Mono, %	7.52	1.93	2.26	-	15	10	-
Neut, #, 10^9/L	3.63	1.58	1.37	-	6	4	10/2.5/–
Neut, %	1.24	1.53	0.69	6	3	2	-
Eos, #, 10^9/L	9.85	9.52	1.68	-	25	20	10
Eos, %	10.91	4.69	7.37	-	20	15	-
Baso, #, 10^9/L	5.83	1.74	0.92	-	40	25	20
Baso, %	0.97	0.0	0.95	-	30	20	-
NRBC, #, 10^9/L	20.58	11.27	3.78	-	+/−0.1	20	-
NRBC, %	8.86	13.25	4.56		+/−1.5	20	-
Ret, #, $\times 10^{12}$/l	9.19	3.07	3.16	-	20	10	10
Ret, %	9.05	2.75	3.00	-	12	8	10
BF WBC, $\times 10^9$/l		2.66	0.94		15	5	
BF RBC, $\times 10^{12}$/l		3.95	3.07		5	-	
	Between-run precision control samples CV%			**Acceptance criteria for between-run precision CV%**			
Parameter ($n = 25$)	Abnormal Control Low	Normal control	Abnormal control high	Siemens low	Siemens normal	Siemens high	SOTA
WBC, $\times 10^9$/l	2.28	1.11	0.66	5	4	3	6.0/2.5/1.5
RBC, $\times 10^{12}$/l	0.67	0.50	0.91	2.5	2	2	1.1
Hb, g/dl	0.86	0.26	0.27	2.5	2	2	1.0
Hct, l/l	0.77	0.77	0.89	4	3.5	3	1.4
PLT-I, $\times 10^9$/l	4.74	2.07	2.07	15	8	6	4.5/3.0/–4.5/3.0/–
PLT-O, $\times 10^9$/l	3.66	1.96	1.58	15	8	6	2.5
MPV (fl)	1.09	0.88	2.54	6	5	5	0.8
MCV (fl)	0.26	0.54	0.26	4	3	3	1.5
MCH, pg	0.58	0.48	0.69	3	2.5	2	1.2
MCHC, g/l	0.62	0.64	0.84	5	5	5	2.0
RDW, CV, %	1.73	1.38	1.09	4	4	4	
WBCD, $\times 10^9$/l	1.89	1.36	1.01	5	4	3	6.0/2.5/1.5
Lymph, #, 10^9/L	5.23	3.61	4.14	8	8	8	3.5

(Continues)

TABLE 1 (Continued)

Parameter ($n = 25$)	Between-run precision control samples CV%			Acceptance criteria for between-run precision CV%			
	Abnormal Control Low	Normal control	Abnormal control high	Siemens low	Siemens normal	Siemens high	SOTA
Lymph, %	3.14	3.35	4.51	8	8	8	-
Mono, #, 10^9/L	15.23	6.89	3.89	25	15	15	8.5
Mono, %	12.01	5.80	3.54	25	15	15	-
Neut, #, 10^9/L	3.01	1.59	1.18	6	4	3	10/2.5/–
Neut, %	1.52	1.49	0.88	6	4	3	-
Eos, #, 10^9/L	8.34	7.98	4.52	16	15	10	10
Eos, %	8.59	6.72	5.62	16	15	10	-
Baso, #, 10^9/L	2.14	1.67	0.89	16	14	14	20
Baso, %	0.94	0.20	0.61	16	14	14	-
NRBC, %	4.48	8.06	12.32	20	15	15	-
NRBC, #, 10^9/L	4.59	10.30	10.23	20	15	15	-
Ret, #, $\times 10^{12}$/l	8.37	4.35	3.18	18	10	8	10
Ret, %	8.11	4.24	2.92	18	18	18	10
BF WBC, $\times 10^9$/l		2.82	1.29		10	5	
BF RBC, $\times 10^{12}$/l		2.94	3.21		6	4	

Abbreviations: BASO, basophil; BF, body fluid; EOS, eosinophil; Hb, hemoglobin; Hct, hematocrit; LYMPH, lymphocyte; MCH, mean cell hemoglobin; MCHC, mean cell hemoglobin concentration; MCV, mean cell volume; MONO, monocyte; MPV, mean platelet volume; NEUT, neutrophil; NRBC, nucleated red blood cell; PLT-I, platelet impedance; PLT-O, platelet optical; RBC, red blood cell; RDW, red cell distribution width; Ret, reticulocyte count; SOTA, state of the art; WBC, white blood cell; WBCD, white blood cell differential.

manual DIFF including statistical, slide distribution and morphological interpretation., ed.[8]

All samples were run within 4 h of collection. Samples covered clinical decision levels and the full reportable measuring ranges of the Atellica Hema 580. This included 53 abnormal samples with hematological malignancies ($n = 11$), hemolytic disorders ($n = 9$) and infection/inflammation ($n = 33$). The performance of the PLT-O channel was evaluated using samples with PLT <150 $\times$ 10^9/l selected by the impedance PLT (PLT-I) for reflex analysis and compared to the fluorescent platelet count (PLT-F) on the Sysmex XN-1000. Statistical analysis was performed with EP-evaluator Software. (Colchester, VT, USA) using the Bland–Altman method and Passing-Bablok regression statistical methods.

Alarms triggered for abnormal WBC, RBC and PLT morphology were evaluated on the same samples used for method comparison. Peripheral blood smear morphology was assessed by competent morphologists. Consensus criteria of the International Consensus Group for Hematology Review were used to define an abnormal (positive) PBS.[9] The sensitivity, specificity and efficiency were calculated for overall WBC, RBC and PLT alarms.

2.6 | Linearity

The background (limit of blank) and linearity (analytical measurement range) were assessed. Linearity for WBC, RBC, Hb and PLT-I was performed by carrying out eight serial dilutions of patient samples with high concentrations (WBC 62.95 $\times$ 10^9/l; RBC 7.55 $\times$ 10^{12}/l; Hb 20.6 g/L; PLT 633 $\times$ 10^9/).[6] The lowest dilution reached the limit of quantitation established by the manufacturer (WBC = 0.1–300 $\times$ 10^9/l, RBC = 0.3–8 $\times$ 10^{12}/l, Hb = 0.8–24 g/dL and PLT-I = 10–2500 $\times$ 10^9/l). The WBC of <1.0 $\times$ 10^9/l were analyzed on the instrument's low WBC mode. The background (limit of blank) was assessed with a blank sample, run three times after priming the instrument. The results were compared to the manufacturer's limits (WBC = 0.3 $\times$ 10^9/l, RBC = 0.05 $\times$ 10^{12}/l, Hb = 0.2 g/dL and PLT-I = 7 $\times$ 10^9/l).

2.7 | Carryover

Carryover was evaluated by measuring whole blood samples with high target values for WBC, RBC, Hb, and PLT-I counts three consecutive times (H1, H2, and H3) followed by three consecutive analyses of samples with low target values (L1, L2, and L3).[6] Percentage carry-over was calculated using the Broughton method: [(L1 − L3)/(H3 − L3)] $\times$ 100. The results were compared to the manufacturer's limits (<0.5% for WBC and PLT and <1% for Hb and RBC).

2.8 | Throughput

In this study, the throughput of the autosampler for FBC, DIFF and Retic was assessed using 60 randomly selected patient samples

TABLE 2 Comparison between Sysmex XN-1000 (reference method) and the Atellica Hema 580 (validation method) for full blood count, differential and reticulocyte count.

			Passing-Bablok regression		Bland–Altman statistics	
Parameter	**Correlation coefficient**	**Range**	**Intercept (95% CI)**	**Slope (95% CI)**	**Bias (95% CI)**	**95% LOA**
WBC, $\times 10^9$/l	0.998	0.81–186.36	−0.05 (−0.16 to 0.08)	0.96 (0.94 to 0.98)[c]	−0.74 (−1.40 to −0.07)	−8.53 to 7.05
RBC, $\times 10^{12}$/l	0.997	1.84–6.47	0.23 (0.17 to 0.28)[b]	0.93 (0.91 to 0.94)[c]	−0.075 (−0.09 to −0.06)	−0.24 to 0.10
Hb, g/dl	0.998	5.40–17.20	0.20 (0.20 to 0.20)[b]	0.10 (1.0 to 1.0)	0.22 (0.19 to 0.25)	−0.11 to 0.54
Hct, l/l	0.977	0.17 to 0.51	0 (−0.01 to 0.02)	0.96 (0.93 to 1.00)	−0.01 (−0.01 to-0.01)	−0.04 to 0.02
PLT-I, $\times 10^9$/l	0.990	5 to 696	−1.23 (−9.61 to 4.71)	1.01 (0.98 to1.04)	0.6 (−2.57 to 3.71)	−35.9 to 37.0
PLT-O, $\times 10^9$/l[a]	0.982	2 to 135	−0.05 (−1.79 to 4.41)	0.98 (0.91 to 1.07)	0.4 (−2.19 to 3.07)	−14.3 to 15.2
MPV (fl)	0.916	6.50 to 11.40	−1.60 (−1.60 to −0.70)[b]	1.00 (0.91 to1.00)	−1.56 (−1.63 to-1.48)	−2.38 to −0.74
MCV (fl)	0.930	65.30 to 103.50	−8.76 (−14.4 to −2.9)[b]	1.09 (1.02 to 1.15)[c]	−1.24 (−1.77 to −0.71)	−7.23 to 4.76
MCH, pg	0.978	20.70 to 35.70	1.00 (0.10 to 1.53)	1.00 (0.98 to 1.03)	0.96 (0.86 to 1.07)	−0.26 to 2.18
MCHC, g/dl	0.330	30.70 to 37.10	20.76 (17.14 to 23.83)[b]	0.40 (0.30 to 0.51)[c]	1.10 (0.84 to 1.35)	−1.70 to 3.89
RDW, CV, %	0.881	11.30 to 33.70	1.08 (−1.24 to 2.67)	1.07 (0.96 to 1.22)	2.19 (1.90 to 2.48)	−1.22 to 5.59
Lymph, #, 10^9/L	0.992	0.13 to 5.74	0.01 (−0.01 to 0.05)	0.97 (0.95 to 1.00)	−0.05 (0.08 to −0.03)	−0.34 to 0.24
Lymph, %	0.965	1.61 to 96.50	0.08 (−0.26 to 0.30)	1.00 (0.99 to 1.02)	0.51 (−0.26 to 1.29)	−8.52 to 9.55
Mono, #, 10^9/L	0.985	0.01 to 2.44	−0.03 (−0.05 to 0.00)	1.09 (1.05 to 1.15)[c]	0.02 (0.01 to 0.03)	−0.14 to 0.18
Mono, %	0.945	1.50 to 27.40	0.19 (−0.26 to 0.69)	1.04 (0.97 to 1.09)	0.46 (0.21 to 0.70)	−2.26 to 3.17
Neut, #, 10^9/L	0.964	0.14 to 26.80	0.02 (−0.05 to 0.06)	0.98 (0.96 to 0.99)[c]	−0.24 (−0.41 to −0.07)	−2.19 to 1.71
Neut, %	0.991	6.40 to 91.30	0.04 (−0.91 to) 1.03	0.10 (0.98 to 1.01)	−0.26 (−0.65 to 0.12)	−4.73 to 4.20
Eos, #, 10^9/L	0.986	0.00 to 1.14	0.01 (0.00 to 0.02)	0.97 (0.91 to 1.00)	0.00 (−0.01 to 0.01)	−0.09 to 0.09
Eos, %	0.985	0.01 to 22.70	0.20 (0.10 to 0.26)[b]	0.95 (0.91 to 1.00)	0.01 (−0.11 to 0.14)	−1.37 to 1.39
Baso, #, 10^9/L	0.632	0.00 to 0.10	−0.01 (−0.01 to 0.00)	0.75 (0.60 to 1.00)	−0.01 (−0.02 to −0.01)	−0.06 to 0.03
Baso, %	0.579	0.00 to 2.70	−0.10 (−0.20 to −0.07)[b]	1.00 (0.83 to 1.05)	−0.12 (−0.19 to −0.06)	−0.84 to 0.59
LIC, #, 10^9/L	0.557	0.00 to 1.37	-	-	−0.4 (−0.06 to −0.01)	−0.31 to 0.24
LIC, %	0.691	0.00 to 4.40	-	-	−0.63 (−0.76 to −0.49)	−2.18 to 0.92
Ret, #, $\times 10^{12}$/l	0.882	0.00 to 0.16	0.01 (−0.01 to 0.01)	0.93 (0.80 to 1.09)	0.00 (−0.01 to 0.01)	−0.04 to 0.04
Ret, %	0.921	0.13 to 4.44	0.07 (−0.24 to 0.25)	0.95 (0.83 to 1.11)	0.03 (−0.10 to 0.15)	−0.76 to 0.81

Abbreviations: BASO, basophil; EOS, eosinophil; Hb, hemoglobin; Hct, hematocrit; LIC, large immature cells; LYMPH, lymphocyte; MCH, mean cell hemoglobin; MCHC, mean cell hemoglobin concentration; MCV, mean cell volume; MONO, monocyte; MPV, mean platelet volume; NEUT, neutrophil; PLT-I, platelet impedance; PLT-O, platelet optical; RBC, red blood cell; RDW, red cell distribution width; Ret, reticulocyte count; WBC, white blood cell.

[a]Analysis on 34 reflexed samples with PLT <150 $\times$ 10^9/l.

[b]Systematic difference.

[c]Proportional difference.

submitted as a batch to represent the typical workload experienced in a large sized academic laboratory. Patient samples were loaded on sample racks. Each sample rack holds ten samples. Throughput was defined as the time measured from bar code reading of the first patient sample to the last patient sample reaching the output tray. The results were compared to the manufacturer's claims of 1 h for FBC+ DIFF and FBC + Retic respectively.

3 | RESULTS

3.1 | Precision

Table 1 shows the calculated % CV for the within-run precision. All parameters, measured in whole blood and body fluid were within the manufacturer's specifications and state of the art criteria. Between-run precision results are also shown in Table 1. Platelets (low), absolute lymphocytes (low, normal, high) and absolute monocytes (low) exceeded the state of the art acceptance criteria, but were within the manufacturer's specifications.

3.2 | Comparison study

A very strong correlation was observed for the FBC parameters, with the exception of mean corpuscular hemoglobin concentration (MCHC) (Table 2 and Figure 1). The Atellica Hema 580 showed higher results than the Sysmex XN-1000 for the MCHC parameter. The WBC DIFF of the Atellica Hema 580 was also comparable to the Sysmex XN-1000, and the correlation coefficient values were greater than 0.95, except for basophils and LIC. Mean differences represented by the Bland–Altman statistics were small for all parameters with few outliers.

The PLT-O was reflexed in 34 samples and showed a very strong correlation (0.982) with the PLT-F on the Sysmex XN-1000. For PLT-O compared with the PLT-I on the Atellica Hema 580, however,

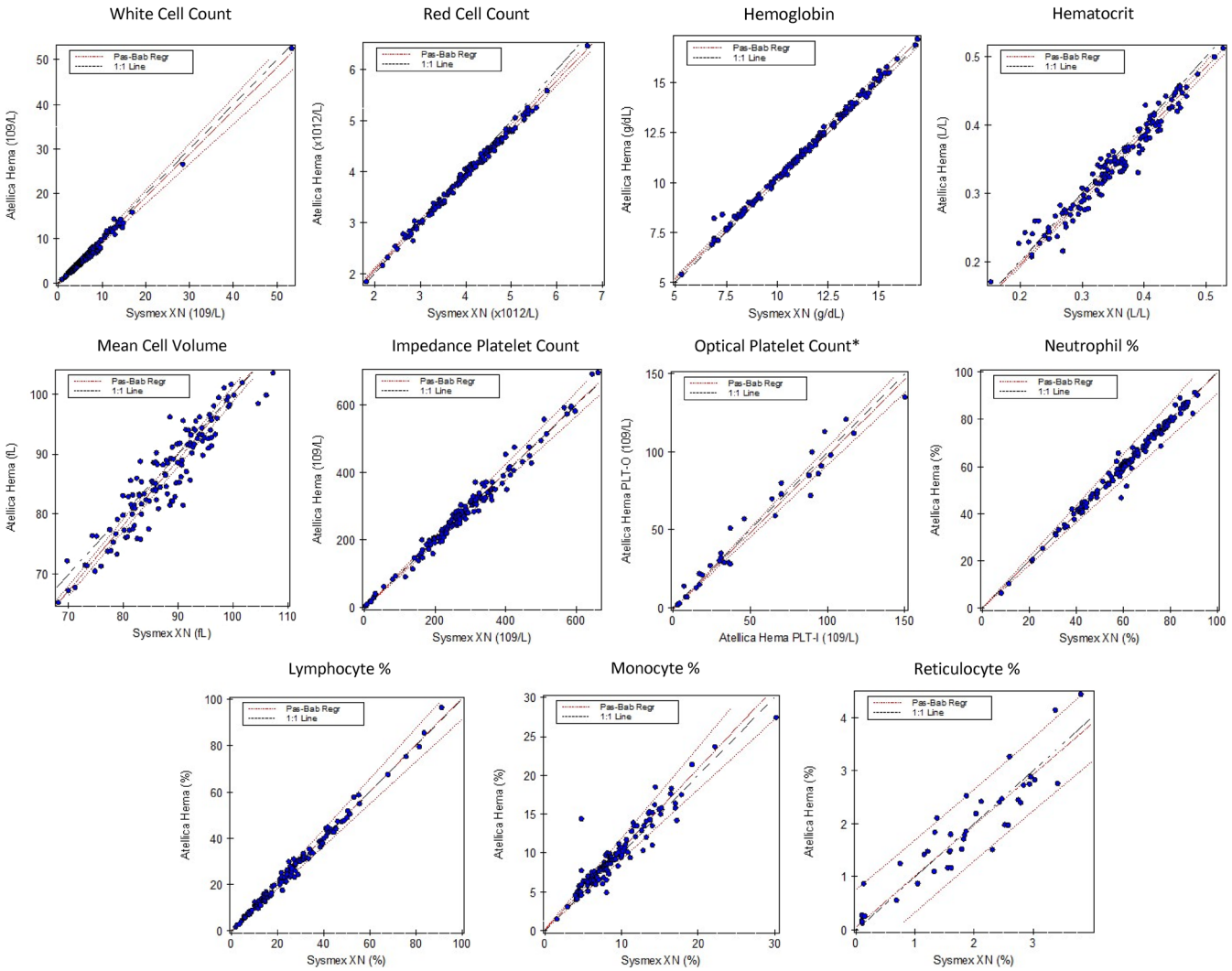

FIGURE 1 Passing and Bablok regression of Atellica Hema 580 versus Sysmex XN-1000 for FBC, DIFF and Retic. *Analysis on 34 reflexed samples with PLT <150 $\times$ 10^9/l

TABLE 3 Atellica Hema 580 alarms compared to manual peripheral blood smear review.

Alarms	Sensitivity (95% CI)	Specificity (95% CI)	Efficiency (95% CI)
WBC, %	96.00 (86.29–99.51)	89.02 (80.18–94.86)	91.67 (85.58–95.77)
RBC, %	100.00 (59.04–100.00)	95.20 (89.85–98.22)	95.45 (90.37–98.31)
PLT, %	80.00 (28.36–99.49)	87.40 (80.35–92.62)	87.12 (80.18–92.32)

Note: WBC Alarms generated from WBC/Hb, WBC/BASO and WBC/DIFF channels; RBC alarms generated by RBC/PLT, WBC/Hb channels; PLT alarms generated by RBC/PLT channel.

TABLE 4 Linearity and carryover of the Atellica Hema 580 in whole blood.

Parameter	Carryover %	Linearity		
		Concentration range	Correlation coefficient	Regression line
WBC, $\times 10^9$/l	0.01	0.05–62.95	0.99	$y = 0.97x - 0.3$
RBC, $\times 10^{12}$/l	0.85	0.07–7.55	1.00	$y = 0.99x + 0$
Hb, g/dl	0.00	0.2–20.6	1.00	$y = 0.99x - 0.1$
PLT-I, $\times 10^9$/l	0.23	3–633	1.00	$y = 1.01x - 5.5$

Abbreviations: Hb, hemoglobin; PLT-I, platelet (impedance); RBC, red blood cell; WBC, white blood cell.

a mean difference of −4.1 (95% CI, −7.51 to −0.60) was found. There were ten samples analyzed on the low WBC mode which also showed a very strong correlation (0.994) with a small % bias of 0.02 (95% CI, −0.03 to 0.06).

Table 3. shows the sensitivity, specificity and efficiency of the morphology alarms as compared to manual PBS review. There were 31 (23.48%) false positive results of which 9 (6.82%) were WBC alarms, 6 (4.55%) were RBC alarms and 16 (12.12%) were PLT alarms. There were 3 (2.23%) false negative results of which 2 (1.52%) were WBC morphology namely, the presence of immature granulocytes on PBS and 1 (0.76%) was PLT morphology namely, the presence of platelet clumping on PBS.

3.3 | Linearity

The Atellica Hema 580 was linear over the measured concentrations. Table 4. shows the correlation coefficients for the whole blood parameters, WBC, RBC, Hb, and PLT-I which were close to 1. The background counts measured 0 for RBC, Hb and PLT. The background count for the WBC was 0.03 and within the manufacturer's limit.

3.4 | Carryover

The percentage carryover was within the manufacturer's specifications (Table 4)

3.5 | Throughput

The throughput for 60 samples was 34 min for FBC, DIFF and Retic analysis.

4 | DISCUSSION

The FBC/ DIFF is one of the most important diagnostic screening and laboratory tests. Over the years, improved measurement technologies and the introduction of additional reportable parameters and new algorithms in automated hematology analyzer systems have led to more accurate, precise, and efficient results. In this report, we evaluated the analytical performance of the newly introduced Atellica Hema 580.

The performance characteristics of the Atellica Hema 580 namely, precision; method comparison; linearity; carry-over and throughput were within the manufacturer's specifications. Within-run and between-run precision measurements performed in whole blood and body fluid showed satisfactory performance, consistent with the manufacturer's specifications. When compared to the precision limits of the current state of the art criteria, all parameters too showed satisfactory performance except for the between-run precision of PLT (low), absolute lymphocytes (low, normal, high) and absolute monocytes (low).

The Atellica Hema 580 showed comparable performance with the Sysmex XN-1000 for FBC, DIFF and Retic results. The Sysmex XN automated hematology system is one of the most widely validated analyzers.[10,11] A few proportional and systemic differences were observed; however, these are mostly likely due to inter-instrument differences. There were very strong correlations with correlation coefficients of greater than 0.88 (most ≥0.95) for most parameters except for MCHC, absolute and % of basophils and LIC. A weak correlation for MCHC between different multi-channel analyzers which use different technologies is well recognized. In comparison studies with the Alinity hq (Abbott Laboratories, Santa Clara, CA,USA), Woo et al. showed a correlation coefficient of 0.683 for the MCHC with the Sysmex XN-1000 and Van der Beken et al. showed a correlation coefficient of 0.780 with the Abbott CELL-DYN Sapphire (Abbott Laboratories, Santa Clara, CA,USA).[12,13] We also observed a moderate correlation in the

absolute and % of basophils and LIC which is an expected result, as these cells account for very low proportion of total WBC. This is consistent with previously published studies which describe a weak correlation between analyzers for cells present in low concentrations, such as basophils and immature granulocytes on different hematology analyzers.[13,14]

Different PLT detection principles have been applied to hematology analyzers. Of these, the fluorescence method has been found to be the most accurate for low PLT counts, compared with optical and impedance methods.[15–18] The Atellica Hema 580 utilizes the double hydrodynamic sequential system when the impedance PLT count is not accurate. The Atellica Hema 580 PLT-I results were precise and demonstrated a strong correlation with the Sysmex XN-1000 PLT-I results for the whole measuring range. In the low PLT range ($<150 \times 10^9$/l), when the PLT-I was compared to the PLT-O on 34 samples on the Atellica Hema 580, a slight positive bias was observed. This finding is similar to reports of other commercially available impedance methods.[15–18] Nonetheless, the Atellica Hema 580 PLT-O results, demonstrated a strong correlation with the reference Sysmex XN-1000 PLT-F. The new PLT-O channel allows for accurate and precise counting of thrombocytopenic samples.

Another feature of the Atellica Hema is the automatic re-measurement of samples with a low WBC concentration in the "low WBC mode". This produced comparable results to the Sysmex XN-1000 through an extended counting sequence, consistent with earlier reports.[10,11] The false negative rate for all WBC, RBC and PLT alarms triggered was <5%. This implies that the absence of alarms is reliable, hence improving the workflow efficiency and reducing the need of performing PBS review. However, the false positive rate was increased for the PLT alarm, namely platelet clumping. A limitation of this study is that the research parameters were not evaluated. Specifically, the Double Hydrodynamic Sequential System in the DIFF mode detects abnormal WBC precursor subpopulations according to cell size, content, and distribution. This technology has been designed to reduce the number of PBS particularly in laboratories with a large volume of abnormal WBC populations. A further study limitation is that in the body fluid mode, only precision using commercial controls was evaluated. This was owing to the unavailability of patient samples of all fluid types to perform a verification study of automated body fluid counts.

In conclusion, to the best of our knowledge, for the first time we describe here the performance characteristics of the new Atellica Hema 580 hematology analyzer. The measurement technologies are comparable to the reference Sysmex XN-1000, precise and efficient for FBC, DIFF and Retic measurement in whole blood. In particular, this technology showed accurate counting of low PLT and WBC counts. The Atellica Hema 580 represents a reliable automated solution for medium to large academic laboratories.

AUTHOR CONTRIBUTIONS

All authors contributed to the design of the study. E. Schapkaitz, A. Baiden and S. Raburabu performed the research and analyzed the data. E. Schapkaitz wrote the paper. All authors revised the text critically and agreed with the final contents.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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