DIAGNOSTICS

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Comparative Study of Automated Blood Counts on CELL-DYN Emerald 22, CELL-DYN Ruby, and CELL-DYN Sapphire

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Summary

Objective

The purpose of this study was to compare parameters reported by CELL-DYN Emerald 22 to those obtained with CELL-DYN Ruby and CELL-DYN Sapphire. As modern hematology laboratories may use various types of hematology analyzers depending on workload, technical resources, and staff, it is important for the user to understand inter-platform variability.

Methods

A total of 300 EDTA-anticoagulated samples were tested in singlet on each instrument within two hours from each other at Abbott Hematology's laboratory located in Santa Clara, CA, USA.

Two hundred-sixty (260) samples were either from apparently healthy volunteers, or were de-identified remnant samples from area hospitals. In addition, 40 samples were contrived by either dilution or concentration by gradient centrifugation to obtain low and high RBC/HGB, PLT and WBC values, to provide data across the expected range of clinical samples.

Data were processed by Passing-Bablok regression analysis to obtain slope and intercept. Deming regression was performed for the comparison of BASO and %B. Pearson's correlation coefficients (r) were also calculated.

Results

In comparison of CELL-DYN Emerald 22 to CELL-DYN Ruby, correlation coefficients for the main CBC parameters (WBC, RBC, HGB, HCT, MCV, PLT) ranged from 0.95 (MCV) to 1.00 (WBC and HGB), and for WBC differential ranged from 0.48 (BASO) to 1.00 (NEU and LYM).

In comparison of CELL-DYN Emerald 22 to CELL-DYN Sapphire, correlation coefficients for the main CBC parameters ranged from 0.98 (MCV) to 1.00 (WBC and HGB), and for WBC differential ranged from 0.49 (BASO) to 1.00 (NEU).

In addition, in comparison of CELL-DYN Ruby to CELL-DYN Sapphire, correlation coefficients for the main CBC parameters ranged from 0.97 (MCV) to 1.00 (WBC, RBC, HGB, HCT and PLT), and for WBC differential ranged from 0.87 (BASO) to 1.00 (NEU and LYM).

Conclusion

CBC and WBC differential results obtained with the CELL-DYN Emerald 22 demonstrated close correlation and were substantially equivalent with those generated by CELL-DYN Ruby and CELL-DYN Sapphire.

Introduction and Objective

CELL-DYN Emerald 22 (Abbott Hematology, Santa Clara, CA, USA) is a compact hematology analyzer designed for small and medium-sized laboratories (Figure 1.), but it can also be used as secondary (back-up) instrument in larger laboratories.

It provides a complete blood count (CBC), including a 5-part white blood cell (WBC) differential. The analyzer combines impedance technology for cell counts with UNI-FLOW dual-angle light scatter for the differential (1).

The goal of the study was to assess the performance of CELL-DYN Emerald 22 in comparison with CELL-DYN Ruby (Abbott) and CELL-DYN Sapphire (Abbott), and to demonstrate that results generated by CELL-DYN Emerald 22 are substantially equivalent and commutable with those generated by CELL-DYN Ruby and CELL-DYN Sapphire.

Figure 1.

CELL-DYN Emerald 22

Methods

CELL-DYN Sapphire uses impedance method to count red blood cells (RBC), while CELL-DYN Ruby utilizes optical method (Table 1). Both instruments create a 5-part WBC differential by a process known as Multi-Angle-Polarized-Scatter-Separation (MAPSS™) (2-5).

Table 1. Principles of technologies in the three hematology analyzers (2, 3).

Measurand	**CELL-DYN Emerald 22**	**CELL-DYN Sapphire**	**CELL-DYN Ruby**
RBC	Impedance	Impedance	Optical
PLT	Impedance	Optical	Optical
WBC	Impedance	Optical	Optical
WBC Differential	Optical (UNI-FLOW)	Optical (MAPSS™)	Optical (MAPSS™)

A total of 300 EDTA-anticoagulated samples were tested in singlet on each instrument within two hours from each other at Abbott Hematology's laboratory located in Santa Clara, CA, USA.

Samples (n=260) were either from apparently healthy volunteers, or were de-identified remnant samples from area hospitals. Informed consent has been obtained from volunteers (per protocol ADD-SC-13-001). IRB approval has been obtained for using leftover patient samples from area hospitals per protocol T630-02-0901.

In addition, to ensure coverage of the Analytical Measuring Range (AMR), 40 samples were contrived by either diluting samples with phosphate buffered saline (PBS), or concentrating cells by gradient centrifugation to obtain low and high RBC/HGB, PLT and WBC values, respectively.

Measurand values in Table 2 were compared between the three instruments.

Table 2. Measurands in the comparison study

Measurand name	**Abbreviation**
Red Blood Cell count	RBC
Hemoglobin concentration	HGB
Hematocrit	HCT
Mean Corpuscular Volume	MCV
Mean Corpuscular Hemoglobin	MCH
Mean Corpuscular Hemoglobin Concentration	MCHC
Red Cell Distribution With	RDW
Platelet count	PLT
Mean Platelet Volume	MPV
Neutrophil #	NEU
Lymphocyte #	LYM
Monocyte #	MONO
Eosinophil #	EOS
Basophil #	BASO
Neutrophil %	%N
Lymphocyte %	%L
Monocyte %	%M
Eosinophil %	%E
Basophil %	%B

Reticulocyte count and % reticulocytes were not included, as CELL-DYN Emerald 22 does not have the capability of measuring reticulocytes.

Data were processed by Passing-Bablok regression analysis to obtain slope and intercept. Pearson's correlation coefficient (r) was also calculated. Deming regression was used to analyze concordance for Basophil count and Basophil%. Regression analysis was not performed if the Person's correlation coefficient was < 0.5.

Results outside of the AMR of the respective instruments, as well as results invalidated by the analyzer, were excluded from the analysis. Two additional samples were excluded because of apparent transcription error.

Results

The AMR of the three analyzers is shown below.

Table 3. Analytical Measuring Ranges

Measurand	Unit	AMR		
		CELL-DYN Emerald 22	**CELL-DYN Ruby**	**CELL-DYN Sapphire**
WBC	10^9/L	0.4 - 90.0	0.02 – 246.8	0.4 – 250.0
RBC	10^{12}/L	1.2 - 8.3	0.0-7.5	0.22 – 7.50
HGB	g/dL	5.5 - 22.0	0.0 - 25.0	1.0 - 24.8
HCT	%	12.1 - 66.1	8.3 - 79.8	N/D
MCV	fL	53.2 - 118.4	58.0-139.0	37.0 – 179.0
PLT	10^9/L	11 - 1485	0.00 - 3000	11.0 - 2000
RDW	%	N/D	10.0 - 29.8	N/D
MPV	fL	N/D	4.3 - 17.2	4.2 – 19.0

N/D: Not defined

The tested samples have sufficiently spanned the AMR for CELL-DYN Emerald 22, except for RBC, where the highest value obtained was just slightly above 6.0 x 10^{12}/L.

The results of the correlation and regression analyses are shown in the Tables below.

Table 4. CBC and WBC differential comparison between CELL-DYN Emerald 22 and CELL-DYN Ruby

Emerald 22 vs Ruby	n	Range	Pearson's r	Passing Bablok	
				Slope	Intercept
WBC	254	0.40 - 90.10	1.00	0.95	0.16
RBC	266	1.17 - 6.04	0.99	1.01	-0.14
HGB	258	5.61 – 19.6	1.00	0.98	0.13
HCT	266	11.2 - 61.9	0.99	0.98	-0.34
MCV	266	64.7 - 115.0	0.95	1.01	-0.73
MCH	266	17.1 - 40.1	0.93	0.95	1.97
MCHC	266	26.4 – 36.9	0.68	0.65	12.9
RDW	266	9.8 - 25.7	0.89	0.83	3.80
PLT	270	18.8 – 1291.0	0.99	1.05	-2.69
MPV	270	4.62 - 12.00	0.86	0.55	4.27
NEU	223	0.49 - 20.20	1.00	0.95	0.08
LYM	227	0.04 – 11.10	1.00	0.99	0.07
MONO	227	0.01 - 6.87	0.96	0.92	0.00
EOS	223	0.00 – 1.32	0.96	0.86	0.00
BASO	232	0.00 - 0.35	0.48	N/A	N/A
%N	223	21.50 - 94.40	0.99	1.00	-0.05
%L	227	1.76 - 94.70	0.99	1.03	0.70
%M	227	1.40 - 59.60	0.93	0.97	-0.17
%E	223	0.00 - 13.20	0.97	0.89	-0.01
%B	232	0.00 - 2.31	0.04	N/A	N/A

N/A: Not Applicable; regression analysis has not been performed as r < 0.50

Table 5. CBC and WBC differential comparison between CELL-DYN Emerald 22 and CELL-DYN Sapphire

Emerald 22 vs Sapphire	n	Range	Pearson's r	Passing Bablok	
				Slope	Intercept
WBC	231	0.47 - 83.40	1.00	0.93	0.12
RBC	273	1.17 - 6.20	0.99	0.98	-0.05
HGB	265	5.63 - 18.80	1.00	1.00	-0.05
HCT	273	11.3 - 61.3	0.99	0.98	-0.48
MCV	273	64.4 - 116.0	0.98	1.02	-2.97
MCH	273	19.1 - 40.1	0.96	1.03	0.15
MCHC	273	29.2 – 36.8	0.71	0.79	8.08
RDW	273	10.6 – 32.5	0.92	0.87	3.3
PLT	251	16.0 - 882.0	0.99	0.97	4.55
MPV	247	6.15 – 14.3	0.87	0.72	2.17
NEU	207	0.01 - 21.00	1.00	0.93	0.08
LYM	207	0.02 - 11.40	0.99	0.93	0.07
MONO	207	0.01 - 3.89	0.97	0.88	0.01
EOS	207	0.01 - 1.28	0.93	0.86	-0.01
BASO	205	0.00 - 0.27	0.49	N/A	N/A
%N	207	1.68 - 95.90	0.99	0.97	1.80
%L	207	1.01 – 89.90	0.99	0.98	1.13
%M	207	1.23 - 49.70	0.97	0.92	0.43
%E	207	0.09 - 13.90	0.95	0.89	-0.14
%B	205	0.00 - 1.86	0.04	N/A	N/A

N/A: Not Applicable; regression analysis has not been performed as r < 0.50

Table 6. CBC and WBC differential comparison between CELL-DYN Ruby and CELL-DYN Sapphire

Ruby vs Sapphire	n	Range	Pearson's r	Passing Bablok	
				Slope	Intercept
WBC	234	0.47 - 83.40	1.00	0.98	-0.03
RBC	278	1.01 - 6.20	1.00	0.98	0.08
HGB	279	2.75 – 24.5	1.00	1.03	-0.25
HCT	274	11.3 - 61.3	1.00	1.00	-0.2
MCV	278	64.4 – 116.0	0.97	1.01	-2.55
MCH	278	19.1 - 40.1	0.94	1.06	-1.29
MCHC	278	29.2 - 36.8	0.74	1.24	-7.09
RDW	278	10.6 - 32.5	0.95	1.06	-0.77
PLT	256	13.2 - 1780.0	1.00	0.95	2.83
MPV	256	6.15 - 17.50	0.74	1.23	-3.20
NEU	230	0.35 - 50.20	1.00	0.98	0.00
LYM	230	0.05 - 41.90	1.00	0.95	0.00
MONO	229	0.00 - 6.87	0.99	1.01	-0.01
EOS	230	0.01 - 2.65	0.99	1.02	-0.01
BASO	231	0.00 - 1.22	0.87	1.71*	0.04*
%N	230	18.80 - 95.9	0.99	0.98	1.03
%L	230	1.01 - 91.80	0.99	0.96	0.19
%M	229	1.53 - 49.70	0.97	0.99	0.25
%E	230	0.09 - 14.30	0.98	1.00	-0.10
%B	231	0.00 - 1.86	0.28	N/A	N/A

**Deming regression*

N/A: Not Applicable; regression analysis has not been performed as r < 0.50

Correlation coefficients for the main CBC parameters (WBC, RBC, HGB, HCT, MCV, PLT) ranged from 0.95 (MCV) to 1.00 (WBC and HGB) in comparison of CELL-DYN Emerald 22 to CELL-DYN Ruby, and from 0.98 (MCV) to 1.00 (WBC and HGB) in comparison of CELL-DYN Emerald 22 to CELL-DYN Sapphire.

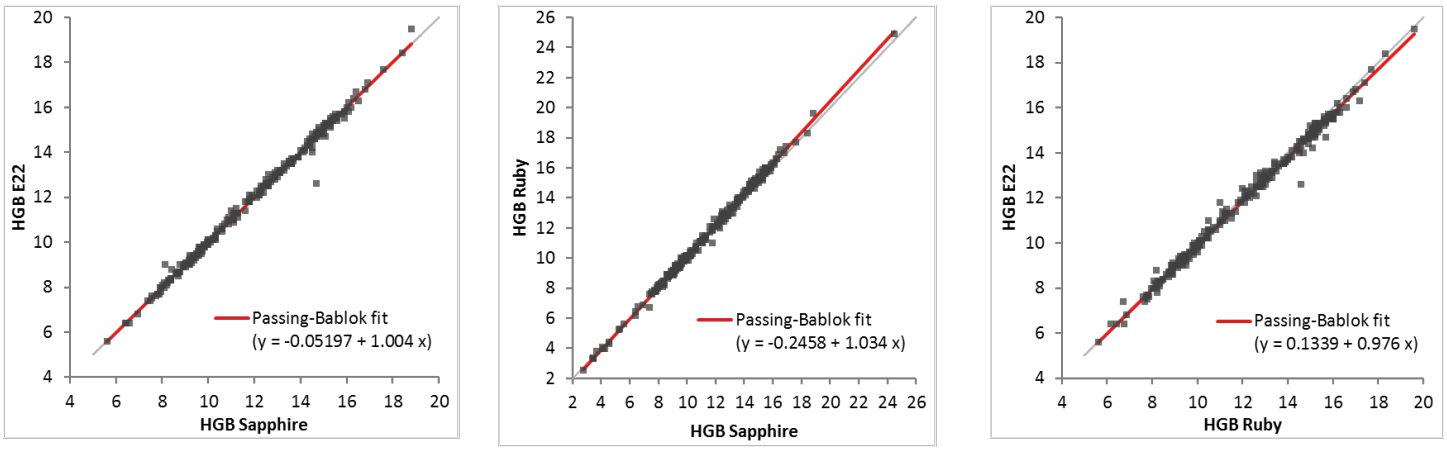
In addition, correlation coefficients for the main CBC parameters ranged from 0.97 (MCV) to 1.00 (WBC, RBC, HGB, HCT and PLT) in comparison of CELL-DYN Ruby to CELL-DYN Sapphire.

The high degree of concordance and lack of bias between the instruments can be visually verified on the regression graphs (Figure 2).

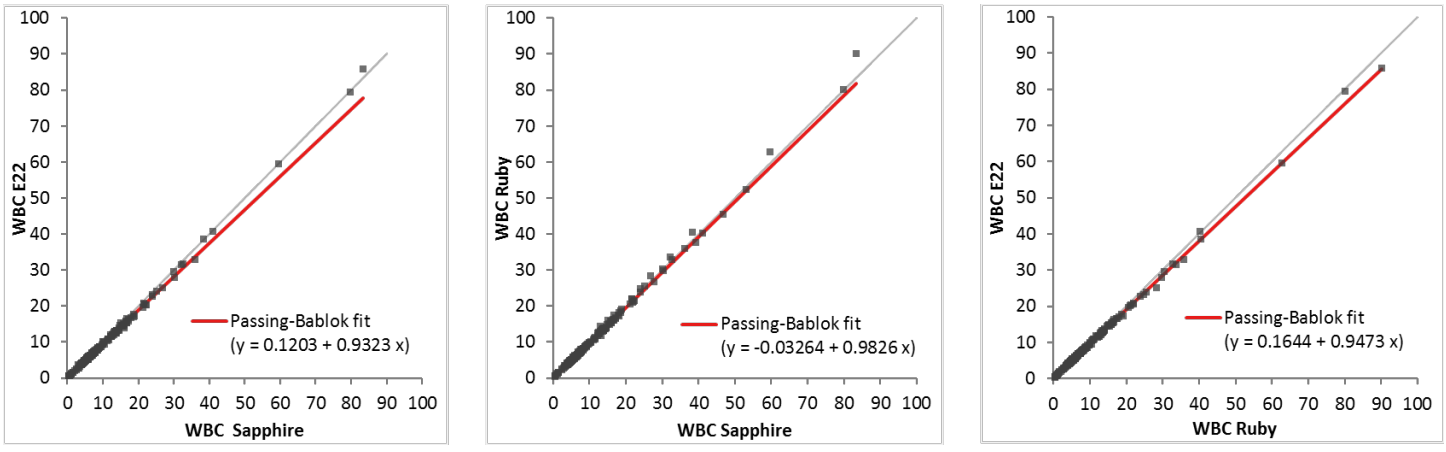
Figure 2.

Passing Bablok regression graphs for HGB (A), WBC (B) and PLT (C) among the three analyzers.

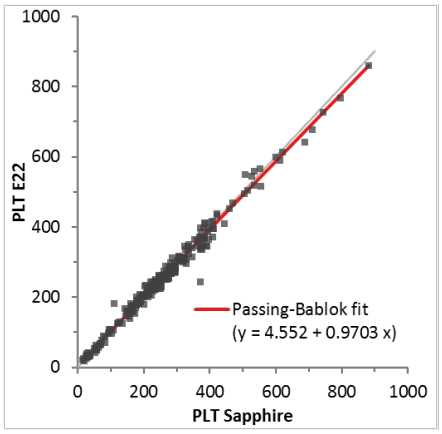
A)

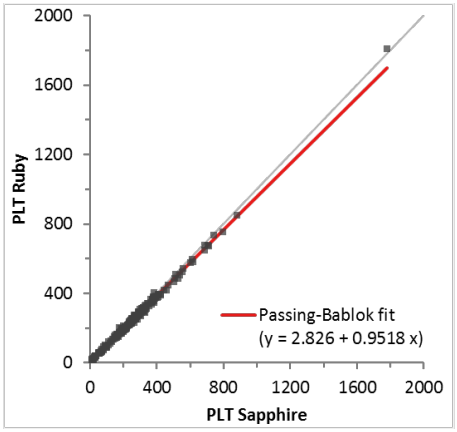


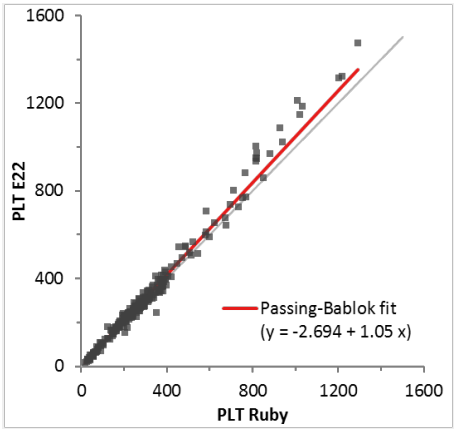
B)



C)







In addition, excellent correlation was demonstrated between CELL-DYN Emerald 22 and both CELL-DYN Ruby and CELL-DYN Sapphire, and between CELL-DYN Ruby and CELL-DYN Sapphire for WBC differential parameters, specifically NEU, LYM, MONO and EOS, as well as for %N, %L, %M and %E (r ranged from 0.93 to 1.00). Weak to moderate correlation was obtained for BASO (r=0.48 to 0.87), and no to weak correlation was observed for %B (r=0.04 to 0.28, respectively). This analyte is well known to vary between analyzers, and establishing the reference value with manual differential is also challenging (6, 7).

Despite the strong concordance between RBC and RBC-related parameters, only weak to moderate correlation was detected for MCHC between CELL-DYN Emerald 22 and both CELL-DYN Ruby and CELL-DYN Sapphire (r=0.68 and 0.71, respectively). This measurand also showed low correlation between CELL-DYN Ruby and CELL-DYN Sapphire (r=0.74). Due to the dominance of normal samples in the cohort, the tested range was narrow, which might have contributed to the lower correlation coefficient (8). MPV was another measurand that showed only moderate correlation between the three analyzers (r=0.74 to 0.87).

Limitations of the study

The tested range was narrower than the AMR of CELL-DYN Emerald 22 for RBC.

The AMR of CELL-DYN Emerald 22 is narrower for WBC and PLT that those for CELL-DYN Ruby and CELL-DYN Sapphire, and although the upper limit is similar for HGB, the lower limit of the AMR for Emerald 22 is higher than those for CELL-DYN Ruby and CELL-DYN Sapphire.

There were not enough pathological samples in the cohort to assess the comparative performance of morphological flagging.

Conclusion

The study has shown negligible inter-platform variability between the three studied instruments, and demonstrated substantial equivalence of hematology results between CELL-DYN Emerald 22, CELL-DYN Ruby and CELL-DYN Sapphire.

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