Performance comparison of the entry-level Medonic™ M51 hematology system with a reference system intended for use in large hospital laboratory settings

Hematology analyses are routinely performed both by large clinical hospital laboratories on fully automated, high-throughput analyzers as well as by smaller physician's office laboratories on stand-alone analyzers. As clinical laboratory tests form the basis for patient diagnosis, analyzer accuracy and precision are equality important independent of sample scale or clinical setting. Medonic M51 is an entry-level hematology system intended for the smaller laboratory. This work compares the performance of Medonic M51 with a that of reference system intended for the large hospital laboratory.

Introduction

A complete blood count (CBC) is among the most frequently requested analyses by physicians and tests are routinely performed in clinical laboratories. Such an analysis provides data that aid in diagnosis and monitoring of numerous blood-related conditions, including anemia, infections, and certain forms of cancer. Modern hematology analyzers also provide a differentiation of the white blood cells (WBCs) into their five major sub-populations neutrophils (NEU), lymphocytes (LYM), monocytes (MONO), eosinophils (EOS), and basophils (BASO).

Technology advancements have provided access to more advanced hematology analyzers, not only for large hospital laboratories, but also for smaller clinical laboratories. Today, CBC tests with 5-part differentiation of the WBCs are performed in hospital laboratories as well as in the typical physician's office laboratory (POL).

Medonic M51 is a hematology analyzer intended for smaller clinical and hospital laboratories (Fig 1). The analyzer provides information on 29 parameters (20 for use in IVD, 9 for RUO) for the CBC, including red blood cells (RBC) and platelets (PLT), hemoglobin (HGB), as well as a 5-part differential of the WBCs. This work evaluates the performance of Medonic M51 for the 20 IVD parameters compared with a reference system intended for the larger hospital laboratory. The study was conducted in collaboration with Dr. Ravindra Patwadkar and coworkers at the Dr. Hedgewar Hospital, Aurangabad, Maharashtra, India.

Figure 1. Medonic M51 is an entry-level 5-part hematology analyzer intended for the cost-minded clinical laboratory. The user-friendly design makes system operations easy. Robust software and hardware components ensure a reliable system performance. With its small footprint, Medonic M51 is well suited for the typical physician office laboratory.

Materials and methods

Analyzers and reagents

Medonic M51 5-part hematology analyzer and its associated reagents were used as test system. As reference system, the DxH™ 800 hematology analyzer and its associated reagents (Beckman Coulter) were used.

Abbreviations and acronyms: Basophiles, BASO; complete blood count, CBC; eosinophils, EOS; hematocrit, HCT; hemoglobin, HGB; in vitro diagnostics, IVD; lymphocytes, LYM; mean cell volume, MCV; mean corpuscular hemoglobin, MCH; mean corpuscular hemoglobin concentration, MCHC; mean platelet volume, MPV; monocytes, MONO; neutrophils, NEU; platelets, PLT; platelet distribution width, PDW; red blood cells, RBC; red cell distribution width, RDW; research use only, RUO; white blood cells, WBC.

Quality control

BC-1807B (Mindray) was used as control for the test system and FP, 6G Cell Control 9X (Beckman Coulter) was used as control for the reference system. Controls were analyzed daily, before and after sample analysis according to the manufactures' advice. Background values were determined prior to control analysis.

Statistical analyses

All statistical analyses were performed using Analyse-it statistics add-in for Microsoft Excel®. The Shapiro-Wilk test was performed to determine the normal distribution of the cell count. The differences between the means or the medians of the cell count analyzed in the test and the reference analyzers were evaluated by the Student's t-test or the Sign-test (at 5% significance level), respectively.The strength of the relationship between the cell count in the test and the reference systems was determined using Pearson correlation coefficient (r). The correlations were ranked as "excellent" for r = 0.93–0.99, "good" for r = 0.80–0.92, "fair" for r = 0.59–0.79, and "poor" for r < 0.59. Passing-Bablok regression analysis and Bland Altman difference plots for estimation of agreement and possible systematic bias between the test and the reference systems were performed on matched samples.

Analysis of clinical samples

Fresh normal and abnormal human whole blood samples, collected for routine analyses, were analyzed in singlicate on both test system and in duplicate on the reference system. Normal ranges established by the Mayo Clinic were used for selecting samples for co-calibration of the analyzers. Selected values were combined for both male and female adults. As the difference in values for the main parameters between the test and the reference systems was small, the analyzers were only co-calibrated for RBC (and thereby HCT) and MPV prior to the statistical analyses.

The specification limits, based on normal (unflagged) samples, for the correlation coefficient (r) and bias between test and reference systems are given in Table 1.

Table 1. Specification limits for performance evaluation of a new method or analyzer

Parameter	Unit	Specification limits	
		r	Bias
WBC	109/L	≥ 0.99	≤ ± 5%
NEU%	%	≥ 0.90	≤ ± 5
LYM%	%	≥ 0.90	≤ ± 5
MONO%	%	≥ 0.75	≤ ± 5
EOS%	%	≥ 0.80	≤ ± 5
BASO%	%	≥ 0.56	≤ ± 5
NEU	10^9/L	≥ 0.90	NA
LYM	10^9/L	≥ 0.90	NA
MONO	10^9/L	≥ 0.75	NA
EOS	10^9/L	≥ 0.80	NA
BASO	10^9/L	≥ 0.56	NA
RBC	10^{12}/L	≥ 0.99	≤ ± 2.5%
HGB	g/dL	≥ 0.98	± 2.5%
MCV	fL	≥ 0.98	≤ ± 3%
HCT	%	≥ 0.98	≤ ± 1
RDW	%	≥ 0.90	≤ ± 2
MCH	pg	NA	NA
MCHC	g/dL	NA	NA
PLT	10^9/L	≥ 0.95	≤ ± 7%
MPV	fL	≥ 0.80	≤ ± 10%

NA = not applicable

Study design

The following standards were used as guidance for study design:

- Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard – Second Edition. CLSI H26-A2
- Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition. CLSI EP09-A3
- Performance evaluation of in vitro diagnostic medical devices. EN 13612

Results

Descriptive statistics of the parameters measured with the test and reference analyzers are presented in Table 2. At the 5% significance level, there were no statistically significant differences between the means of the parameters measured in the test and the reference analyzers. A significant difference between the means of the MPV in the test and the reference analyzers was observed, however, eliminated by co-calibration of the analyzers.

Table 3 summarizes the results from the comparison of the test and reference analyzers. The correlation between the cell count with the test and reference analyzers was excellent for most parameters, good for the MCHC, MONO%, and MPV, and fair for the MONO# and BASO#. The correlation coefficients were all higher than the given specification limits. The slopes were close to 1 except for the RDW, MONO, and BASO. The intercepts were close to 0 for most parameters. The bias estimates, obtained from the Bland-Altman difference plots for method comparison, between the test and the reference analyzers were relatively low and within the specification limits for all parameters of the cell count.

Descriptive statistics of the WBC differential count measured with the test and reference analyzers on both normal (unflagged) and abnormal (flagged) samples are presented in Table 4, and the results are shown in Table 5. The comparison results of the WBC differential counts in the test and reference analyzer, when all samples (normal unflagged and abnormal flagged) were included, were close to those for normal samples (unflagged) only in the statistical analyses.

Passing-Bablok regression graphs, showing agreement between cell count in the Medonic M51 test and DxH 800 reference hematology analyzers, are displayed in Figure 2.

Table 2. Descriptive statistics of parameter values obtained with the test and reference systems on whole blood samples

Parameter	Unit	n	DxH 800 analyzer		Medonic M51 analyzer	
			Mean ± SD (Min, Max)	Median (1st, 3rd Q)	Mean ± SD (Min, Max)	Median (1st, 3rd Q)
WBC	10^9/L	196	8.42 ± 3.71 (2.80, 30.2)	7.60 (6.30, 9.50)	8.38 ± 3.71 (2.84, 30.2)	7.54 (6.37, 9.42)
NEU%	%	188*	59.5 ± 13.9 (20.5, 98.6)	58.3 (50.8, 67.0)	59.6 ± 13.5 (22.5, 93.5)	58.2 (50.8, 68.4)
LYM%	%	188*	28.6 ± 11.5 (0.80, 67.7)	29.1 (22.5, 35.9)	30.0 ± 11.7 (3.70, 69.7)	30.8 (23.4, 37.9)
MONO%	%	185*	7.86 ± 3.77 (0.20, 33.5)	7.50 (5.97, 9.20)	6.08 ± 2.63 (0.20, 19.9)	6.00 (4.50, 7.30)
EOS%	%	175*	2.96 ± 2.87 (0, 14.3)	2.10 (0.90, 4.17)	2.90 ± 2.78 (0, 14.4)	2.00 (0.80, 4.10)
BASO%	%	190*	0.61 ± 0.37 (0, 2.20)	0.50 (0.30, 0.80)	0.87 ± 0.46 (0.10, 3.10)	0.80 (0.59, 1.10)
NEU	10^9/L	188*	5.34 ± 3.57 (1.60, 27.2)	4.40 (3.40, 5.90)	5.31 ± 3.49 (1.39, 26.5)	4.44 (3.41, 5.87)
LYM	10^9/L	188*	2.20 ± 0.99 (0.20, 7.70)	2.10 (1.60, 2.66)	2.31 ± 1.00 (0.46, 7.46)	2.23 (1.70, 2.73)
MONO	10^9/L	185*	0.61 ± 0.29 (0, 2.00)	0.60 (0.40, 0.70)	0.48 ± 0.25 (0.01, 1.80)	0.46 (0.31, 0.59)
EOS	10^9/L	175*	0.23 ± 0.23 (0, 1.20)	0.20 (0.10, 0.30)	0.22 ± 0.22 (0, 1.08)	0.15 (0.06, 0.31)
BASO	10^9/L	190*	0.04 ± 0.07 (0, 0.40)	0 (0, 0.10)	0.07 ± 0.06 (0, 0.63)	0.06 (0.03, 0.08)
RBC†	10^{12}/L	196	4.33 ± 0.72 (2.07, 5.97)	4.39 (3.93, 4.82)	4.24 ± 0.69 (2.04, 5.91)	4.29 (3.87, 4.69)
HGB	g/dL	196	12.2 ± 1.99 (5.10, 17.7)	12.4 (11.1, 13.5)	12.3 ± 2.08 (5.10, 18.6)	12.5 (10.9, 13.6)
MCV	fL	196	85.2 ± 9.97 (54.1, 117)	85.1 (79.7, 90.1)	85.9 ± 9.36 (56.5, 114)	86.3 (80.4, 90.3)
HCT†	%	196	36.6 ± 5.57 (17.9, 52.0)	36.9 (33.4, 40.0)	36.2 ± 5.74 (18.2, 52.8)	36.5 (32.6, 40.0)
RDW	%	196	15.3 ± 2.52 (12.4, 30.2)	14.8 (13.6, 16.1)	14.0 ± 1.65 (12.0, 22.4)	13.6 (13.0, 14.6)
MCH	pg	196	28.5 ± 3.90 (17.2, 41.3)	28.7 (26.3, 30.4)	27.8 ± 3.56 (16.3, 39.2)	28.0 (25.8, 29.6)
MCHC	g/dL	196	33.4 ±1.15 (28.4, 36.1)	33.6 (32.8, 34.0)	32.3 ± 1.12 (26.2, 35.1)	32.4 (31.8, 33.0)
PLT	10^9/L	190	263 ± 111 (13.0, 851)	256 (203, 315)	276 ± 122 (6.00, 944)	263 (215, 327)
MPV†	fL	189	8.09 ± 0.99 (5.90, 11.8)	8.00 (7.40, 8.70)	7.99 ± 0.90 (5.70, 10.8)	7.90 (7.34, 8.52)

SD; Standard Deviation, Q; Quartile

* Normal (unflagged) samples only

† The test and the reference analyzers were co-calibrated for this analyte

Table 3. Comparison of test and reference systems on whole blood samples

Parameter	Unit	n	DxH 800 and Medonic M51 analyzers			
			r	I (lower, upper CI)	S (lower, upper CI)	Bias (lower, upper CI)
WBC	10^9/L	196	1.00	-0.05 (-0.16, 0.08)	1.00 (0.98, 1.01)	-0.48% (-1.00%, 0.04%)
NEU%	%	188*	0.99	0.79 (-0.68, 2.22)	0.98 (0.96, 1.01)	0.01 (-0.32, 0.35)
LYM%	%	188*	0.98	1.09 (0.69, 1.50)	1.02 (1.00, 1.03)	1.35 (0.99, 1.71)
MONO%	%	185*	0.76	-0.53 (-1.13, -0.04)	0.88 (0.81, 0.96)	-1.78 (-2.14, -1.42)
EOS%	%	175*	0.99	0.03 (0, 0.10)	0.97 (0.94, 1.00)	-0.06 (-0.14, 0.01)
BASO%	%	190*	0.69	0.05 (-0.05, 0.16)	1.33 (1.14, 1.50)	0.26 (0.21, 0.31)
NEU	10^9/L	188*	1.00	0.03 (-0.05, 0.10)	0.99 (0.97, 1.00)	-0.24% (-1.02%, 0.53%)
LYM	10^9/L	188*	0.99	0.08 (0.02, 0.12)	1.02 (1.00, 1.05)	6.45% (4.74%, 8.17%)
MONO	10^9/L	185*	0.82	-0.04 (-0.08, 0)	0.88 (0.80, 0.95)	-27.0% (-31.8%, -22.3%)
EOS	10^9/L	175*	0.98	0 (-0.01, 0)	1.00 (0.94, 1.02)	16.5% (5.12%, 27.8%)
BASO	10^9/L	190*	0.66	0.03 (0.02, 0.03)	1.40 (1.00, 1.80)	112% (96.0%, 129%)
RBC[†]	10^{12}/L	196	0.99	0.06 (-0.04, 0.14)	0.97 (0.95, 0.99)	-2.14% (-2.49%, -1.80%)
HGB	g/dL	196	1.00	-0.53 (-0.76, -0.32)	1.05 (1.03, 1.06)	0.16% (-0.08%, 0.41%)
MCV	fL	196	0.99	5.55 (4.26, 6.78)	0.94 (0.92, 0.95)	0.92% (0.71%, 1.13%)
HCT[†]	%	196	0.99	-1.95 (-2.99, -1.09)	1.05 (1.02, 1.07)	-0.42 (-0.55, -0.30)
RDW	%	196	0.97	4.06 (3.60, 4.51)	0.65 (0.62, 0.68)	-1.26 (-1.40, -1.11)
MCH	pg	196	0.99	1.68 (1.12, 2.24)	0.91 (0.89, 0.94)	-2.42% (-2.72%, -2.12%)
MCHC	g/dL	196	0.83	-1.10 (-3.15, 3.12)	1.00 (0.88, 1.06)	-3.32% (-3.61%, -3.03%)
PLT	10^9/L	190	0.96	6.72 (-4.72, 16.9)	1.01 (0.96, 1.07)	4.58% (2.81%, 6.35%)
MPV[†]	fL	189	0.90	0.80 (0.19, 0.89)	0.89 (0.89, 0.97)	-1.19% (-1.92%, -0.46%)

r; Pearson correlation coefficient, I; Intercept, CI; Confidence Interval, S; Slope, Spec.; Specification Limits

* Normal (unflagged) samples only

[†] The test and the reference analyzers were co-calibrated for this analyte

Table 4. Descriptive statistics of WBC differential count values obtained with the test and reference systems on normal (unflagged) and abnormal (flagged) samples

Parameter	Unit	n	DxH 800 analyzer		Medonic M51 analyzer	
			Mean ± SD (Min, Max)	Median (1st, 3rd Q)	Mean ± SD (Min, Max)	Median (1st, 3rd Q)
NEU%	%	196	58.9 ± 14.2 (20.5, 98.6)	58.0 (50.4, 66.0)	59.5 ± 13.8 (22.5, 93.5)	58.2 (50.7, 68.5)
LYM%	%	196	29.2 ± 11.8 (0.80, 67.7)	29.4 (22.8, 36.2)	30.2 ± 12.0 (3.70, 69.7)	30.8 (23.3, 38.0)
MONO%	%	196	7.94 ± 3.75 (0.20, 33.5)	7.50 (6.00, 9.30)	6.16 ± 2.66 (0.20, 19.9)	6.10 (4.60, 7.30)
EOS%	%	196	3.44 ± 3.53 (0, 16.1)	2.25 (0.94, 4.40)	3.35 ± 3.44 (0, 15.7)	2.10 (0.94, 4.40)
BASO%	%	196	0.63 ± 0.40 (0, 2.20)	0.50 (0.30, 0.80)	0.88 ± 0.47 (0.10, 3.10)	0.80 (0.60, 1.10)
NEU	10^9/L	196	5.21 ± 3.56 (0.70, 27.2)	4.30 (3.30, 5.60)	5.22 ± 3.47 (0.76, 26.5)	4.43 (3.30, 5.86)
LYM	10^9/L	196	2.24 ± 1.10 (0.20, 7.90)	2.10 (1.60, 2.70)	2.33 ± 1.09 (0.46, 7.46)	2.23 (1.67, 2.73)
MONO	10^9/L	196	0.64 ± 0.35 (0, 2.00)	0.60 (0.40, 0.76)	0.51 ± 0.34 (0.01, 2.85)	0.46 (0.31, 0.60)
EOS	10^9/L	196	0.27 ± 0.29 (0, 1.20)	0.20 (0.10, 0.40)	0.26 ± 0.28 (0, 1.31)	0.16 (0.07, 0.36)
BASO	10^9/L	196	0.04 ± 0.07 (0, 0.40)	0 (0, 0.10)	0.07 ± 0.06 (0, 0.63)	0.06 (0.03, 0.08)

SD; Standard Deviation, Q; Quartile

Table 5. Comparison of test and reference systems for WBC differential counts on normal (unflagged) and abnormal (flagged) samples

Parameter	Unit	n	DxH 800 and Medonic M51 analyzers			
			r	I (lower, upper CI)	S (lower, upper CI)	Bias (lower, upper CI)
NEU%	%	196	0.94	0.65 (-0.85, 2.05)	0.98 (0.96, 1.01)	0.53 (-0.17, 1.22)
LYM%	%	196	0.92	1.02 (0.58, 1.50)	1.02 (1.00, 1.03)	0.99 (0.34, 1.65)
MONO%	%	196	0.76	-0.53 (-1.09, -0.07)	0.88 (0.81, 0.95)	-1.79 (-2.13, -1.45)
EOS%	%	196	0.99	0.03 (0, 0.10)	0.97 (0.95, 1.00)	-0.08 (-0.15, -0.02)
BASO%	%	196	0.66	0.03 (-0.04, 0.19)	1.27 (1.10, 1.50)	0.25 (0.20, 0.30)
NEU	10^9/L	196	0.99	0.03 (-0.04, 0.10)	0.99 (0.97, 1.00)	0.68% (-0.71%, 2.08%)
LYM	10^9/L	196	0.96	0.08 (0.02, 0.12)	1.02 (0.99, 1.04)	4.92% (2.51%, 7.34%)
MONO	10^9/L	196	0.86	-0.05 (-0.09, -0.01)	0.89 (0.82, 0.95)	-26.0% (-31.5%, -22.3%)
EOS	10^9/L	196	0.98	0 (-0.01, 0.01)	0.99 (0.94, 1.00)	14.9% (4.22%, 25.6%)
BASO	10^9/L	196	0.66	0.03 (0.02, 0.03)	1.40 (1.00, 1.80)	111% (94.9%, 127%)

r; Pearson Correlation Coefficient, I; Intercept, CI; Confidence Interval, S; Slope, Spec.; Specification Limits

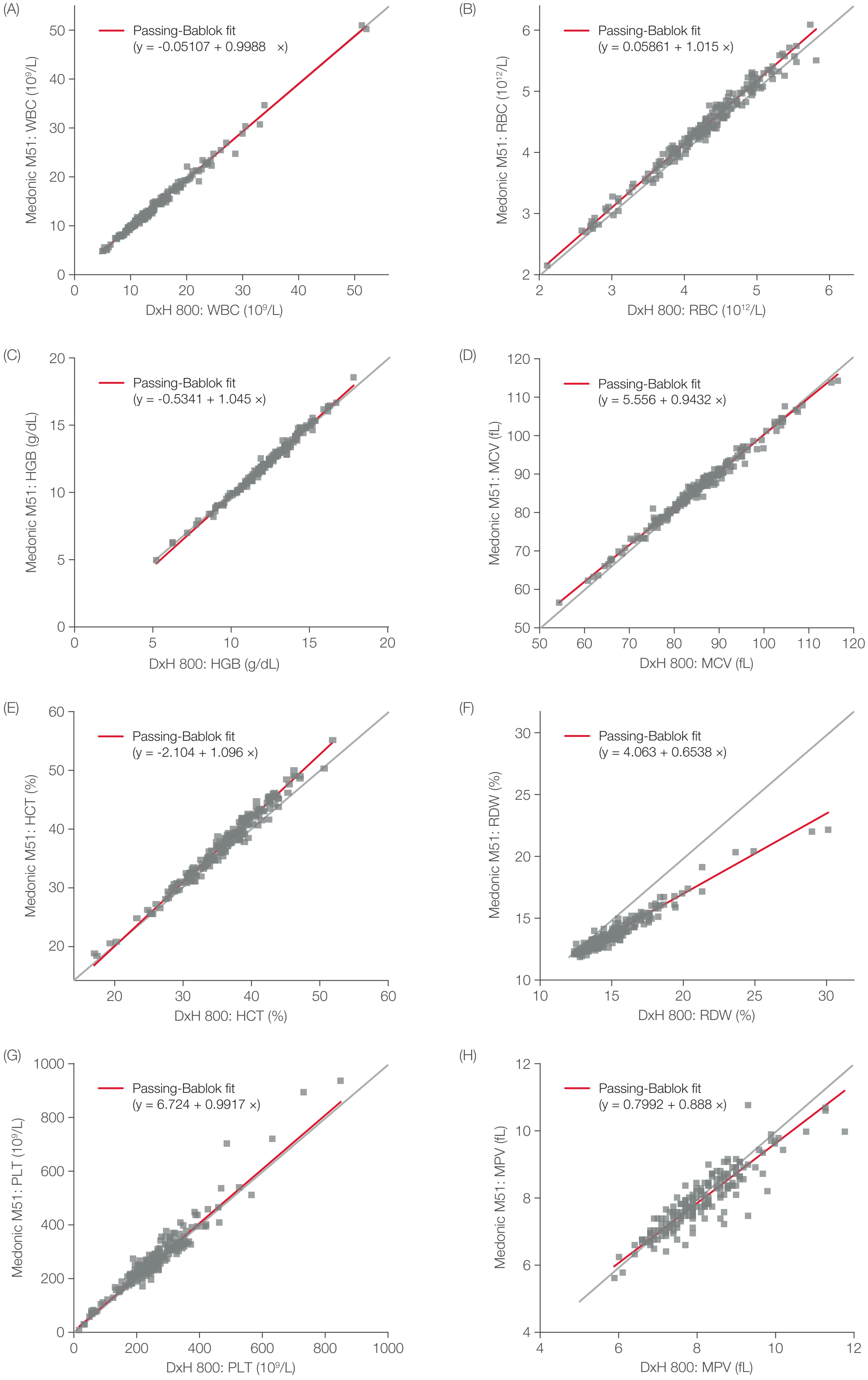

Figure 2. Agreement between cell count in the Medonic M51 test and DxH 800 reference hematology analyzers. Passing-Bablok regression graphs are shown for (A) WBC, (B) RBC, (C) HGB, (D) MCV, (E) HCT, (F) RDW%, (G) PLT, and (H) MPV. In regression plots, the gray line is the line of identity (x = y) and the red line is the line of best fit.

Conclusion

In this study, the performance of the entry-level Medonic M51 hematology analyzer was compared with that of a reference analyzer. The results show high correlation and low bias between the analyzers, indicating good agreement between the systems.

Overall, the performance of Medonic M51 was approved for all analyzed parameters according to the specification limits. Based on the study results, the performance of Medonic M51 is considered acceptable for routine hematology analysis when compared with the reference analyzer.

> *"More than 200 live samples with various value ranges were evaluated simultaneously in the test instrument Medonic M51 and reference instrument Beckman Coulter DxH 800 in the month of August 2018.*
>
> *The generated data shows that analysis results obtained with the Medonic M51 5-part hematology system agrees well with those obtained with the reference system. The demonstrated performance of Medonic M51 in comparison with the reference system indicates the suitability of Medonic M51 for use in routine hematology analysis."*

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Disclaimer

The results and conclusions presented in this study are valid for this specific study only. Other study conditions and assumptions could have significant impact on the outcome

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