# Evaluation of the performance of Medonic™ M51 hematology system

Medonic M51 is an entry-level hematology analyzer intended for the smaller clinical laboratory or the physician's office laboratory (POL). This work aims to evaluate the performance of Medonic M51 in comparison with a reference system intended for the larger clinical laboratory such as the core hospital laboratories. The results show that the analyzers are in good agreement, indicating the suitability of the use of Medonic M51 in routine hematology analysis.

## Introduction

Typically, hematology analyses are performed in large clinical core laboratories. However, there are circumstances, under which near-patient monitoring of blood cell counts can be essential. Frequent analyses of a patient's blood status can facilitate monitoring of disease progression and effect of treatments, for example, in oncology or in management of infectious diseases. Independent of clinical setup, accuracy and precision of the clinical analyses are of equal importance.

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 count 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. S.P. Ganesan and coworkers at the Hitech Diagnostic Centre (HDC) in Chennai, 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 XN-1000™ hematology analyzer and its associated reagents (Sysmex Corp.) were used.

### *Quality control*

BC-1807B (Mindray) was used as control for the test system and XN CHECK™ (Sysmex Corp) 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.

***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.

### *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 not co-calibrated prior to the statistical analyses, except for the MPV where the difference between the means of MPV between the analyzers was about 9%.

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.

### *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

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

| Parameter | Unit | Specification limits | |
|---|---|---|---|
| | | r | Bias |
| WBC | $10^9$/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

## 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.

Table 3 summarizes the results from the comparison of the test and reference analyzers. The correlation between the test and reference analyzers, evaluated by Passing-Bablok regression analysis, was excellent for almost all parameters, and good for the MCHC, MONO, BASO, and MPV. The correlation coefficients were all higher than the given specification limits, except for the correlation coefficient for the MCV that was slightly lower than the given specification limit. The slopes were close to 1, except for MONO, BASO, RDW, and MCHC. The intercepts were generally close to 0 except for some of the 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 almost all parameters. However, for the NEU count, the bias estimate was slightly higher than the specification limit.

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

| Parameter | Unit | n | XN-1000 analyzer | | Medonic M51 analyzer | |
|---|---|---|---|---|---|---|
| | | | Mean ± SD (Min, Max) | Median (1st, 3rd Q) | Mean ± SD (Min, Max) | Median (1st, 3rd Q) |
| WBC | $10^9$/L | 179 | 8.87 ± 5.54 (1.91, 53.1) | 7.71 (6.22, 9.89) | 8.91 ± 5.50 (1.85, 51.9) | 7.80 (6.29, 10.2) |
| NEU% | % | 167* | 66.5 ± 10.2 (43.9, 90.2) | 65.5 (57.8, 73.1) | 60.6 ± 11.2 (33.7, 87.2) | 59.7 (52.1, 68.2) |
| LYM% | % | 167* | 25.5 ± 9.45 (3.10, 47.4) | 26.1 (19.3, 32.9) | 28.8 ± 10.3 (3.50, 52.7) | 29.1 (22.6, 36.5) |
| MONO% | % | 167* | 3.34 ± 1.24 (1.60, 11.1) | 3.15 (2.55, 3.76) | 6.03 ± 2.81 (1.50, 21.5) | 5.60 (4.02, 7.10) |
| EOS% | % | 167* | 3.71 ± 3.96 (0, 32.2) | 2.88 (1.56, 4.45) | 3.58 ± 3.82 (0, 30.3) | 2.70 (1.52, 4.45) |
| BASO% | % | 167* | 0.51 ± 0.41 (0, 4.05) | 0.41 (0.30, 0.60) | 0.93 ± 0.68 (0.20, 7.20) | 0.80 (0.60, 1.10) |
| NEU | $10^9$/L | 167* | 5.86 ± 3.34 (1.23, 20.9) | 4.897 (4.00, 6.68) | 5.42 ±3 .25 (0.82, 21.1) | 4.60 (3.57, 6.23) |
| LYM | $10^9$/L | 167* | 2.00 ± 0.83 (0.45, 5.77) | 1.85 (1.40, 2.58) | 2.29±0.91 (0.43, 6.30) | 2.20 (1.62, 2.94) |
| MONO | $10^9$/L | 167* | 0.29 ± 0.20 (0.04, 2.03) | 0.24 (0.19, 0.31) | 0.52 ± 0.41 (0.12, 4.02) | 0.44 (0.31, 0.57) |
| EOS | $10^9$/L | 167* | 0.32 ± 0.46 (0, 4.67) | 0.20 (0.11, 0.38) | 0.30 ± 0.45 (0, 4.54) | 0.20 (0.11, 0.36) |
| BASO | $10^9$/L | 167* | 0.05 ± 0.05 (0, 0.52) | 0.03 (0.02, 0.05) | 0.07 ± 0.08 (0, 0.89) | 0.06 (0.04, 0.08) |
| RBC† | $10^{12}$/L | 221 | 4.35 ± 0.92 (1.91, 6.70) | 4.40 (3.86, 4.98) | 4.37 ± 0.88 (2.00, 6.44) | 4.45 (3.89, 4.94) |
| HGB | g/dL | 221 | 11.7 ± 2.84 (3.20, 20.0) | 11.9 (10.2, 13.6) | 11.7 ± 2.85 (3.20, 20.1) | 11.9 (10.1, 13.5) |
| MCV | fL | 221 | 85.5 ± 9.70 (51.7, 118) | 86.6 (82.0, 90.6) | 85.2 ± 9.73 (50.9, 113) | 86.7 (81.7, 91.0) |
| HCT† | % | 221 | 36.9 ± 7.97 (14.6, 58.2) | 37.0 (32.8, 42.1) | 37.1 ± 8.28 (14.6, 60.0) | 37.5 (33.0, 42.6) |
| RDW | % | 218 | 15.2 ± 2.85 (11.8, 25.3) | 14.1 (13.2, 16.3) | 14.7 ± 2.10 (12.2, 25.9) | 14.0 (13.3, 15.3) |
| MCH | pg | 221 | 27.0 ± 4.06 (11.9, 38.5) | 27.9 (25.6, 29.4) | 26.7 ± 3.80 (12.5, 37.4) | 27.6 (25.3, 28.8) |
| MCHC | g/dL | 221 | 31.5 ± 2.15 (21.6, 36.1) | 31.9 (30.6, 32.8) | 31.3 ± 1.75 (21.7, 35.4) | 31.6 (30.9, 32.2) |
| PLT | $10^9$/L | 221 | 268 ± 130 (10.0, 1040) | 269 (201, 328) | 283 ± 133 (8.00, 1137) | 282 (217, 347) |
| MPV† | fL | 204 | 10.0 ± 0.98 (7.90, 13.9) | 9.90 (9.30, 10.6) | 9.05 ± 0.99 (6.70, 12.9) | 8.98 (8.37, 9.68) |

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 | XN-1000 and Medonic M51 analyzers | | | |
|---|---|---|---|---|---|---|
| | | | r | I (lower, upper CI) | S (lower, upper CI) | Bias (lower, upper CI) |
| WBC | $10^9$/L | 179 | 1.00 | -0.06 (-0.14, 0.05) | 1.01 (1.00, 1.03) | 0.46% (-0.10%, 1.02%) |
| NEU% | % | 167* | 0.98 | -12.2 (-14.7, -10.0) | 1.10 (1.07, 1.13) | -5.96 (-6.35, -5.57) |
| LYM% | % | 167* | 0.99 | 1.08 (0.53, 1.69) | 1.08 (1.06, 1.10) | 2.70 (2.42, 2.98) |
| MONO% | % | 167* | 0.87 | -2.85 (-4.05, -1.87) | 2.72 (2.44, 3.07) | 2.75 (2.47, 3.03) |
| EOS% | % | 167* | 0.99 | 0.07 (-0.01, 0.18) | 0.96 (0.93, 0.98) | -0.13 (-0.22, -0.04) |
| BASO% | % | 167* | 0.83 | 0 (-0.11, 0.12) | 1.78 (1.51, 2.12) | 0.42 (0.36, 0.48) |
| NEU | $10^9$/L | 167* | 1.00 | -0.32 (-0.42, -0.23) | 0.99 (0.97, 1.01) | -9.10% (-10.1%, -8.13%) |
| LYM | $10^9$/L | 167* | 0.99 | 0.09 (0.03, 0.14) | 1.10 (1.07, 1.13) | 14.3% (13.2%, 15.4%) |
| MONO | $10^9$/L | 167* | 0.95 | -0.09 (-0.14, -0.05) | 2.24 (2.07, 2.42) | 53.8% (50.0%, 57.6%) |
| EOS | $10^9$/L | 167* | 0.99 | 0 (-0.01, 0.01) | 0.97 (0.93, 1.00) | -1.83% (-5.22%, 1.56%) |
| BASO | $10^9$/L | 167* | 0.93 | -0.01 (-0.01, 0) | 1.87 (1.50, 2.00) | 49.9% (42.7%, 57.2%) |
| RBC | $10^{12}$/L | 221 | 1.00 | 0.21 (0.16, 0.26) | 0.96 (0.95, 0.97) | 0.82% (0.50%, 1.13%) |
| HGB | g/dL | 221 | 1.00 | 0 (0, 0) | 1.00 (1.00, 1.00) | -0.06% (-0.26%, 0.13%) |
| MCV | fL | 221 | 0.97 | -1.91 (-4.66, 0.98) | 1.02 (0.98, 1.05) | -0.31% (-0.65%, 0.02%) |
| HCT | % | 221 | 0.99 | -1.11 (-1.74, -0.50) | 1.04 (1.02, 1.05) | 0.24 (0.10, 0.39) |
| RDW | % | 218 | 0.95 | 3.94 (3.40, 4.50) | 0.71 (0.67, 0.75) | -0.47 (-0.62, -0.33) |
| MCH | pg | 221 | 0.99 | 1.63 (1.00, 2.21) | 0.93 (0.91, 0.96) | -0.93% (-1.26%, -0.60%) |
| MCHC | g/dL | 221 | 0.92 | 8.98 (7.22, 10.3) | 0.71 (0.67, 0.76) | -0.62% (-1.01%, -0.24%) |
| PLT | $10^9$/L | 221 | 0.97 | 12.7 (6.41, 20.1) | 0.99 (0.96, 1.03) | 6.92% (5.25%, 8.59%) |
| MPV† | fL | 204 | 0.85 | -1.31 (-2.23, -0.91) | 1.01 (1.01, 1.14) | -10.2% (-10.9%, -9.37%) |

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

The comparison results of the WBC differential counts in the reference and test analyzers did not change when all samples (flagged and non-flagged) were included in the statistical analyses (Table 4 and 5).

Passing-Bablok regression graphs, showing agreement between cell count in the Medonic M51 test and XN-1000 reference hematology analyzers, are displayed in Figure 2.

**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 | XN-1000 analyzer | | Medonic M51 analyzer | |
|---|---|---|---|---|---|---|
| | | | Mean ± SD (Min, Max) | Median (1st, 3rd Q) | Mean ± SD (Min, Max) | Median (1st, 3rd Q) |
| NEU% | % | 208 | 63.8 ± 12.7 (26.2, 91.2) | 63.8 (55.9, 71.9) | 57.8 ± 13.8 (19.1, 89.6) | 57.6 (48.7, 67.2) |
| LYM% | % | 208 | 28.0 ± 12.1 (2.97, 68.3) | 28.0 (20.2, 35.2) | 31.6 ± 13.2 (3.50, 71.1) | 31.7 (23.2, 39.6) |
| MONO% | % | 208 | 3.46 ± 1.82 (0.90, 20.1) | 3.15 (2.55, 3.76) | 6.21 ± 3.29 (1.40, 25.2) | 5.70 (4.10, 7.10) |
| EOS% | % | 207 | 3.61 ± 3.71 (0, 32.2) | 2.85 (1.52, 4.53) | 3.48 ± 3.60 (0, 30.3) | 2.70 (1.50, 4.28) |
| BASO% | % | 208 | 0.52 ± 0.43 (0, 4.05) | 0.42 (0.30, 0.60) | 0.93 ± 0.68 (0.20, 7.20) | 0.80 (0.60, 1.10) |
| NEU | $10^9$/L | 208 | 5.99 ± 3.91 (0.20, 35.9) | 5.07 (3.81, 6.86) | 5.51 ± 3.86 (0.18, 35.3) | 4.53 (3.49, 6.29) |
| LYM | $10^9$/L | 208 | 2.46 ± 1.87 (0.34, 16.0) | 1.98 (1.47, 2.85) | 2.79 ± 2.06 (0.37, 19.1) | 2.31 (1.68, 3.22) |
| MONO | $10^9$/L | 208 | 0.32 ± 0.33 (0.02, 3.69) | 0.25 (0.20, 0.34) | 0.57 ± 0.51 (0.03, 4.60) | 0.46 (0.32, 0.65) |
| EOS | $10^9$/L | 208 | 0.32 ± 0.46 (0, 4.54) | 0.20 (0.11, 0.38) | 0.32 ± 0.44 (0, 4.67) | 0.22 (0.11, 0.40) |
| BASO | $10^9$/L | 208 | 0.05 ± 0.05 (0, 0.52) | 0.04 (0.02, 0.05) | 0.08 ± 0.08 (0, 0.89) | 0.06 (0.04, 0.09) |

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 | XN-1000 and Medonic M51 analyzers | | | |
|---|---|---|---|---|---|---|
| | | | r | I (lower, upper CI) | S (lower, upper CI) | Bias (lower, upper CI) |
| NEU% | % | 208 | 0.97 | -11.3 (-13.1, -10.0) | 1.09 (1.06, 1.12) | -6.04 (-6.48, -5.60) |
| LYM% | % | 208 | 0.99 | 1.16 (0.68, 1.70) | 1.08 (1.06, 1.10) | 3.57 (3.24, 3.91) |
| MONO% | % | 208 | 0.84 | -2.83 (-3.57, -1.76) | 2.63 (2.42, 2.95) | 2.75 (2.47, 3.03) |
| EOS% | % | 207 | 0.98 | 0.03 (-0.04, 0.12) | 0.96 (0.93, 0.99) | -0.13 (-0.23, -0.04) |
| BASO% | % | 208 | 0.83 | 0.01 (-0.10, 0.11) | 1.74 (1.49, 2.02) | 0.41 (0.36, 0.46) |
| NEU | $10^9$/L | 208 | 0.99 | -0.33 (-0.43, -0.22) | 0.98 (0.96, 1.00) | -10.3% (-11.5%, -9.02%) |
| LYM | $10^9$/L | 208 | 0.99 | 0.12 (0.08, 0.17) | 1.08 (1.06, 1.10) | 13.7% (12.6%, 14.8%) |
| MONO | $10^9$/L | 208 | 0.91 | -0.08 (-0.12, -0.04) | 2.17 (2.00, 2.35) | 53.8% (50.2%, 57.3%) |
| EOS | $10^9$/L | 208 | 0.98 | 0 (-0.01, 0.01) | 0.96 (0.93, 1.00) | -0.27% (-4.87%, 4.32%) |
| BASO | $10^9$/L | 208 | 0.89 | 0 (-0.01, 0.01) | 1.71 (1.50, 2.00) | 47.7% (41.1%, 54.3%) |

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

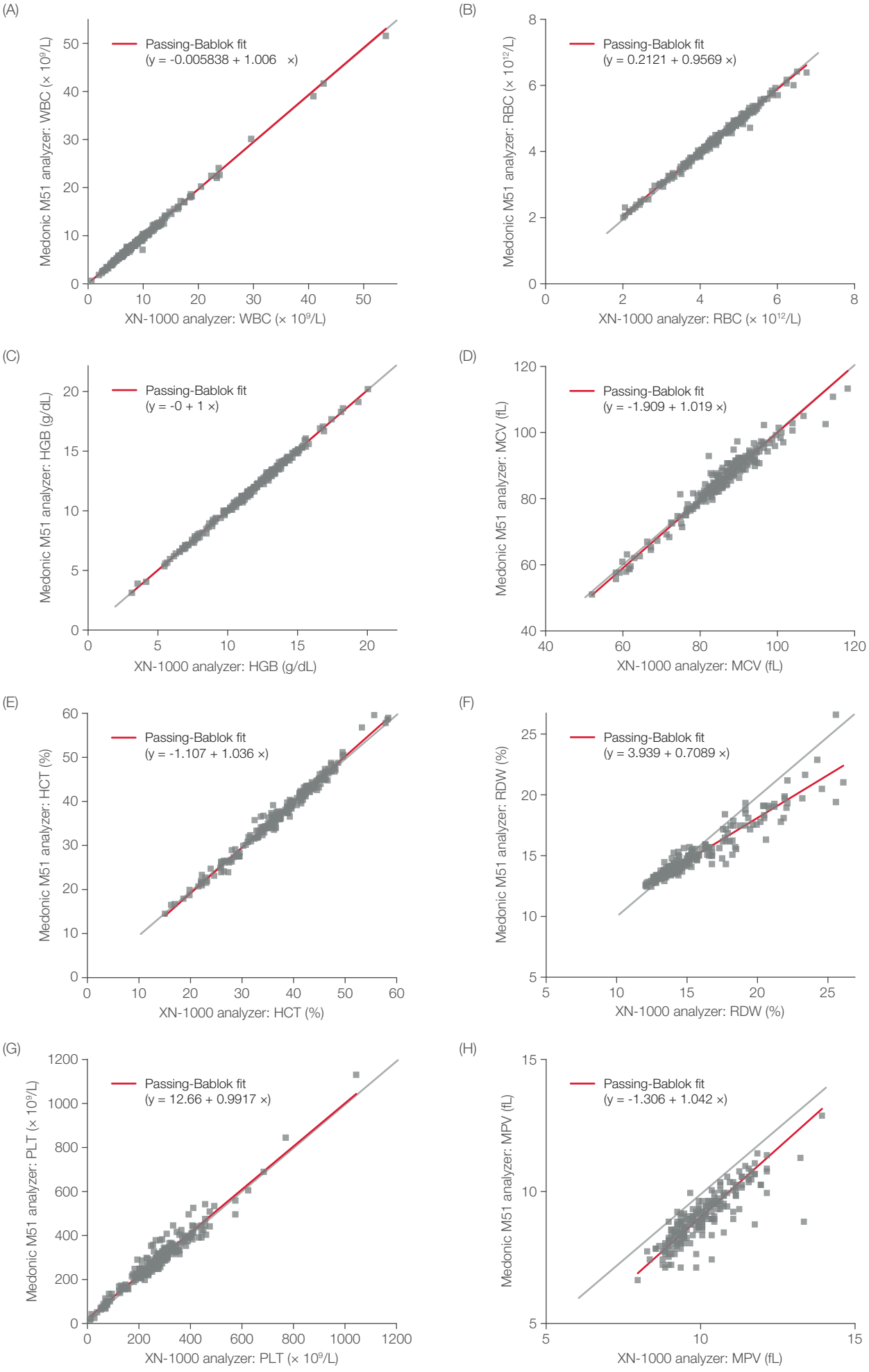


**Figure 2.** Agreement between cell count in the Medonic M51 test and XN-1000 reference hematology analyzers. Passing-Bablok regression graphs are shown for (A) WBC, (B) RBC, (C) HGB, (D) MCV, (E) HCT, (F) RDW%, (G) PLT, and (H) MPV. In regression plots, the gray line is the line of identity (x = y) and the red line is the line of best fit.

## Conclusion

The performance of the 5-part Medonic M51 hematology (test) analyzer was compared with that of the 5-part XN-1000 (reference) analyzer. Medonic M51 operates with the same technology as the reference analyzer, except for the WBC differential count. The reference analyzer uses fluorescence flow cytometry as the detection method for the WBC differential, whereas Medonic M51 uses laser-based flow cytometry for the WBC differential. Differences observed for LYM, MONO, and BASO are believed to be due to the different detection and calculation methods of the WBC differential count between the analyzers. The estimated bias was relatively low for all parameters, which indicates that the test and the reference hematology analyzers are in good agreement. The bias for MPV was reduced by co-calibration of the analyzers. Although the correlation coefficient for MCV was slightly below the specification limit, the correlation between the analyzers was considered acceptable as the estimated bias was low. Overall, the performance of Medonic M51 was approved for almost all parameters according to the specification limits. Based on these results, the performance of the Medonic M51 hematology analyzer is considered acceptable for routine hematology analysis when compared to the reference analyzer.

> *”Medonic M51 is an entry-level hematology system intended for the smaller laboratory. The work conducted in collaboration between Boule Diagnostics and Hitech Diagnostic Centre (HDC) in Chennai, India compares the performance of Medonic M51 with the XN-1000 reference hematology system (Sysmex Corp.) intended for the large clinical laboratory.*
>
> *The results show that Medonic M51 is in good agreement with the reference system. The analyzers provide similar conditions for patient decisions. Medonic M51 generated analytical data close to microscopic examination and is a good option for the smaller clinical and hospital laboratories.”*

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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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