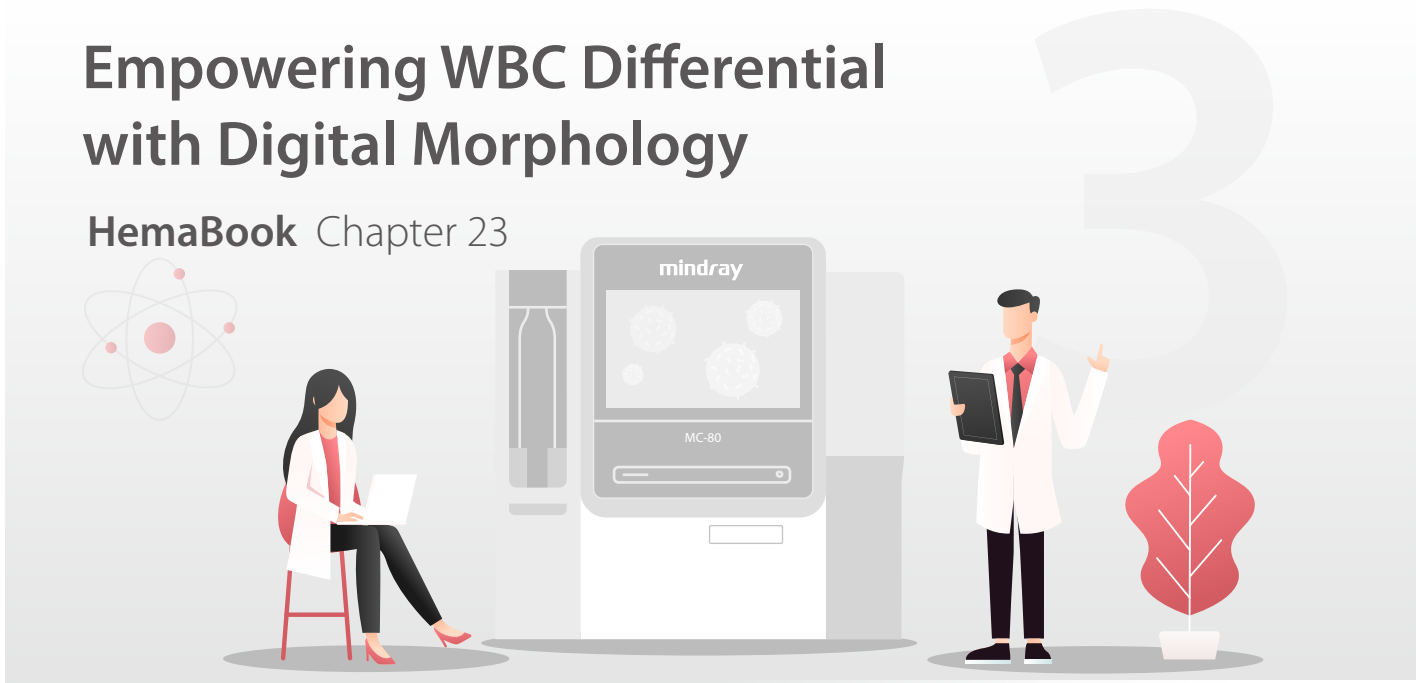
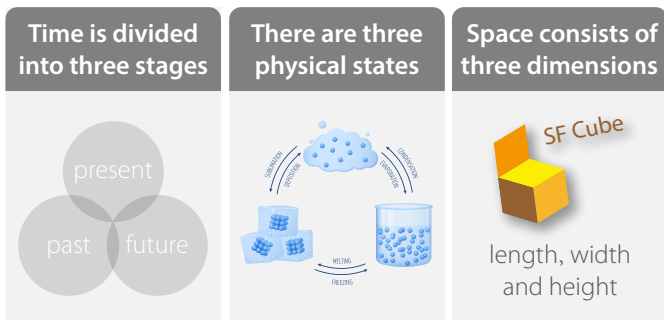


Empowering WBC Differential with Digital Morphology

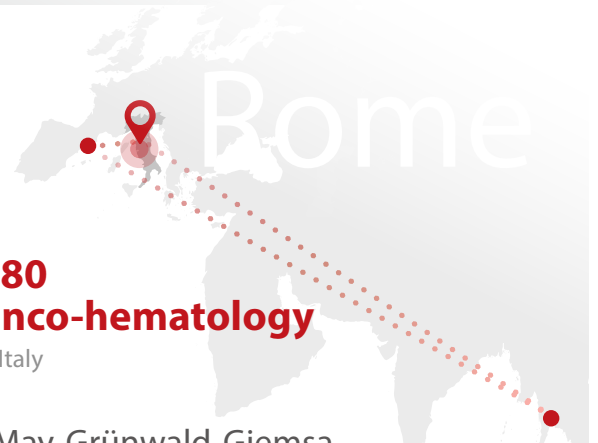
HemaBook Chapter 23



Throughout human history, the number 3 has always had a unique significance. In Ancient Greek philosophy, the number 3 was considered as the perfect number, the number of harmony, wisdom and understanding.



Recently, the MC-80 Digital Morphology Analyzer underwent rigorous evaluation by 3 top university hospitals worldwide, quickly earning global recognition. The International Journal of Laboratory Hematology recently published three professional evaluation reports on the WBC differential performance of MC-80, providing insights from different perspectives.



Stain: May-Grünwald-Giemsa
(Carlo Erba Reagenti/ Merck KGaA)

"Advances in technology mean that moving from microscopes to digital alternatives can now be achieved without sacrificing image quality." Professor Gina Zini shares her views on the main benefits of digital development, including better quality screening, time savings for busy morphologists, better clinical collaboration, and improved training in the interview.¹ Prof. Zini is very concerned about the application of this technology in the most challenging hematology departments. After conducting a systematic and rigorous evaluation of the MC-80, she called this work "artificial intelligence and blood film"! ²

Artificial intelligence and the blood film: Performance of the MC-80 digital morphology analyzer in samples with neoplastic and reactive cell types

Gina Zini^{1,2} | Francesca Mancini³ | Elena Rossi^{1,2} | Stefania Landucci³ | Giuseppe d'Onofrio¹

It's a two-university study. A vast proportion of samples from hematology patients with blood disorders and a few with viral infections (591 patients in total) were selected to include most types of cells that do not normally circulate in the peripheral blood.

Sample selection & collection & anonymization

"La Sapienza" University – Hematology laboratory, Rome

Smearing, fixing and staining of four peripheral blood smears

Slide A.
Manually
prepared

Slide B.
Manually
prepared

Slide C.
by SC-120

Slide C.
by SC-120

"La Sapienza" University - Hematology laboratory, Rome

Morphology Examination

Slide A.
Manual
differentiation
I

Slide B.
Manual
differentiation
II

Slide C.
MC-80
pre-
classification

Slide D.
MC-80
pre-
classification

"La Sapienza"
University -
Hematology
laboratory,
Rome

Fondazione Policlinico Universitario A.
Gemelli IRCSS – Università Cattolica
del S. Cuore, Rome

Validation

Manual
differentiation

MC-80
Post-classification

Supervised differential from
a third morphologist, in case
of discrepancies between
the two manual differentials

Slide C.
validation at screen of
MC-80 sample differential

Fondazione Policlinico Universitario A. Gemelli IRCSS –
Università Cattolica del S. Cuore, Rome

Data analysis & statistics

Fondazione Policlinico Universitario A. Gemelli IRCSS –
Università Cattolica del S. Cuore, Rome

Duplicate analysis (two runs of each of 413 films)

The results confirm the excellent internal consistency of the MC-80 differential count, even in the presence of abnormal cells.

TABLE 1 Results of duplicate analysis of 413 films.

	Neutrophils ^a	Lymphocytes	Monocytes	Eosinophils	Basophils	Immature granulocytes ^b	Neoplastic cells ^c	Reactive lymphocytes	NBICs
Pass rate	94.67%	93.70%	93.70%	94.92%	96.06%	95.40%	87.89%	93.22%	93.46%
\bar{x}	0.980	0.963	0.942	0.947	0.941	0.940	0.992	0.867	0.956
σ^2	0.061	0.065	0.069	0.097	0.007	0.022	0.004	0.066	0.015
Slope	0.981	0.969	0.962	0.979	0.987	0.954	1.006	0.888	0.948
Intercept	0.080	0.040	0.026	0.048	0.045	0.031	0.019	0.014	0.004

Note: Three samples not included for technical problems.

Abbreviation: NBICs, nucleated red blood cells.

^aNeutrophils include segmented and band neutrophils.

^bImmature granulocytes include metamyelocytes, myelocytes and promyelocytes.

^cNeoplastic cells include cells classified by the system as lymphoblasts, myeloblasts, abnormal (lymphomatous) lymphocytes, abnormal promyelocytes and circulating plasma cells in multiple myeloma patients.

Distributional inaccuracy

The correlation coefficients (r) between MC-80 post-classification results and manual differential (reference) for the five types of normal leukocytes and the four primary populations of abnormal cells are high for all types of cells except for reactive lymphocytes.

TABLE 2 Comparison of the MC-80 post-classification results with the optical microscope reference method (Carlo Erba™ stain).

	Neutrophils ^a	Lymphocytes	Monocytes	Eosinophils	Basophils	Immature granulocytes ^b	Neoplastic cells ^c	Reactive lymphocytes	NBICs
Pass rate (%)	88.5	87.2	91.8	93.8	98.4	82.2	81.5	75.1	91.3
\bar{r}	0.949	0.845	0.666	0.949	0.665	0.357	0.907	0.427	0.689
σ^2	0.899	0.748	0.764	0.900	0.748	0.734	0.822	0.190	0.790
Slope	0.997	0.830	0.857	0.876	0.823	0.507	1.094	0.798	0.975
Intercept	2.439	2.153	0.578	0.291	0.748	0.015	1.739	0.689	0.380

Note: See Table 53 for the comparison of MC-80 pre-classification data with reference microscopy.

Abbreviation: NBICs, nucleated red blood cells.

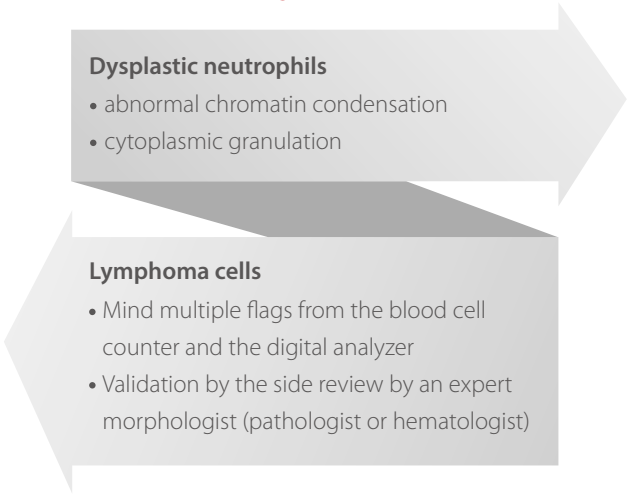
^aNeutrophils include segmented and band neutrophils.

^bImmature granulocytes include metamyelocytes, myelocytes and promyelocytes.

^cNeoplastic cells include cells classified by the system as lymphoblasts, myeloblasts, abnormal (lymphomatous) lymphocytes, abnormal promyelocytes, and circulating plasma cells in multiple myeloma patients.

The results between pre-classification and the post-classification MC-80 results are compared too. It's reported, differences between the major normal leukocyte classes were minimal, while the most relevant adjustments due to the operators' revision (post-classification) were observed for basophils and reactive lymphocytes.

Explanation of outliers
(distributional disagreements)



Clinical sensitivity: Identification of films with pathological cells

<ul style="list-style-type: none">• The MC-80 displays extremely good sensitivity in identifying immature granulocytes.	<ul style="list-style-type: none">• The MC-80 displays good efficiency and sensitivity in identifying reactive lymphocytes.
Immature granulocytes	Reactive lymphocytes
<ul style="list-style-type: none">• It has a sensitivity of 97.5% and a predictive value of a negative result equal to 96.9% for NRBC.	<ul style="list-style-type: none">• All samples were flagged by the digital morphology analyzer. Expert morphological review under the microscope is recommended.
NRBC	Neoplastic cells

TABLE 3 Specific performance of the MC-80 in identifying films with specific types of cells that do not normally circulate in the blood of healthy subjects.

	Granulocyte precursors (>1%)	Neoplastic cells* (>0%)	Reactive lymphocytes (>3%)	NRBCs (>1/100 WBC)
Sensitivity	98.8%	83.8%	93.6%	97.5%
Specificity	87.7%	86.1%	92.9%	89.9%
PV of positives	83.5%	80.6%	81.1%	81.4%
PV of negatives	99.2%	88.4%	97.8%	96.9%
Total efficiency	92.0%	85.2%	95.2%	92.0%

*Neoplastic cells include cells classified by the system as lymphoblasts, myeloblasts, abnormal (lymphomatous) lymphocytes, abnormal promyelocytes, and circulating plasma cells in multiple myeloma patients. Abbreviations: NRBCs, nucleated red blood cells; PV, predictive value.

Conclusion
(excerpted from “Abstract - Conclusion”)

“Our study highlights the outstanding diagnostic performance of this artificial intelligence–based blood film analyzer for hematology patients with circulating abnormal cells. We appreciated the morphological harmonization of cells observed on the screen and those seen in the microscope.”



MC-80
in a State-of-the-art Fully
Automated Core Laboratory

Barcelona, Spain

Stain: May-Grünwald-Giemsa (RAL)

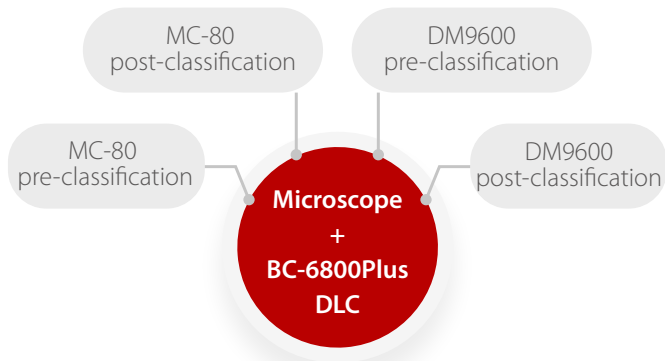
Performance of the new MC-80 automated digital cell morphology analyser in detection of normal and abnormal blood cells: Comparison with the CellaVision DM9600

Anna Merino | Javier Laguna | María Rodríguez-García | Judit Julian | Alexandra Casanova | Angel Molina

A total of 445 samples were used, and WBC pre-classification values with the MC-80 and DM9600 were compared with the manual reference (microscope), Mindray BC-6800Plus differentials (only normal samples), and confirmed or reclassified images (post-classification).³

Comparative study and statistical analysis

The pre-classification and post-classification of WBC using the MC-80 and DM9600 in normal samples were compared with the manual reference method using the microscope and with the differential leukocyte count (DLC) obtained on the BC-6800Plus.



Comparison with DM9600 - routine cell types

Table 1 shows the pre- and post-classification percentages of WBC obtained using the MC-80, which exhibited a strong correlation and concordance for all types of leucocytes, including immature granulocytes (IG) (values between 0.91 and 1).

TABLE 1 Pearson's r and Lin's k coefficient values, Passing-Bablok regressions, and Bland-Altman analysis comparing pre-classification MC-80 and DM9600 results with the manual reference method (A) and the MC-80/DM9600 30-min manual samples

MC-80 pre-classification						DM9600 pre-classification					
Cell type	r	k	Intercept (95% CI)	Slope (95% CI)	Mean difference (95% CI)	Cell type	r	k	Intercept (95% CI)	Slope (95% CI)	Mean difference (95% CI)
Neutrophils	0.980	0.979	-4.361 (-8.35 to 0.59)	0.97 (0.95 to 0.99)	0.41 (-1.42 to 0.20)	0.972	0.979	-4.321 (-8.35 to 0.59)	0.97 (0.95 to 0.99)	0.41 (-1.42 to 0.20)	0.42 (-1.43 to 0.20)
Lymphocytes	0.925	0.921	-2.051 (-5.25 to 0.40)	0.94 (0.91 to 0.97)	-0.761 (-1.23 to 0.70)	0.979	0.979	-1.051 (-5.45 to 0.40)	0.94 (0.91 to 0.97)	-0.441 (-0.94 to 0.06)	-0.441 (-0.94 to 0.06)
Monocytes	0.915	0.907	0.251 (-0.81 to 1.31)	0.96 (0.93 to 0.99)	-0.331 (-0.45 to 0.79)	0.930	0.930	-2.251 (-4.57 to 0.06)	0.93 (0.90 to 0.96)	0.031 (-0.03 to 0.09)	0.031 (-0.03 to 0.09)
Eosinophils	0.946	0.947	0.021 (-0.23 to 0.27)	0.96 (0.93 to 0.99)	0.291 (-0.77 to 0.36)	0.948	0.948	0.021 (-0.23 to 0.27)	0.96 (0.93 to 0.99)	0.291 (-0.77 to 0.36)	0.291 (-0.77 to 0.36)
Basophils	0.921	0.914	0.001 (-0.00 to 0.00)	0.96 (0.93 to 0.99)	0.091 (-0.05 to 0.23)	0.953	0.953	0.001 (-0.00 to 0.00)	0.96 (0.93 to 0.99)	0.091 (-0.05 to 0.23)	0.091 (-0.05 to 0.23)
Immature granulocytes	0.914	0.913	0.001 (-0.00 to 0.00)	0.96 (0.93 to 0.99)	-0.081 (-0.05 to 0.23)	0.947	0.947	0.001 (-0.00 to 0.00)	0.96 (0.93 to 0.99)	0.091 (-0.05 to 0.23)	0.091 (-0.05 to 0.23)

MC-80 post-classification						DM9600 post-classification					
Cell type	r	k	Intercept (95% CI)	Slope (95% CI)	Mean difference (95% CI)	Cell type	r	k	Intercept (95% CI)	Slope (95% CI)	Mean difference (95% CI)
Neutrophils	0.996	0.998	-0.721 (-1.62 to 0.17)	0.99 (0.98 to 1.00)	0.41 (-1.42 to 0.20)	0.998	0.998	-0.721 (-1.62 to 0.17)	0.99 (0.98 to 1.00)	0.41 (-1.42 to 0.20)	0.41 (-1.42 to 0.20)
Lymphocytes	0.986	0.988	-0.491 (-1.02 to 0.04)	0.99 (0.98 to 1.00)	-0.761 (-1.23 to 0.70)	0.997	0.997	-0.491 (-1.02 to 0.04)	0.99 (0.98 to 1.00)	-0.441 (-0.94 to 0.06)	-0.441 (-0.94 to 0.06)
Monocytes	0.971	0.970	-0.491 (-1.02 to 0.04)	0.99 (0.98 to 1.00)	-0.331 (-0.45 to 0.79)	0.997	0.997	-0.491 (-1.02 to 0.04)	0.99 (0.98 to 1.00)	0.031 (-0.03 to 0.09)	0.031 (-0.03 to 0.09)
Eosinophils	0.958	0.958	-0.491 (-1.02 to 0.04)	0.99 (0.98 to 1.00)	0.291 (-0.77 to 0.36)	0.997	0.997	-0.491 (-1.02 to 0.04)	0.99 (0.98 to 1.00)	0.291 (-0.77 to 0.36)	0.291 (-0.77 to 0.36)
Basophils	0.976	0.976	0.001 (-0.00 to 0.00)	0.99 (0.98 to 1.00)	0.091 (-0.05 to 0.23)	0.997	0.997	0.001 (-0.00 to 0.00)	0.99 (0.98 to 1.00)	0.091 (-0.05 to 0.23)	0.091 (-0.05 to 0.23)
Immature granulocytes	0.979	0.980	0.001 (-0.00 to 0.00)	0.99 (0.98 to 1.00)	-0.081 (-0.05 to 0.23)	0.997	0.997	0.001 (-0.00 to 0.00)	0.99 (0.98 to 1.00)	0.091 (-0.05 to 0.23)	0.091 (-0.05 to 0.23)

Abbreviations: CI, confidence interval.

Comparison with DM9600 – blast cells and immature granulocytes

As observed in samples from acute leukemia patients, when comparing pre- and post-classification percentages of blast cells in this group of patients, the MC-80 exhibited the highest correlation and concordance values.

In samples from patients with myelodysplastic syndromes (MDS) /myeloproliferative neoplasm (MPN), percentages of blast cells using the microscope were similar to pre- and post-classification values provided by the MC-80 and the DM9600.

The pre- and post-classification percentages of immature granulocytes (IG) provided by MC-80 showed much higher correlation and concordance values in patients with infections, especially in the pre-classification.

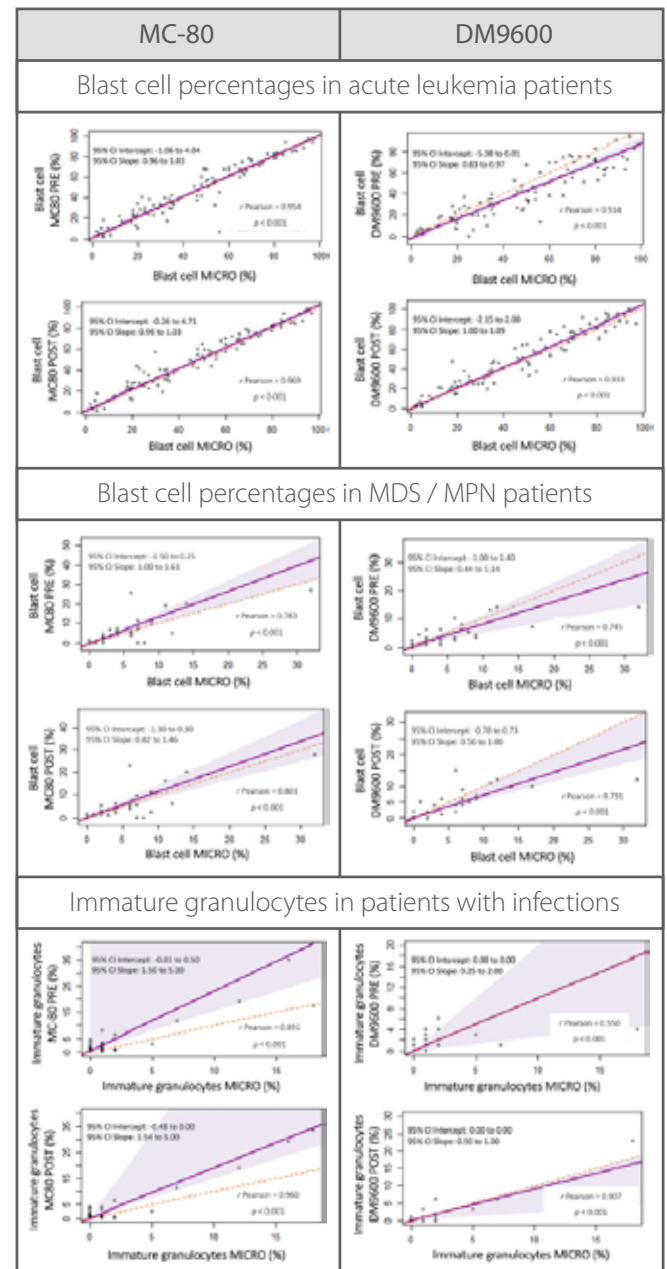
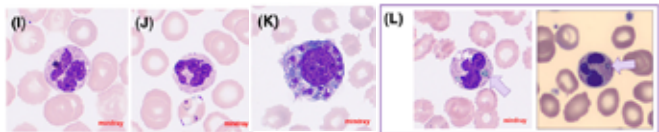


FIGURE 2 Passing-Bablok regressions and correlation coefficient values of reference manual method and pre- and post-classification results provided by Mindray MC-80 and ColiVizion® DM9600. (A) Blast cell percentages in acute leukemia patients; (B) Blast cell percentages in myelodysplastic syndromes/myeloproliferative neoplasm patients; and (C) Immature granulocytes in patients with infections. POST, post-classification percentages; PRE, pre-classification percentages.

"Discussion" Highlights

- Correlation and concordance between pre- and post-classification using the MC-80 were higher than with DM9600, suggesting that reviewing samples in the MC-80 may be faster.

- The images provided by the MC-80 showed good quality for the specialists to recognize malignant cells, dysplastic cells, malaria, Leishmania and inclusions such as green crystals in neutrophils.



Conclusion
(excerpted from “Abstract - Conclusion”)

“We found that the MC-80 shows high performance for WBC differentials for both normal samples and patients with hematological diseases.”



Stain: Wright-Giemsa (Baso Diagnostics)

Nine hundred and thirty-four samples (100 normal and 834 blood samples triggered a flag on the hematology analyzers) were randomly collected.⁴

Precision

The WBC counts of 24 selected samples ranged from 2.74 x 10⁹/L to 62.33 x 10⁹/L. All cell types showed acceptable precision.

TABLE 1 Precision of MC 80				
Cell class	n (cases)	Median percentage (range)	Median SD (range)	Median CV (range)
Segmented neutrophils	50	43.4 (0.5-92.1)	1.0 (0.2-3.4)	2.5 (0.4-42.2)
Band forms	50	5.7 (0-22.8)	0.7 (0-3.4)	30.4 (0-51.6)
Lymphocytes	50	13.1 (1.1-65.7)	0.6 (0.2-2.4)	5.6 (0.7-53.7)
Monocytes	50	9.2 (0.9-28.3)	0.4 (0-2.3)	4.2 (0-41.3)
Eosinophils	40	2 (0.5-13.2)	0.2 (0-2.4)	12.2 (0-73.6)
Basophils	34	6.2 (0.5-30)	0.2 (0-1)	34.6 (0-57.9)
Metamyelocytes	30	1.9 (0.5-24.4)	0.2 (0-1.4)	14.6 (0-60.4)
Mycoblasts	25	3.1 (0.5-15)	0.2 (0-1.8)	20.1 (0-57.9)
Proerythrocytes	22	0.8 (0.5-4.6)	0 (0-0.7)	29.8 (0-51.6)
Blasts	23	30 (1.5-98)	0 (0-1.6)	9.6 (0.9-51.6)
Reactive lymphocytes	33	0.8 (0.5-4.3)	0.2 (0-1.4)	46.4 (0-59.2)
Plasma cells	6	4.0 (1.0-7.9)	1.1 (0.5-7.8)	42.1 (11.8-50.5)
Nucleated red blood cells	28	0.9 (0.5-55.4)	0.1 (0-1.5)	5.8 (0-67.1)

Cell identification performance

The cell identification performance was analyzed on 194,009 cells from 934 blood smears. Overall, the specificity of cell identification was higher than 95% for all cell classes, and sensitivity greater than 95% for most cell classes. The lowest sensitivity was found in plasma cells. It should be noted that the total number of analyzed plasma cells was considerably low (n = 5).

TABLE 2 Identification rate for MC 80-white blood cell (WBC) pre-classification												
Cell class	Post classification											
	Neutrophils	Lymphocytes	Monocytes	Eosinophils	Basophils	RBCs	Platelets	Plasma cells	NRBCs	Pre-classification		
Pre-classification	124 365	57	175	1	34	3075	2	3	0	17	124 457	
Lymphocytes	41	95 (61)	0	0	0	0	0	0	0	1	96	93.78%
Monocytes	20	55	14 (2)	0	0	0	0	0	0	2	77	14.00%
Eosinophils	81	0	0	46 (0)	0	0	0	0	0	0	81	47.57%
Basophils	1	0	0	0	0	0	0	0	0	0	1	1.36%
Immature granulocytes (IG)	27	4	135	0	4	5703	6	0	0	0	369	5889%
RBCs	0	0	0	0	0	2	20	2009	90	1	2712	
Reactive lymphocytes	1	0	48	0	0	0	70	1025	0	1	124	1.04%
Plasma cells	0	0	0	0	0	0	0	2	3	0	5	
Nucleated red blood cells (NRBCs)	27	4	2	0	0	0	1	34	0	0	65	60.72%
Post classification Total	124 365	30 624	14 912	464	532	4704	204	104	12	1047	194 009	
True Positive	124 364	30 747	14 341	464	534	4702	200	100	3	1043		
False Positive	121	93	229	57	32	330	40	345	2	37		
True Negative	47 659	343 175	179 917	389 345	372 433	388 275	390 418	372 781	374 964	147 974		
False Negative	184	87	65	4	16	1073	407	348	9	32		
Sensitivity	99.1%	99.7%	99.4%	99.9%	99.8%	99.4%	99.7%	99.7%	99.9%	99.7%		
Specificity	99.7%	99.7%	99.6%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%		

Method comparison study

Compared to manual counting, MC-80 yields a good correlation ($r > 0.90$) and minimal differences for most cell classes. The highest correlation was found in nucleated red blood cells (NRBC) ($r = 0.99$).

TABLE 3 Passing-Bablok and Bland-Altman analysis for method comparison of pre-classification and post-classification for the MC 80 compared to manual microscope													
Cell class	N	Pre-classification			Post-classification			N	Manual microscope				
		Median	Interquartile range	Mean	Median	Interquartile range	Mean		Median	Interquartile range	Mean		
Segmented neutrophils	230	0.56	7.38 [1.34-34.5]	1.08	0.02-5.10	-0.70	0.33 [0-5.10]	0.56	0.71	10.22 [0-2.20]	1.36	0.02-5.10	0.39 [0.70-5.10]
Band neutrophils	230	0.30	0.56 [0.04-1.58]	0.02	0.01-0.15	0.11	0.02-0.15	0.29	0.40	13.27 [0-0.40]	3.75	0.04-20.00	7.38 [0.29-35.47]
Segmented band neutrophils	230	0.93	3.11 [0.03-1.02]	0.07	0.03-0.11	-0.04	0.11 [0-0.15]	0.93	0.04	1.52 [0-0.15]	1.00	0.02-0.15	0.12 [0.15-0.15]
Lymphocytes	230	0.93	1.71 [0.23-1.08]	0.95	0.06-6.95	-1.70	12.31 [0-10.98]	0.93	1.28	1.09 [0-0.15]	0.96	0.02-0.15	-0.39 [0.70-5.10]
Monocytes	230	0.82	1.81 [0.16-0.36]	1.30	0.02-1.20	12.40	5.13 [0-43.78]	0.93	0.94	1.99 [0-0.36]	1.39	0.02-0.15	-0.39 [0.70-5.10]
Eosinophils	230	0.93	0.10 [0.03-0.38]	1.30	0.02-1.50	0.80	5.17 [0-4.55]	0.93	-0.17	0.33 [0-0.38]	1.30	0.02-0.15	0.80 [0.50-4.55]
Basophils	230	0.89	0.86 [0.03-0.89]	4.01	0.16-4.80	0.50	1.14 [0-1.40]	0.86	0.86	0.86 [0-0.89]	4.01	0.16-4.80	0.50 [0.50-4.80]
Immature granulocytes	34	0.74	0.76 [0.13-1.08]	-0.39	1.39 [0.02-0.40]	2.25	0.30-3.70	0.75	-0.36	0.99 [0-0.40]	2.25	0.30-3.70	0.75 [0.30-3.70]
Myelocytes	19	0.93	0.10 [0.04-0.93]	-0.10	0.04-0.90	1.34	0.16-1.53	0.93	-0.10	0.44 [0-0.93]	1.34	0.16-1.53	0.93 [0.93-1.53]
Metamyelocytes	19	0.80	3.48 [1.33-0.44]	0.95	0.13-0.44	3.40	0.30-0.44	0.80	-0.95	1.40 [0-0.44]	3.40	0.30-0.44	0.80 [0.80-0.44]
Immature granulocytes	30	0.94	0.96 [0.50-0.50]	0.02	0.02-0.25	1.20	0.87 [0-0.40]	0.94	-0.49	0.37 [0-0.40]	1.20	0.02-0.25	1.20 [0.87-0.40]
Blasts	30	0.97	0.98 [0.99-0.98]	0.02	0.02-0.25	0.36	4.87 [0-5.80]	0.97	-0.49	0.99 [0-0.98]	0.02	0.02-0.25	0.36 [0.36-5.80]
Reactive lymphocytes	18	0.93	0.99 [0.82-0.89]	2.34	0.25-11.26	0.94	2.60 [0-1.50]	0.93	-0.97	2.60 [0-1.50]	2.34	0.25-11.26	0.93 [0.93-11.26]
Nucleated red blood cells	25	0.99	0.11 [0.79-0.16]	1.35	0.14-1.67	0.25	2.27 [0-2.40]	0.99	-0.11	0.67 [0-0.16]	1.35	0.14-1.67	0.25 [0.25-2.40]

Mean, arithmetic mean; granulocytes, monocytes, metamyelocytes, blasts, reactive lymphocytes, and nucleated red blood cells were performed only on manual slides for these cells.

Conclusion

In conclusion, the performance of the WBC differential of the newly released Mindray MC-80 automated digital cell morphology analyzer is acceptable compared to the manual differential.



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The number 3 holds great inspiration. 3 esteemed morphologists, through their remarkable work on MC-80's 3-year evaluation, have instilled incredible confidence in the analyzer. This has established MC-80 as a trusted tool for serving laboratories worldwide.

References

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