〈Original Article〉

Performance evaluation of Celltac G: a new automated hematology analyzer

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Summary Nihon Kohden develops and manufactures portable hematology equipment for private clinics. They are now marketing the Celltac G (MEK-9100), which is a stand-alone automated hematology analyzer for medium-sized clinical laboratories (processing capacity: 90 samples/hour). This analyzer is equipped with a novel original sheath flow control technology (DynaHelix Flow) for measuring the complete blood count, which shows improvements in accuracy and precision, especially for low cell counts. When a differential white blood cell count is determined, white blood cells are classified while their morphological characteristics are maintained as intact as possible. In this study, we evaluated the performance of the Celltac G in accordance with international standards, and the results of our basic investigation and assessment of its clinical performance are reported here. The parameters that we assessed for the Celltac G included the detection limit, carryover, imprecision (within-run and within-laboratory imprecision), linearity (measurement range), comparability (comparison with a standard analyzer and with a manual counter, and mode-to-mode comparability), and sample stability. All parameters were evaluated according to the Clinical and Laboratory Standard Institute standards and the International Council for Standardization in Haematology guidelines. Both the basic investigation and assessment of clinical performance generally yielded favorable results. In regards to the accuracy of the platelet count via the Celltac G, the limit of quantitation was $4x10^9$/L, the carryover was 0.07%, and imprecision (coefficient of variation) was 1.6 to 2.6%. These results suggested that the Celltac G is reliable enough for testing samples from patients undergoing platelet transfusion. The analyzer has a transport system with colored racks that allows for successive loading of samples. When handling emergency samples, the progress of the current workflow, from initial measurements to end results, can be displayed on the analyzer screen. Furthermore, a linkage of the samples in the colored racks

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allows for easy identification and efficient analysis of target samples. Control of the analyzer and data editing can both be conducted on the display, which was designed to be easy to understand. In conclusion, the Celltac G is considered to be an appropriate analyzer for small to medium-sized clinical laboratories, where multiple clinical laboratory technicians are performing the analysis.

Key words: Hematology analyzer, Complete blood count, Differential WBC

1. Introduction

Nihon Kohden develops and manufactures portable hematology equipment for private clinics.[1,2] In April 2016, they began marketing the Celltac G, which is a compact stand-alone automated hematology analyzer for medium-sized clinical laboratories. The dimensions of the device are 675 mm (width) x 576 mm (height) x 589 mm (depth). It has a built-in compressor without requiring an external personal computer, and is capable of processing 90 samples/hour and measuring 24 parameters. This analyzer is equipped with a novel original sheath flow control technology for measuring the complete blood count (CBC). The analyzer had eight colored racks ("Smart ColoRac Match") for the transport of samples. The workflow progress, from the initial measurements to the end results, can be displayed on the analyzer screen. The system also incorporates ColoRac, thus allowing target samples to be processed immediately for more efficiency in analyses.

The Celltac G requires a 40 µl sample volume of whole blood when operating in the "standard mode." In patients, such as infants from whom blood collection is difficult and only a small sample volume can be obtained, the "pre-dilution mode" can be selected to allow for measurements using 20 µL of whole blood. The Celltac G measures cells accurately by employing an original flow rotation processing technology (DynaHelix flow technology) developed by Nihon Kohden for determining the CBC. In addition, this analyzer also shows improved measurement accuracy and precision at low cell counts. When the differential white blood cell count measurement is performed, white blood cells can be classified while largely maintaining their morphological characteristics (DynaScatter laser technology).[3] In this study, we evaluated the Celltac G analyzer in accordance with international standards by carrying out a basic investigation and assessing its clinical performance. The parameters assessed were the detection limit, carryover, imprecision (within-run and within-laboratory precision), linearity (measurement range), comparability (comparison with a standard analyzer and with manual counting, and mode-to-mode comparability), and sample stability. All of the parameters were evaluated according to the Clinical and Laboratory Standard Institute (CLSI) standards and the International Council for Standardization in Haematology (ICSH) guidelines.[4-8]

2. Materials and methods

2.1 Analyzer

The test automated analyzer (TAA) was the Celltac G (Nihon Kohden Corporation), a multi-function automated hematology analyzer. The comparison automated analyzer (CAA) was the XE-5000 (Sysmex Corporation), a multi-function automated hematology analyzer.

2.2 Samples

Peripheral venous blood samples for the performance evaluation were collected from healthy volunteers in tubes containing EDTA-2K.[9] The blood collection tubes,[10] blood collection procedure,[11] and stirring procedure[4,12,13] were all according to the methods described by ICSH and CLSI. The minimum detection sensitivity, carryover, imprecision (pathological samples), and linearity (measurement range) were evaluated after

the separation of plasma from the blood cells by centrifugation. The sample concentrations were adjusted according to the CLSI H26-A2 method before the measurements.[7] To investigate comparability, 360 venous blood samples were collected from hospitalized patients and outpatients in tubes containing EDTA-2K. The measurements were conducted within 4 hours of blood collection. May Giemsa staining of the blood films were then performed.

2.3 Evaluation

The evaluation was performed according to the CLSI[7] and ICSH[4,5] automated hematology analyzer assessment guidelines. The CLSI exclusion criteria for measured values were adopted.[7] Statistical analyses were conducted using Excel (Microsoft), StatisPro (CLSI), and MedCalc (MedCalc) softwares.

(1) Minimum detection sensitivity[14]

To investigate the sensitivity of Celltac G for determining the WBC, hemoglobin (HGB), and platelet count (PLT), blank samples and samples with values near the detection limit were prepared and measured 60 times. The limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) were then calculated.

(2) Carryover[4,5,7,15]

Samples with high and low test values of test parameters (WBC, red blood cell count [RBC], HGB, and PLT) were prepared. The samples with high test values were measured thrice successively (denoted HTV1-3), followed by 3 successive measurements of the samples with low test values (denoted as LTV1-3). The influence of prior measurements from samples with a high test value on the results for samples with a low test value was evaluated by calculating the carryover.

(3) Imprecision[7]

3.1) Within-run imprecision (reproducibility)

Using 4 normal blood samples and 3 pathological samples, measurements were performed 31 times in the "Sampler Mode (Autoloader)" and "Pre-dilution Mode (Manual)." Then the coefficient of variation (CV) was determined and the within-run imprecision was assessed. The WBC concentration in the pathological blood samples was adjusted to the leukopenia range (WBC: 0-2x10^9/L) by using normal blood, which is a criterion for blood transfusion (HGB: 60-100 g/L, PLT: 0-50x10^9/L).

3.2) Within-laboratory imprecision (total imprecision)

Total imprecisions including of repeatability within-day imprecision and between-day imprecision were assessed by measuring controls with 3 different concentrations (high, normal, and low concentrations) twice a day (measurement interval: 5-12 hours) at an interval of 25 days or longer as well as by calculating the CV.

(4) Linearity (measurement range)[7,16]

To prepare reference samples, concentrated blood cells were diluted with autologous platelet poor plasma (PPP). The diluted samples were prepared kinds of 7-11 concentration in each analytical measurement intervals (measurement ranges) for all parameters. Using these samples as a reference, measurements were conducted in duplicates or more frequently, and the linearity between the lower and upper limits of the measurement range was assessed according to the CLSI method. The parameters assessed were the WBC, RBC, HGB, hematocrit (HCT), PLT, and mean corpuscular volume (MCV).

(5) Comparability[7,17,18]

5.1) Comparisons with the comparator analyzer and manual counting

For comparisons with the comparator analyzer, measurements were taken with the Celltac G (TAA) and XE-5000 (CAA), and correlation coefficients (least squares method) were calculated. Regression analysis (Passing-Bablok method) and differential analysis (Bland-Altman method) of the data were also conducted. For the 5-parameter differential WBC, a similar analysis was conducted by

comparisons with data obtained by manual counting (2 laboratory technologists counted 200 cells each).[19,20]

5.2) Mode to mode comparability

Results obtained with the "Sampler mode" and "Manual mode" were compared using 10 normal samples.

(6) Sample stability[4,5]

At 1, 4, 8, and 24 hours after the blood collection, samples from 5 healthy volunteers were measured at both room temperature (18-22°C) and a low temperature (4-8°C), and any changes in the mean values were evaluated. The following differential parameters were assessed: WBC, RBC, HGB, HCT, MCV, PLT, and WBC differential parameters. Then, the stability data were analyzed with the Mann-Whitney test.

3. Results

(1) Minimum detection sensitivity

The LoB, LoD, and LoQ were 0.10, 0.15, and 0.15, respectively, for WBC (x 10^9/L); 1, 1, and 1, respectively, for HGB (g/L); and 2, 4, and 4, respectively, for PLT (x 10^9/L).

(2) Carryover

The carryover (HTV3, LTV3) for WBC, RBC, HGB, and PLT was 0.77% (99.34, 0.88 x10^9/L), 0.00% (7.91, 0.82 x10^{12}/L), 0.25% (240.7, 27.1 g/L), and 0.07% (1060.9, 17.6 x10^9/L), respectively.

(3) Imprecision

3.1) Within-run imprecision

Within-run imprecision data are shown in Table 1. In the "Sampler mode," the CV of normal samples was 1.2-1.5% for WBC, 0.8-0.9% for RBC, 0.5-0.7% for HGB, 0.1-0.9% for MCV, and 1.6-2.6% for PLT. When the pathological samples were measured with the WBC set at 0.89-1.25 x10^9/L, the CV was 3.2-3.5%; with the HGB set at 73-79 g/L, the CV was 0.9-1.1%; and with the PLT set at 28-34 x10^9/L, the CV was 5.0-5.1%.

3.2) Within-laboratory imprecision (total imprecision)

The results for integrated precision are shown in Table 1. The CV for within-laboratory imprecision of the CBC (WBC, RBC, HGB, HCT, MCV, PLT) was 0.9-2.1% with the samples at a normal concentration, whereas it was 1.2-4.0% for samples with a low concentration, and 0.9-1.9% for samples with a high concentration. Regarding the differential WBC, the CV of the absolute neutrophil count (NE) and absolute lymphocyte count (LY) was 3.6-4.1% for samples with a normal concentration, 2.2-4.0% for samples with a low concentration, and 2.4-5.2% for samples with a high concentration.

(4) Linearity (measurement range)

The linear measurement range was 2.73-98.22 x 10^9/L for WBC, 1.25-8.54 x 10^{12}/L for RBC, 40-275 g/L for HGB, 0.118-0.809 L/L for HCT, and 29-1248 x 10^9/L for PLT. In addition, the MCV was within 1% (87.0-88.3 fL) at the HCT range of 0.164-0.581 L/L.

(5) Comparability

5.1) Comparison with the comparator analyzer and manual counting

In total, 359 samples were tested, including negative samples (n=214) and positive samples (n=145). Data on the correlation coefficients and results of the regression analysis and differential analysis are shown in Table 4. The results obtained from the CAA and TAA are shown in Figs 1-3. The differential WBC data obtained from manual counting and TAA are shown in Fig. 4.

The correlation coefficients (r) between CAA and TAA for the CBC parameters in all samples were as follows in Fig.1: 0.994 for WBC, 0.998 for RBC, 0.997 for HGB, 0.989 for HCT, 0.940 for MCV, and 0.988 for PLT. Using all the samples, the r values between CAA and TAA for the components of the 5-parameter differential WBC were as follows in Fig.3: 0.964 for %NE, 0.946 for %LY, 0.845 for %MO, 0.949 for %EO, and 0.848 for %BA. In addition, the correlations (r) between manual counting

and TAA were as follows in Fig.4: 0.929 for %NE, 0.919 for %LY, 0.611 for %MO, 0.890 for %EO, and 0.560 for %BA. Shown in Fig. 5 are distinctive scattergrams (case A with different monocyte populations, case B with different lymphocytes populations, and case C with different eosinophil populations).

5.2) Mode-to-mode comparability

The mean differences between "Sampler mode" and "Manual mode" were as follows: 0.09 x 10^9/L for WBC, 0.097 x 10^{12}/L for RBC, 1.5 g/L for HGB, 0.006 L/L for HCT, and 5.9 x 10^9/L for PLT.

(6) Sample stability

From the Mann-Whitney test, no significant differences were observed for the tested parameters for 24 hours after the blood collection when the samples were stored at room temperature. Furthermore, no significant differences were observed for the tested parameters after the blood collection when the samples were stored at refrigeration temperature except for %NE. The %NE was not significantly different for 8 hours since blood collection when samples were stored at room temperature.

4. Discussion

Overall, the Celltac G analyzer performed well with respect to the detection limit, carryover, imprecision, linearity, comparability, and sample stability. The precision for samples with lower concentrations is clinically important for measuring PLT in patients undergoing procedures such as chemotherapy, bone marrow transplants, or platelet transfusions.[7] In the present study, the PLT (x 10^9/L) was determined to be precise as indicated by the LoB and LoQ,[14] which were 2 and 4 (x 10^9/L), and the carryover and imprecision were determined to be 0.07% and 1.6-2.6%, respectively. Data obtained in the present study suggest that accurate decisions regarding platelet transfusions could be made using the Celltac G.

In regard to correlations with the comparator analyzer, the CBC parameters (WBC, RBC, HGB, HCT, MCV, and PLT) showed stronger correlations between the Celltac G and the XE-5000 when all samples were compared (n=359). The 5-part differential WBC showed good correlations between the two analyzers when negative samples (n=214) and positive samples (n=145) were tested.

The Celltac G uses flow cytometry to determine the differential WBC based on information from how much light is scattered. In brief, the cell size is determined from the specified forward small angle scatter (FSS) for WBC differential, information on the internal cellular architecture is obtained from the specified forward large angle scatter (FLS), and granularity is assessed from the side scatter (SDS).[3] The FSS (vertical axis) is initially displayed for lymphocytes, which are small, followed by monocytes and immature cells at the upper end of the scattergram. The FLS (horizontal axis) first identifies lymphocytes with a simple internal structure and then shows monocytes, basophils, neutrophils, and eosinophils to the right. The SDS (horizontal axis) shows basophils with limited granularity information, followed by neutrophils and eosinophils behind these cells in a three-dimensional manner. The three kinds of distinctive scattergrams obtained by the Celltac G were picked up for discussion.

The sample A (Fig. 5, Case A) that showed different monocyte populations were from a patient with acute myeloid leukemia. The differential WBC determined by the Celltac G was 50.9 for %MO, 27.2 for %LY, 19.1 for %NE, 2.2 for %EO, and 0.6 for %BA. According to the manual reassessment, the differential WBC was 34.0% for myeloblasts, 1.0% for promyelocytes, 6.0% for myelocytes, 11.0% for promonocyte-like cells, 2.0% for monocytes, 43.0% for lymphocytes, 1.0% for band neutrophils, and 2.0% for segmented neutrophils. The manual assessment suggested that blast cells or blast-like cells were counted as monocytes by the Celltac G, which may have led to measurement errors. However, a flag message indicating blast cells ("Blasts") was triggered by this sample, indicating the need for a manual assessment.

The sample B (Fig. 5, Case B) that showed different lymphocyte populations was from a patient with chronic myelomonocytic leukemia. The

differential WBC obtained with the Celltac G was 58.8 for %MO, 10.3 for %LY, 29.8 for %NE, 0.9 for %EO, and 0.2 for %BA. Manual re-assessment showed 75.0% for monocytes (including immature mononuclear cells), 7.0% for lymphocytes, and 18.0% for neutrophils; thus, the Celltac G reported similar results. The presence of large cells, such as monocytes, blast cells, and immature mononuclear cells, which affects both of vertical axis (FSS) and horizontal axis (FLS), results in an unclear border on the scattergram and affects the differential ratios. The scattergram, obtained by Celltac G, captured abnormalities that were increased by the complexity in the chromatin structure of mononuclear cells. This may have led to measurement errors. However, a flag message indicating immature granulocytes and blast cells ("Blasts") was triggered by this sample, indicating the need for manual assessment.

The sample C (Fig. 5, Case C) that showed different eosinophil populations was from a patient with eosinophilia. The manual assessment suggested that there were many eosinophils with an abnormal distribution of granules. The differential WBC of Celltac G was 9.9 for %EO, 69.3 for %NE, 15.9 for %LY, 4.6 for %MO, and 0.3 for %BA. The manual differential WBC was 19.5% for eosinophils, 54.0% for neutrophils, 22.5% for lymphocyte, 4.0% for monocytes, and 0.0% for basophils. Furthermore, the manual assessment suggested that the events that registered as eosinophils were counted as neutrophils by the Celltac G. The percentage of eosinophils that affected the gating line between eosinophils and neutrophils had an unclear border on the scattergram and also affected the differential ratio. This may have led to measurement errors. However, a flag message indicating "Eosinophilia" and "Ne-Eo Interference" was triggered by all samples, indicating the need for manual assessment.

Conclusion

We investigated the performance of the Celltac G analyzer and obtained good results for most of the parameters tested. Overall, we consider it suitable for small to medium-sized clinical laboratories with multiple laboratory technologists.

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Table 1 Within-run imprecision on peripheral blood and total imprecision on stored blood of the Celltac G

	Mode		Autoloader mode									
	Imprecision		**Within-run** (Reproducibility)							**Total**		
			Repeat 31 times on 5 tubes							108 times (48 days)		
	Samples		**Normal**				**Pathological**			**Stored blood**		
Parameter	value	Unit	N1	N2	N3	N4	P1	P2	P3	Low	Nomal	High
WBC	Mean	$x10^9$/L	5.29	5.00	4.16	6.78	1.25	0.89	1.02	2.75	7.77	25.15
	CV	%	**1.3**	**1.5**	**1.2**	**1.2**	**3.3**	**3.5**	**3.2**	**2.0**	**1.4**	**1.2**
RBC	Mean	$x10^{12}$/L	4.47	4.19	5.08	4.98	2.29	2.57	2.26	2.45	4.70	5.30
	CV	%	**0.9**	**0.8**	**0.8**	**0.9**	**1.1**	**1.6**	**1.3**	**1.2**	**1.2**	**1.0**
HGB	Mean	g/L	143	147	151	142	73	79	76	65	139	168
	CV	%	**0.5**	**0.7**	**0.6**	**0.5**	**1.1**	**1.0**	**0.9**	**1.5**	**0.9**	**0.9**
HCT	Mean	L/L	0.394	0.398	0.428	0.404	0.195	0.217	0.203	0.212	0.460	0.566
	CV	%	**1.0**	**1.3**	**0.9**	**0.9**	**1.0**	**1.7**	**1.3**	**1.9**	**1.6**	**1.3**
MCV	Mean	fL	88.29	95.00	84.33	81.10	85.54	84.51	89.86	86.47	97.86	106.92
	CV	%	**0.2**	**0.9**	**0.1**	**0.2**	**0.3**	**0.2**	**0.2**	**1.4**	**0.9**	**1.1**
MCH	Mean	pg	32.0	35.1	29.7	28.6	31.7	30.8	33.5	26.4	29.7	31.8
	CV	%	**1.0**	**1.0**	**1.0**	**1.0**	**1.3**	**1.4**	**1.3**	**1.9**	**1.4**	**1.5**
MCHC	Mean	g/L	363	369	352	353	371	365	373	306	303	298
	CV	%	**1.0**	**1.5**	**1.0**	**1.1**	**1.3**	**1.4**	**1.3**	**1.9**	**1.5**	**1.6**
RDW-CV	Mean	fraction	12.9	11.8	13.6	13.0	10.2	10.0	9.8	16.3	16.5	15.2
	CV	%	**1.3**	**1.2**	**1.5**	**1.8**	**0.8**	**0.6**	**0.8**	**1.6**	**2.0**	**1.3**
RDW-SD	Mean	fL	45.7	44.8	45.7	42.3	34.9	33.8	35.1	56.8	64.4	64.8
	CV	%	**1.3**	**1.5**	**1.5**	**1.8**	**0.9**	**0.5**	**0.8**	**6.0**	**2.2**	**2.4**
PLT	Mean	$x10^9$/L	302	204	206	233	34	28	30	40	186	394
	CV	%	**1.6**	**2.1**	**2.6**	**1.9**	**5.0**	**5.1**	**5.0**	**4.0**	**2.1**	**1.9**
PCT	Mean	L/L	0.0025	0.0018	0.0017	0.0017	0.0003	0.0002	0.0002	0.0003	0.0012	0.0030
	CV	%	**2.6**	**3.0**	**3.3**	**3.2**	**0.0**	**0.0**	**0.0**	**14.9**	**3.8**	**4.3**
MPV	Mean	fL	8.30	8.98	8.34	7.48	8.54	7.73	6.82	6.53	6.65	7.35
	CV	%	**1.1**	**0.9**	**1.0**	**1.1**	**1.7**	**1.6**	**1.8**	**2.2**	**1.5**	**2.7**
PDW	Mean	fraction	17.5	16.7	17.1	16.8	16.9	16.9	16.1	18.6	17.8	17.0
	CV	%	**1.7**	**1.8**	**1.8**	**2.3**	**3.3**	**3.3**	**3.5**	**5.2**	**3.3**	**3.7**
P-LCR	Mean	fraction	41.48	50.15	42.65	33.18	46.98	37.52	26.03	23.27	23.93	32.15
	CV	%	**2.2**	**1.8**	**2.5**	**2.8**	**3.5**	**4.7**	**7.3**	**7.8**	**4.6**	**3.8**
NE	Mean	$x10^9$/L	3.09	2.41	2.62	4.30	0.84	0.55	0.72	0.93	4.40	18.43
	CV	%	**2.7**	**2.6**	**2.4**	**1.9**	**4.0**	**5.6**	**4.3**	**4.1**	**2.2**	**2.4**
LY	Mean	$x10^9$/L	1.62	1.96	1.19	2.07	0.28	0.19	0.20	1.40	2.23	3.05
	CV	%	**4.2**	**3.5**	**5.1**	**2.9**	**11.4**	**11.0**	**7.6**	**3.6**	**4.0**	**5.2**
MO	Mean	$x10^9$/L	0.35	0.31	0.23	0.30	0.07	0.05	0.04	0.26	0.67	1.43
	CV	%	**6.4**	**6.1**	**7.3**	**8.7**	**16.5**	**15.9**	**17.7**	**11.4**	**8.7**	**7.6**
EO	Mean	$x10^9$/L	0.16	0.29	0.10	0.08	0.04	0.10	0.05	0.13	0.35	2.04
	CV	%	**14.3**	**11.7**	**14.9**	**24.9**	**51.2**	**19.4**	**25.4**	**17.9**	**20.5**	**16.3**
BA	Mean	$x10^9$/L	0.07	0.03	0.03	0.03	0.02	0.01	0.01	0.04	0.12	0.20
	CV	%	**16.7**	**20.5**	**32.3**	**20.7**	**34.0**	**38.3**	**60.5**	**38.8**	**39.6**	**55.6**
%NE	Mean	fraction	58.49	48.18	62.83	63.47	67.13	61.25	70.60	33.64	56.59	73.28
	CV	%	**2.2**	**2.5**	**2.4**	**1.3**	**3.6**	**3.4**	**2.3**	**3.6**	**1.5**	**1.4**
%LY	Mean	fraction	30.59	39.14	28.45	30.57	22.12	21.06	19.55	50.74	28.71	21.14
	CV	%	**4.2**	**3.0**	**4.7**	**2.9**	**9.8**	**9.7**	**8.0**	**2.8**	**3.2**	**4.4**
%MO	Mean	fraction	6.52	6.18	5.63	4.42	5.95	5.31	4.03	9.54	8.64	5.67
	CV	%	**6.3**	**5.6**	**6.9**	**8.6**	**14.6**	**15.8**	**14.3**	**11.3**	**9.1**	**7.8**
%EO	Mean	fraction	3.07	5.88	2.48	1.11	3.51	11.11	4.98	4.58	4.51	8.12
	CV	%	**13.9**	**11.4**	**13.8**	**23.1**	**51.3**	**20.8**	**22.8**	**18.5**	**20.9**	**17.1**
%BA	Mean	fraction	1.33	0.63	0.60	0.43	1.29	1.26	0.83	1.53	1.58	0.80
	CV	%	**15.7**	**20.6**	**26.5**	**20.7**	**29.6**	**38.4**	**40.9**	**37.6**	**38.1**	**53.4**

Table 2 Within-run imprecision on peripheral blood of the Celltac G

	Mode		Manual pre-dilution mode						
	Imprecision		**Within-run** (Reproducibility)						
			Repeat 31 times on 5 tubes						
	Samples		**Normal samples**				**Pathological samples**		
Parameter	value	Unit	N1	N2	N3	N4	P1	P2	P3
WBC	Mean	$x10^9$/L	4.78	4.43	3.73	6.16	1.26	0.90	1.00
	CV	%	**4.1**	**3.8**	**3.7**	**2.5**	**4.9**	**8.2**	**6.1**
RBC	Mean	$x10^{12}$/L	4.56	4.22	5.03	4.98	2.31	2.61	2.30
	CV	%	**1.8**	**1.5**	**1.6**	**1.4**	**2.3**	**1.9**	**2.1**
HGB	Mean	g/L	139	140	143	135	65	72	69
	CV	%	**1.4**	**1.4**	**1.3**	**1.6**	**2.2**	**1.6**	**1.7**
HCT	Mean	L/L	0.399	0.396	0.420	0.399	0.198	0.220	0.206
	CV	%	**1.8**	**1.6**	**1.6**	**1.4**	**2.2**	**2.0**	**2.1**
MCV	Mean	fL	87.30	93.81	83.46	80.25	85.51	84.16	89.56
	CV	%	**0.1**	**0.2**	**0.2**	**0.1**	**0.3**	**0.3**	**0.3**
MCH	Mean	pg	30.5	33.1	28.4	27.1	28.0	27.8	30.0
	CV	%	**1.7**	**1.7**	**1.7**	**1.7**	**1.9**	**2.0**	**2.5**
MCHC	Mean	g/L	349	353	340	338	328	330	335
	CV	%	**1.7**	**1.8**	**1.7**	**1.7**	**1.9**	**2.0**	**2.5**
RDW-CV	Mean	fraction	10.4	9.4	9.9	9.4	9.4	9.3	9.1
	CV	%	**0.9**	**1.3**	**1.0**	**1.3**	**1.3**	**1.3**	**1.0**
RDW-SD	Mean	fL	36.2	35.4	33.0	30.3	32.2	31.2	32.4
	CV	%	**0.9**	**1.4**	**0.9**	**1.3**	**1.3**	**1.4**	**1.0**
PLT	Mean	$x10^9$/L	323	203	205	240	35	35	33
	CV	%	**3.9**	**4.3**	**4.8**	**4.1**	**10.7**	**17.8**	**14.3**
PCT	Mean	L/L	0.0025	0.0017	0.0015	0.0017	0.0003	0.0003	0.0002
	CV	%	**5.4**	**5.5**	**5.4**	**5.4**	**15.5**	**22.1**	**19.8**
MPV	Mean	fL	7.84	8.30	7.45	7.01	8.00	8.00	6.91
	CV	%	**2.6**	**2.2**	**2.3**	**2.7**	**4.1**	**4.9**	**5.6**
PDW	Mean	fraction	16.7	15.9	16.5	16.2	17.1	17.9	16.6
	CV	%	**3.1**	**3.0**	**2.7**	**2.9**	**7.5**	**8.4**	**10.4**
P-LCR	Mean	fraction	38.34	44.28	34.12	28.79	40.26	40.49	26.44
	CV	%	**5.9**	**5.8**	**7.0**	**8.3**	**11.2**	**14.4**	**18.3**

Table 3 Correlation statistics between the Celltac G and a comparative hematology analyzer

Parameters	Unit	XE-5000 (All: n=359)			XE-5000 (Negative: n=214)		
			Passing and Bablok regression			Passing and Bablok regression	
		r	Slople (95% CI)	Intercept (95% CI)	*r*	Slople (95% CI)	Intercept (95% CI)
WBC	x10^9/L	0.994	0.986 (0.975 to 0.997)	-0.127 (-0.194 to -0.063)	0.992	0.992 (0.973 to 1.010)	-0.145 (-0.259 to -0.041)
RBC	x10^{12}/L	0.998	1.044 (1.036 to 1.053)	-0.188 (-0.218 to -0.155)	0.997	1.066 (1.053 to 1.078)	-0.282 (-0.336 to -0.230)
HGB	g/L	0.997	1.010 (1.001 to 1.019)	0.76 (-0.35 to 1.73)	0.995	1.015 (1.000 to 1.029)	0.11 (-1.80 to 1.88)
HCT	L/L	0.989	1.0910 (1.073 to 1.110)	-0.0362 (-0.0430 to -0.0296)	0.980	1.1540 (1.119 to 1.189)	-0.0620 (-0.0760 to -0.0490
MCV	fL	0.940	0.992 (0.950 to 1.033)	0.03 (-3.66 to 3.92)	0.926	0.994 (0.936 to 1.053)	0.24 (-5.09 to 5.63)
PLT	x10^9/L	0.988	1.046 (1.032 to 1.061)	-3.07 (-5.47 to -0.26)	0.989	1.062 (1.041 to 1.083)	-4.01 (-8.09 to 0.07)
NE	x10^9/L	0.996	0.982 (0.971 to 0.992)	-0.115 (-0.154 to -0.077)	0.994	0.968 (0.950 to 0.985)	-0.076 (-0.134 to -0.019)
LY	x10^9/L	0.832	0.950 (0.919 to 0.979)	0.029 (-0.016 to 0.069)	0.959	0.959 (0.918 to 1.000)	0.029 (-0.040 to 0.096)
MO	x10^9/L	0.978	1.028 (0.971 to 1.099)	-0.032 (-0.056 to -0.010)	0.783	1.050 (0.958 to 1.154)	-0.023 (-0.062 to 0.009)
EO	x10^9/L	0.928	1.068 (1.025 to 1.107)	0.018 (0.013 to 0.024)	0.967	1.054 (1.000 to 1.095)	0.017 (0.009 to 0.025)
BA	x10^9/L	0.890	1.500 (1.375 to 1.667)	0.015 (0.010 to 0.016)	0.689	1.500 (1.333 to 1.750)	0.015 (0.008 to 0.017)
%NE	fraction	0.964	1.025 (1.002 to 1.046)	-2.603 (-4.036 to -1.183)	0.968	1.004 (0.969 to 1.038)	-1.577 (-3.719 to 0.394)
%LY	fraction	0.946	1.000 (0.976 to 1.024)	0.330 (-0.314 to 0.991)	0.970	0.987 (0.953 to 1.021)	0.892 (-0.100 to 1.946)
%MO	fraction	0.845	1.127 (1.048 to 1.214)	-0.832 (-1.349 to -0.366)	0.747	1.127 (1.006 to 1.275)	-0.715 (-1.456 to 0.059)
%EO	fraction	0.949	1.103 (1.069 to 1.139)	0.333 (0.269 to 0.402)	0.968	1.102 (1.063 to 1.144)	0.241 (0.179 to 0.342)
%BA	fraction	0.848	1.360 (1.250 to 1.500)	0.290 (0.245 to 0.330)	0.730	1.283 (1.150 to 1.450)	0.323 (0.258 to 0.373)

Table 4 Correlation statistics between the Celltac G and manual differential count

Parameters	Unit	Manual count (All: n=338)			Manual count (Negative: n=202)		
			Passing and Bablok regression			Passing and Bablok regression	
		r	Slople (95% CI)	Intercept (95% CI)	*r*	Slople (95% CI)	Intercept (95% CI)
%NE	fraction	0.929	0.946 (0.909 to 0.983)	0.35 (-2.11 to3.06)	0.916	0.913 (0.863 to 0.967)	2.50 (-1.05 to 5.60)
%LY	fraction	0.919	0.889 (0.854 to 0.925)	3.22 (2.21 to 4.07)	0.911	0.834 (0.784 to 0.885)	4.74 (3.45 to 5.99)
%MO	fraction	0.611	1.213 (1.098 to 1.348)	0.36 (-0.18 to 0.88)	0.549	1.028 (0.866 to 1.218)	1.43 (0.60 to 2.14)
%EO	fraction	0.890	1.284 (1.210 to 1.371)	0.46 (0.32 to 0.57)	0.847	1.211 (1.119 to 1.320)	0.48 (0.29 to 0.68)
%BA	fraction	0.560	0.820 (0.713 to 0.950)	0.45 (0.38 to 0.49)	0.426	0.713 (0.580 to 0.860)	0.50 (0.43 to 0.55)

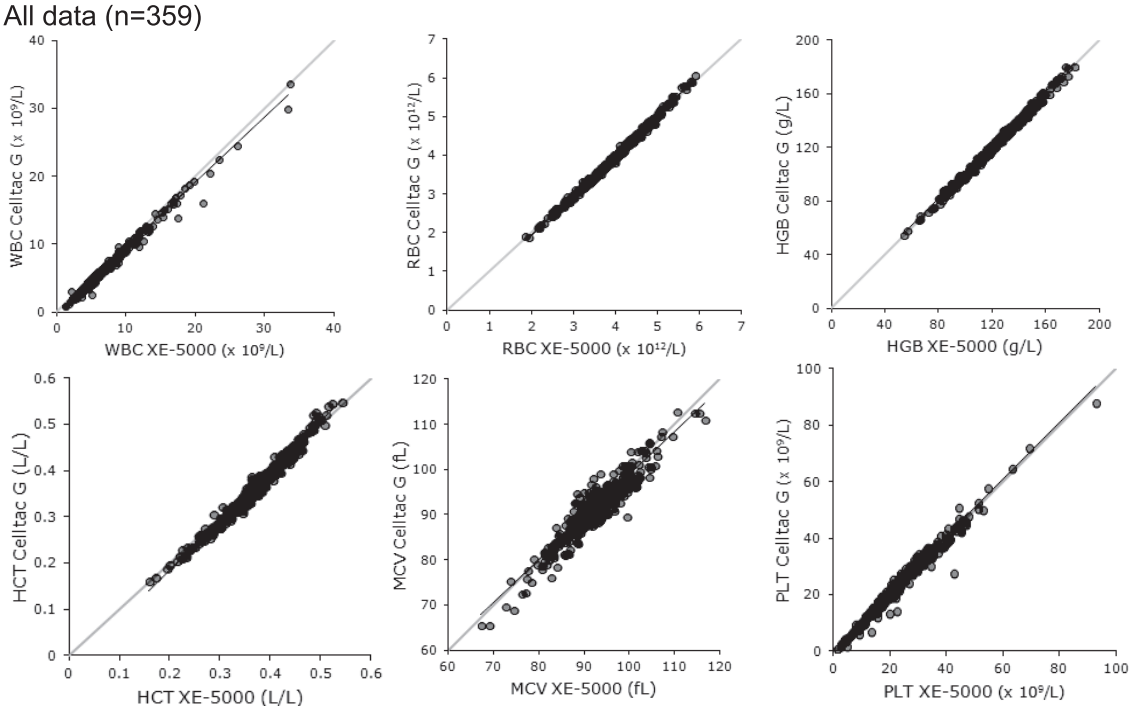


Fig.1 A comparison of some parameters of CBC (WBC, RBC, HGB, HCT, MCV, and PLT): Celltac G vs. XE-2000 on 359 peripheral blood samples

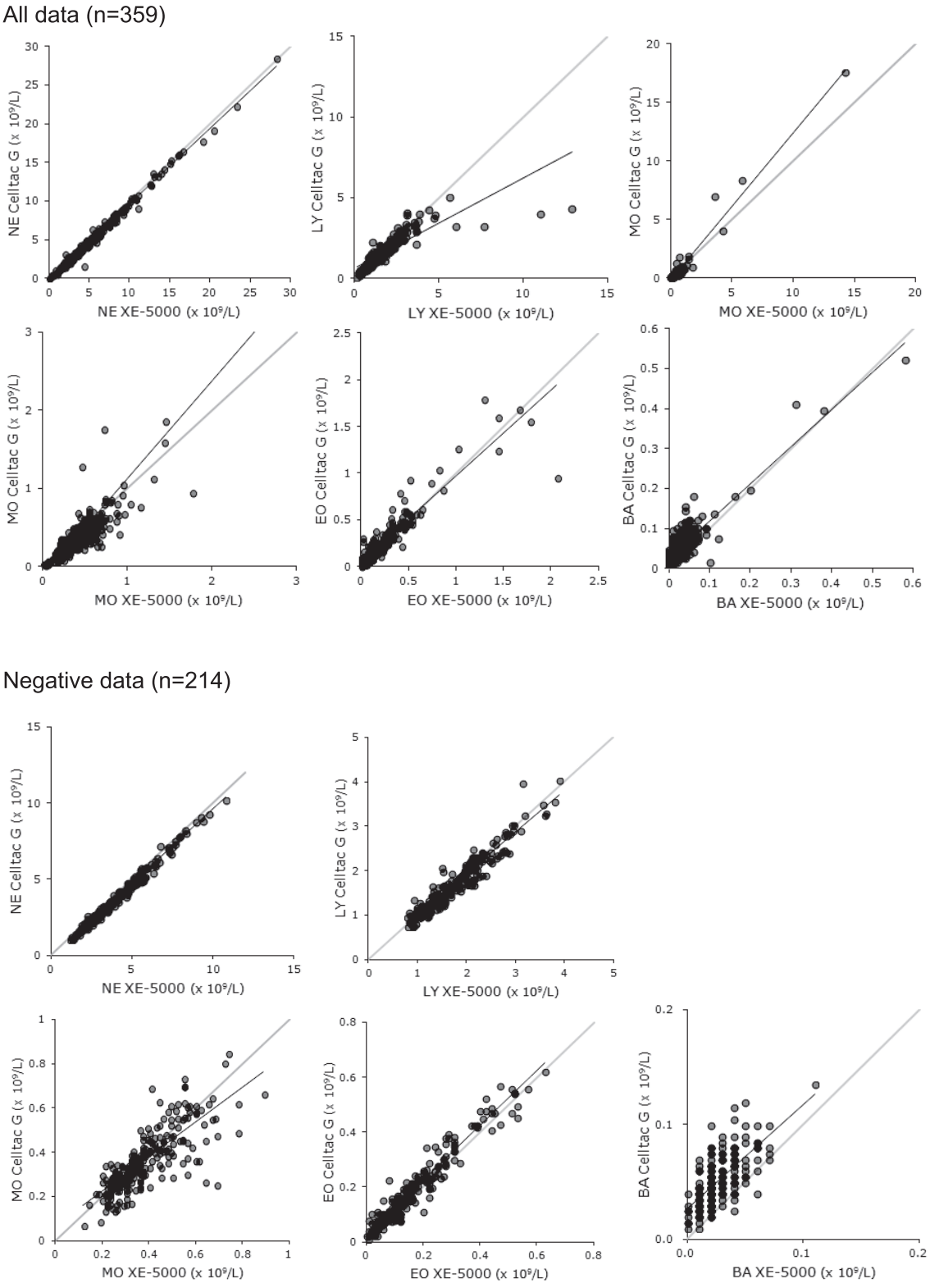


Fig.2 A comparison of the leukocyte differential parameters (NE, LY, MO, EO, and BA): Celltac G vs. XE-2000 on 359 peripheral blood samples and 214 negative peripheral blood samples.

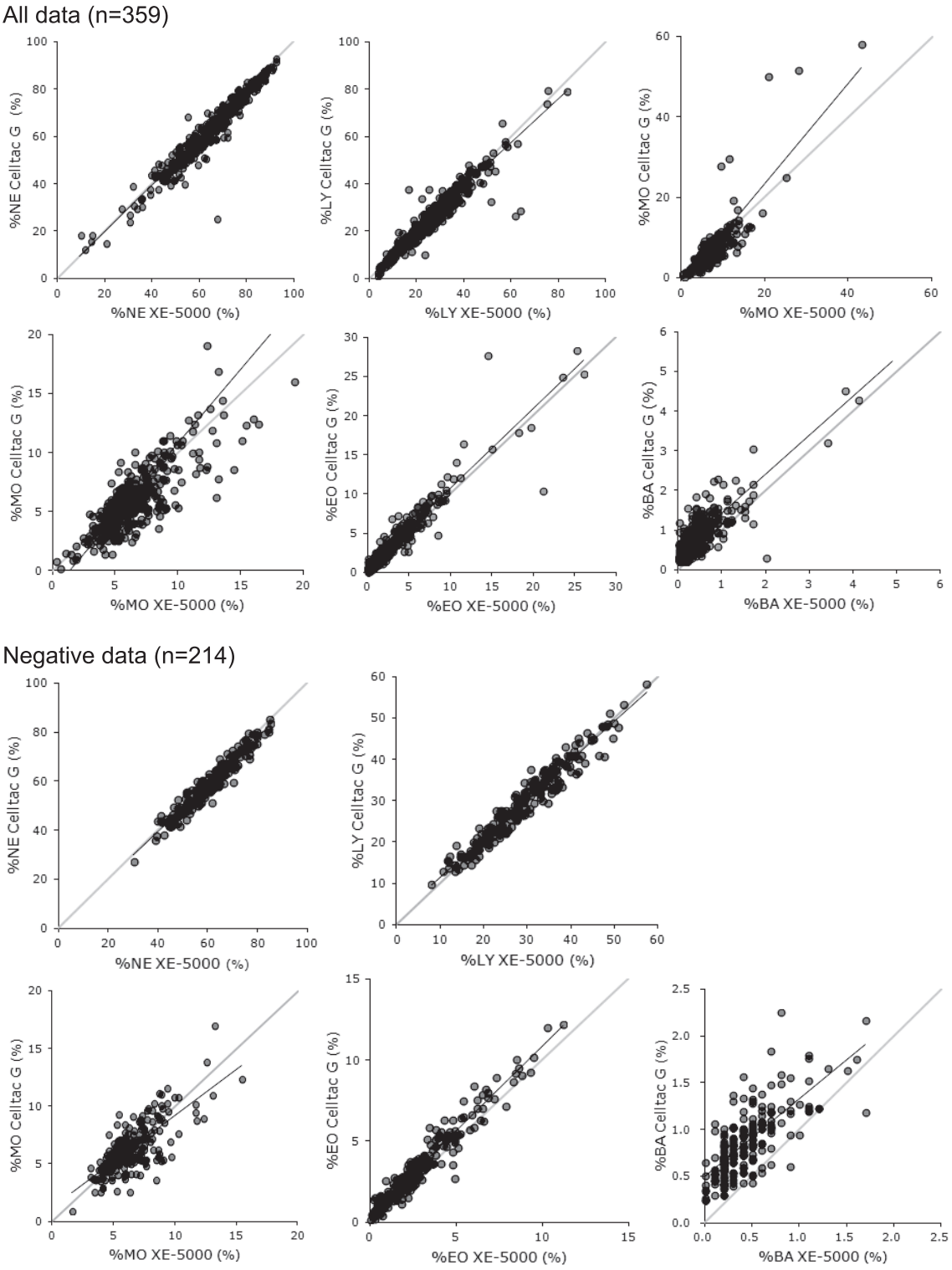


Fig.3 A comparison of the leukocyte differential parameters (%NE, %LY, %MO, %EO, and %BA): Celltac G vs. XE-2000 on 359 peripheral blood samples and 214 negative peripheral blood samples

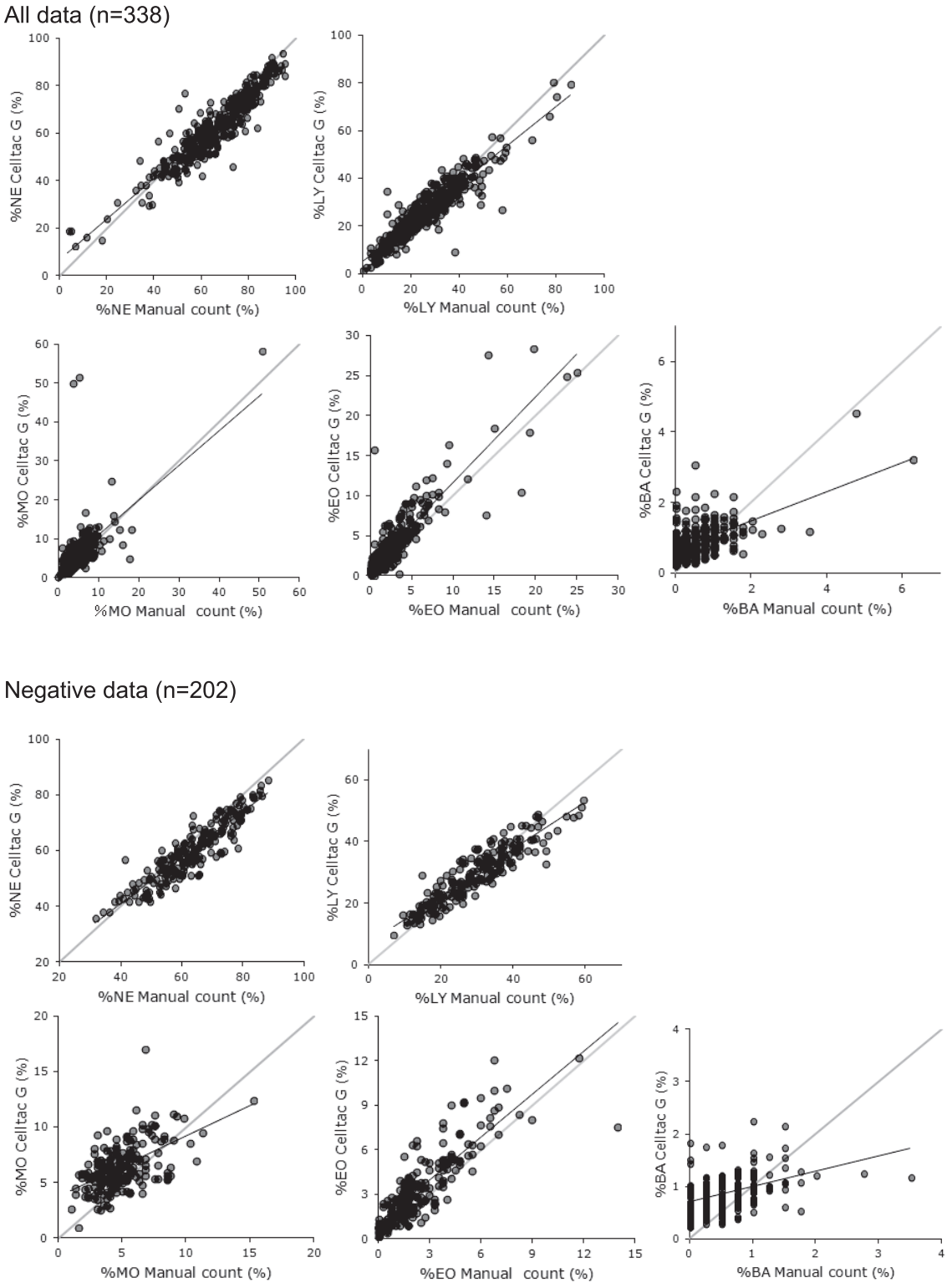
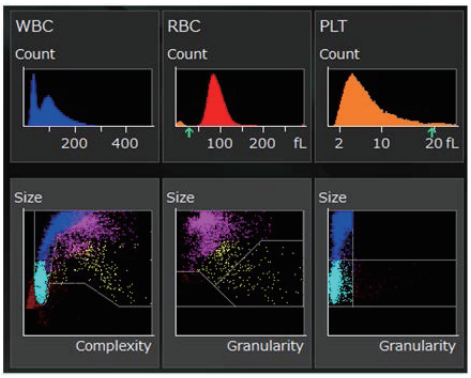


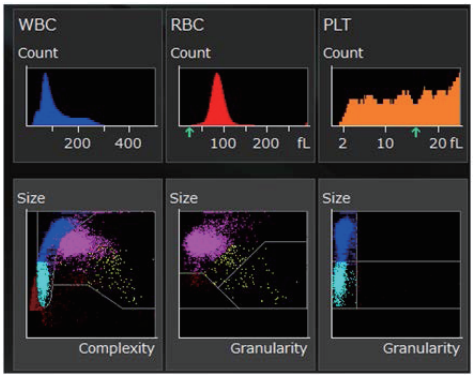
Fig.4 A comparison of the leukocyte differential parameters (%NE, %LY, %MO, %EO, and %BA): Celltac G vs. manual count on 338 peripheral blood samples and 202 negative peripheral blood samples.

Case A: Acute monoblastic and monocytic leukemia



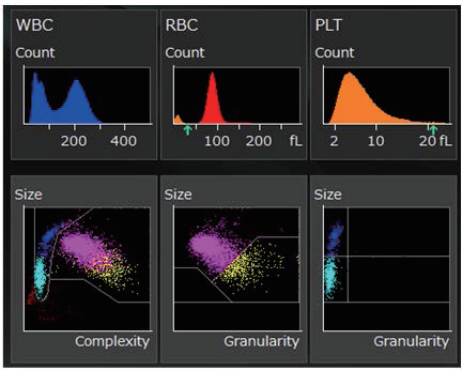
CBC			Diff			
Parameters	Unit	Celltac G	Parameters	Unit	Celltac G	Manual count
WBC	x10^9/L	15.92	Abnormal cell	x10^9/L	-	-
RBC	x10^{12}/L	2.66	NE Stab	x10^9/L	3.04	-
HGB	g/L	90.3	NE Seg	x10^9/L		-
HCT	L/L	0.256	LY	x10^9/L	4.32	-
MCV	fL	96.2	MO	x10^9/L	8.10	-
MCH	pg	33.9	EO	x10^9/L	0.36	-
MCHC	g/L	353	BA	x10^9/L	0.10	-
RDW-CV	fraction	17.0	%Abnormal cell	fraction	-	52.00
RDW-SD	fL	65.4	%NE %Band	fraction	19.07	1.00
PLT	x10^9/L	97.2	%NE %Seg	fraction		2.00
PCT	L/L	0.0007	%LY	fraction	27.16	43.00
MPV	fL	7.2	%MO	fraction	50.91	2.00
PDW	fraction	18.9	%EO	fraction	2.23	0.00
P-LCR	fraction	32.1	%BA	fraction	0.63	0.00

Case B: Chronic myelomonocytic leukemia (CMML)



CBC			Diff			
Parameters	Unit	Celltac G	Parameters	Unit	Celltac G	Manual count
WBC	x10^9/L	30.21	Abnormal cell	x10^9/L	-	-
RBC	x10^{12}/L	2.79	NE Stab	x10^9/L	9.01	-
HGB	g/L	89.5	NE Seg	x10^9/L		-
HCT	L/L	0.258	LY	x10^9/L	3.11	-
MCV	fL	92.5	MO	x10^9/L	17.75	-
MCH	pg	32.1	EO	x10^9/L	0.27	-
MCHC	g/L	347	BA	x10^9/L	0.07	-
RDW-CV	fraction	16.6	%Abnormal cell	fraction	-	0.00
RDW-SD	fL	61.4	%NE %Band	fraction	29.84	0.00
PLT	x10^9/L	24.4	%NE %Seg	fraction		18.00
PCT	L/L	0.0002	%LY	fraction	10.31	7.00
MPV	fL	9.2	%MO	fraction	58.75	75.00
PDW	fraction	18.8	%EO	fraction	0.88	0.00
P-LCR	fraction	58.5	%BA	fraction	0.22	0.00

Case C: Eosinophilia



CBC			Diff			
Parameters	Unit	Celltac G	Parameters	Unit	Celltac G	Manual count
WBC	x10^9/L	9.19	Abnormal cell	x10^9/L	-	-
RBC	x10^{12}/L	3.32	NE Stab	x10^9/L	6.37	-
HGB	g/L	104.9	NE Seg	x10^9/L		-
HCT	L/L	0.314	LY	x10^9/L	1.46	-
MCV	fL	94.6	MO	x10^9/L	0.42	-
MCH	pg	31.6	EO	x10^9/L	0.91	-
MCHC	g/L	334	BA	x10^9/L	0.03	-
RDW-CV	fraction	12.0	%Abnormal cell	fraction	-	0.00
RDW-SD	fL	45.4	%NE %Band	fraction	69.31	1.50
PLT	x10^9/L	330.7	%NE %Seg	fraction		52.50
PCT	L/L	0.0023	%LY	fraction	15.88	22.50
MPV	fL	7.1	%MO	fraction	4.61	4.00
PDW	fraction	16.8	%EO	fraction	9.86	19.50
P-LCR	fraction	31.2	%BA	fraction	0.34	0.00

Fig. 5 Examples of results of measurement using the Celltac G