Celltac Report

Celltac Es MEK-7300 Performance Evaluation

Evaluation Facility

Central Clinical Laboratory, Keio University Hospital

The automated hematology analyzer Celltac Es MEK-7300 is designed to "make reliable CBC as well as WBC 5 part differential measurement."

As we had an opportunity to evaluate the device recently, we would like to report on our review regarding its accuracy, correlation with other models, and operability.

Evaluation details

Sample: Venous blood with K_2 EDTA
Evaluation device: Celltac Es (MEK-7300) automated hematology analyzer
Reagent: Diluent (ISOTONAC·3)
Detergent (CLEANAC, CLEANAC·3)
Hemolyzing reagent (HEMOLYNAC·5, HEMOLYNAC·3N)
Comparison device: XE-5000, SP-1000i (Sysmex)

Evaluation parameters

1. Within-run reproducibility
2. Carryover
3. Linearity
4. Sample stability
5. Correlation
6. Flagging performance
7. Within-run reproducibility in low WBC and PLT specimens
8. Linearity in low WBC and PLT specimens

Evaluation method and result

1. Within-run reproducibility

By measuring a normal specimen 31 times in succession[*1], the average, SD, and CV were calculated. The results are shown in Table 1. In this evaluation, stable within-run reproducibility was confirmed in each parameter.

*1) Compliant with CLSI H26-A2

Table 1 Within-run reproducibility

Blood cell count	Average	SD	CV
WBC × $10^2/\mu L$	52.8	0.7	1.3%
RBC × $10^4/\mu L$	508.8	3.8	0.7%
HGB g/dL	15.15	0.07	0.5%
HCT %	45.40	0.34	0.8%
MCV fL	89.23	0.30	0.3%
PLT × $10^4/\mu L$	25.82	0.68	2.7%

WBC 5 part differential	Average	SD	CV
NE %	67.82	0.90	1.3%
LY %	19.53	0.90	4.6%
MO %	6.17	0.38	6.2%
EO %	5.98	0.47	7.8%
BA %	0.50	0.15	30.0%

2. Carryover

Based on the CLSI H26-A2 guidelines, carryover was evaluated.
We confirmed excellent carryover rate as each parameter was less than 1%.

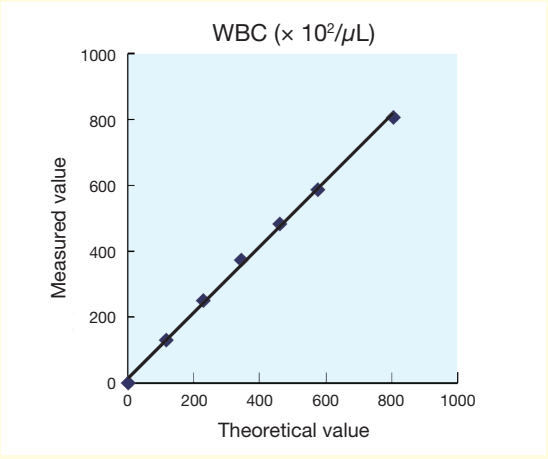
Table 2 Carryover

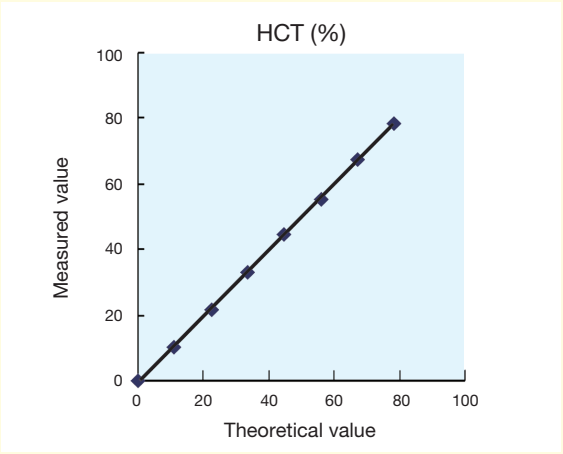
	WBC	RBC	HGB	PLT
Carryover rate	0.1%	0.7%	0.7%	0.4%

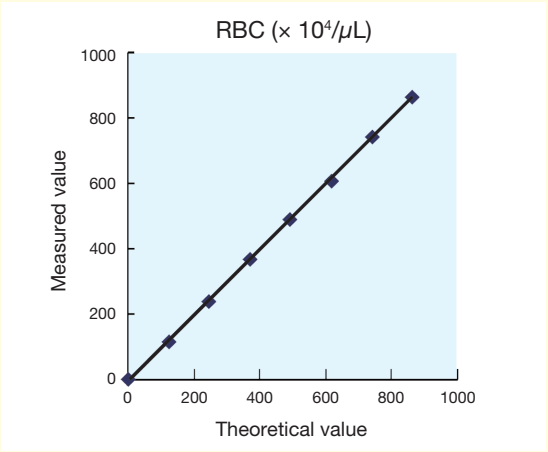
3. Linearity

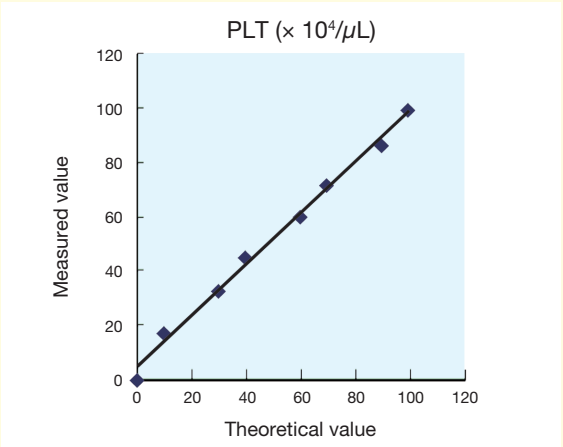
The results of the measurements by using serial dilution technique are shown in Figure 1.
Linearity was confirmed up to WBC: 800 × 10^2/μL, RBC: 860 × 10^4/μL, HGB: 25.6 g/dL, HCT: 78.0%, PLT: 99.0 × 10^4/μL.

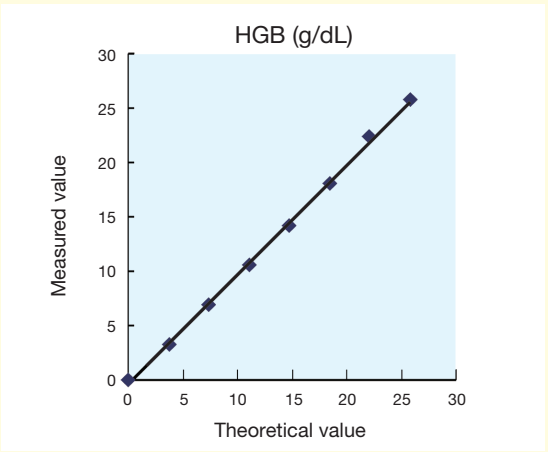
Figure 1 Linearity







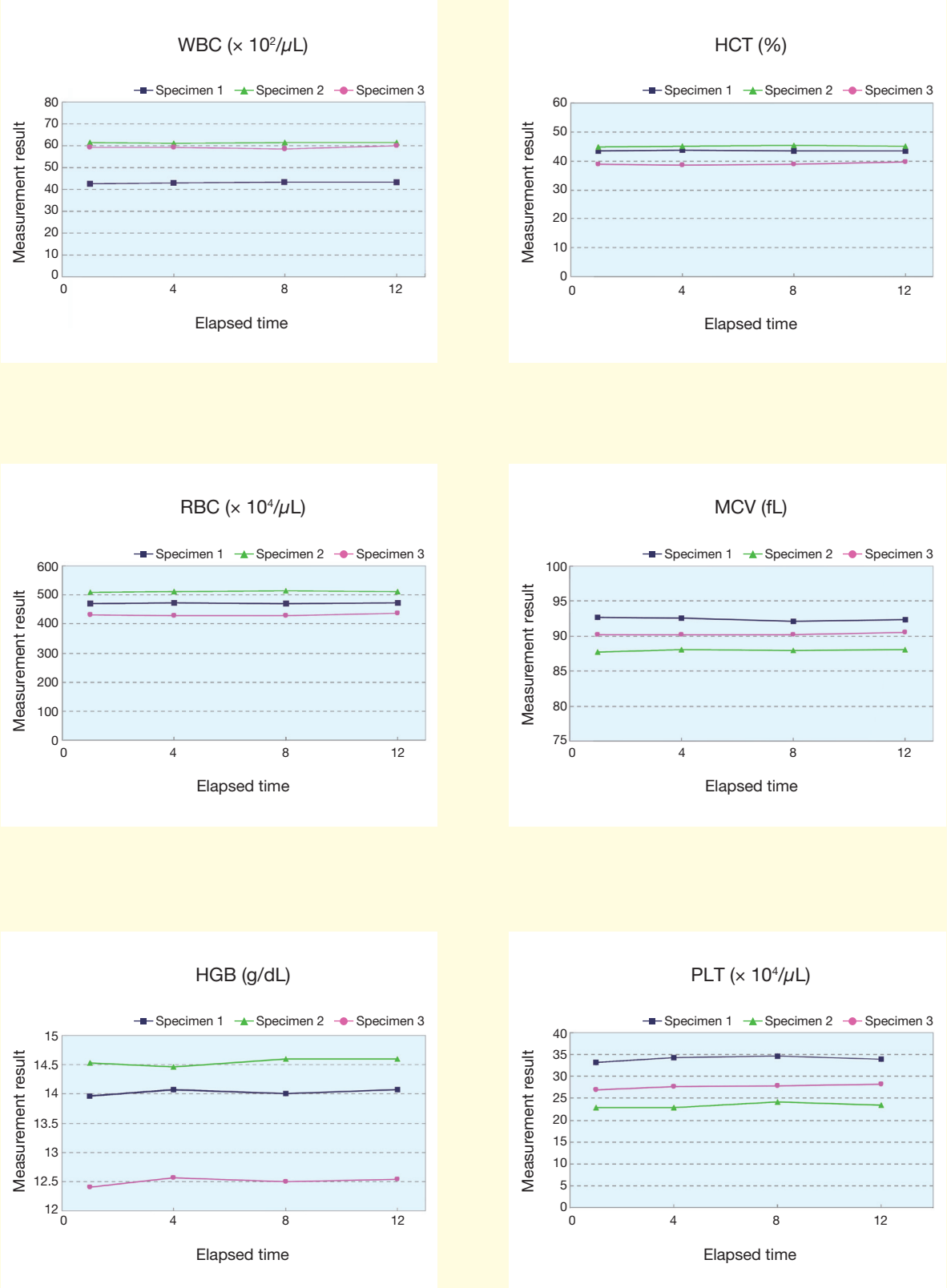




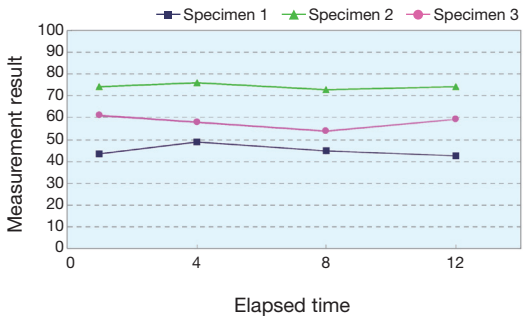
4. Sample stability

The results of 1-12 h sample stability are shown in Figure 2.
In this evaluation, excellent stability was confirmed in each parameter.

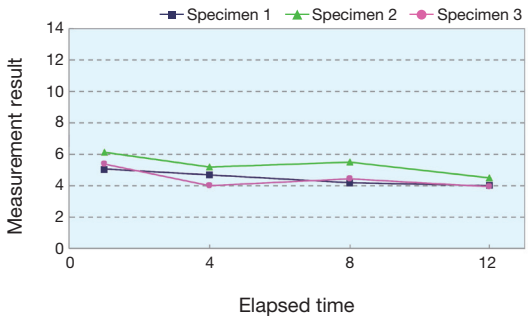
Figure 2 Sample stability



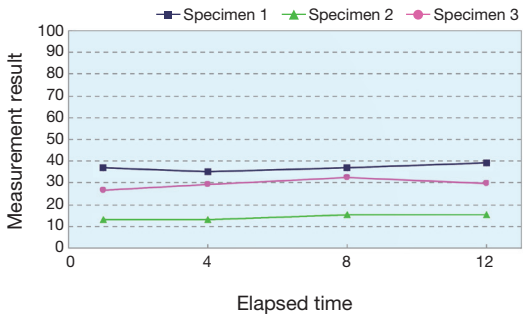
NE (%)


Specimen 1
Specimen 2
Specimen 3
Measurement result
100
90
80
70
60
50
40
30
20
10
0
0
4
8
12
Elapsed time

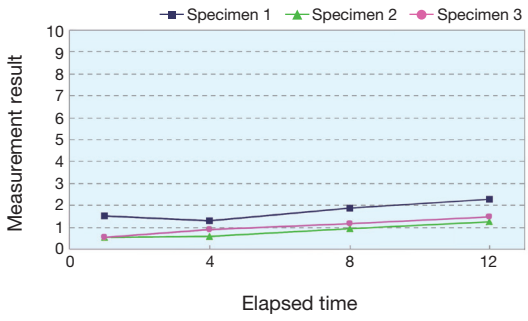
EO (%)


Specimen 1
Specimen 2
Specimen 3
Measurement result
14
12
10
8
6
4
2
0
0
4
8
12
Elapsed time

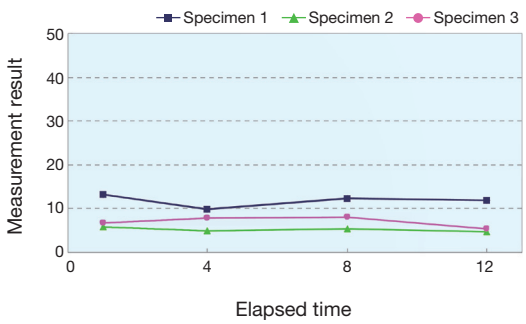
LY (%)


Specimen 1
Specimen 2
Specimen 3
Measurement result
100
90
80
70
60
50
40
30
20
10
0
0
4
8
12
Elapsed time

BA (%)


Specimen 1
Specimen 2
Specimen 3
Measurement result
10
9
8
7
6
5
4
3
2
1
0
0
4
8
12
Elapsed time

MO (%)


Specimen 1
Specimen 2
Specimen 3
Measurement result
50
40
30
20
10
0
0
4
8
12
Elapsed time

5. Correlation

The results of reviewing 100 blood samples are shown in Tables 3, 4 and Figures 3-5. XE-5000 was used as a comparison device. In this evaluation, smears were created automatically with the SP-1000i for leukocyte classification and 2 technicians performed 200 manual differential counting for each smear.

Table 3 Correlation table (against comparison device)

Parameter	Unit	Regression formula	Correlation coefficient
WBC	$10^2/\mu L$	Y = 0.959X + 1.911	0.997
RBC	$10^4/\mu L$	Y = 0.981X – 4.204	0.999
HGB	g/dL	Y = 1.008X + 0.062	0.999
HCT	%	Y = 1.028X – 1.031	0.993
MCV	fL	Y = 1.043X – 1.174	0.949
PLT	$10^4/\mu L$	Y = 1.044X + 0.513	0.993

Parameter	Unit	Regression formula	Correlation coefficient
NE	%	Y = 1.018X – 1.529	0.985
LY	%	Y = 1.020X – 0.092	0.982
MO	%	Y = 1.044X – 0.331	0.940
EO	%	Y = 0.748X + 0.435	0.924
BA	%	Y = 0.186X + 0.743	0.474
IG	%	Y = 0.655X + 0.486	0.799

X = XE-5000 Y = Celltac Es

Table 4 Correlation table (against manual differential count)

Parameter	Unit	Regression formula	Correlation coefficient
NE	%	Y = 0.955X – 0.998	0.953
LY	%	Y = 0.975X + 5.498	0.935
MO	%	Y = 0.717X + 1.632	0.828
EO	%	Y = 0.590X + 0.880	0.813
BA	%	Y = 0.339X + 0.649	0.564
IG	%	Y = 0.765X + 0.841	0.798

X = Visual Y = Celltac Es

Figure 3 Correlation graph

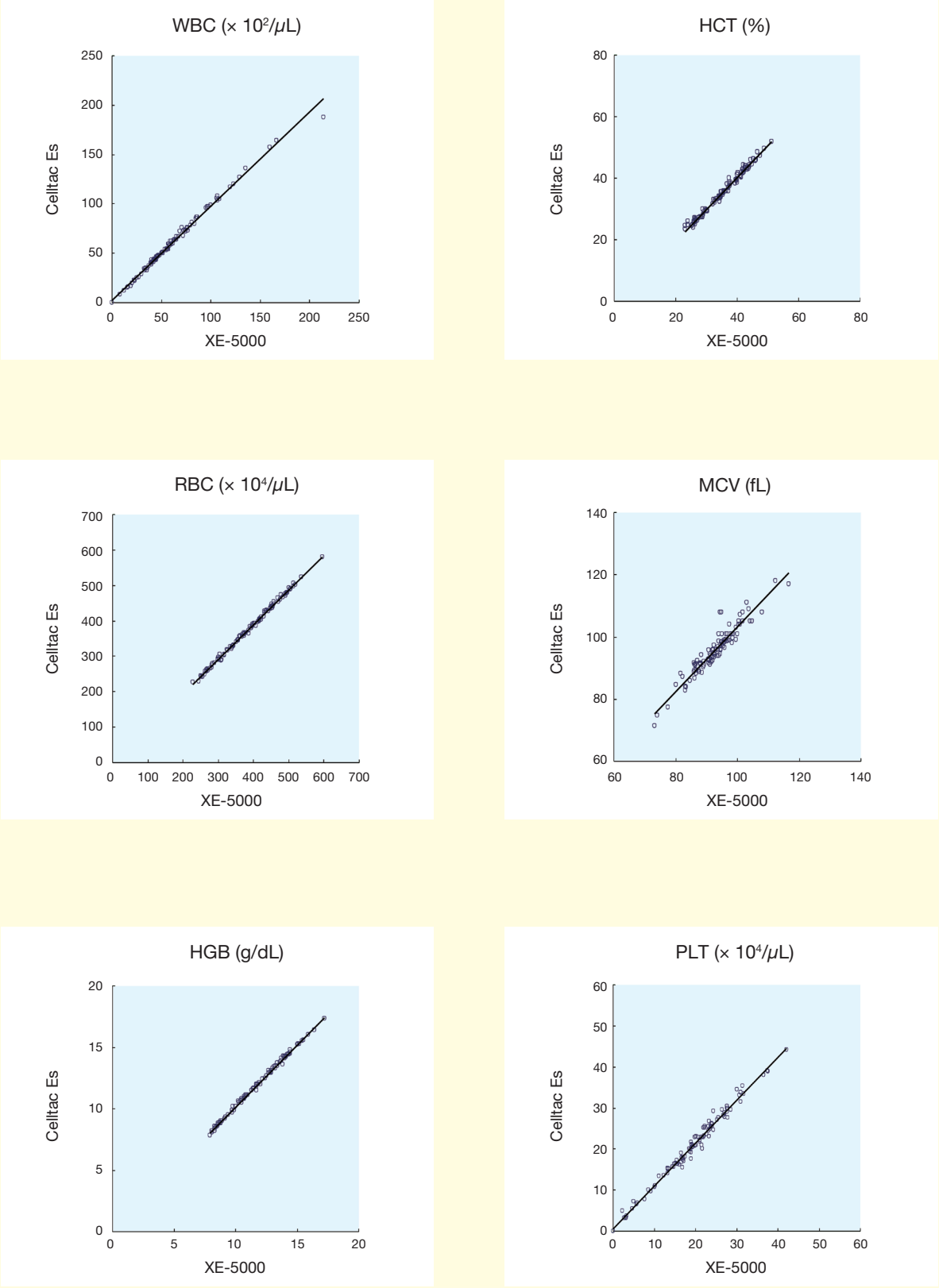


Figure 4 Correlation graph

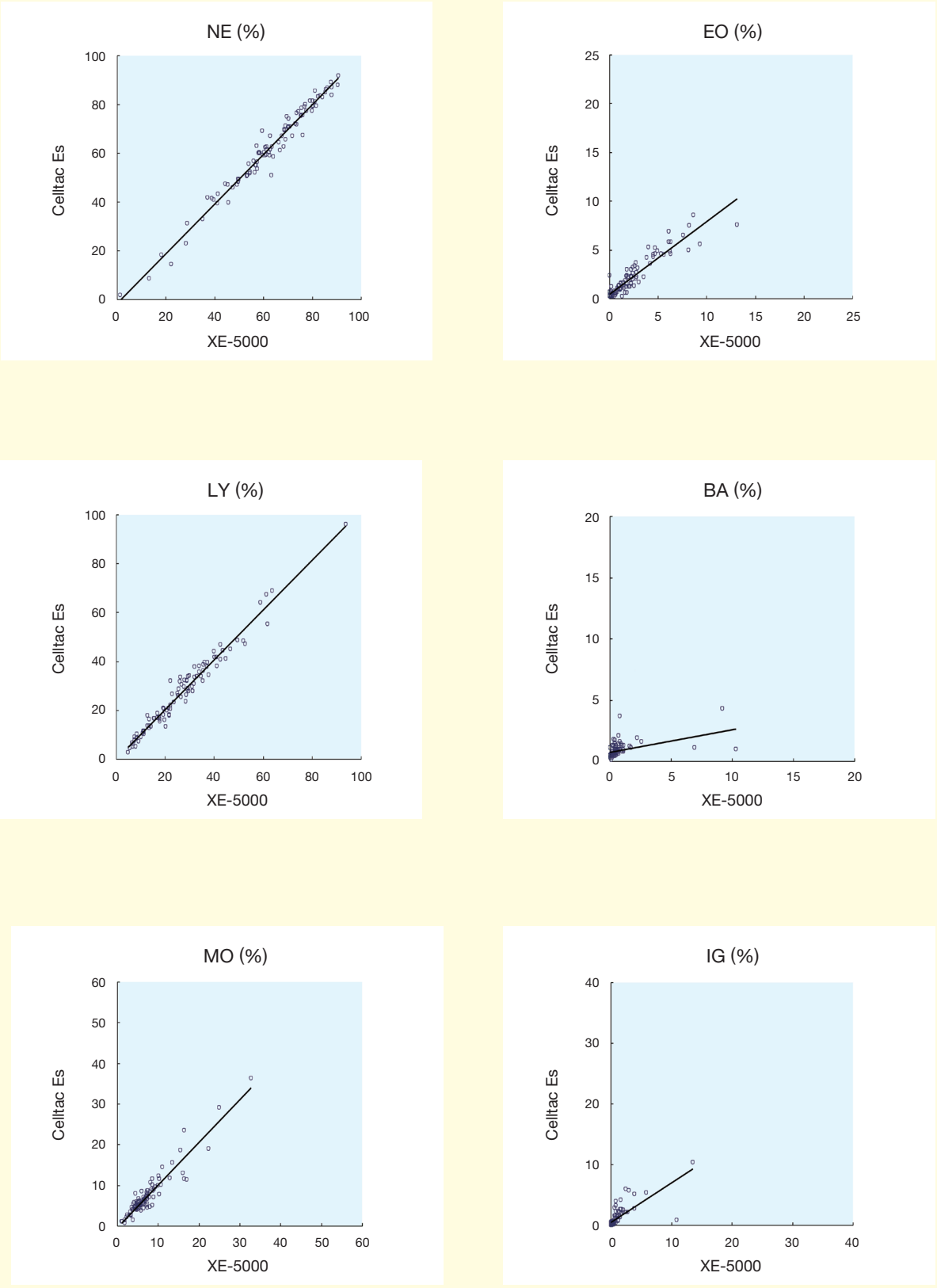
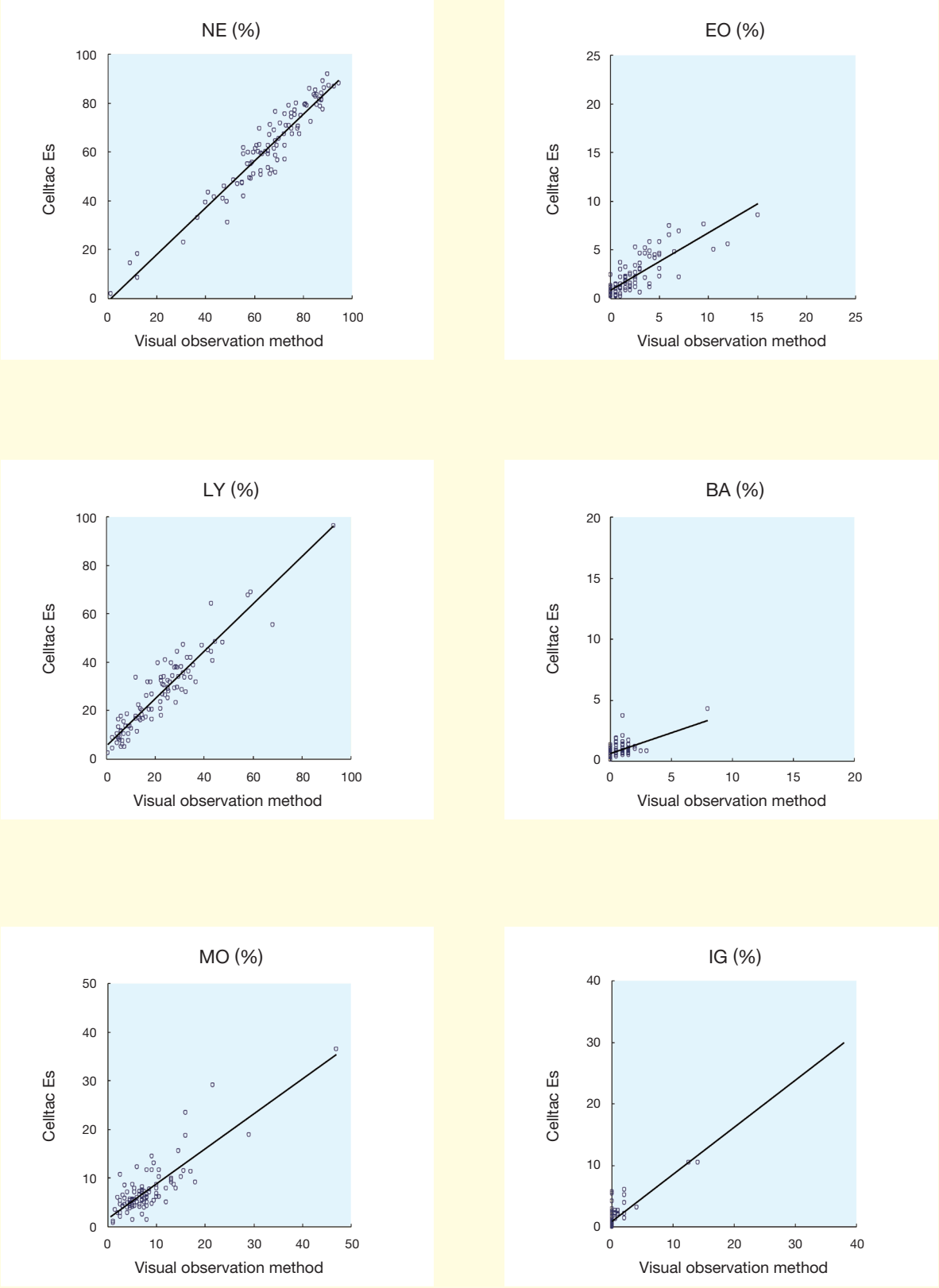


Figure 5 Correlation graph



6. Flagging performance

Flagging performance for 100 blood samples are shown in Tables 5, 6 and 7. The manual review criteria for abnormal cell determination is as follows: myeloblast ≥ 1%, promyelocyte or myelocyte ≥ 1%, metamyelocyte > 2%, atypical lymphocyte > 5%, or stab cell > 6%.

Table 5 Sensitivity / specificity of abnormal cell flags

Model	TP	FN	FP	TN	Sensitivity	Specificity
Celltac Es	10	5	14	71	66.7%	83.5%
XE-5000	10	5	11	74	66.7%	87.1%

Table 6 Sensitivity / specificity of Blast flag

Model	TP	FN	FP	TN	Sensitivity	Specificity
Celltac Es	1	0	10	89	100.0%	89.9%
XE-5000	1	0	2	97	100.0%	98.0%

[Myeloblast]

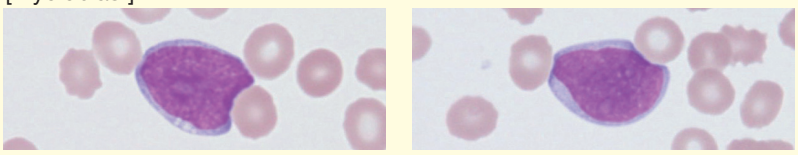


Table 7 Sensitivity / specificity of IG flag

Model	TP	FN	FP	TN	Sensitivity	Specificity
Celltac Es	6	2	5	87	75.0%	94.6%
XE-5000	7	1	3	89	87.5%	96.7%

[Immature granulocyte] Promyelocyte Myelocyte Metamyelocyte

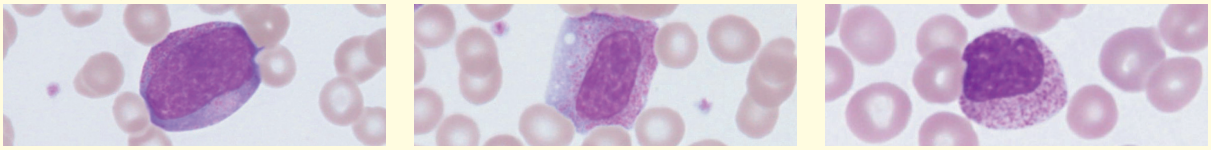


Table 8 shows the relationship of sensitivity and specificity

Table 8 Calculation method

		Abnormal cell by manual review		Total
		Yes	No	
Flag (Device)	Yes	TP	FP	TP + FP
	No	FN	TN	FN + TN
Total		TP + FN	FP + TN	N

TP (True Positive), FP (False Positive), FN (False Negative), TN (True Negative)

Calculation formula for sensitivity and specificity

$$\text{Sensitivity} = \frac{TP}{TP + FN} \times 100$$

$$\text{Specificity} = \frac{TN}{FP + TN} \times 100$$

7. Within-run reproducibility in low WBC and PLT specimens

WBC < 20 × 10^2/μL and PLT < 6.0 × 10^4/μL specimens were measured 31 times in succession[*2].
The results of the calculated average, SD, and CV are shown in Table 9 and 10.
In this evaluation, good results were confirmed for each parameter.

*2) Compliant with CLSI H26-A2

Table 9 For low WBC specimen / within-run reproducibility

WBC average (× 10^2/μL)	SD	CV
9.0	0.4	4.5%
16.3	0.6	3.9%
20.8	0.9	4.1%

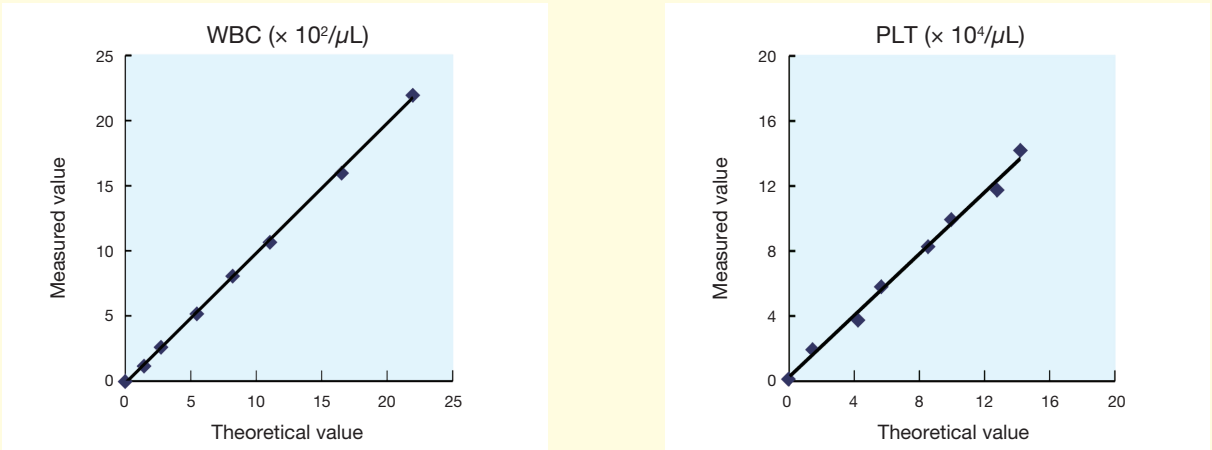
Table 10 For low PLT specimen / within-run reproducibility

PLT average (× 10^4/μL)	SD	CV
2.51	0.15	5.8%
3.16	0.23	7.3%
5.41	0.32	5.9%

8. Linearity in low WBC and PLT specimens

The results of the measurements by using serial dilution technique are shown in Figure 6.
In this evaluation, linearity was confirmed up to WBC: 2 × 10^2/μL, PLT: 2.0 × 10^4/μL.

Figure 6



Data Contribution

Erika Yoshiba, MT, Marie Aneobi, MT, Emiri Osada, MT, Tomoko Arai, MT, Naoko Katagiri, MT, Nobuko Shimizu, MT
Central Clinical Laboratory, Keio University Hospital

Takayuki Mitsuhashi, MD, PhD
Department of Laboratory Medicine, School of Medicine, Keio University

Mitsuru Murata, MD, PhD, Professor
Department of Laboratory Medicine, School of Medicine, Keio University

* Executed with authorization of Ethics Committee, School of Medicine, Keio University

NIHON KOHDEN

NIHON KOHDEN CORPORATION
1-31-4 Nishiochiai, Shinjuku-ku, Tokyo 161-8560, Japan
Phone +81 (3) 5996-8036 Fax +81 (3) 5996-8100
www.nihonkohden.com

7174 **SP62-019** '13.2. SE. B.

Printed in Japan