Introduction of Products

Summary of the Automated Hematology Analyzer

XS-1000*i*/XS-800*i*

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FOREWORD

Compact automated hematology analyzers, the XS series have been developed. The XS-1000*i*, a closed blood collection tube model is shown in ***Fig 1*** and the XS-800*i*, an open tube model is shown in ***Fig 2***. These analyzers can simultaneously measure a 5-part leukocyte differential count (WBC 5 DIFF), in addition to complete blood count (CBC). They were built on the technologies of our top model, the XE-2100 Automated Hematology Analyzer. They were developed for medium and small laboratories or for the testing which can be performed at or near the patients' locations such as out-patient facilities. Small-sized and high-performance devices have been created with scattergrams and reagents that are compatible with XE-2100. We shall introduce the summary of this XS series together with some basic data.

Fig. 1 *XS-1000i*

Fig. 2 *XS-800i*

CONCEPT DEVELOPMENT

The XS series was developed with the following key concepts; "high-performance, high reliability, miniaturization, and a small sample of blood".

MAJOR SPECIFICATIONS

1. Name
1) Name: Automated Hematology Analyzer
2) Models: XS-1000*i*, XS-800*i*

2. Application
These analyzers are to measure hemocyte-counting items in EDTA-added human blood.

3. Structure
1) Analyzer Unit
2) Information Processing Unit (IPU)

4. Analysis Parameters and detection principles
Analysis Parameters and detection principles are shown in ***Table 1***.

5. Required sample volume
1) Manual mode: Approx. 20µL
2) Capillary mode: Approx. 20µL

6. Throughput
1) CBC: Approx. 60 samples/hour
2) CBC + DIFF: Approx. 60 samples/hour

7. Data storage capacity
1) Analysis data: up to 10,000 samples (including scattergram)
2) Test order information: up to 1,000 samples

8. Reagents
Reagents to be used and their applications are shown in ***Table 2***.

Table 1 *Measurement items and principles*

Parameters		Principles
White blood cell count	(WBC)	Flow cytometory method using semicondductor laser
Red blood cell count	(RBC)	Sheath flow DC detection method
Hemoglobin concentration	(HGB)	SLS hemoglobin detection method
Hematocrit	(HCT)	RBC cumulative pulse height detection method
Mean cell Volume	(MCV)	Calculation with RBC and HCT
Mean corpuscular cell hemoglobin	(MCH)	Calculation with RBC and HGB
Mean corpuscular cell hemoglobin concentration	(MCHC)	Calculation with HGB and HCT
Platelet count	(PLT)	Sheath flow DC detection method
RBC distribution width-standard deviation	(RDW-SD)	Analysis from size distribution of RBC
RBC distribution width-coefficient of variation	(RDW-CV)	
RBC distribution width	(PDW)	Analysis from size distribution of PLT
Mean platelet volume	(MPV)	
PLT-large cell ratio	(P-LCR)	
Plateletcrit	(PCT)	PLT cumulative pulse height detection method
Neutrophil ratio	(NEUT%)	Flow cytometory method using semiconductor laser
Lymphocyte ratio	(LYMPH%)	
Monocyte ratio	(MONO%)	
Eosinophil ratio	(EO%)	
Basophil ratio	(BASO%)	
Neutrophil count	(NEUT#)	
Lymphocyte count	(LYMPH#)	
Monocyte count	(MONO#)	
Eosinophil count	(EO#)	
Basophil count	(BASO#)	
Immature granulocyte ratio*	(IG%)	
Immature granulocyte count*	(IG#)	
Other white blood cell retio*	(OTHER%)	
Other white blood cell count*	(OTHER#)	

* Research items

Table 2 *Reagents*

Reagents	Parameters
CELLPACK	Diluent, Sheath solution for flow cytometry and RBC/PLT
STROMATOLYSER-4DL	WBC, NEUT, LYMPH, MONO, EO, BASO
STROMATOLYSER-4DS	
SULFOLYSER	HGB

TECHNOLOGIES

1. Principles of measurement

1) WBC 5 DIFF by the flow cytometry method using a semiconductor laser

High performance and miniaturization were achieved by having the flow cytometry method using a semiconductor laser, as with the XE-2100 and by a newly employed APD (Avalanche Photodiode) as a fluorescent detector (***Fig 3***). The combination of the lateral scattered light system and lateral fluorescent light system in this flow cytometry creates the scattergrams of WBC 5 DIFF, which are then analyzed by a program (***Fig 4***).

2) Hydro Dynamic focusing DC detection method

The Hydro Dynamic focusing DC detection method is employed for the measurement of red blood cells (RBC) and platelets (PLT) (***Fig 5***). This detection method, measures samples in the center of the detector (aperture) by means of the Sheath solution. Therefore, the particle size distributions of RBC and PLT can be measured with higher precision leading to measurement results of high quality.

3) SLS hemoglobin method

Hemoglobin (HGB) is measured by a colorimetric, SLS hemoglobin. This method ensures high reliability, and is employed for the majority of our automated hematology analyzers. In addition, the reagent used is a safe, non-cyanogen.

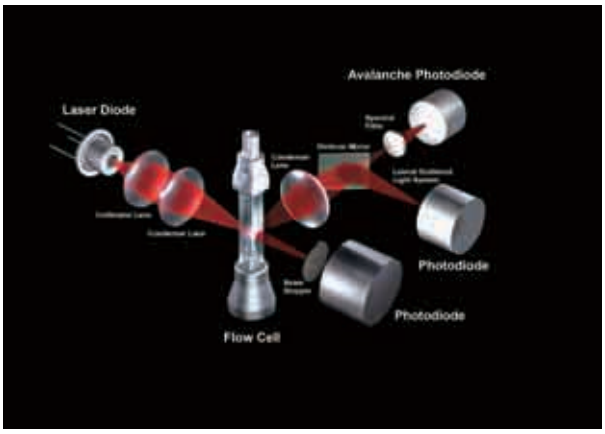

Fig. 3 *Flow cytometry using semiconductor laser*

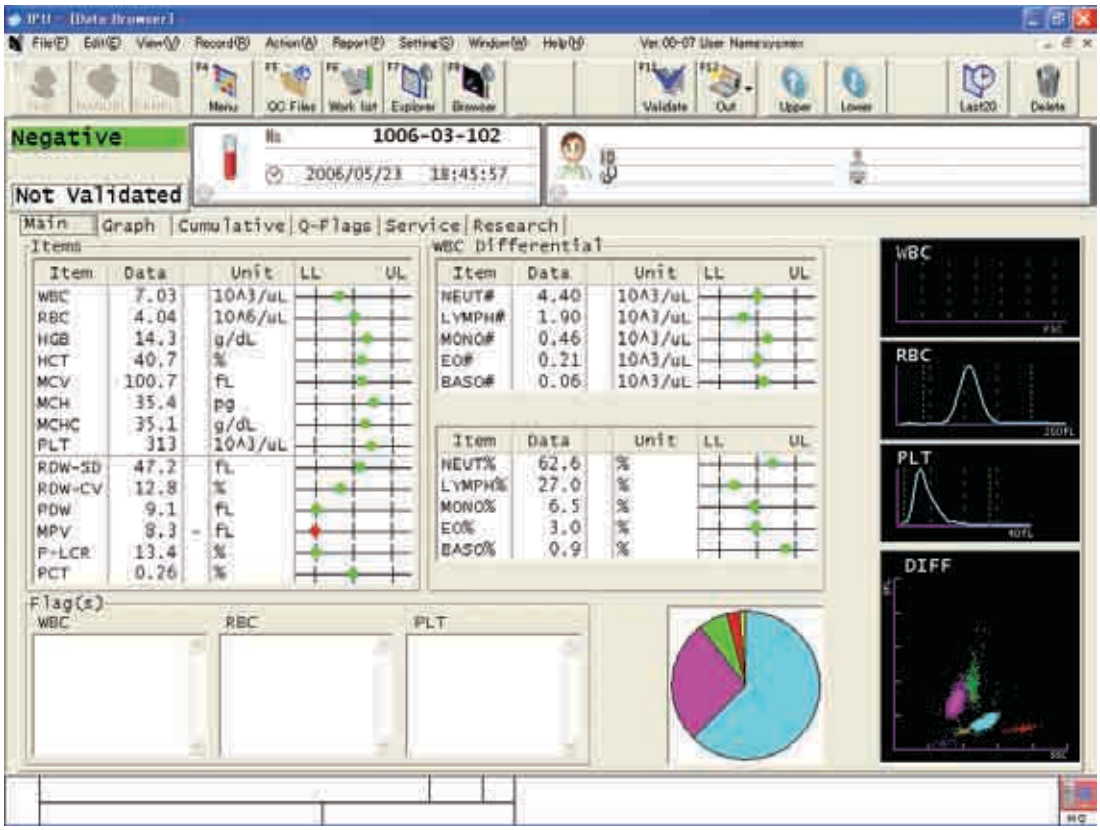

Fig. 4 *Data display screen*

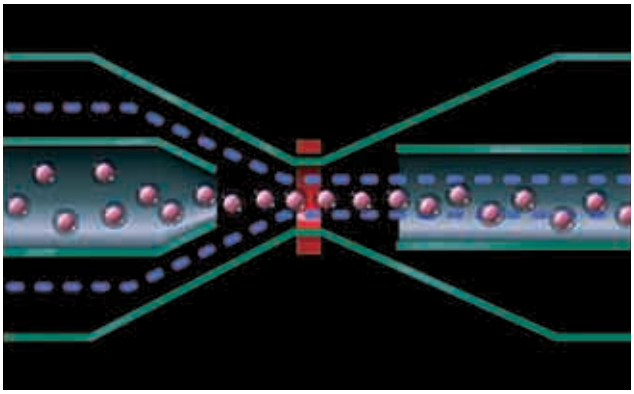

Fig. 5 *Hydrodynamic focusiong DC detection in XS-series*

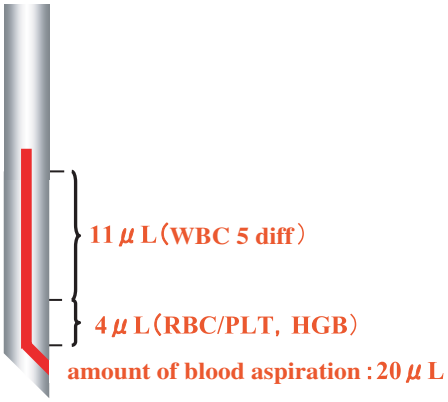

Fig. 6 *Amount of blood aspiration in XS-1000i*

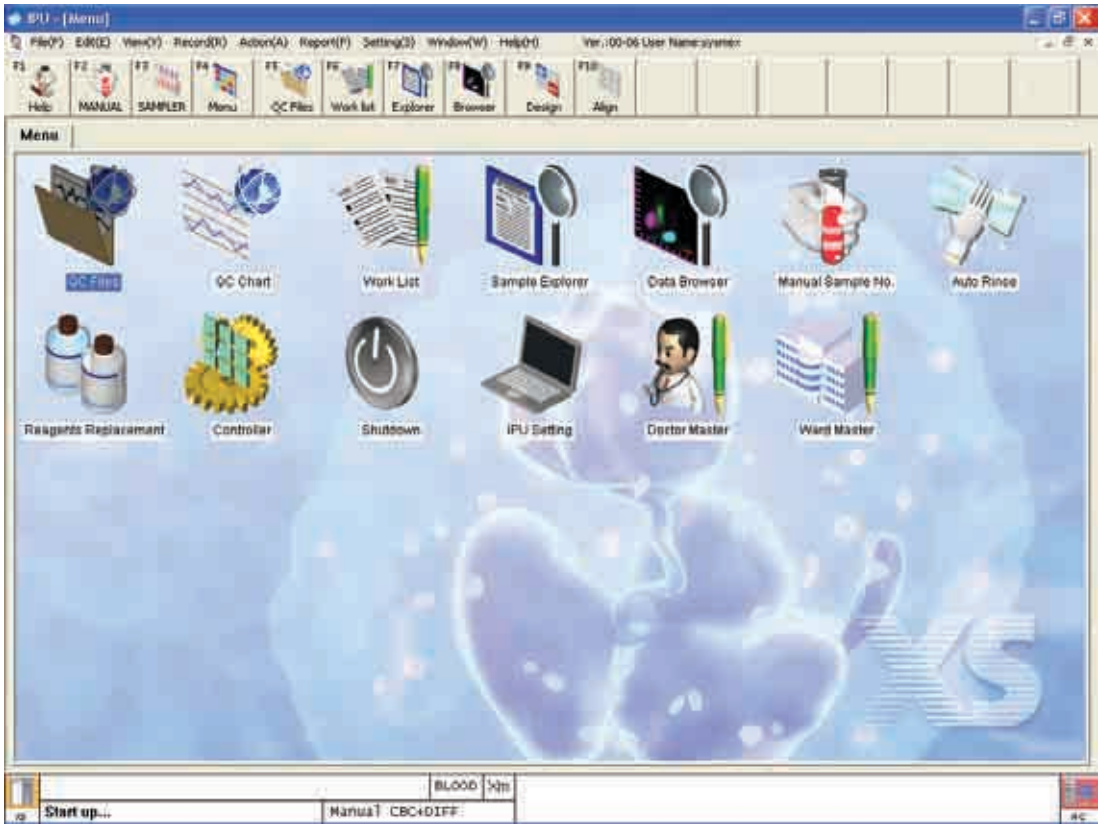

Fig. 7 *Menu Screen of IPF*

2. Compliance with small quantity of blood (amount of blood aspiration 20μL)

In order to be able to measure blood of infants, etc., where only a small amount of blood collection is possible, the dilution system and the blood aspiration piercer (***Fig. 6***) for XS-1000*i* were radically modified. A WBC 5 Diff measurement in addition to the CBC can be performed with a blood aspiration volume of only 20μL.

3. Multifunction / New IPU

XS series employs Windows XP as the OS for the Information Processing Unit (IPU) The icons in the menu / work list screen are larger and more user-friendly and contain processing and measurement information (***Fig 7***). It is also equipped with advanced information processing functions equal to those of the XE-2100. It is compatible with the SNCS, Sysmex Network Communication Systems, connection (where available) including online QC, and real-time communication with the analyzer by means of LAN port with TCP/IP. Its specifications allow satisfactory adaptation for STAT tests at large-scale laboratories, not only middle and small sized laboratories.

PERFORMANCES OF ANALYZERS

1. Reproducibility

The results of within-run reproducibility using 10 consecutive measurements in the manual and capillary modes using blood of healthy subjects (EDTA-2K added) are shown in ***Table 3*** and ***Table 4***. Satisfactory reproducibility was obtained for all parameters.

2. Correlativity

Correlativity in the manual mode on XS-1000*i* and XE-2100 using blood of patients (EDTA-2K added, n=150) are shown in ***Fig 8*** and ***Fig 9***. Satisfactory correlativity with XE-2100 was obtained for all parameters.

Table 3 *Reproducibility in manual mode*

Sample	WBC 10^9/L	RBC 10^{12}/L	HGB g/L	HCT %	MCV fL	MCH pg	MCHC g/L	PLT 10^9/L
1	6.21	4.30	124	37.6	87.4	28.8	330	193
2	6.12	4.28	125	37.5	87.6	29.2	333	195
3	6.10	4.26	125	37.3	87.6	29.3	335	188
4	6.19	4.26	125	37.3	87.6	29.3	335	194
5	6.12	4.28	125	37.5	87.6	29.2	333	187
6	6.08	4.27	124	37.3	87.4	29.0	332	197
7	6.15	4.27	125	37.4	87.6	29.3	334	189
8	6.03	4.27	123	37.4	87.6	28.8	329	194
9	6.29	4.29	124	37.6	87.6	28.9	330	185
10	6.15	4.27	124	37.4	87.6	29.0	332	194
MEAN	6.144	4.275	124.4	37.43	87.56	29.08	332.3	191.6
SD	0.073	0.013	0.70	0.12	0.08	0.20	2.10	4.00
CV%	1.19%	0.30%	0.56%	0.31%	0.10%	0.70%	0.64%	2.09%

Sample	RDW-SD fL	RDW-CV %	PDW fL	MPV fL	P-LCR %	PCT %
1	45.1	14.8	13.6	10.4	28.6	0.20
2	45.8	14.8	12.0	10.4	27.2	0.20
3	45.4	14.8	12.0	10.4	27.5	0.19
4	45.8	14.7	12.6	10.4	28.0	0.20
5	45.2	14.7	12.4	10.4	27.7	0.20
6	45.8	14.8	12.6	10.5	28.3	0.21
7	45.4	14.7	12.2	10.0	25.5	0.19
8	45.3	14.8	12.0	10.2	27.2	0.20
9	45.7	14.8	13.0	10.3	27.6	0.19
10	45.4	14.8	12.9	10.4	27.1	0.20
MEAN	45.49	14.77	12.53	10.34	27.47	0.198
SD	0.26	0.05	0.53	0.14	0.85	0.006
CV%	0.58%	0.33%	4.19%	1.38%	3.09%	3.19%

Sample	NEUT # 10^9/L	LYMPH # 10^9/L	MONO # 10^9/L	EO # 10^9/L	BASO # 10^9/L	NEUT % %	LYMPH % %	MONO % %	EO % %	BASO % %
1	3.95	1.53	0.51	0.18	0.04	63.7	24.6	8.2	2.9	0.6
2	3.86	1.55	0.49	0.18	0.04	63.1	25.3	8.0	2.9	0.7
3	3.88	1.50	0.49	0.20	0.03	63.6	24.6	8.0	3.3	0.5
4	3.95	1.55	0.45	0.19	0.05	63.8	25.0	7.3	3.1	0.8
5	3.88	1.51	0.49	0.20	0.04	63.3	24.7	8.0	3.3	0.7
6	3.91	1.49	0.47	0.18	0.03	64.3	24.5	7.7	3.0	0.5
7	3.90	1.50	0.51	0.19	0.05	63.4	24.4	8.3	3.1	0.8
8	3.81	1.47	0.49	0.20	0.06	63.2	24.4	8.1	3.3	1.0
9	4.01	1.50	0.54	0.19	0.05	63.8	23.8	8.6	3.0	0.8
10	3.89	1.50	0.53	0.19	0.04	63.2	24.4	8.6	3.1	0.7
MEAN	3.904	1.510	0.497	0.190	0.043	63.54	24.57	8.08	3.10	0.71
SD	0.055	0.026	0.027	0.008	0.009	0.37	0.40	0.39	0.16	0.15
CV%	1.42%	1.71%	5.37%	4.30%	22.06%	0.59%	1.62%	4.84%	5.04%	21.46%

Table 4 *Reproducibility in capillary mode*

Sample	WBC 10^9/L	RBC 10^{12}/L	HGB g/L	HCT %	MCV fL	MCH pg	MCHC g/L	PLT 10^9/L
1	11.36	4.62	146	45.9	99.4	31.6	318	242
2	11.22	4.58	145	45.4	99.1	31.7	319	246
3	11.58	4.66	148	46.1	98.9	31.8	321	247
4	11.40	4.63	146	45.7	98.7	31.5	319	241
5	11.54	4.62	149	45.6	98.7	32.3	327	247
6	11.52	4.59	147	45.3	98.7	32.0	325	236
7	11.22	4.50	147	44.5	98.9	32.7	330	243
8	11.19	4.63	148	45.5	98.3	32.0	325	235
9	11.34	4.57	146	44.9	98.2	31.9	325	243
10	11.55	4.58	145	45.1	98.5	31.7	322	246
MEAN	11.392	4.598	146.7	45.40	98.74	31.92	323.1	242.6
SD	0.150	0.045	1.30	0.48	0.36	0.36	3.90	4.30
CV%	1.32%	0.97%	0.91%	1.05%	0.36%	1.12%	1.22%	1.77%

Sample	RDW-SD fL	RDW-CV %	PDW fL	MPV fL	P-LCR %	PCT %
1	45.1	13.1	12.2	10.3	28.3	0.25
2	45.4	13.2	12.5	10.5	30.4	0.26
3	44.9	13.0	12.3	10.4	28.8	0.26
4	44.6	13.2	11.8	10.1	27.1	0.24
5	45.1	13.2	12.2	10.4	28.1	0.26
6	44.3	13.0	11.7	10.3	27.2	0.24
7	44.5	13.1	11.2	10.1	26.7	0.24
8	44.3	13.0	11.6	10.1	25.9	0.24
9	44.0	12.9	10.8	10.1	26.4	0.25
10	43.9	13.0	11.1	9.9	24.8	0.24
MEAN	44.61	13.07	11.74	10.22	27.37	0.248
SD	0.50	0.11	0.57	0.19	1.59	0.009
CV%	1.13%	0.81%	4.86%	1.83%	5.83%	3.71%

Sample	NEUT # 10^9/L	LYMPH # 10^9/L	MONO # 10^9/L	EO # 10^9/L	BASO # 10^9/L	NEUT % %	LYMPH % %	MONO % %	EO % %	BASO % %
1	7.01	2.71	0.83	0.68	0.13	61.7	23.9	7.3	6.0	1.1
2	6.89	2.67	0.84	0.69	0.13	61.4	23.8	7.5	6.1	1.2
3	7.24	2.66	0.84	0.70	0.14	62.5	23.0	7.3	6.0	1.2
4	7.14	2.57	0.84	0.69	0.16	62.6	22.5	7.4	6.1	1.4
5	7.06	2.66	0.93	0.73	0.16	61.1	23.1	8.1	6.3	1.4
6	7.15	2.69	0.78	0.72	0.18	61.9	23.4	6.8	6.3	1.6
7	6.92	2.65	0.84	0.66	0.15	61.7	23.6	7.5	5.9	1.3
8	7.06	2.48	0.85	0.66	0.14	63.0	22.2	7.6	5.9	1.3
9	6.88	2.72	0.90	0.68	0.16	60.7	24.0	7.9	6.0	1.4
10	7.02	2.70	0.91	0.76	0.16	60.7	23.4	7.9	6.6	1.4
MEAN	7.037	2.651	0.856	0.697	0.151	61.73	23.29	7.53	6.12	1.33
SD	0.119	0.073	0.045	0.032	0.016	0.79	0.60	0.37	0.22	0.14
CV%	1.69%	2.77%	5.20%	4.54%	10.56%	1.28%	2.56%	4.97%	3.60%	10.66%

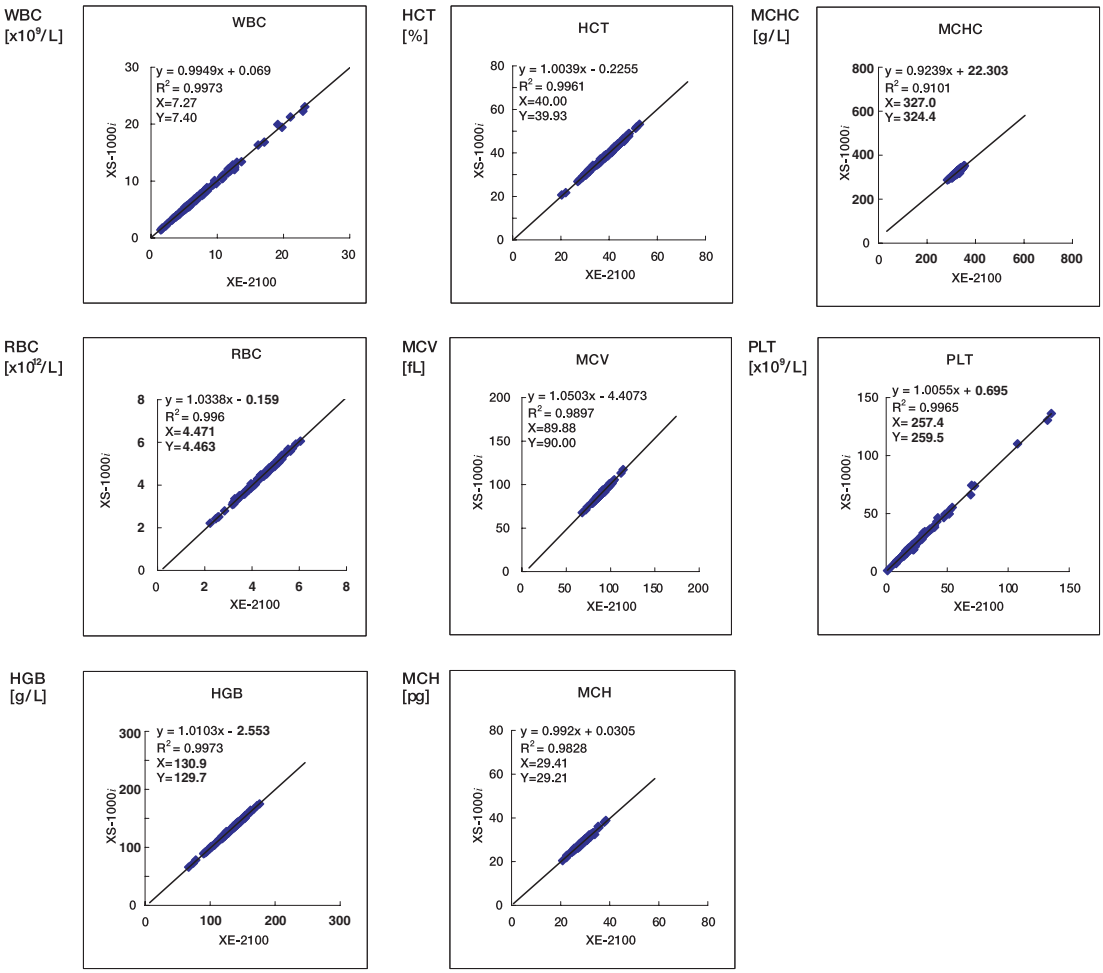

Fig. 8 *CBC8 analysis parameters correlativity in the manual mode on XS-1000i and XE-2100 (n=150)*

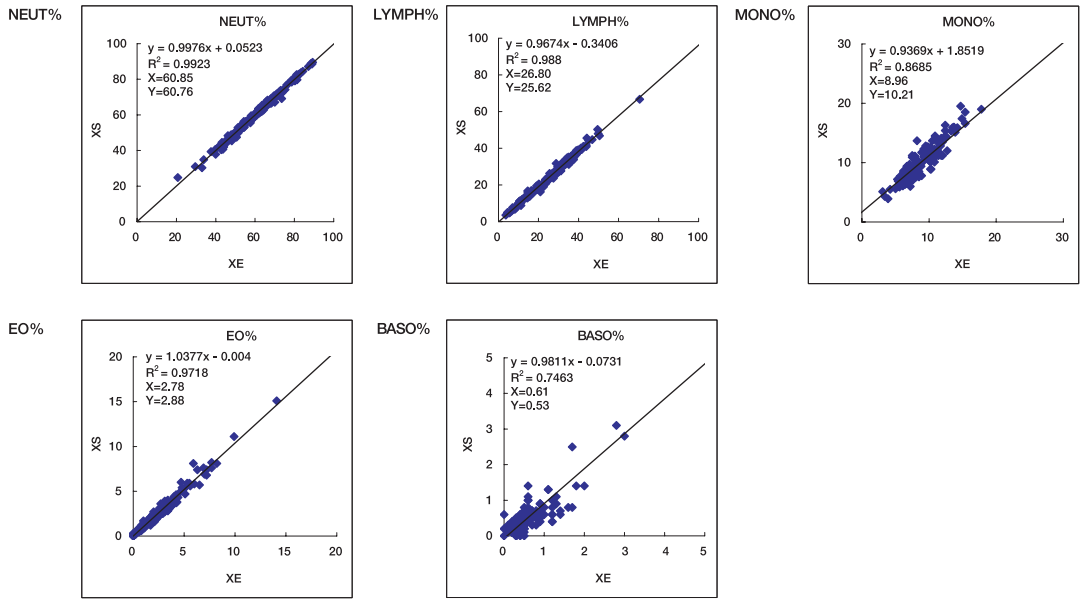

Fig. 9 *WBC 5 DIFF correlativity in the manual mode on XS-1000i and XE-2100 (n=150)*

AFTERWORD

This was an introduction of the summary of the newly developed automated hematology analyzer XS series, including part of the characteristic technologies and performance evaluation of the analyzers. The XS series is an automated hematology analyzer with high performance and functions despite its size and simplicity, which is considered to exert its full power for medium and small laboratories or near on-sites patient testing.

It would be our pleasure to be able to provide it to you for actual use. It would be most appreciated if you could let us know how you found it - any requests or where you think improvements could be made.