Performance Evaluation of the Sysmex XE-2100™, Automated Hematology Analyzer

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The XE-2100 is a new automated hematology analyzer that integrates reticulocyte and nucleated red blood cell (NRBC) analysis with the simultaneous determination of complete blood count (CBC) and white blood cell (WBC) 5-part differential, all from a single 200μL aspiration of whole blood. An automatic barcode reader and cap piercer allows for the efficient, safe analysis of approximately 150 samples per hour.

The Carle Clinic Laboratory evaluated the performance of the XE-2100 and compared it to the SE-9500™ and R-3000™. Carryover, Reproducibility, Linearity, Correlation, and Pre-dilute (capillary) mode comparisons were performed. Carryover and reproducibility were well within the manufacturer specifications, and the linearity met or exceeded the specified range on all parameters studied. The XE-2100 showed excellent correlation with the results from the SE-9500 for the following parameters: WBC, Neutrophil %, Lymphocyte %, Monocyte %, Eosinophil %, red blood cell (RBC), hemoglobin (Hgb), Hct, MCV, MCH, MCHC, Platelets, RDW-SD, RDW-CV, and MPV. Good correlation of the reticulocyte (RET) % and RET # to the R-3000 was also observed. The pre-dilute (capillary) mode compared to the open and closed sampler modes on the XE-2100 showed exceptional correlation for both normal and abnormal samples.

The overall performance of the XE-2100 is very good and compares well to the SE-9500 and R-3000.

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Key Words Automated Hematology Analyzer, XE-2100, Performance, Comparison

INTRODUCTION

The XE-2100™ is a new fully automated hematology analyzer intended for *in vitro diagnostic use* in clinical laboratories. This hematology analyzer provides analysis of 32 parameters including simultaneous white blood cell (WBC) 5-part differential and nucleated red blood cell (NRBC) counting, and is capable of processing approximately 150 samples per hour. Discrete analysis allows Reticulocyte counting (RET#) in addition to routine analysis of a whole blood specimen. The XE-2100 displays and prints the scattergrams of WBC, including specific detection of abnormal cells, and the histograms for red blood cell (RBC), and platelets.

Using flow cytometry with a semi-conductor laser, radio frequency (RF) and direct current (DC), the scatter, fluorescence, and impedance changes are analyzed to provide information about the size and the structural complexity of the cells. Selective dyes and reagent reactions assist in differentiating the WBC, NRBC, and reticulocytes as they pass through the measurement areas producing accurate cell size distributions and scattergrams. The RBC count and platelets are measured using the sheath flow DC detection method; however when large numbers of large platelets or RBC fragments are present, a more accurate optical platelet count is provided. This reduces the need for additional manual confirmatory platelet counts. Hemoglobin (Hgb) concentration is measured using a non-cyanide hemoglobin method.

The XE-2100 was fully evaluated for carryover, precision, and linearity, using blood samples from patients and normal, healthy adult individuals. Correlation to the SE-9500™ on normal and abnormal specimens and a comparison of the pre-dilute (capillary) mode to the open and closed sampler mode were also performed.

MATERIALS AND METHODS

The XE-2100 tested was made available through Sysmex Corporation, Japan.

The XE-2100 was compared to a pair of SE-9500, hematology analyzers for the following parameters: WBC, Neutrophil %, Lymphocyte %, Monocyte %, Eosinophil %, Basophil %, RBC, Hgb, Hct, MCV, MCH, MCHC, Platelets, RDW-SD, RDW-CV, and MPV. The results from both SE-9500 analyzers were combined for the comparison, as though they were from one analyzer. Over 150 whole blood specimens were analyzed on the SE-9500, and more than 130 on the R-3000™ using the residual material from patient specimens sent to the clinical laboratory at the Carle Clinic for routine testing, and blood specimens from consenting volunteers. Of all the specimens analyzed, 1/3 were from normal, healthy adult individuals. Except for specimens used for long term stability, all specimens were analyzed within 6 hours of collection and included samples with high WBC counts, platelet clumps, NRBCs, atypical lymphocytes, immature

Table 1 *Correlation results to SE-9500 and R-3000*

Parameter	n	r	r^2	Regression
WBC	155	0.9998	0.9996	y = 0.9114x + 0.7015
RBC	156	0.9974	0.9949	y = 0.9826x + 0.1042
HGB	156	0.9977	0.9954	y = 0.9838x + 0.2395
HCT	156	0.9971	0.9943	y = 0.9795x + 0.7722
PLT	156	0.9943	0.9887	y = 0.9707x + 6.7569
MCV	156	0.9933	0.9867	y = 0.9486x + 3.9077
MCH	156	0.9686	0.9382	y = 0.9781x + 0.5191
MCHC	156	0.9157	0.8385	y = 0.9044x + 3.286
RDW-SD	155	0.9970	0.9941	y = 0.9404x + 0.8201
RDW-CV	155	0.9967	0.9935	y = 0.9514x + 0.2239
MPV	150	0.9466	0.8960	y = 0.9503x + 1.039
NEUT%	142	0.9104	0.8289	y = 0.8268x + 10.912
LYMPH%	148	0.9637	0.9287	y = 0.8819x + 2.3231
MONO%	147	0.9003	0.8105	y = 0.9161x + 1.9875
EOSI%	153	0.9857	0.9717	y = 0.9139x + 0.0668
BASO%	112	0.3058	0.0935	y = 0.3733x + 0.471
RET%	139	0.9586	0.9189	y = 0.956x − 0.114
RET#	139	0.9778	0.9561	y = 0.8992x + 0.0002

granulocytes, blast forms, left shift, atypical/abnormal lymphocytes, anemia, etc.

Carryover was performed using the Inrternational Council for Standardization in Heamatology (ICSH) procedure for the following parameters: WBC, RBC, Hgb, Hct, and Platelet. Carryover was assessed by analyzing a high patient sample three consecutive times (H1, H2, H3) followed by a low sample analyzed three consecutive times (L1, L2, L3). The percentage of carryover for each parameter was calculated from the formula:

$$\text{Carryover (\%)} = \frac{L1 - L3}{H3 - L3} \times 100^{1)}$$

Reproducibility was evaluated by the within run precision study performed using three patient specimens run ten times consecutively in both the open and closed sampler mode.

Linearity on WBC, RBC, Hgb, Hct, and Platelets was performed using a series of dilutions of patient specimens beginning at or above the high end and ending at the low end of linearity specified for each parameter. The following criteria was used for linearity performance testing: the data must fit a linearity regression line; the coefficient of determination (r^2) should be > 0.95; a minimum of five dilutions distributed throughout the linearity range must be used; the dilutions must cover the reportable range for the parameter; each dilution result should be the mean value of duplicate (or more) measurements on the same range.

Both normal and abnormal samples analyzed in the predilute (capillary) mode, were compared to the open mode and closed sampler mode. The following parameters were studied: WBC, RBC, Hgb, Hct, Platelets and NRBC.

The short term stability study consisted of 8 normal samples analyzed at baseline immediately after blood was drawn and at 5, 15, 30, and 60 minutes. The following parameters were studied: WBC, Neutrophil %, Lymphocyte %, Monocyte %, Eosinophil %, Basophil %,

Table 2 *Carryover results*

Parameter	Carryover	Manufacturer Specifications
WBC %	0.04	≤3.0%
RBC %	− 0.14	≤1.5%
HGB %	0.00	≤1.5%
HCT %	0.00	≤1.5%
PLT %	− 0.04	≤5.0%

RBC, Hgb, Hct, MCV, MCH, MCHC, Platelets, RDW-SD, RDW-CV, MPV, RET# and RET%. Blood specimens for the long term stability study at room temperature and 4°C were run at 0, 4, 8, 12, 16, 24, 36, 48, 56, and 72 hours. One set of samples was kept at room temperature and another set of samples was kept at 4°C throughout the entire study. The following parameters were studied: WBC, Neutrophil%, Lymphocyte%, Monocyte%, Eosinophil%, Basophil%, RBC, Hgb, Hct, MCV, MCH, MCHC, Platelets, RET# and RET%.

RESULTS

As shown in ***Table 1***, the overall correlation between XE-2100 and SE-9500 was very good with r^2 values for most parameters > 0.9, and excellent > 0.99 for the directly measured parameters: WBC, RBC, Hgb, Hct and Platelets. Results for carryover, reproducibility and linearity are shown in ***Tables 2-5***. We observed no problems with comparison between pre-dilute mode and open and closed sampler modes (***Tables 6 and 7***). RET# and RET% also correlated well between the XE-2100 and R-3000 (r^2 > 0.9).

The short term stability study showed stable results from 0 to 60 minutes for WBC, Neutrophil %, Lymphocyte %, Monocyte %, Eosinophil %, Basophil %, RBC, Hgb, Hct, MCV, MCH, MCHC, Platelets, RET# and RET%. ***Fig. 1*** displays the results. The long term stability showed samples with normal results for WBC, Neutrophil %,

Table 3 Within run precision results (open mode)

Sample 1

	WBC ($\times10^3/\mu L$)	NEUT (%)	LYMPH (%)	MONO (%)	EO (%)	BASO (%)	RBC ($\times10^6/\mu L$)	HGB (g/dL)	HCT (%)	MCV (fL)
Mean	8.85	62.72	28.81	6.32	1.67	0.48	4.72	13.93	41.42	87.76
SD	0.112	0.632	0.559	0.266	0.082	0.092	0.017	0.048	0.162	0.217
CV%	1.26	1.01	1.94	4.21	4.93	19.14	0.36	0.35	0.39	0.25
Specs CV	3.00	8.00	8.00	20.00	25.00	40.00	1.50	1.00	1.50	1.00

	MCH (pg)	MCHC (g/dL)	PLT ($\times10^3/\mu L$)	RDW-SD (fL)	RDW-CV (%)	PDW (fL)	MPV (fL)	P-LCR (%)	RET# ($\times10^6/\mu L$)	RET% (%)
Mean	29.50	33.65	357.90	42.83	13.29	12.70	10.70	30.65	0.04	0.95
SD	0.133	0.178	4.533	0.309	0.074	0.194	0.067	0.158	0.003	0.057
CV%	0.45	0.53	1.27	0.72	0.56	1.53	0.62	0.52	5.89	6.04
Specs CV	1.50	1.50	4.00	2.00	2.00	10.00	3.00	15.00	15.00	15.00

Sample 2

	WBC ($\times10^3/\mu L$)	NEUT (%)	LYMPH (%)	MONO (%)	EO (%)	BASO (%)	RBC ($\times10^6/\mu L$)	HGB (g/dL)	HCT (%)	MCV (fL)
Mean	8.12	67.05	23.69	6.91	1.87	0.48	4.33	13.86	40.62	93.80
SD	0.077	0.546	0.370	0.448	0.206	0.114	0.024	0.052	0.199	0.194
CV%	0.95	0.81	1.56	6.49	11.00	23.65	0.55	0.37	0.49	0.21
Specs CV	3.00	8.00	8.00	20.00	25.00	40.00	1.50	1.00	1.50	1.00

	MCH (pg)	MCHC (g/dL)	PLT ($\times10^3/\mu L$)	RDW-SD (fL)	RDW-CV (%)	PDW (fL)	MPV (fL)	P-LCR (%)	RET# ($\times10^6/\mu L$)	RET% (%)
Mean	32.00	34.13	286.60	42.97	12.45	11.95	10.12	26.04	0.07	1.57
SD	0.156	0.157	3.978	0.267	0.053	0.184	0.079	0.591	0.003	0.070
CV%	0.49	0.46	1.39	0.62	0.42	1.54	0.78	2.27	4.41	4.48
Specs CV	1.50	1.50	4.00	2.00	2.00	10.00	3.00	15.00	15.00	15.00

Sample 3

	WBC ($\times10^3/\mu L$)	NEUT (%)	LYMPH (%)	MONO (%)	EO (%)	BASO (%)	RBC ($\times10^6/\mu L$)	HGB (g/dL)	HCT (%)	MCV (fL)
Mean	5.03	50.87	35.90	7.06	5.45	0.72	3.85	11.97	35.86	93.05
SD	0.074	0.896	0.929	0.378	0.317	0.193	0.017	0.067	0.151	0.085
CV%	1.47	1.76	2.59	5.35	5.82	26.84	0.44	0.56	0.42	0.09
Specs CV	3.00	8.00	8.00	20.00	25.00	40.00	1.50	1.00	1.50	1.00

	MCH (pg)	MCHC (g/dL)	PLT ($\times10^3/\mu L$)	RDW-SD (fL)	RDW-CV (%)	PDW (fL)	MPV (fL)	P-LCR (%)	RET# ($\times10^6/\mu L$)	RET% (%)
Mean	31.07	33.37	458.50	43.69	12.77	12.22	10.68	29.96	0.05	1.42
SD	0.283	0.271	5.817	0.341	0.067	0.155	0.063	0.331	0.003	0.074
CV%	0.91	0.81	1.27	0.78	0.53	1.27	0.59	1.10	5.07	5.18
Specs CV	1.50	1.50	4.00	2.00	2.00	10.00	3.00	15.00	15.00	15.00

Table 4 *Within run precision results (closed sampler mode)*

Sample 1

	WBC ($\times10^3/\mu L$)	NEUT (%)	LYMPH (%)	MONO (%)	EO (%)	BASO (%)	RBC ($\times10^6/\mu L$)	HGB (g/dL)	HCT (%)	MCV (fL)
Mean	7.03	56.61	30.83	8.12	3.91	0.53	4.46	13.67	39.94	89.55
SD	0.097	0.569	0.660	0.434	0.390	0.116	0.025	0.067	0.207	0.184
CV%	1.38	1.00	2.14	5.35	9.97	21.88	0.55	0.49	0.52	0.21
Specs CV	3.00	8.00	8.00	20.00	25.00	40.00	1.50	1.00	1.50	1.00

	MCH (pg)	MCHC (g/dL)	PLT ($\times10^3/\mu L$)	RDW-SD (fL)	RDW-CV (%)	PDW (fL)	MPV (fL)	P-LCR (%)	RET# ($\times10^6/\mu L$)	RET% (%)
Mean	30.66	34.23	208.50	40.15	12.35	13.19	10.97	33.02	0.02	0.55
SD	0.178	0.170	3.923	0.151	0.053	0.412	0.082	0.864	0.002	0.040
CV%	0.58	0.50	1.88	0.38	0.43	3.12	0.75	2.62	7.21	7.23
Specs CV	1.50	1.50	4.00	2.00	2.00	10.00	3.00	15.00	15.00	15.00

Sample 2

	WBC ($\times10^3/\mu L$)	NEUT (%)	LYMPH (%)	MONO (%)	EO (%)	BASO (%)	RBC ($\times10^6/\mu L$)	HGB (g/dL)	HCT (%)	MCV (fL)
Mean	5.23	50.85	36.12	6.84	5.60	0.59	3.86	11.97	35.85	92.98
SD	0.041	1.009	0.639	0.548	0.380	0.166	0.021	0.106	0.196	0.210
CV%	0.79	1.98	1.77	8.01	6.79	28.19	0.55	0.89	0.55	0.23
Specs CV	3.00	8.00	8.00	20.00	25.00	40.00	1.50	1.00	1.50	1.00

	MCH (pg)	MCHC (g/dL)	PLT ($\times10^3/\mu L$)	RDW-SD (fL)	RDW-CV (%)	PDW (fL)	MPV (fL)	P-LCR (%)	RET# ($\times10^6/\mu L$)	RET% (%)
Mean	31.04	33.37	435.70	43.31	12.74	12.23	10.63	29.65	0.05	1.36
SD	0.295	0.313	4.322	0.242	0.052	0.316	0.048	0.525	0.003	0.070
CV%	0.95	0.94	0.99	0.56	0.41	2.59	0.45	1.77	5.45	5.15
Specs CV	1.50	1.50	4.00	2.00	2.00	10.00	3.00	15.00	15.00	15.00

Sample 3

	WBC ($\times10^3/\mu L$)	NEUT (%)	LYMPH (%)	MONO (%)	EO (%)	BASO (%)	RBC ($\times10^6/\mu L$)	HGB (g/dL)	HCT (%)	MCV (fL)
Mean	8.46	80.07	7.12	11.70	0.68	0.43	4.36	13.86	41.64	95.50
SD	0.146	0.485	0.527	0.548	0.103	0.116	0.024	0.070	0.246	0.115
CV%	1.73	0.61	7.40	4.68	15.19	26.97	0.55	0.50	0.59	0.12
Specs CV	3.00	8.00	8.00	20.00	25.00	40.00	1.50	1.00	1.50	1.00

	MCH (pg)	MCHC (g/dL)	PLT ($\times10^3/\mu L$)	RDW-SD (fL)	RDW-CV (%)	PDW (fL)	MPV (fL)	P-LCR (%)	RET# ($\times10^6/\mu L$)	RET% (%)
Mean	31.80	33.30	435.50	47.17	13.44	11.96	10.33	27.14	0.04	1.01
SD	0.226	0.245	5.503	0.200	0.052	0.201	0.067	0.510	0.003	0.071
CV%	0.71	0.74	1.26	0.42	0.38	1.68	0.65	1.88	6.67	7.01
Specs CV	1.50	1.50	4.00	2.00	2.00	10.00	3.00	15.00	15.00	15.00

Table 5 *Linearity results*

Parameter	Range tested	Regression equation	r^2
WBC (low level)	$0.18 - 14.3 \times 10^3/\mu L$	y = 1.0329x – 0.3572	0.9983
WBC (high level)	$15.87 - 455.09 \times 10^3/\mu L$	y = 1.0615x – 23.695	0.9986
RBC	$0.08 - 8.78 \times 10^6/\mu L$	y = 0.9474x + 0.4052	0.9970
HGB	0.2 – 26.3 g/dL	y = 0.9492x + 1.4788	0.9976
HCT	0.7 – 80.4 %	y = 0.9618x – 2.5485	0.9955
PLT (low level)	$2 - 61 \times 10^3/\mu L$	y = 1.0309x – 1.4646	0.9983
PLT (high level)	$10 - 1129 \times 10^3/\mu L$	y = 1.0225x – 38.828	0.9986

Table 6 *Comparsion of pre-dilute to open mode with normal and abnormal samples*

Parameter	n	r	r^2	Regression
WBC	40	0.9992	0.9985	y = 1.0261x + 0.1027
RBC	40	0.9985	0.9970	y = 1.0418x – 0.0407
HGB	40	0.9980	0.9960	y = 1.0764x – 0.3225
HCT	40	0.9976	0.9952	y = 1.018x + 0.127
PLT	40	0.9972	0.9944	y = 0.9959x + 5.7109
NRBC	40	0.9773	0.9552	y = 1.0109x + 0.0034

Table 7 *Comparsion of pre-dilute to closed sampler mode with normal and abnormal samples*

Parameter	n	r	r^2	Regression
WBC	31	0.9992	0.9984	y = 1.0019x + 0.0649
RBC	31	0.9980	0.9961	y = 1.0235x + 0.0442
HGB	31	0.9980	0.9960	y = 1.0286x + 0.0954
HCT	31	0.9981	0.9962	y = 0.9915x + 1.0000
PLT	31	0.9966	0.9933	y = 0.9959x + 1.3153
NRBC	31	0.9615	0.9244	y = 1.0153x + 0.0047

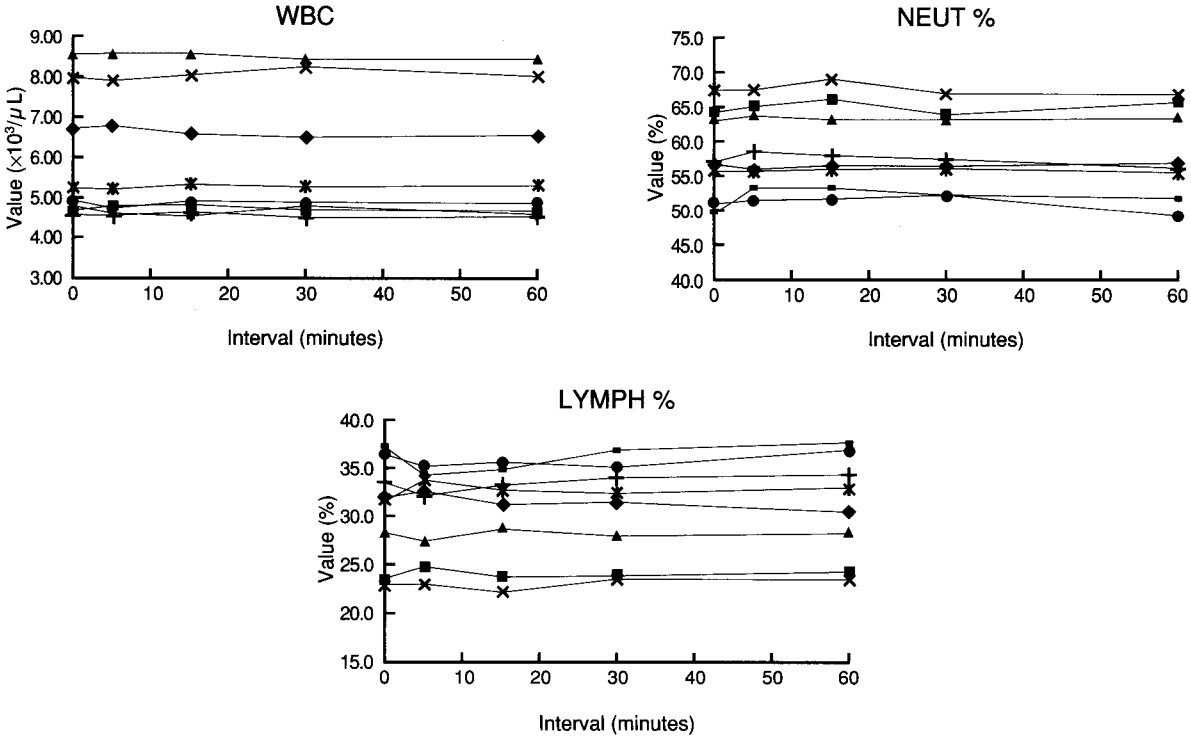

Fig. 1 *Short term stability (n=8)*

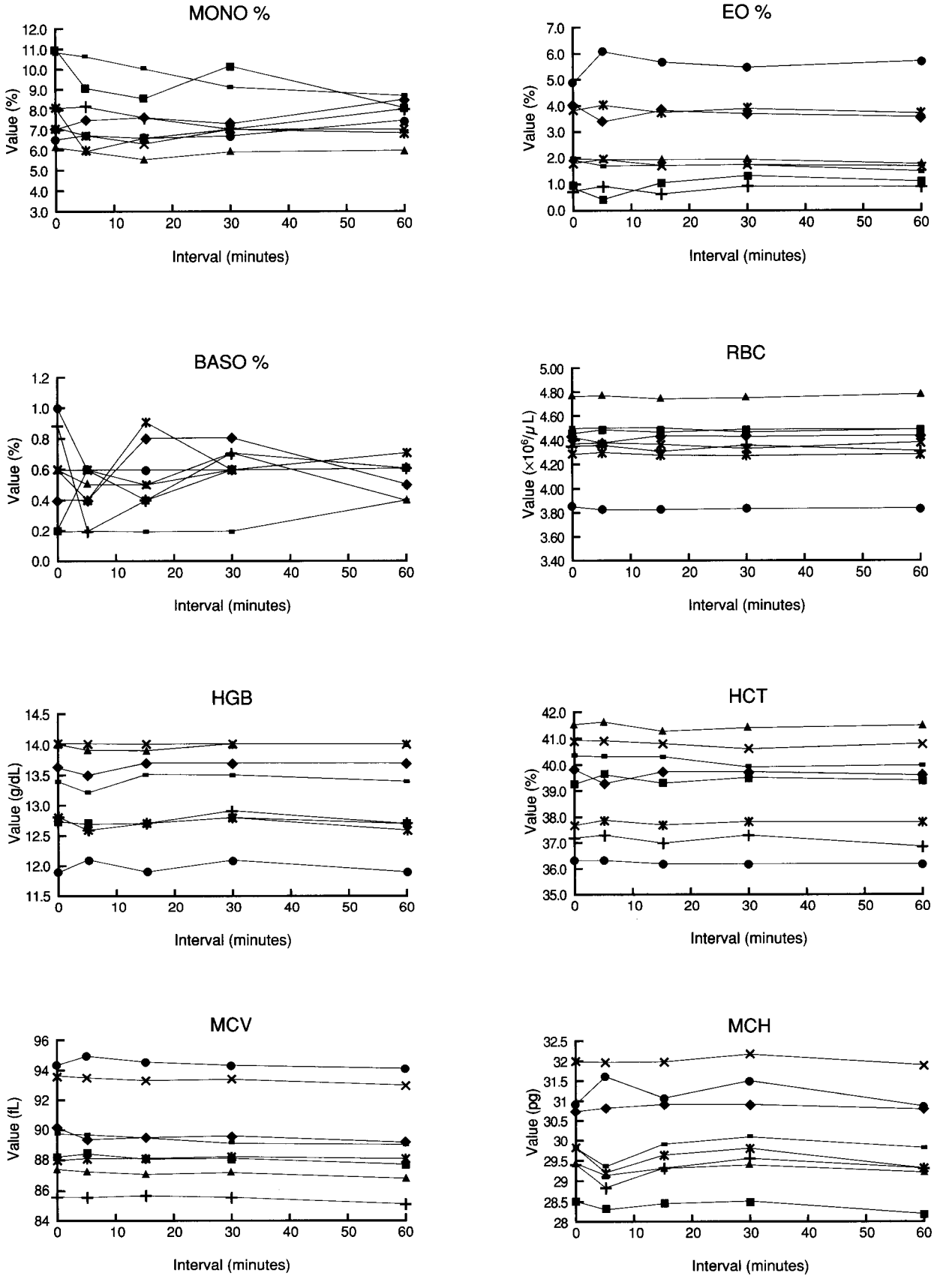

Fig. 1 Short term stability (n=8)

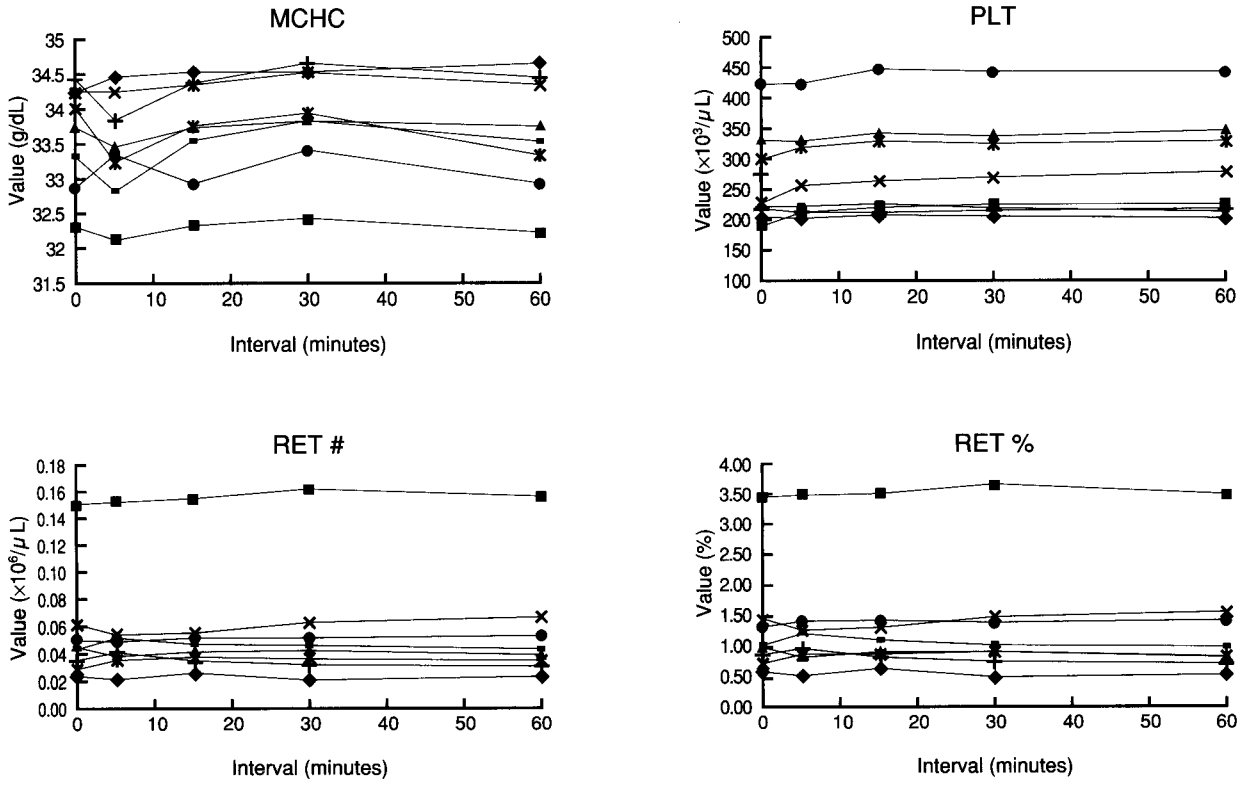

Fig.1 Short term stability (n=8)

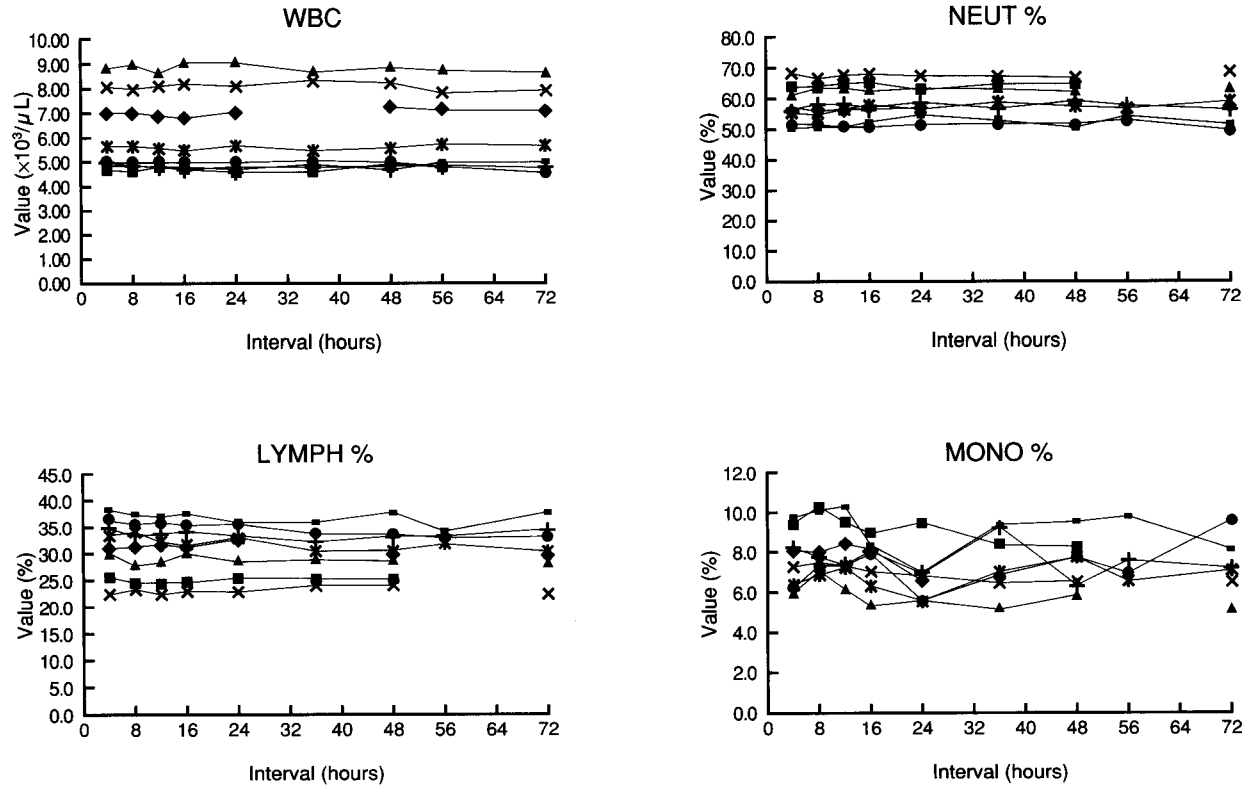

Fig. 2 Long term stability (4°C)

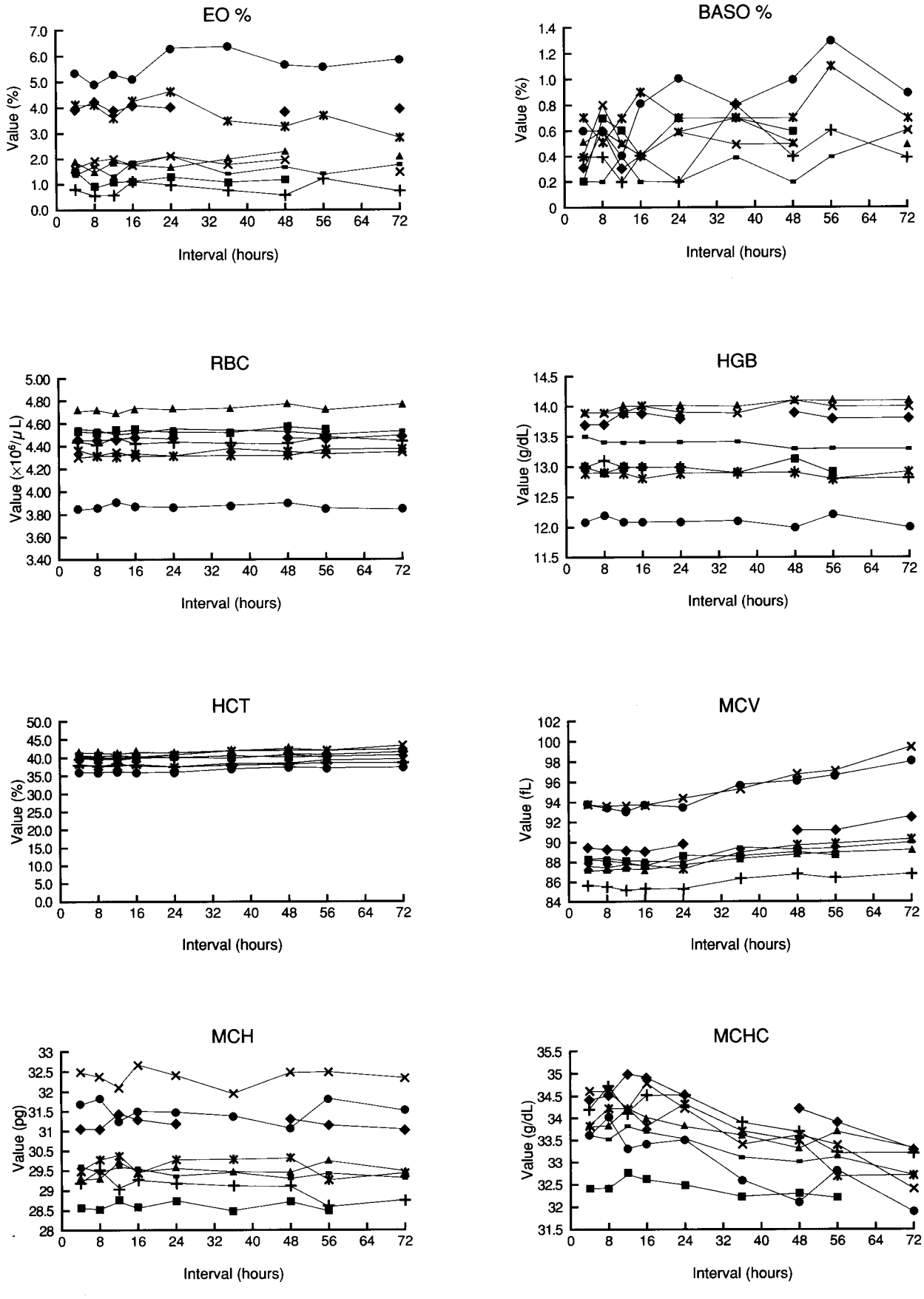

Fig. 2 Long term stability (4°C)

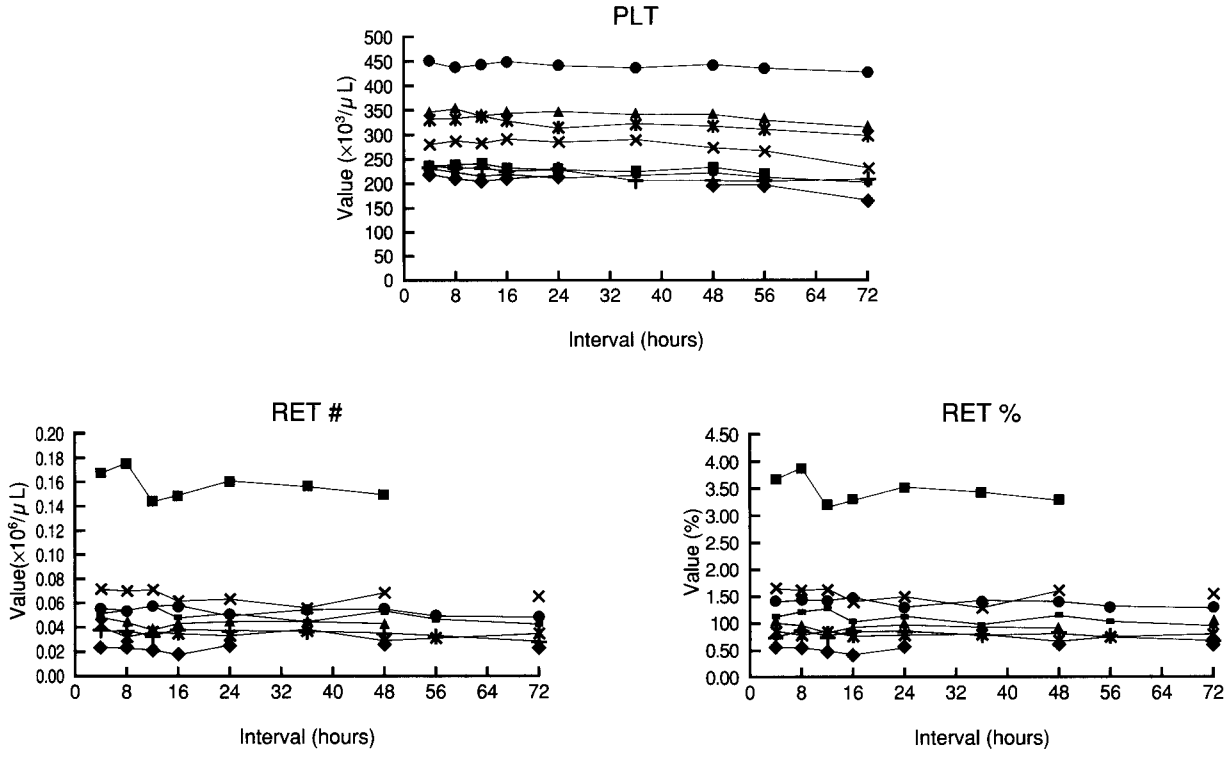

Fig. 2 Long term stability (4°C)

Lymphocyte %, Monocyte %, Eosinophil %, Basophil %, RBC, Hgb, Hct, MCH, Platelets and RET% and RET# are stable for 36 hours at room temperature: MCV, MCHC are stable for 24 hours. At refrigerated temperature (4°C) the long term stability for samples with normal results for WBC, Neutrophil %, Lymphocyte %, Monocyte %, Eosinophil %, Basophil %, RBC, Hgb, Hct, MCH, Platelets, RET% and RET# are stable for 48 hours. MCV and MCHC are stable for 36 hours (***Fig. 2***).

DISCUSSION

Inter-instrument correlation between XE-2100 and SE-9500, carryover, reproducibility and linearity were found to be excellent. The Pre-Dilute Mode comparison to open and closed modes also showed exceptional correlation for both normal and abnormal samples.

The XE-2100 showed excellent performance on very fresh samples. Short-term stability studies demonstrated that CBC, WBC five-part differential remain stable when analyzed immediately from time of draw to 60 minutes. Samples stored at room temperature showed stability for Hct, MCV, MCHC and RET# for up to 16 hours and for the five-part differential for 8-16 hours. However, samples stored at 4°C showed 24-hour stability for the basic eight parameters and the Lymphocyte and Neutrophil %. Long term stability of up to 48 hours was noted for WBC, RBC, Hgb, PLT and MCH. The Monocyte %, Eosinophil % and Basophil% are stable only up to 16 hours at 4°C due to fragility of some of these cell types.

In conclusion, the Sysmex XE-2100 automated hematology analyzer performed very well in all studies performed. The XE-2100 is able to provide accurate and reliable results over a wide range of levels and abnormal sample types. The addition of the optical platelet count and the potential for extended high level WBC and platelet linearity presents the opportunity to reduce the number of manual confirmatory procedures performed. In addition, this analyzer provides discrete reticulocyte analysis along with a complete blood cell analysis and differential, using only 200μL of whole blood. With its large throughput The Sysmex XE-2100 would be very useful in a medium to large laboratory.

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