Comparison of the Sysmex XE-2100 to the SE-9500+RAM-1, Automated Hematology Analyzer

Nina GAMPERLING MBA, MT (ASCP), RAC and Cathy TRESTER, MT (ASCP)

Sysmex Corporation of America, Gilmer Road, 6699 Wildlife Way, Long Grove, IL 60047-9596, USA.

The Sysmex XE-2100 automated hematology analyzer was evaluated at a Sysmex Hematology Research Center. Results from 230 patient samples were compared to the Sysmex SE-9500+RAM-1. The XE-2100 showed excellent correlation with the results to the SE-9500+RAM-1 for the following parameters: white blood cell (WBC), neutrophil (Neut) %, lymphocyte (Lymph) %, monocyte (Mono) %, eosinophil (Eo) %, basophil (Baso) %, red blood cell (RBC), hemoglobin (HGB), hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (HCH), mean corpuscular hemoglobin concentration (MCHC), RBC distribution width-coefficient of variation (RDW-CV), RBC distribution width-standard deviation (RDW-SD), reticulocyte (RET) % and #, immature reticulocyte fraction (IRF), platelet (PLT), mean platelet volume (MPV). It can be concluded that the overall performance of the XE-2100 compares favorably to the SE-9500+RAM-1.

The XE-2100 is a fully automated hematology analyzer with simultaneous analysis of 32 parameters (26 reportable in the USA) including the NRBC and IRF parameters. The XE-2100 uses several methodologies from previous Sysmex instrumentation, along with a newly developed optical detection unit for the following parameters: WBC, WBC 5-part differential, NRBC count, reticulocyte analysis and optical platelet counting. The XE-2100 can process approximately 150 samples per hour, has various discrete analysis capabilities for cost-effective testing, and uses the Windows NT system for easy operation.

(Sysmex J Int 12 : 24-29, 2002)

Key Words Automated Hematology Analyzer, XE-2100, Comparison, SE-9500+RAM-1

Received 2 April, 2002; Accepted 12 April, 2002

INTRODUCTION

The Sysmex XE-2100 is an automated hematology analyzer which incorporates random-access analysis of complete blood count (CBC) and differential, nucleated red blood cells (NRBC) and reticulocytes (RET) including the immature reticulocyte fraction (IRF) parameter. The XE-2100 is fully automated and performs simultaneous analysis of 32 parameters (26 reportable in the USA). These parameters are: white blood cell (WBC), neutrophil (Neut) % and #, lymphocyte (Lymph) % and #, monocyte (Mono) % and #, eosinophil (Eo) % and #, basophil (Baso) % and #, NRBC % and #, red blood cell (RBC), hemoglobin (HGB), hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (HCH), mean corpuscular hemoglobin concentration (MCHC), RBC distribution width-coefficient of variation (RDW-CV), RBC distribution width-standard deviation (RDW-SD), RET%, IRF, high fluorescence ratio (HFR)*, middle fluorescence ratio (MFR)*, low fluorescence ratio (LFR)*, platelet (PLT), mean PLT volume (MPV), PLT distribution width (PDW)*, PLT- large cell ratio (P-LCR)*, and plateletcrit (PCT)*. (*These parameters are not reportable in the USA.)

The XE-2100 can process approximately 150 samples per hour, has a number of discrete analysis capabilities for cost-effective testing, and uses the Windows NT system for its easy operation and networking capabilities.

The XE-2100 performs hematology analyses using the following methods: RF/DC detection method, sheath flow DC detection method, flow cytometry methods using a semiconductor laser, and a non-cyanide SLS-hemoglobin method. The RF/DC detection method detects the volume of blood cells by changes in direct-current resistance, and the density of the blood cell interior by changes in radio-frequency resistance. Blood cells pass through the aperture of the detector surrounded by sheath fluid in the sheath flow method (also known as hydrodynamic focusing). The principle of flow cytometry is similar to that used in the Sysmex SF-3000, although the optical unit is a new design. A semiconductor laser beam is emitted to the blood cells passing through the flow cell. The forward scattered light is received by a photodiode, and a photo multiplier tube receives the side scattered light and lateral fluorescent light. This light is converted into electrical pulses, thus making it possible to obtain detailed blood cell information.

The XE-2100 employs fluorescent flow cytometry to obtain information for the analysis for WBC 5-part differential, NRBC, RET and optically measured PLT. The semiconductor laser offers distinct advantages over the traditional Argon or Helium-Neon laser. These advantages include: longer life cycle, lower power consumption, longer stability, and compact size. Using the RF/DC detection method as in previous Sysmex instruments, the XE-2100 measures immature cell information in the IMI channel. The IMI channel serves to obtain information on the presence of immature granulocytes (IG), blasts, and hematopoietic progenitor cells.

Table 1 *Correlation results to SE-9500+RAM-1*

Parameter	n	r	r^2	Regression
WBC	230	1.0	0.995	y= 0.011 + 0.998x
Neut%	230	0.99	0.980	y= 0.992 + 0.980x
Lymph%	230	0.99	0.982	y= 0.677 + 0.985x
Mono%	230	0.89	0.787	y= 0.995 + 0.914x
Eo%	230	0.94	0.885	y= 0.012 + 0.836x
Baso%	166	0.82	0.672	y= 0.483 + 0.439x
RBC	230	1.0	0.995	y= 0.174 + 0.969x
HGB	230	1.0	0.996	y= 0.376 + 0.982x
HCT	230	1.0	0.995	y= 1.373 + 0.962x
MCV	230	1.0	0.995	y= 1.900 + 0.966x
MCH	230	0.98	0.961	y= 0.951 + 0.968x
MCHC	230	0.97	0.933	y= 2.258 + 0.944x
RDW-CV	230	1.0	0.997	y=–0.280 + 1.000x
RDW-SD	230	1.0	0.995	y=–0.365 + 0.973x
RET%	230	0.98	0.970	y= 0.017 + 0.848x
RET#	230	0.98	0.962	y= 0.002 + 0.844x
IRF	230	0.90	0.818	y= 1.569 + 0.807x
PLT	230	0.99	0.981	y=–0.336 + 1.038x
MPV	230	0.96	0.924	y= 0.446 + 0.947x

Hemoglobin is measured with the non-cyanide SLS-hemoglobin method using Sodium Lauryl Sulfate, which is the well-proven hemoglobin analysis method used in Sysmex instrumentation since 1991[1].

The XE-2100 has four modes of sample analysis: manual mode (which requires approximately 130µL of sample), capillary mode (which requires approximately 40µL of blood for dilution), sampler mode (which requires approximately 200µL of sample) and manual closed mode (which requires approximately 200µL of sample). The sampler mode, which automatically mixes, aspirates, and analyzes samples without removing their caps, was used in this study.

Additional features of the XE include: automated maintenance procedures, comprehensive QC program including modem transfer capabilities, remote maintenance, delta checking, random access discrete testing, and various automation platforms (options).

The XE-2100 was compared to the SE-9500+RAM-1 at a Sysmex Hematology Research Center.

MATERIALS AND METHODS

For this evaluation, residual material was used from patient specimens collected in K_3EDTA that was sent to a clinical laboratory for routine clinical testing, and blood specimens from volunteers after obtaining informed consent. The XE-2100 tested was made available through Sysmex Corporation Japan.

Both analyzers were calibrated upon installation by Sysmex Corporation Japan according to the manufacturer's guidelines. Three levels of quality control material (*e*-Check) were used (low, normal, and high) throughout the duration of the study. The XE-2100 required minimal maintenance in order to keep the XE-2100 in optimal operating condition.

The XE-2100 was compared to the Sysmex SE-9500 hematology analyzer for the following parameters: WBC, Neut %, Lymph%, Mono%, Eo%, Baso%, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, RET%, RET#, IRF, PLT, and MPV. For this comparison, 230 whole blood specimens were analyzed, of which approximately 1/3 were from normal, healthy adult individuals. All specimens were analyzed within 8 hours of collection and included samples with high WBC counts, lipemia, high bilirubin, platelet clumps, NRBCs, atypical lymphocytes, immature granulocytes, blast forms, left shift, atypical/abnormal lymphocytes, iron deficiency, thalassemia, etc.

Table 2 *Linearity ranges for the XE-2100*

Parameter	Range Tested	Units
WBC	0.0 - 173.02	$\times 10^9$/L
RBC	0.44 - 8.78	$\times 10^{12}$/L
HGB	0.2 - 26.3	g/dL
HCT	0.8 - 79.5	%
PLT	0 -5000*	$\times 10^9$/L
RET%	0.77 - 18.46*	%
RET#	0.0216 - 0.4707	$\times 10^{12}$/L
NRBC%	0.0 - 464.10	/100WBC
NRBC#	0.0 - 19.25	$\times 10^9$/L

*Performed by Plasma Replacement Technique

RESULTS

As can be seen in ***Table 1***, overall correlation between XE-2100 and SE-9500+RAM-1 for all measured parameters was excellent with r values for most parameters > 0.90. Parameters with r-values > 0.80 were monocyte%, and BASO%. No significant bias was detected. ***Figs. 1a-1d*** shows comparisons in graphic display.

Carryover and precision were performed and were within manufacturer specifications. Linearity was also performed. The range of linearity is displayed in ***Table 2***. (Data for these studies not shown here.)

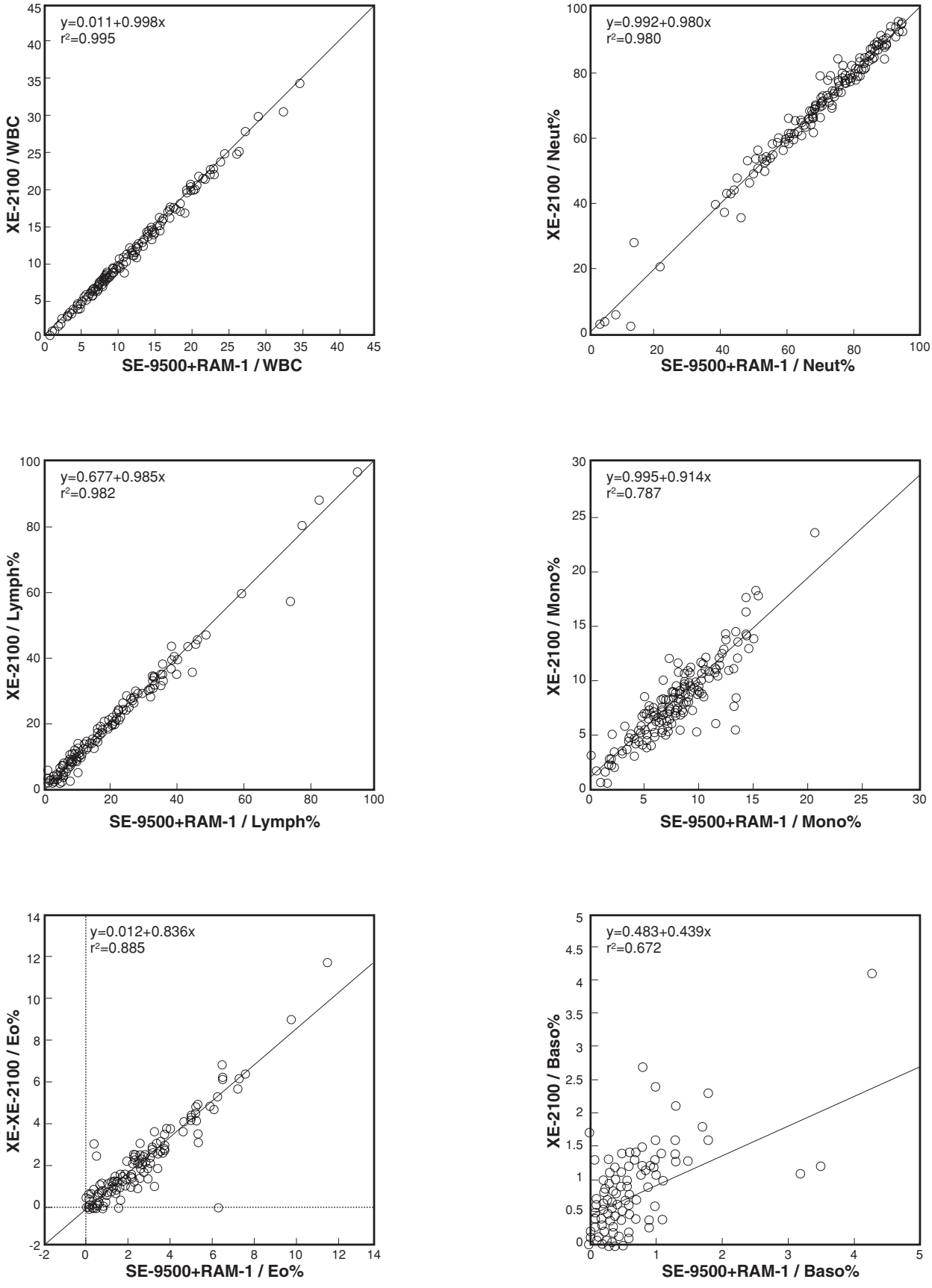

Fig. 1a *Correlation of XE-2100 to SE-9500+RAM-1*

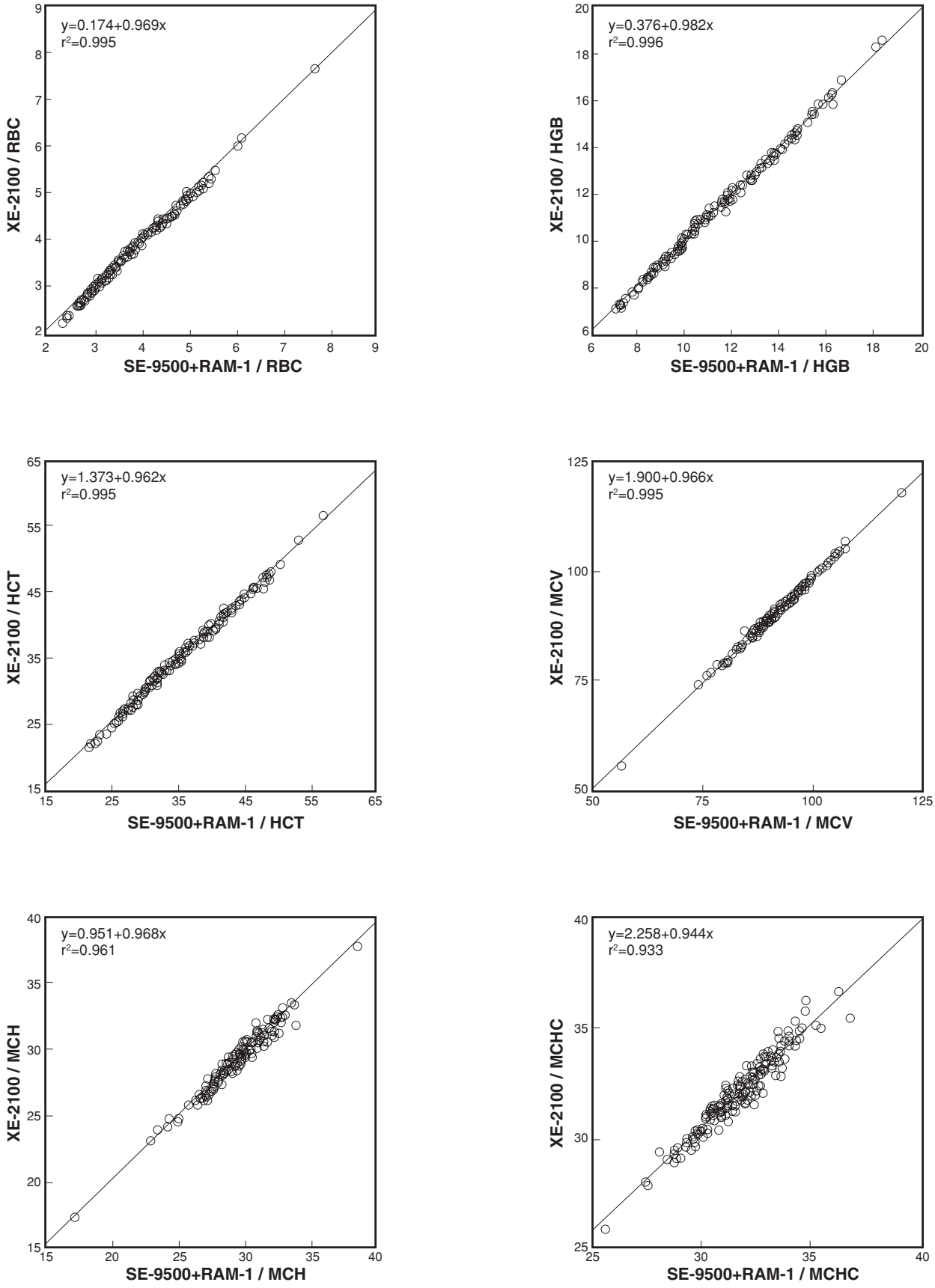

Fig. 1b *Correlation of XE-2100 to SE-9500+RAM-1*

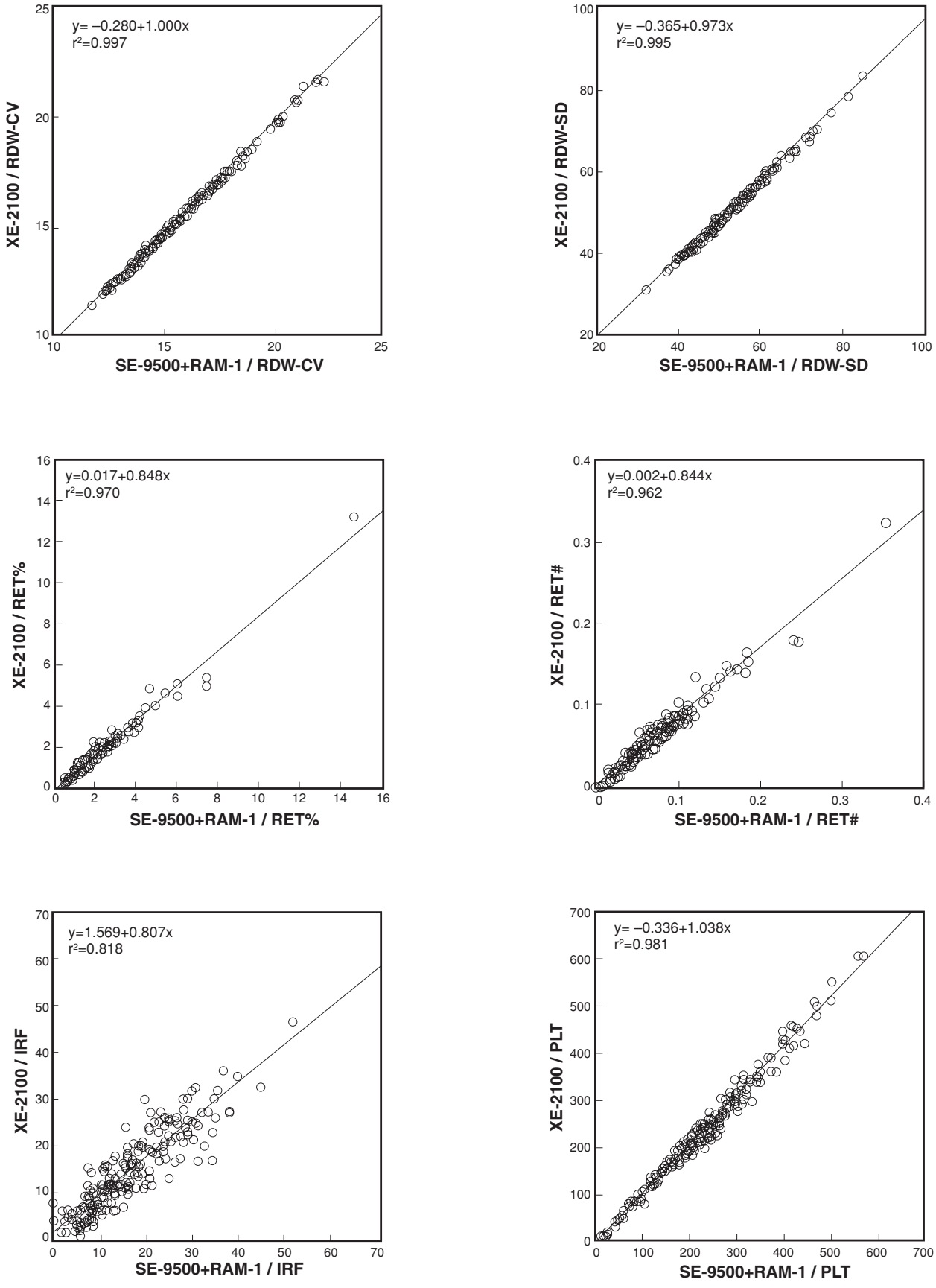

Fig. 1c *Correlation of XE-2100 to SE-9500+RAM-1*

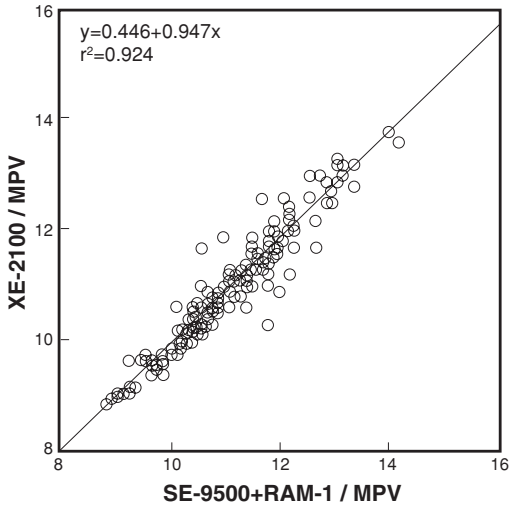

Fig. 1d *Correlation of XE-2100 to SE-9500+RAM-1*

DISCUSSION AND CONCLUSIONS

Correlation between the XE-2100 and the SE-9500+RAM-1 showed excellent results for all CBC and WBC differential parameters. The XE-2100 is able to provide accurate and reliable results over a wide range of abnormal sample types. The additional detector channels on the XE allow for increased sensitivity and specificity in flagging abnormal samples.

The XE-2100 utilizes a newly developed optical detection method for PLT in conjunction with the proven hydrodynamically focused impedance method, which enhances the reliability of PLT counting. Furthermore, the instrument's ability to perform discrete RET analysis and IRF is a great advantage. The XE-2100 also offers increased diagnostic information with the NRBC count, and includes automatic correction of WBC and differential when NRBCs are present. In addition, the XE-2100 is easy to operate and requires little maintenance. Maintenance for the study period was as simple as executing a bleach shutdown each day. No other maintenance was necessary or performed.

In conclusion, the Sysmex XE-2100 automated hematology analyzer performed very well compared to the SE-9500+RAM-1. The XE-2100 provides accurate and reliable results over a wide range of abnormal sample types. Use of the XE-2100 should enhance the quality of result reporting and add efficiency by optimizing human resources in the hematology laboratory.

References

1) *Pearson RW, Houwen B, and Mast B: SULFOLYSER automated hemoglobin reagent—Introduction of a new cyanide—free method. Monograph, TOA Medical Electronics (USA), Inc. 1991.*

2) *Gould N, et al. : Performance evaluation of the Sysmex XE-2100, automated hematology analyzer. Sysmex J Int, 9: 120-128, 1999.*

3) *Inoue H: Overview of automated hematology analyzer XE-2100. Sysmex J Int, 9: 58-64, 1999.*

4) *International Committee for Standardization in Hematology (ICSH): Protocol for evaluation of automated hematology analyzer. ICSH, 6: 69, 1984.*

5) *Machin SJ, et al.: Improved platelet counting on a new automated blood cell counter. Poster Abstract, Lab Hematol, 5: 99, 1999.*

6) *Weber N, Mast BJ, and Houwen B : Performance evaluation of hematology analyzers: An outline for clinical laboratory testing. Sysmex J Int, 5: 103-113, 1995.*

7) *Zini G, et al.: Automated counting of nucleated red blood cells (NRBC): evaluation of the Sysmex XE-2100 system. Poster Abstract, Lab Hematol, 5: 94, 1999.*