Evaluation of the Basic Performance and Usability of the Automated Blood Coagulation Analyzer CS-1600

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The automated blood coagulation analyzer CS-1600 (CS-1600; Sysmex Corporation, Kobe, Japan), which is the next-generation model of the automated blood coagulation analyzer CA-1500 (CA-1500; Sysmex Corporation, Japan), utilizes multi-wave detection and has additional functions that enhance its usability. Here we report the results of our evaluation of basic performance and usability of the CS-1600.

Performance evaluation of the CS-1600 and correlation with the routinely-used automated blood coagulation analyzer CA-530 (CA-530; Sysmex Corporation, Japan) were favorable. In our evaluation of usability, we noted that the sample volume checking function could objectively determine that excessive or insufficient volume of blood was collected. The task handover screen allows for smooth handoff of tasks to on-duty staff, which should reduce inefficiency. Furthermore, progress status and sample information are aggregated on a single screen in the job list, which enables prompt responses to inquiries from clinical staff. The analyzer is also very safe, equipped with a cap piercing function to reduce biohazard risks. It is a useful analyzer suited for routine laboratory tasks, and may improve testing efficiency.

Key Words CS-1600, CA-530

INTRODUCTION

Blood coagulation tests for monitoring the action of anticoagulants and for understanding the status of thrombus formation have been increasingly done in recent years. Along with this, there is a demand for better usability, high speed analysis capability and other similar characteristics in fully automated blood coagulation analyzers.

The automated blood coagulation analyzer CS-1600 (CS-1600; Sysmex Corporation, Kobe, Japan) uses a multi-wavelength detection system in which measurements are made by splitting the light from a halogen lamp into beams of wavelength 405, 575, 660 and 800 nm. Therefore, the detector is not limited by the measurement principle employed. The throughput is not negatively effected, even when the parameters analyzed by chromogenic substrate method or immunoturbidimetry are added to those measured by the coagulation time method [1]. Besides this, the analysis can be carried out with a secondary wavelength for samples in which the change in intensity of the transmitted light of the dominant wavelength is difficult to detect because of the effect of interfering substances, etc. As for usability, a task handover screen, vial specific QC, auto start-up function, and alert function are new on the CS-1600. The sample volume check function and cap piercing function are also available in all CS Series analyzers.

Here we report the results of an evaluation of the basic performance and usability of CS-1600.

METHODS

1. Parameters analyzed

1) Clotting method

Prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen (Fbg), and hepaplastin test (HPT)

2) Chromogenic method

Antithrombin (AT)

2. Reagents

The reagents used in this examination and the reagents conventionally used for routine testing are listed in ***Table 1***.

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3. Analyzers

The performance of the analyzer CS-1600 was investigated. Correlation of the analysis results with those obtained using our conventionally used CA-530 was studied.

4. Methods of investigation

1) Within run reproducibility
Twenty consecutive measurements were made with Control Plasma N (CPN; SIEMENS, Germany) and Control Plasma P (CPP; SIEMENS, Germany) for blood coagulation tests.
2) Between day reproducibility
Tests were conducted on five days using two concentrations each of control plasmas CPN and CPP.
3) Linearity
Measurements were made with a 10-step dilution series of high Fbg samples from patients diluted with Owren's veronal buffer (SIEMENS, Germany).
4) Effects of interfering substances
Interference check A Plus (Sysmex Corporation, Japan) was added to CPN and Coag QAP control IIX (Sysmex Corporation, Japan) and the effects of hemoglobin, conjugated bilirubin, free bilirubin and lipids on the measurement were examined.
5) Correlation
Correlation of CS-1600 and CA-530 was evaluated by using patient plasmas.
6) Usability
Ease of use of six functions (sample volume check, task handover screen, result screen (job list), cap piercing, reagent cap storage, and auto start-up of the analyzer) of CS-1600 was analyzed.

RESULTS

1. Within run reproducibility

The CV (%) was 0.21-2.00 for CPN and 0.55-3.66 for CPP (***Table 2***).

2. Between day reproducibility

The CV (%) was 0.31-2.52 for CPN and 0.94-5.02 for CPP (***Table 3***).

Table 1 *Reagents used*

	Reagent examined	Marketed by	Reagent used currently for routine testing	Marketed by
PT	Thromborel® S	SIEMENS	Thromborel® S	SIEMENS
APTT	Thrombocheck® APTT-SLA	Sysmex	Thrombocheck® APTT-SLA	Sysmex
Fbg	Thrombocheck® Fib (L)	Sysmex	Thrombocheck® Fib AUTO	Sysmex
HPT	Complex factor H Kokusai®	Sysmex	Complex factor H Kokusai®	Sysmex
AT	L-System® AT III	Sysmex	Test Team® S AT III	Sekisui Medical

Table 2 *Within run reproducibility*

n=20

	PT (%)		PT (INR)		APTT (sec)		Fbg (mg/dL)		HPT (%)		AT (%)	
Sample	CPN	CPP	CPN	CPP	CPN	CPP	CPN	CPP	CPN	CPP	CPN	CPP
MEAN	98.92	37.98	1.004	1.674	26.01	92.92	286.16	90.29	120.73	38.64	101.36	34.61
SD	0.85	0.61	0.005	0.020	0.06	0.51	4.51	1.67	1.02	0.31	2.03	1.27
CV (%)	0.86	1.60	0.50	1.09	0.21	0.55	1.58	1.85	0.84	0.79	2.00	3.66

Table 3 *Between day reproducibility*

	PT (%)		PT (INR)		APTT (sec)		Fbg (mg/dL)		HPT (%)		AT (%)	
Sample	CPN	CPP	CPN	CPP	CPN	CPP	CPN	CPP	CPN	CPP	CPN	CPP
MEAN	95.47	36.89	1.025	1.711	26.24	95.96	282.10	89.90	121.96	36.89	98.33	33.24
SD	2.41	0.64	0.015	0.021	0.08	0.90	5.00	2.63	2.37	0.66	1.58	1.67
CV (%)	2.52	1.74	1.44	1.22	0.31	0.94	1.77	2.92	1.95	1.80	1.60	5.02

3. Effects of interfering substances

Hemoglobin up to 509 mg/dL, conjugated bilirubin up to 21.1 mg/dL, free bilirubin up to 20.0 mg/dL and lipids up to 1,400 FTU did not affect any of the parameters measured (***Fig. 1***).

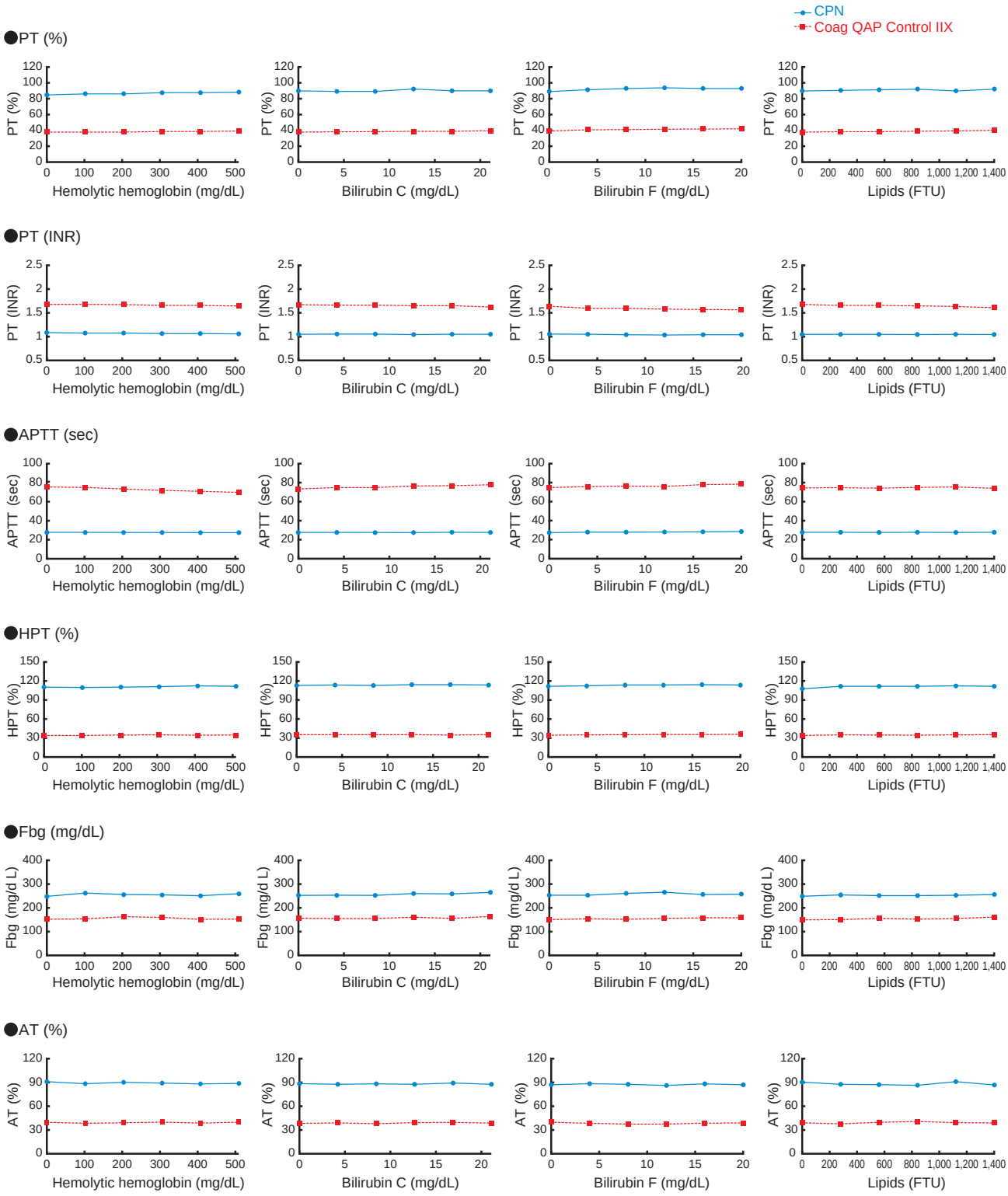

Fig. 1 *Effect of interfering substances*

4. Linearity

Linearity was seen up to about 700 mg/dL with Fbg. Below this concentration level, the correlation coefficient was 0.998 (***Fig. 2***).

5. Correlation with conventional method

Fig. 3 shows the correlation between the CS-1600 and CA-530 results. The correlation coefficients were in the range 0.976 - 0.997.

6. Usability

Table 4 gives the results of evaluation of usability.

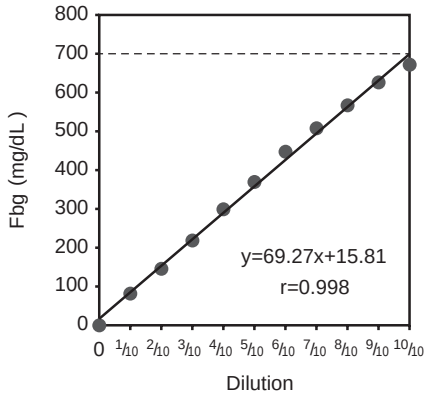

Fig. 2 *Linearity*

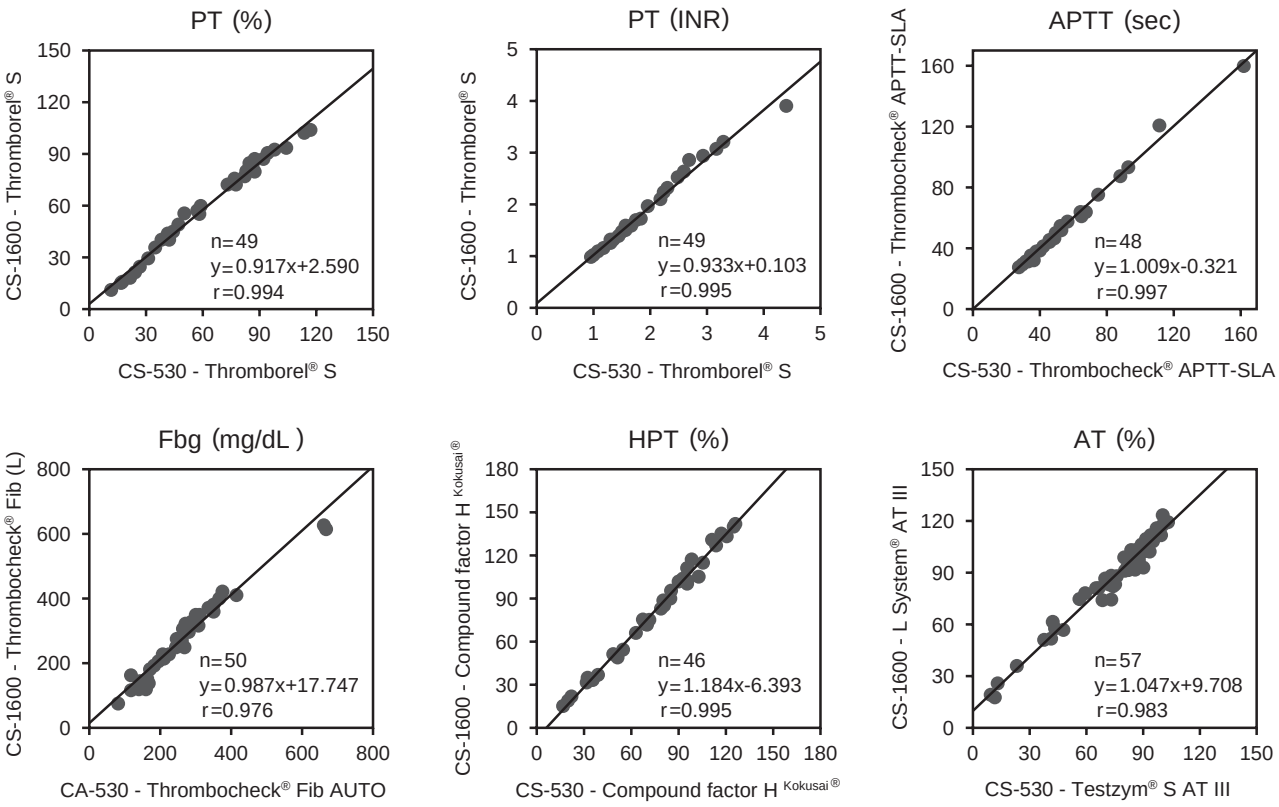

Fig. 3 *Correlation*

Table 4 *Usability*

	Item	Function and details
1	Sample volume check	The “VOL” flag was displayed when the sample volume was outside the specified range. This enabled detection of deficiency in sample volume ***(Fig. 4-A)***. The tolerance could be set by each laboratory, which allowed continuity with the existing set criteria.
2	Cap piercing	Measurements could be made without removing the blood collection tube cap. This saved the labor involved in removing the caps and reduced biohazards.
3	Results screen (job list)	The analysis progress status of each sample and the expected time to completion could be viewed on the screen ***(Fig. 4-B)***.
4	Task handover screen	The number of tests that could be done with the remaining reagents, the number of consumable items used, information about the errors that occurred during the previous 24 hours, etc. could all be viewed on this screen. Analyzer status could be easily reviewed before analyzer operation was assumed by the next operators. The names of reagents with low remaining volumes were highlighted in yellow which made visual checking easier ***(Fig. 4-C)***.
5	Reagent cap storage	A dedicated space for organized storage of reagent caps has been provided and it was possible to write the name of the reagent on the tray containing that reagent’s caps ***(Fig. 4-D)***
6	Auto start-up of analyzer	The analyzer could be started automatically at pre-set times and days, which shortened the time of waiting for the analyzer to reach the standby state.

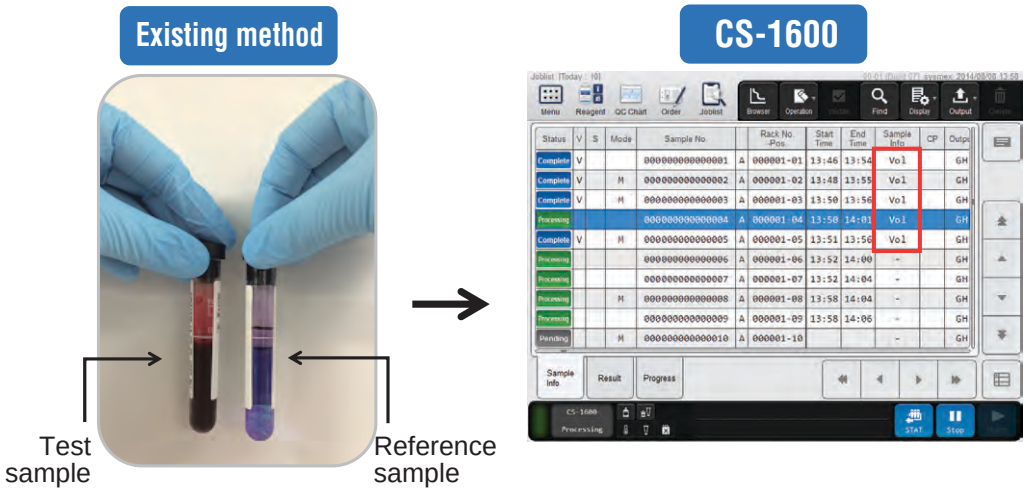

Fig. 4-A *Sample volume check*

In the existing method, the sample volume is checked by visually comparing with a reference sample in which the upper and lower tolerance limits of sample volume are marked. In CS-1600 on the other hand, the "VOL" flag is displayed against samples outside the sample volume tolerance range.

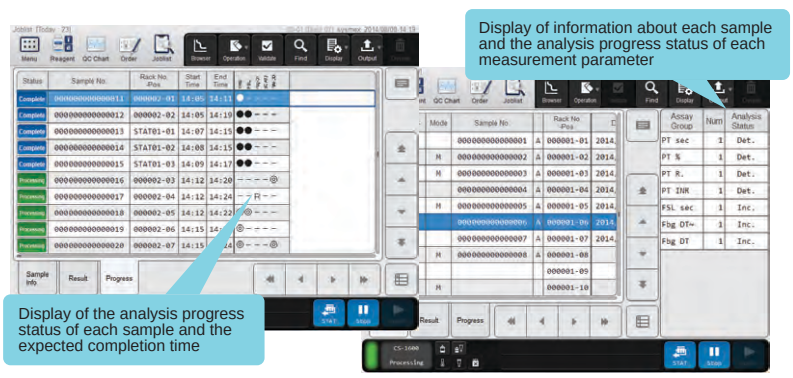

Fig. 4-B *Analysis results screen (Job list)*

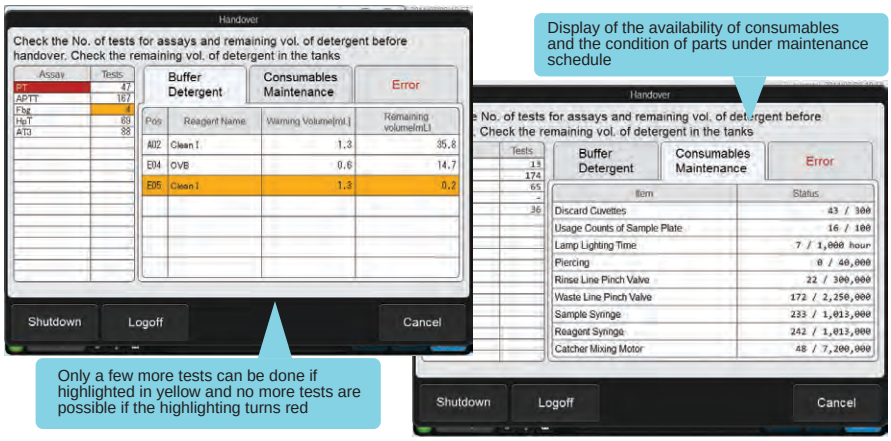

Fig. 4-C *Task handover screen*

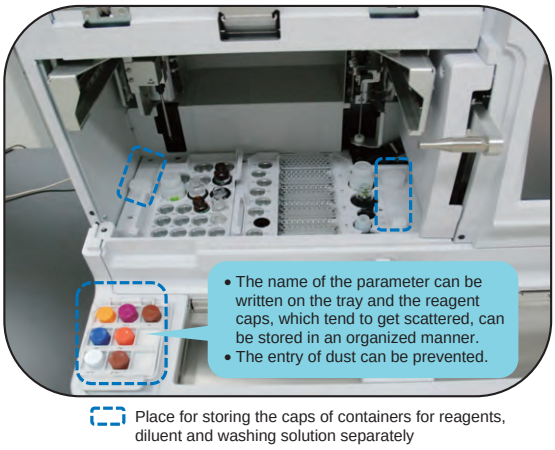

Fig. 4-D *Storing of reagent caps*

DISCUSSION

We obtained good results for both within run and between day reproducibility. None of the measured parameters were affected by the following interfering substances: hemoglobin, conjugated bilirubin, free bilirubin or lipids. Correlations coefficients for CA-530 were very good at 0.976-0.997. Fibrinogen measurements were linear up to about 700 mg/dL, which was higher than the 500 mg/dL limit reported for CA-530 [2)]. The improved linearity of measurement would reduce the number of retest cases and shorten the time to report results.

Usability of the analyzer was examined by evaluating six of its functions. The adequacy of sample volume is currently checked in our hospital by comparing the patient's sample with a reference blood collection sample tube marked with the reference range. Thus, there is some variation between operators. The sample volume check function of CS-1600 allowed objective, standardized assessment and would be useful. The cap piercing function reduces the labor involved in opening the caps, and lowers biohazard exposure and the risk of sample loss when the tube is inadvertently overturned. Additional features such as the task handover screen, analysis results screen (job list), reagent cap storage facility, and auto start-up of the analyzer, enhance usability and make for a more efficient work flow.

CONCLUSION

We obtained good results in an examination of the basic performance of the CS-1600 analyzer. Compared to CA-530, the CS-1600 has additional safety features and functions to improve the efficiency of analysis. Therefore, it is considered to a useful analyzer suitable for routine laboratory tests.

References

1) *Mukaide K. An overview of the fully automated blood coagulation analyzer CS-5100: Sysmex J. 2011; 34 (Suppl. 3): 1-10*
2) *Tanaka M. et al. An examination of the basic performance of the fully automated blood coagulation analyzer CA-530: Sysmex J. 1998; 21(2): 162-170*