Evaluation of Sysmex CA-7000 Automated Coagulation Analyzer

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In the last few years, the Coagulation Laboratory has met an increased number of requests for the samples, not only for routine parameters but also for special tests as APC resistance, D-Dimer and so on. For this reason the instrumentation suitable for the modern Coagulation Laboratory has to grant a high throughput as well as the possibility to perform the special tests within the routine.

Our Laboratory has evaluated Sysmex CA-7000, the newest analyzer for the coagulation laboratory of Sysmex Corporation distributed by DASIT S.p.A. Sysmex CA-7000 performs a wide variety of tests: clotting, chromogenic or immunologic at the same time and therefore it is suitable for the modern Coagulation Laboratory.

(Sysmex J Int 10 : 93 – 95, 2000)

Key Words Automated Coagulation Analyzer, CA-7000

INTRODUCTION

The evaluation of Sysmex CA-7000 (Sysmex Corporation, Kobe, Japan; ***Fig. 1***) distributed in Italy by Dasit S.p.A. has had the following objective:

1. To evaluate the throughput for single test and in conditions of normal routine
2. To evaluate the imprecision in and between the series
3. To evaluate the stability of reagents on board
4. To evaluate the reliability of the result of the prothrombin time (PT) on the patients in Oral Anticoagulant Therapy (OAT)

Fig. 1 *CA-7000*

MATERIALS

Instrument

Sysmex CA-7000 is a completely automated coagulation analyzer that performs clotting, chromogenic and immunological tests. The instrument is equipped with a 100 tube, continuous loading sampler which handles sample racks of 10 tubes which can be capped or open. The reagents are located in a total of 66 positions (some cooled) in a rack system. They can be loaded with three vials of the same reagent in order to increase the auto nomy of the instrument and, the reagents are continuously reloadable. The handling of reagents, standards and controls are made through a bar code scanner system. The instrument is equipped with a hopper which can carry a maximum load of 1200 cuvettes which can also be loaded continuously. All these characteristics make the CA-7000 an ideal instrument for large routine workload. The software is user friendly and enables simultaneous analysis of routine and specialist assays. In addiion, it is possible to use Reflex testing which will enable the next appropriate test to be added to the profile without operator interven-

tion. Additionally, the Multi Dilution Analysis option is useful in screening for factor inhibitors. These last two characteristics make the CA-7000 particularly useful for the specialist laboratory and make it unique in the market.

Reagents

1. The PT is produced by Diagnostic Reagents LTD (UK).
2. Controls, Standards, activated partial thromboplastin time (APTT), Fibrinogen (Fbg), Antithrombin(AT III) and PC are produced by Biopool International (USA).

RESULTS

One of the main features of the instrument to be evaluated was its high productivity because the CA-7000 was proposed for the large routine laboratories. The tests carried out in our laboratory have confirmed the expectations since this instrument can produce more than 500 tests/hour when PT tests are executed at the same time as the APTT, but, more important, its productivity does not drop when PT, APTT, Fbg and AT III tests are loaded in the same routine with samples that can be also pathological. In fact, the throughput has averaged on the 340 tests/hour.
Beyond the throughput, a high data reliability is required by modern Coagulation Laboratories and Sysmex CA-7000 has shown to be able to satisfy also these requirements. To estimate the instrumental imprecision our laboratory has executed the tests of imprecision intra and inter assay. For the first test we have dissolved at the same time some lyophilized plasmas on which we have performed PT, APTT, Fbg, AT III and PC tests at the same time: the result are shown in ***Table 1***.
We have performed also a test of imprecision intra-assay for PT, APTT, Fbg and AT III tests using a pool of fresh plasmas instead of lyophilised plasmas. Results are shown in ***Table 2***.
A further test of imprecision intra-assay has been performed using a pool of patients under Oral Anticoagulant Therapy (OAT) and executing the PT and APTT tests. Results are shown in ***Table 3***.
For the test of imprecision inter-assay we have used lyophilised plasmas dissolved at the same moment and on these plasmas we have performed PT, APTT, Fbg and AT III tests at the same time. The test has been run on lyophilised plasmas with normal and abnormal values for 5 consecutive days. Results are shown in ***Table 4***.
The test on the stability of reagents on board has been performed by repeating every day, for 5 consecutive days, normal and abnormal controls on reagents left on board 24 hours a day. Results are shown in ***Table 5***.
The last point of our evaluation was the comparison of the recombinant PT reagent used in our laboratory with the reagent supplied by Diagnostic Reagents. The comparison has been made on 113 patients in OAT at various levels of INR and the results confirmed the perfect correlation of the two reagents. Results are shown in ***Fig. 2***.

Table 1 *Intra-assay precision (lyophilised plasma)*

Normal plasma					n=20
	PT (Sec)	APTT (Sec)	Fbg (mg/dL)	AT III (%)	PC (%)
$\bar{X}$	11.8	29.8	254	114	110
SD	0.1	0.4	3.6	2.5	0.9
CV (%)	0.6	1.4	1.4	2.2	0.8

Abnormal plasma					n=20
	PT (Sec)	APTT (Sec)	Fbg (mg/dL)	AT III (%)	PC (%)
$\bar{X}$	36.8	71.5	143	59	42
SD	0.6	1.3	2.3	1.7	0.9
CV (%)	1.7	1.8	1.6	2.9	2.2

Table 2 *Intra-assay precision (fresh pooled plasma)*

Fresh pool				n=20
	PT (Sec)	APTT (Sec)	Fbg (mg/dL)	AT III (%)
$\bar{X}$	12.0	26.5	284	112
SD	0.05	0.5	3.5	2.8
CV (%)	0.4	1.7	1.2	2.5

Table 3 *Intra-assay precision (fresh pooled plasma OAT patients)*

OAT fresh pool		n=20
	PT (Sec)	APTT (Sec)
$\bar{X}$	26.6	36.3
SD	0.2	0.2
CV (%)	0.6	0.7

Table 4 *Intra-assay precision (lyophilised plasma)*

Normal plasma				n=20
	PT	APTT	Fbg	AT III
20/09/2000	12.0	30.6	253	123
21/09/2000	12.3	30.8	253	121
22/09/2000	12.1	31.0	242	120
23/09/2000	12.3	30.9	256	128
24/09/2000	12.1	30.5	259	129
$\overline{X}$	12.2	30.8	253	124
SD	0.1	0.2	6.4	3.8
CV (%)	1.1	0.7	2.5	3.0

Abnormal plasma				n=20
	PT	APTT	Fbg	AT III
20/09/2000	36.3	70.4	141	63
21/09/2000	35.4	69.4	141	63
22/09/2000	35.3	72.7	139	68
23/09/2000	36.4	71.2	141	66
24/09/2000	36.9	69.6	137	66
$\overline{X}$	36.1	70.7	140	124
SD	0.7	1.3	1.6	2.1
CV (%)	1.9	1.9	1.1	3.2

Table 5 *Reagent stability (lyophilised plasma)*

Normal plasma				n=20
	PT	APTT	Fbg	AT III
20/09/2000	13.0	30.6	253	115
21/09/2000	12.2	30.7	247	109
22/09/2000	12.4	31.6	245	107
23/09/2000	12.6	30.9	247	111
24/09/2000	12.2	30.6	247	108
$\overline{X}$	12.5	30.9	249	110
SD	0.3	0.4	4.3	3.2
CV(%)	2.7	1.4	1.7	2.9

Abnormal plasma				n=20
	PT	APTT	Fbg	AT III
20/09/2000	36.3	70.4	141	53
21/09/2000	36.4	69.6	138	49
22/09/2000	35.6	72.5	136	54
23/09/2000	34.6	72.4	142	50
24/09/2000	35.1	71.8	136	52
$\overline{X}$	35.6	71.3	139	52
SD	0.8	1.3	2.9	2.2
CV(%)	2.2	1.8	2.1	4.3

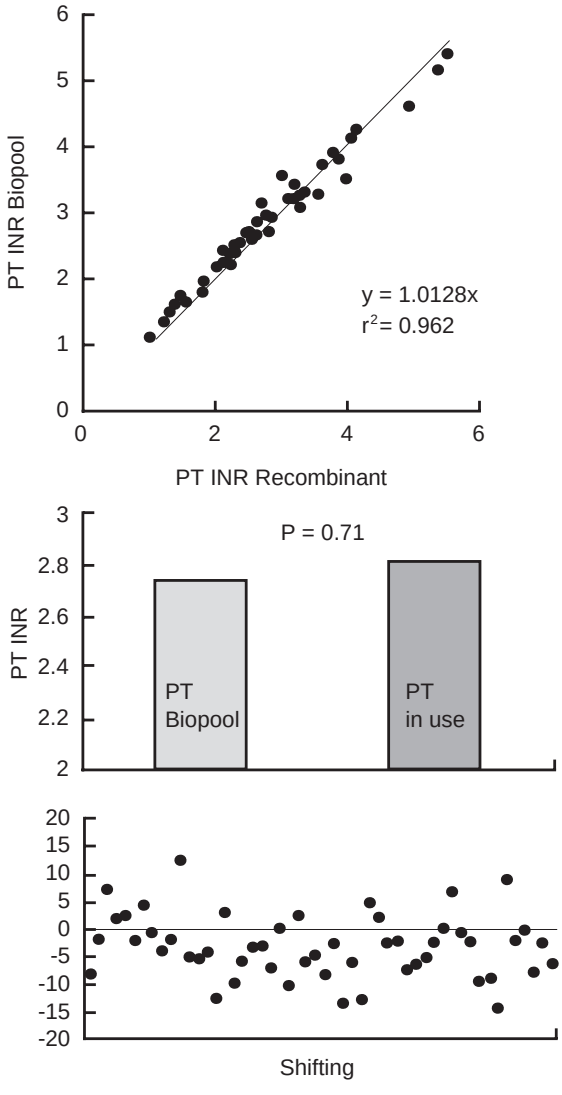

Fig. 2 *Comparison of routine PT reagent and recombinant PT reagent on CA-7000*

CONCLUSION

Sysmex CA-7000 has proved to be an instrument of high analytic throughput that places it among the faster analysers in the market. Its high performances guarantee precision and absolute accuracy and its high productivity make it suitable for large routines. The tests of stability have given very good results and the linearity of reagents is acceptable. The correlation tests of the PT on OAT patients has also given good results.

To conclude, Sysmex CA-7000 looks like an instrument able to always resolve the problems of the laboratory of haemostasis, from the simplests routine tests to the specialistic ones with great reliability of the results and the highest throughput.