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SOLEA 100

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Pierangelo Bellio[a], Simonetta De Angelis[a], Antonio Caliendo[a], Simonetta Santini[b], Gianfranco Amicosante[a], Mariagrazia Perilli[a], Giuseppe Celenza[a*]

[a]Department of Biotechnological and Applied Clinical Sciences, University of l'Aquila, L'Aquila, Italy.
[b]Clinical Laboratory, Regional Hospital "San Salvatore", l'Aquila, Italy.

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PURPOSE OF THE STUDY

The aim of this study is to evaluate the performance of the coagulation analyser BIOLABO SOLEA 100 for the determination of routine parameters (APTT, PT and FIB) and its reagents.

Biolabo Solea 100 is a fully automated coagulation analyser using an optical system to detect coagulation. Chronometric, chromogenic and immunological tests are performed at two wavelengths (405 nm and 620 nm). The analyser is equipped with 8 reading channels and it can execute approximatively 100 test/hour when set in routine panel analysis (PT, APTT, FIB, TT). It has been conceived to meet the needs of medium and small laboratories.

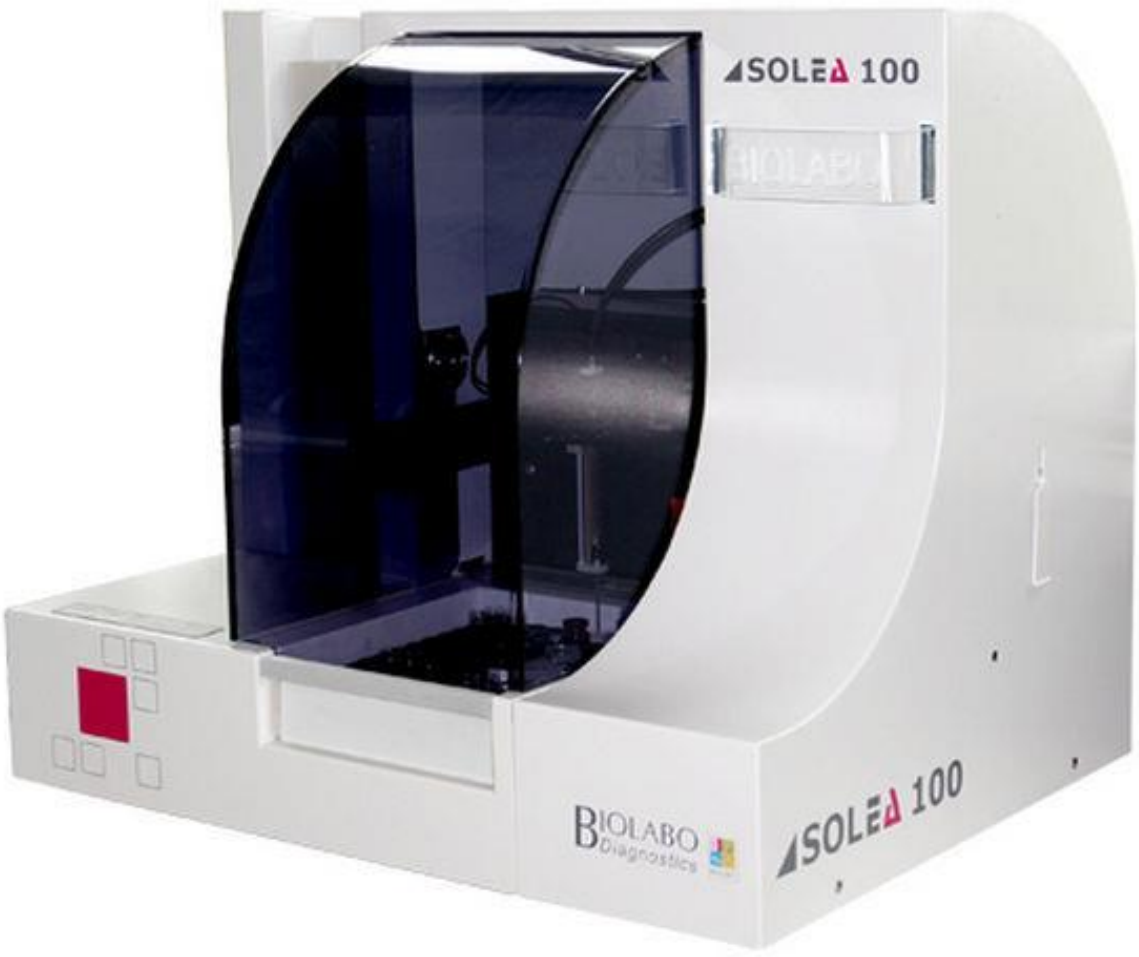


Table 1. Comparison of the results obtain by Stago STA-R and Biolabo SOLEA 100 analysers for Activated Partial Thromboplastin Time (APTT), Fibrinogen (FIB), and Prothrombin Time (PT) using Passing-Bablok method of data analysis.

		Median (range)					
parameter	samples	STA-R	SOLEA 100	linearity verification[a]	slope (95% CI)	intercept (95% CI)	BIAS (%)
APTT *(s)*	184	30.1 (21.6 - 50.5)	29.0 (21.0 - 46.9)	0.87	0.91 (0.85 - 1.00)	1.16 (-1.50 - 3.28)	-4.6
FIB *(mg/dL)*	174	384.0 (80.0 - 966.0)	364.0 (69.1 - 910.1)	0.60	0.98 (0.96 - 1.01)	-18.97 (-29.58 - -10.51)	-7.4
PT *(s)*	103	18.3 (10.6 - 36.0)	18.3 (10.7 - 35.7)	0.91	1.00 (0.99 - 1.00)	0.00 (0.00 - 0.06)	-0.2
PT *(%)*	103	47.8 (18.8 - 121.8)	47.8 (19.0 - 119.9)	0.91	1.00 (1.00 -1.00)	0.00 (-0.14 - 0.00)	0.3
PT *(INR)*	103	1.86 (0.80 - 5.25)	1.86 (0.81 - 5.18)	0.91	1.00 (0.99 - 1.00)	0.00 (0.00 - 0.01)	-0.2

[a]Linear model validity: the Cusum test for linearity is used to evaluate how well a linear model fits the data. The Cusum test for linearity only tests the applicability of the Passing-Bablok method; it has no further interpretation with regards to comparability of the two laboratory methods. A small *P* value ($P<0.05$) indicates that there is no linear relationship between the two measurements and therefore the Passing-Bablok method is not applicable.

Table 2. Reference ranges for activated partial thromboplastin time (APTT), fibrinogen (FIB), and prothrombin time (PT) for Stago STA-R and Biolabo SOLEA 100. The "reference range" is the reference value as reported by the manufacturer, while the "calculated reference range" is the 95% confidence interval of a number of apparently normal subjects.

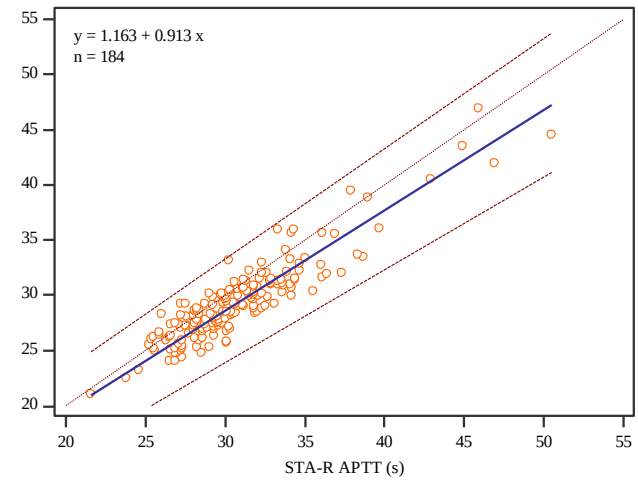
		STA-R		SOLEA 100	
Parameter	samples	calculated range	*p value*[a]	calculated range	*p value*[a]
APTT *(s)*	171	25.3 - 36.3	0.1346	24.0 - 33.4	0.5469
FIB *(mg/dL)*	90	194.6 - 430.4[b]	0.0995	165.5 - 406.0[b]	0.6108
PT *(s)*	39	10.6 - 13.2[b]	0.3326	10.8 - 13.1[b]	0.2596
PT *(%)*	39	82.9 - 117.4[b]	0.4333	84.3 - 116.9[b]	0.5953
PT *(INR)*	39	0.79 - 1.12[b]	0.2376	0.80 - 1.10[b]	0.2006

[a]D'Agostino-Pearson test for Normal distribution ($p>0.05$). [b]Calculated as suggested by CLSI C28-A3 robust method for sample size less than 120.

Figure 1. Passing-Bablok regression analysis for (A) APTT (s), 184 samples; (B) FIB (mg/dL), 174 samples; (C) PT (s), 103 samples; (D) PT (%), 103 samples; (E) PT (INR), 103 samples to evaluate the correlation between STA-R (x-axis) and Solea 100 (y-axis). Regression line is represented with the solid line, theoretical identity with dotted line and the 95% of confidence interval for the regression with dashed line.

Figure 2. Bland-Altman difference plots for (A) APTT (s), 184 samples; (B) FIB (mg/dL), 174 samples; (C) PT (s), 103 samples; (D) PT (%), 103 samples; (E) PT (INR), 103 samples to evaluate the correlation between STA-R and Solea 100.

A



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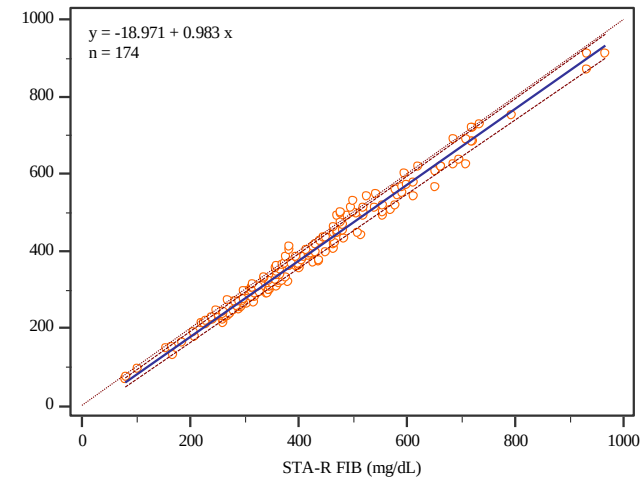

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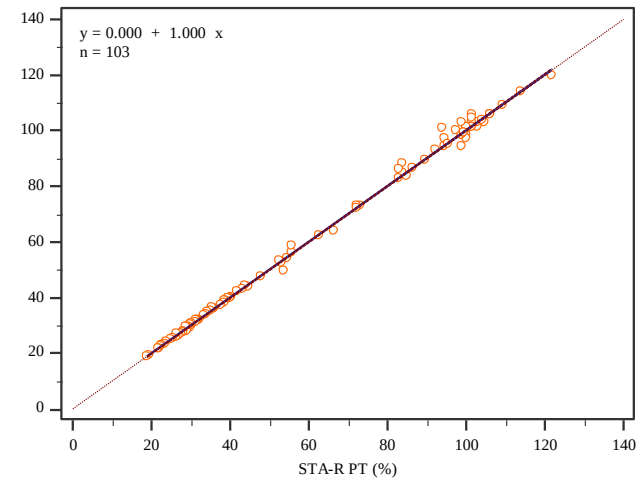

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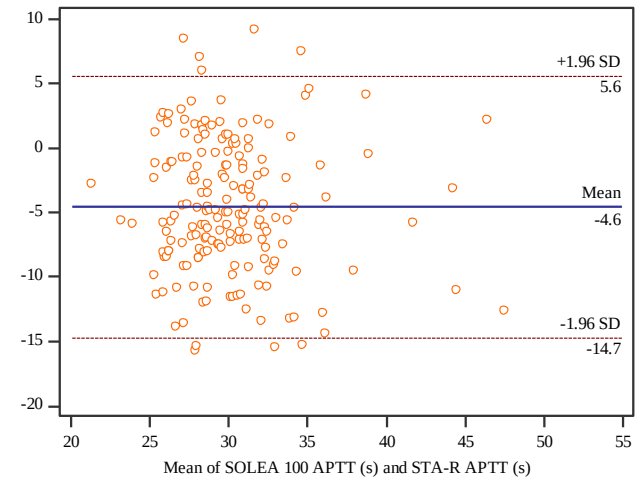

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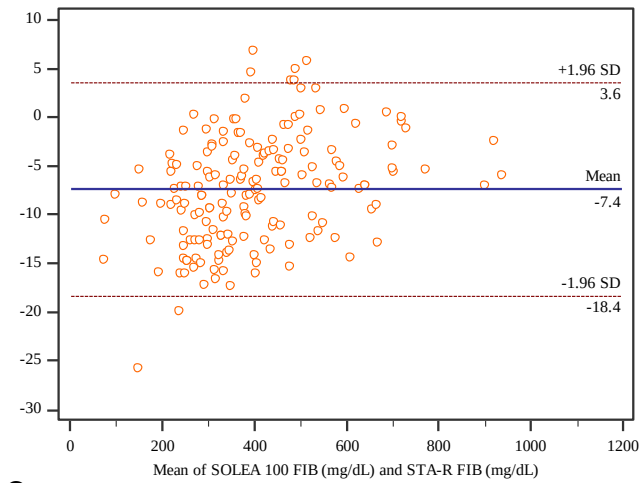

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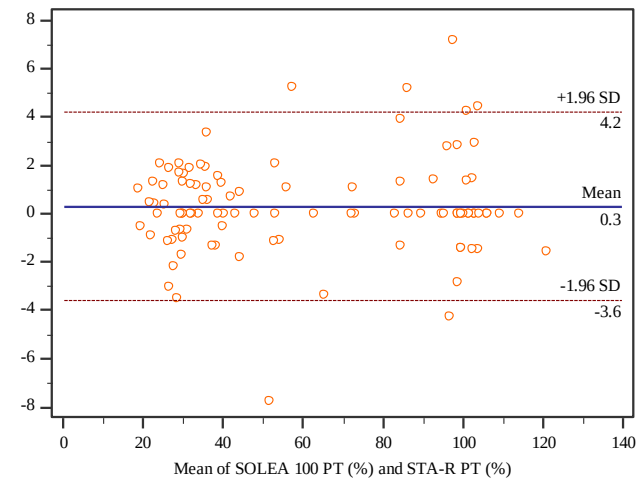

Table 3. Whitin-day imprecision measured on three level control COATROL 1 and Control Plasma 1 (CP level 1) normal, CP level 2 medium pathological, CP level 3 high pathological.

	plasma[a]	target value	calulated value	CV (%)	BIAS (%)
APTT *(s)*	COATROL 1	35.00	34.10	0.90	-2.57
	CP level 3	60.00	61.80	0.40	3.00
FIB *(mg/dL)*	CP level 1	343.00	342.60	4.50	-0.12
	COATROL 2	143.00	133.00	4.41	-6.99
PT *(s)*	CP level 1	12.50	12.50	0.82	0.00
	CP level 2	21.50	21.24	0.97	-1.21
	CP level 3	30.00	29.72	1.22	-0.93
PT *(%)*	CP level 1	90.00	88.91	1.44	-1.21
	CP level 2	36.00	36.02	1.57	0.06
	CP level 3	21.50	21.51	1.85	0.05
PT *(INR)*	CP level 1	1.12	1.12	1.38	0.00
	CP level 2	2.70	2.69	1.61	-0.37
	CP level 3	4.70	4.69	2.01	-0.21

Table 4. Between-day imprecision measured on three level control COATROL 1 and Control Plasma 1 (CP level 1) normal, CP level 2 medium pathological, CP level 3 high pathological. Imprecision (CV%) and Inaccuracy (BIAS%) are used to estimate Total Error (TE) defined as TE=(1.65×CV)+BIAS.

			Between-day Imprecision			Ricos's Criteria (%)			
	plasma	target value	calculated value	CV (%)	BIAS (%)	I	BIAS	TE	TE (%)
APTT *(s)*	COATROL 1	35.00	35.21	2.89	0.60	3.00	2.30	7.25	5.37
	CP level 3	60.00	60.31	4.40	0.52	3.00	2.30	7.25	7.78
FIB *(mg/dL)*	CP level 1	343.00	338.00	3.41	-1.46	3.00	4.80	9.75	7.08
	COATROL 2	143.00	148.00	2.74	3.50	3.00	4.80	9.75	8.02
PT *(s)*	CP level 1	12.50	12.53	1.25	0.24	3.00	2.00	6.95	2.30
	CP level 2	21.50	21.54	3.08	0.19	3.00	2.00	6.95	5.27
	CP level 3	30.00	30.45	2.04	1.50	3.00	2.00	6.95	4.87
PT *(%)*	CP level 1	90.00	89.08	2.17	-1.02	3.00	2.00	6.95	4.60
	CP level 2	36.00	35.13	4.64	-2.42	3.00	2.00	6.95	10.07
	CP level 3	21.50	20.80	3.34	-3.26	3.00	2.00	6.95	8.77
PT *(INR)*	CP level 1	1.12	1.12	2.11	0.00	3.00	2.00	6.95	3.48
	CP level 2	2.70	2.77	4.70	2.59	3.00	2.00	6.95	10.35
	CP level 3	4.70	4.88	3.61	3.83	3.00	2.00	6.95	9.79

Evaluation protocols

Imprecision and accuracy were calculated in accordance with CLSI EP05-A2 guide line by using control plasmas at three decisional levels (normal, medium and high) for each coagulation parameter.

The comparison process was conducted in accordance with CLSI EP09-A3, by comparing analytical results of clinical samples (103 PT, 184 APTT and 174 FIB) from a wide clinical range, to STAGO STA-R mechanical analyzer. Results were analised by Bland Altman graphic method and scatter plot, and by subsequent perpendicular linear regression (Passing Bablok method). Reference ranges for each parameter and analysers were determined as suggested by CLSI C28-A3. Triglycerides, bilirubin, haemoglobin and heparin possible interference was ascertained as recommended by CLSI EP07-A2.

Results

Within and between-day imprecision, inaccuracy and total error are inside the limits of acceptability. Of particular interest is the high degree of correlation between Solea 100 and STA-R concerning PT (seconds, % and INR), which perfectly fit the theoretical identity line (y=0+1.00x). No interferences have been detected in the limits stated by CLSI EP07-A2.

Conclusion

In conclusion, the performances of the optical analyzer Solea 100 are satisfactory and adequate for the determination of the routine coagulation tests. Moreover, they are perfectly comparable to the mechanical systems as STA-R, even taking into account the lack of interference in the tested range.

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