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LETTER TO THE EDITOR

Analytical performance of the new analyzer BA 400 Biosystems with LED technology

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TO THE EDITOR

The BA 400 LED technology (BioSystems S. A., Barcelona, Spain) is a new, fully automated analytical platform designed for clinical chemistry, drugs of abuse, urine chemistries, and special protein and serology assays that uses spectrophotometry, turbidimetry, and potentiometry principles. This analyzer offers an on-board capacity of 60 photometric and three different ion-selective electrode (ISE) tests as well as the possibility to assess lithium. Turnaround times are the same as those declared by the BioSystems S. A. company (400 photometer tests/h and 320 ISE tests/h).

The innovative feature of this analyzer, suitable for a small to medium sized routine system, uses a new technology based on LED (Light Emitting Diodes) optical system which is reliable and stable long-term. This new element increases efficiency with a reduced environmental impact because the LED lumen lifetime is 50,000 hours, with virtually no maintenance, unlike the current lamps.

The photometric range is up to 3.5 absorbance (Abs) and internal resolution is 0.0001 Abs, while a reference photodiode eliminates the interference of scattering light.

The aim of this study was to evaluate the analytical performance of the BA 400, comparing the results obtained to those of the Cobas 8000 (Roche Diagnostics GmbH, Mannheim, Germany) and the Architect c4000 (Abbott Diagnostics, Abbott Park, IL, U.S.A.), according to the

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CLSI guidelines [1].

For the preliminary analytical evaluation of the BA 400, we selected 20 of the clinical chemistry parameters more frequently determined in our clinical laboratory: alanine aminotransferase (ALT), alkaline phosphatase (ALP), amylase, aspartate aminotransferase (AST), C reactive protein, calcium, chloride, cholesterol, creatinine, glucose, iron, lactate dehydrogenase (LDH IFCC), phosphorus, potassium, sodium, total bilirubin, total protein, urea, uric acid, and ferritin. It was used for three months, simulating a workload of 120 - 135 serum samples.

Calibration (if necessary) and CQI execution were carried out for each method, according to the manufacturer's instruction. It is possible to use serum or heparin-plasma sample for all methods of this instrument.

Statistical analysis was carried out with Analyse-it for Microsoft Excel (version 2.26, Leeds, UK).

The within-day imprecision was performed on two different sera pools at low and high concentration of each of the 20 parameters tested and was evaluated in 20 sequential repetition (CV% ranges between 0.1 - 4.3). The between-day imprecision was evaluated, at normal and pathological levels, by carrying out daily measurements of the controls supplied by the manufacturer (Biochemistry control serum level I lot n. 016 and II lot n. 014A were used for all analytes while protein control serum level I lot n. 115 and II lot n. 118 were used for ferritin). The study was assessed during 30 days by using different reagent lots and calibrations. The between-run imprecision was compared with the current analytical quality specifications derived from biological variability [2-4]. The between-run CV% goes from 0.4% (chloride and sodium for the concentrations of 90 mmol/L and 122 mmol/L, respectively) to 4.5% (total bilirubin for the concentration of 15.04 µmol/L) reaching desirable and optimum goals for imprecision in the most cases (Table 1). As seen in Table 1, only 3 (creatinine, total protein, calcium) out of 20 analytes achieved minimum quality specifications, whereas the CV% of the high control level of calcium (3.61 mmol/L) was 3.3%, in line with "state of art" (CV% 3.62). It is noteworthy that sodium reaches a desirable level of quality specification (not based on "state of art") at the concentration of 122 mmol/L and minimum level at the concentration of 158 mmol/L (Table 1).

In addition, percent recovery was assessed according to CLSI protocol. The recovery values obtained range from 96% to 100%.

For each analyte tested, a sample pool at known concentration was serially diluted with deionized water and mixed carefully before beginning the assay. Dilutions were analyzed four times and theoretical values were calculated from measured values of undiluted specimens. Linearity was assessed with Spearman's rank correlation coefficient (r) (0.99 - 1.00). In fact, in Table 1, results of statistical analyses are shown: r values was excellent within the range of values observed in a clinical laboratory, with 14 out of 20 regression coefficients of 1.00.

BA 400 results were compared with those obtained from the Cobas 8000, except for ferritin values which were compared with the results from the Architect c4000. For each of the analytes tested, about 100 routine patient sera were tested displaying a wide range of concentrations. All samples were collected into a VACUETTE® plastic serum tube with a clot activator, separated by centrifugation at 1300 x g for 10 minutes at room temperature and analyzed within 1 hour from collection.

In Table 2 it can be observed that the principle of method is different for calcium, creatinine, glucose, and ferritin. In addition, the linear regression coefficients (R), the indices of Passing-Bablok and confidence interval (CI = 95%) for slope and intercept, the mean bias and 95% CI were calculated with Bland Altman plot analysis [5].

As seen in the table, the statistical analysis of data demonstrates a very good correlation for all analytes. Regression coefficients (R), in fact, vary from 0.965 to 0.999. In the case of creatinine, the R coefficient is the lowest (R = 0.965), because two different methods are employed on two analyzers (Alkaline picrate versus PAP). Results from the comparison method for the creatinine assay confirm that the compensated Jaffe method, used during our study, gives lower values; in fact, for critical serum concentrations of 88 and 135 µmol/L the compensated method gives lower values by 12 - 25% than the enzymatic method used on the Cobas 8000.

Full accordance between the two methods was reached for the majority of analytes because the 95% CI for regression line intercept includes the value zero and the 95% CI for slope includes the value 1.

The Passing-Bablok linear regression analysis for amylase, AST, total bilirubin, total cholesterol, urea, and ferritin revealed a constant difference (intercept 95% CI does not include the value zero) and for C reactive protein a proportional difference (slope 95% CI does not include value 1). However, these differences are minimal and do not interfere with clinical decision levels, while for creatinine proportional and constant differences were found, and these differences are evident from the Bland-Altman plot analysis. Moreover, it shows very limited bias for all analytes.

To conclude, the BA 400 is a very precise and accurate instrument, very easy to use thanks to an elementary software. In addition, LED technology does not need periodic maintenance, unlike traditional systems.

Finally, the BA 400 LED technology is an open analyzer, suitable for small as well as medium clinical laboratories, also in connection with automated solutions.

Table 1. Within-run and between-run imprecision compared with the current analytical quality specifications for the CV% derived from biological variability. The Spearman's rank correlation coefficients are also shown.

Parameter	Within run (n = 20)				Between run (n = 20)			Observed imprecision performance	Linearity
	Mean		SD	CV%	Mean	SD	CV%		
ALP (U/L)	Low	78	1.3	1.6	121	3.7	3.1	Desiderable	1.00
	High	450	9.6	2.1	399	8.5	2.1	Desiderable	
ALT (U/L)	Low	33	0.7	2.1	40	1.3	3.3	Optimum	1.00
	High	163	2.2	1.3	149	4.4	3.0	Optimum	
Amylase (U/L)	Low	61	1.7	2.7	76	1.6	2.1	Optimum	0.99
	High	356	3.7	1.0	213	4.0	1.9	Optimum	
AST (U/L)	Low	12	0.5	4.1	41	1.5	3.5	Desiderable	1.00
	High	105	1.9	1.8	206	3.6	1.7	Optimum	
C Reactive protein (mg/L)	Low	2.8	0.1	3.6	18.0	0.5	2.6	Optimum	1.00
	High	61.0	1.0	1.6	65.0	1.8	2.8	Optimum	
Calcium (mmol/L)	Low	1.91	0.03	1.5	2.17	0.03	1.3	Minimum	1.00
	High	3.77	0.07	1.9	3.61	0.12	3.3		
Chloride (mmol/L)	Low	88	0.4	0.5	90	0.4	0.4	Desiderable	1.00
	High	103	0.2	0.2	122	0.6	0.5	Desiderable	
Creatinine (µmol/L)	Low	41.5	1.8	4.3	102.8	3.1	3.0	Minimum	1.00
	High	209.5	2.4	1.1	237.0	7.4	3.1	Minimum	
Ferritin (µg/L)	Low	12.4	0.4	3.4	41.7	1.1	2.6	Optimum	1.00
	High	308.4	1.6	0.5	86.4	1.6	1.8	Optimum	
Glucose (mmol/L)	Low	3.05	0.11	3.6	5.2	0.14	2.7	Desiderable	1.00
	High	10.7	0.15	1.4	11.5	0.20	1.7	Desiderable	
Iron (µmol/L)	Low	7.6	0.2	2.6	20.9	0.5	2.4	Optimum	0.99
	High	41.0	0.6	1.5	42.1	1.3	3.1	Optimum	
LDH IFCC (U/L)	Low	204	5.8	2.8	207	6.4	3.1	Desiderable	1.00
	High	389	5.4	1.4	396	8.2	2.1	Optimum	
Phosphorus (mmol/L)	Low	1.18	0.03	2.3	1.30	0.03	2.7	Desiderable	1.00
	High	2.75	0.06	2.2	3.00	0.09	3.0	Desiderable	
Potassium (mmol/L)	Low	2.84	0.01	0.5	2.91	0.02	0.6	Optimum	1.00
	High	6.59	0.04	0.6	6.69	0.05	0.7	Optimum	
Sodium (mmol/L)	Low	120	0.5	0.4	122	0.5	0.4	Desiderable	0.99
	High	146	0.2	0.1	158	0.8	0.5	Minimum	
Total Bilirubin (µmol/L)	Low	8.55	0.25	3.0	15.04	0.68	4.5	Optimum	1.00
	High	103.1	1.8	1.8	78.0	3.2	4.2	Optimum	
Total Cholesterol (mmol/L)	Low	3.86	0.11	1.1	4.52	0.09	1.9	Desiderable	0.99
	High	7.29	0.05	0.7	5.99	0.12	1.9	Desiderable	
Total protein (g/L)	Low	53.7	1.0	1.9	63.1	1.3	2.0	Minimum	1.00
	High	81.2	1.2	1.5	85.3	1.6	1.9	Minimum	
Urea (mmol/L)	Low	6.4	0.1	1.6	10.2	0.2	2.0	Optimum	0.99
	High	52.1	0.3	0.6	52.7	1.1	2.1	Optimum	
Uric Acid (µmol/L)	Low	107.6	3.0	2.8	328.9	11.8	3.6	Desiderable	1.00
	High	567.4	8.3	1.4	604.6	16.3	2.7	Desiderable	

Table 2. List of parameters, analytical method, concentration range, regression coefficient (R). Indices of Passing-Bablok regression, confidence interval (CI = 95%) for slope and intercept, and the mean bias and 95% CI confidence interval of the Bland Altman plot analysis.

Parameter	Analytical method		Concentration range	Comparison between BA 400 with Cobas 8000						
	BA 400	Cobas 8000		Regression	Passing Bablok				Bland Altman plot analysis	
					Intercept	Intercept (95% CI)	Slope	Slope (95% CI)	Bias	(95% CI)
ALP (U/L)	AMP [a]	AMP [a]	23 - 493	0.984	-4.16	-9.05/1.07	1.02	0.95/1.07	-1.8	-4.1/ 0.5
ALT (U/L)	IFCC without P5´P [b]	IFCC without P5´P [b]	4 - 568	0.998	0.07	-0.73/0.74	1.05	1.03/1.08	1.6	0.8/ 2.3
Amylase (U/L)	EPS-G7 [c]	EPS-G7 [c]	9 - 418	0.999	7.00	5.05/7.00	1.00	1.00/1.02	6.1	5.7/ 6.5
AST (U/L)	IFCC without P5´P	IFCC without P5´P	6 - 232	0.997	2.18	1.05/2.83	1.05	1.01/1.10	3.3	2.9/ 3.7
C Reactive Protein (mg/L)	Latex Immuno-turbidimetry	Latex Immuno-turbidimetry	0.1 - 205.2	0.997	-0.10	-0.19/0.13	0.96	0.91/0.98	-1.78	-2.55/ 1.00
Calcium (mmol/L)	Arsenazo	NM-Bapta [d]	1.78 - 2.92	0.977	-0.21	-0.30/-0.10	1.09	1.04/1.14	-0.007	-0.016/ 0.002
Chloride (mmol/L)	Direct potentiometry	Indirect potentiometry	83 - 127	0.994	-0.73	-5.70/1.43	1.02	1.00/1.06	1.00	0.70/ 1.20
Creatinine (µmol/L)	Alkaline Picrate	PAP [e]	47.8 - 377.9	0.965	20.65	16.39/24.91	0.67	0.63/0.70	-15.72	-20.07/ -11.36
Glucose (mmol/L)	Glucose Oxidase	Hexokinase	1.05 - 11.71	0.998	0.17	-0.01/0.17	1.00	1.00/1.03	0.17	0.15/ 0.19
Iron (µmol/L)	Ferrozine	Ferrozine	1.78 - 37.01	0.999	-0.30	-0.38/0.22	1.03	1.02/1.04	0.00	-0.07/ 0.06
LDH IFCC (U/L)	Pyruvate (IFCC)	Pyruvate (IFCC)	102 - 595	0.995	-3.96	-9.10/1.99	1.01	0.99/1.03	-1.3	-3.3/ 0.7
Phosphorus (mmol/L)	Phosphomolybdate	Phosphomolybdate	0.55 - 2.38	0.977	0.02	-0.04/0.06	0.96	0.92/1.01	-0.011	-0.025/ 0.003
Potassium (mmol/L)	Direct potentiometry	Indirect potentiometry	2.16 - 7.0	0.988	-0.05	-0.13/0.07	1.00	0.97/1.02	-0.04	-0.05/ -0.03
Sodium (mmol/L)	Direct potentiometry	Indirect potentiometry	120 - 165	0.991	-3.27	-7.38/0.10	1.02	1.00/1.05	0.30	0.20/ 0.50
Total Bilirubin (µmol/L)	DPD [f]	DPD [f]	1.71 - 147.2	0.990	3.48	2.89/3.89	1.03	0.97/1.09	3.74	3.30/ 4.17
Total Cholesterol (mmol/L)	Cholesterol esterase	Cholesterol esterase	1.55 - 9.65	0.996	0.18	0.08/0.21	1.00	0.99/1.03	0.19	0.16/ 0.21
Total protein (g/L)	Biuret	Biuret	14.8 - 83.0	0.991	-0.93	-3.10/0.72	1.02	0.99/1.05	-0.06	-0.30/ 0.19
Urea (mmol/L)	Urease/ GLDH [g]	Urease/ GLDH [g]	1.4 - 46.0	0.998	0.42	0.22/0.50	1.01	0.99/1.03	0.47	0.39/ 0.56
Uric Acid (µmol/L)	Uricase	Uricase	89.3 - 963.9	0.991	1.47	-6.82/8.55	1.00	0.98/1.03	2.65	-1.45/ 6.76

Parameter	Analytical method		Concentration range	Comparison between BA 400 with Architect c4000						
	BA 400	Architect C4000		Regression	Passing Bablok				Bland Altman plot analysis	
					Intercept	Intercept (95% CI)	Slope	Slope (95% CI)	Bias	(95% CI)
Ferritin (µg/L)	Latex Immuno-turbidimetry	CMIA [h]	0.5 - 1480	0.998	-3.45	-4.88/-1.82	0.98	0.96/1.01	-7.90	-10.97/ -4.84

[a] - 2-amino-2-methyl-1-propanol; [b] - pyridoxal 5'phosphate; [c] - 4,6-ethylidene-(G7)-1,4-nitrophenyl-(G1)-α,D-maltoheptaoside (Ethylidene Protected Substrate = EPS); [d] - 5-nitro-5'-metyl-BAPTA; [e] - peroxidase-antiperoxidase; [f] - 3,5-dichlorophenyldiazonium tetrafluoroborate; [g] - glutamate dehydrogenase; [h] - chemiluminescent microparticle immunoassay.

Declaration of Interest:
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