

Comparison of the Performance of Point-of-Care and Device Analyzers to Hospital Laboratory Instruments

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Abstract: Point-of-care testing plays an important role in critical care medicine. This study evaluated the performance of the OPTI CCA and OMNI 9 critical care analyzers by comparing them to our currently used routine instruments (Stat Profile Ultra C, CRT, Dimension RxL, and Cell Dyn). The authors used least squares linear regression, the correlation coefficient, mean bias, and Student *t* test for data analysis. Three levels of aqueous control material were used to perform within-run and between-day evaluation of imprecision, as well as recovery studies, and arterial whole-blood and plasma obtained from critically ill patients were used to perform the comparison study. For within-run and between-day imprecision, the coefficients of variation of analyte measurements obtained with the OPTI and OMNI were within acceptable limits, and the recovery of analytes was close to 100%. Most comparison results from the OPTI and OMNI correlated well with results from currently used routine instruments. Most analytes on the OPTI and OMNI showed acceptable agreement with small mean biases, except pO₂, Na⁺, and Cl⁻. Therefore, users should check these analytes and consider the potential clinical significance of such bias. Otherwise, the OPTI CCA and the OMNI 9 are suitable for analysis of samples from patients in critical care.

Key Words: point-of-care testing, evaluation, precision, accuracy, imprecision

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Point-of-care testing (POCT) plays an important role in the management of critically ill patients and is widely used in the operating room, emergency room, and intensive care unit.

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POCT is no longer performed exclusively by skilled medical technologists but also by multiskilled personnel including nurses, respiratory therapists, emergency personnel medical, physicians, and other medical staff.^{1,2} POCT can improve patient outcomes by providing short therapeutic turnaround time and other advantages.^{3–6}

Several point-of-care (POC) whole-blood analyzers are available commercially, such as the OPTI CCA and OMNI 9. The goals of this study were to determine the precision, accuracy, and reliability of the OPTI CCA and OMNI 9 in terms of imprecision, recovery, and comparison of the analyte results to results obtained with other currently used hospital instruments.

MATERIALS AND METHODS

Equipment

We used 6 analyzers in our study. The characteristics of the instruments are summarized in Table 1. The OPTI CCA is designed for low-volume use and maintenance-free operation.⁷ The OPTI CCA uses an optical fluorescence measurement principle and sensor cassette (Fig. 1) for whole-blood analysis.^{8,9} The OMNI 9 system uses 2 liquid reagents for pCO₂ calibration instead of external gas tanks and uses room air together with 1 liquid solution for the calibration of the pO₂ sensor. The OMNI 9 has a simple touch-screen menu to carry out individual or combined measurements of blood gases, CO₂ oximetry, electrolytes, or metabolites.^{10,11}

Reagents

We used commercial reagents specific for each analyzer. For quality control samples, we used the following materials:

1. Opti Check Multi Control Level 1, 2, and 3, and Standard Reference Control Material Level 1, 2, and 3 (Roche Diagnostics).
2. OMNI COMBI-Trol Plus Multi level 1, 2, and 3 (Roche Diagnostics).
3. Nova Chemistry Control Levels 1 and 2, and Nova Stat Profile Control Multipack Level 1, 2, and 3 (Nova Biomedical).
4. Conformance Chemistry Control Level 1 and 2 (Hematronix, INC, Benicia, CA) for the Dade Behring RxL.

TABLE 1. Characteristics of the Instruments

Model	Type	Analytes	Analytical Principles	Analysis Time (s)	Sample Type	Sample Volume (μ L)	Manufacturer
OPTI CCA	Portable	pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , THb	Optical fluorescence, optical reflectance*	<120	Whole blood, plasma, serum	125	Roche Diagnostics (Roswell, GA)
OMNI 9	Transportable	pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , THb, Hb derivatives, Hct, glucose, lactate, urea	Potentiometry, amperometry, CO-oximetry, conductometry	60–90	Whole blood, plasma, serum	40–161	Roche Diagnostics
Stat Profile Ultra C	Transportable	pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Mg ⁺⁺ , Hct, glucose, lactate	Potentiometry, amperometry, conductometry	300	Whole blood, plasma, serum	225	NOVA Biomedical (Waltham, MA)
Dimension RxL	Laboratory	Na ⁺ , K ⁺ , Cl ⁻ , pCO ₂ , glucose, urea, and other chemical analytes	Potentiometry chemistry technique	90–768	Plasma, serum, CSF, boy fluid	52–103	Dade Berhing (Newark, DE)
CRT	Transportable	Na ⁺ , K ⁺ , Cl ⁻ , pCO ₂	Potentiometry	54	Plasma, serum	220	NOVA Biomedical
Cell Dyn	Laboratory	THb and other hematology analytes	Hematology technique	37	Whole blood	123.5–136.5	Abbott Laboratory (Abbott Park, IL)

*Optical reflectance for measurement of THb.
CSF indicates cerebrospinal fluid; Hb, hemoglobin; Hct, hematocrit; THb, total hemoglobin.

5. CELL-DYN 22 Control (Abbott Laboratories).

The imprecision and recovery study of the OPTI CCA and OMNI 9 were performed using the manufacturer's control materials. The number of measurement days was 20 for between-day analysis. There were 20 repetitions for within-run precision. The test menu evaluated included pH, pCO₂, pO₂,

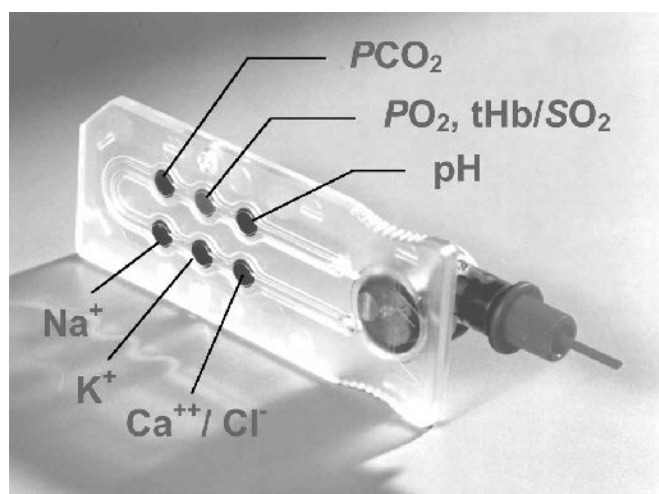


FIGURE 1. The OPTI CCA sensor cassette. The OPTI CCA measures pH, pCO₂, pO₂, Na⁺, K⁺, Ca⁺⁺ (or Cl⁻), and hemoglobin by optical fluorescent and optical reflectance methods using a disposable cassette.

SO₂, sodium (Na⁺), potassium (K⁺), chloride (Cl⁻), ionized calcium (Ca⁺⁺), and total hemoglobin (THb) for the OPTI, and pH, pCO₂, pO₂, Na⁺, K⁺, Cl⁻, Ca⁺⁺, THb, glucose, lactate, and urea for the OMNI.

For the comparison study, arterial whole-blood samples were collected in 3-mL heparinized syringes using the hospital protocols established for critically ill patients. Both analyzers were compared with the SP, RxL, CRT, and Cell Dyn (see Table 1 for individual lists of analytes for each analyzer). The measurement process was finished with in 15 minutes for each sample.

For data analysis, the coefficients of variation (CVs) were calculated for the precision study. Percentage recovery was determined from the between-day data. Recovery values were calculated as follows using the method of Schlebush et al¹²:

$$\text{Recovery (\%)} = \left(\frac{\text{Observed mean of each analyte}}{\text{Target value of each analyte}} \right) \times 100.$$

We used least squares linear regression, the correlation coefficient, mean bias, and Student *t* test for paired differences to analyze data for the comparison study.

RESULTS

Table 2 shows the within-run precision, between-day precision, and recovery results for 9 analytes measured with the OPTI CCA. Within-run CVs were below 1.00% for pH,

TABLE 2. Imprecision and Recovery Data for the OPTI CCA

Analytes	Level	Concentration	Within-run (n = 20), CV (%)	Between-day (n = 20), CV (%)	Recovery (%), n = 20
pH	I	7.12–7.24	0.04 (SD = 0.003)	0.05 (SD = 0.006)	100.2
	II	7.35–7.47	0.10 (SD = 0.007)	0.27 (SD = 0.005)	100.3
	III	7.54–7.64	0.05 (SD = 0.004)	0.06 (SD = 0.006)	100.2
pCO ₂ (mm Hg)	I	63–79	1.21	0.92	98.3
	II	41–49	1.49	0.79	97.7
	III	17–27	1.42	1.04	102.8
pO ₂ (mm Hg)	I	58–82	2.19	2.04	104.0
	II	89–113	1.48	1.43	98.0
	III	132–156	1.83	1.76	96.2
SO ₂ (%)	I	77–83	0.92	0.82	100.4
	II	87–93	0.36	0.76	98.2
	III	93–99	0.58	0.84	100.3
Na ⁺ (mmol/L)	I	117–127	0.38	0.30	101.1
	II	136–150	0.77	0.25	100.8
	III	148–162	0.66	0.35	101.6
K ⁺ (mmol/L)	I	2.6–3.4	0.61	2.36	96.8
	II	4.5–5.3	0.20	0.76	98.9
	III	5.4–6.4	0.43	0.51	99.6
Cl ⁻ (mmol/L)	I	83–93	0.47	0.93	103.7
	II	101–111	0.48	0.46	101.2
	III	114–124	0.26	0.36	99.9
Ca ⁺⁺ (mmol/L)	I	1.40–1.70	0.61	1.00	99.5
	II	1.13–1.33	0.93	0.69	99.8
	III	0.72–0.96	0.97	0.81	100.5
THb (g/dL)	I	17.7–21.7	0.90	0.83	102.3
	II	12.7–15.7	0.52	1.47	101.1
	III	7.6–10.6	0.98	2.19	105.5

CV indicates coefficient of variation; THb, total hemoglobin.

Na⁺, K⁺, Cl⁻, Ca⁺⁺, and THb, and below 2.19% for all other analytes. Between-day CVs were below 2.36% for all analytes, and below 1.05% for pH, pCO₂, SO₂, Na⁺, Cl⁻, and Ca⁺⁺. The CVs for pH showed little variation at 3 levels of control material both for within-run and between-day data sets. The recoveries of all analytes were close to 100%.

Table 3 summarizes the within-run precision, between-day precision, and recovery results calculated for eleven analytes measured with the OMNI 9. Within-run CVs were below 2.89% for all analytes. Between-day CVs were below 3.00%, except for pO₂ at the normal level and for metabolites (all levels of glucose, and urea and lactate at levels II and III). The CVs for pH showed minimum variation at three levels of control material both for within-run and between-day sets. The recoveries of pH, Na⁺, Cl⁻, and THb were close to 100%.

Table 4 summarizes the correlation results between the OPTI CCA and the SP, CRT, RxL, and Cell Dyn. Correlation coefficients (r) ranged from 0.73 to 0.99. The standard errors

of estimate (Sy/x) were less than 1.06 mmol/L for pH, K⁺, and THb, and less than 3.02 mmol/L for all other analytes, except pO₂. Mean biases were less than 1 mmol/L for all analytes, except pO₂ and Na⁺ (OPTI versus CRT) and Cl⁻ (OPTI versus RxL). Statistically significant mean paired differences in bias were not found in pCO₂ (OPTI versus SP), Na⁺ (OPTI versus SP and OPTI versus RxL), and K⁺ (OPTI versus RxL).

Table 5 summarizes the correlation results between the OMNI 9 and the SP, CRT, RxL, and Cell Dyn. Correlation coefficients (r) ranged from 0.73 to 0.99, except Na⁺. The standard errors of estimate (Sy/x) were less than 0.20 for pH, K⁺, and Ca⁺⁺; less than 1.00 mmol/L for THb and metabolites; and less than 3.77 for all other analytes. Mean biases were less than 1 mmol/L for pH, SO₂, K⁺, Ca⁺⁺, THb, glucose, lactate, and urea. Statistically significant differences were not found in K⁺ (OMNI versus SP), glucose (OMNI versus SP), and lactate (OMNI versus SP).

TABLE 3. Imprecision and Recovery Data for the ONMI 9

Analytes	Level	Concentration	Within-run (n = 20), CV (%)	Between-day (n = 20), CV (%)	Recovery (%), n = 20
pH	I	7.15–7.21	0.06	0.09	99.8
	II	7.38–7.44	0.03	0.07	100.0
	III	7.56–7.62	0.02	0.08	99.8
pCO ₂ (mm Hg)	I	65–73	1.16	1.22	95.9
	II	40–46	0.52	0.96	97.9
	III	20–26	0.33	1.10	101.7
pO ₂ (mm Hg)	I	46–70	2.50	1.41	109.0
	II	84–108	2.37	3.15	106.8
	III	127–151	1.51	2.45	104.7
Na ⁺ (mmol/L)	I	115–123	0.64	1.20	99.2
	II	136–144	0.54	0.69	97.9
	III	155–163	0.40	0.77	98.7
K ⁺ (mmol/L)	I	2.9–3.3	0.43	1.42	94.8
	II	4.6–5.0	0.55	1.06	97.7
	III	6.7–7.3	0.37	0.82	98.4
Cl ⁻ (mmol/L)	I	81–89	0.59	0.80	102.8
	II	98–106	0.54	1.05	101.0
	III	117–125	0.48	0.97	100.0
Ca ⁺⁺ (mmol/L)	I	1.40–1.70	0.55	1.61	93.5
	II	1.07–1.27	0.60	1.74	96.6
	III	0.48–0.68	0.97	1.87	110.3
THb (g/dL)	I	7.7–9.5	0.39	0.49	98.4
	II	12.8–14.8	0.94	0.58	97.8
	III	16.8–19.0	0.46	0.57	98.3
Glucose (mmol/L)	I	4.7–6.7	1.54	5.65	94.7
	II	1.8–2.8	2.75	7.87	95.7
	III	18.4–24.4	0.62	5.49	95.8
Lactate (mmol/L)	I	7.7–11.7	1.14	2.21	94.8
	II	1.4–2.4	2.89	5.63	94.7
	III	0.4–1.2	0.00	5.36	93.8
Urea (mmol/L)	I	18.5–24.5	0.82	7.04	97.2
	II	5.8–8.2	1.15	7.12	88.6
	III	1.2–2.6	2.27	4.66	98.5

CV indicates coefficient of variation; THb, total hemoglobin.

DISCUSSION

Imprecision for the OPTI CCA and OMNI 9 was small, with CVs ranging from 0.02 to 3.15%, except for between-day results for the OMNI for all levels of control material for glucose and urea, and except for levels II and III of lactate. For K⁺ the OPTI between-day precision CV at level I was higher than the CVs at other levels. Recovery results for the OPTI for pO₂ at level III and for K⁺ at level I of the control material were slightly lower than the other analytes. For pH, Na⁺, Cl⁻, and THb, the OMNI showed good recovery results.

Westgard¹³ classified the value of the correlation coefficient (r) as very high (r of 0.90–1.00), high (r of 0.70–

0.89), and moderate (r of 0.50–0.69). This classification may overstate the performance for some analytes in this study (Tables 4 and 5). Correlation coefficients are influenced by the ranges of analyte concentrations,¹⁴ some of which were limited in this study. Figure 2 illustrates the effect concentration ranges may have on correlation coefficients. Analytes displaying wide ranges (Figs. 2A–D) may yield higher correlation coefficients than those with narrow ones (Fig. 2E), and because of the span of the graph, scatter may appear smaller. Therefore, in this study we considered values of r of 0.79 or lower (Na⁺ and Cl⁻) as suggestive of poor correlation.

TABLE 4. Correlation Data for the OPTI CCA (n = 61)

Analytes	X	Regression Equation	Sy/x	r	Mean Bias	P Value
pH	SP	$y = 1.03x - 0.25$	0.14	0.98	0.039	<0.05
pCO ₂	SP	$y = 1.02x - 0.66$	2.24	0.97	-0.07	>0.05
pO ₂	SP	$y = 0.92x + 6.82$	9.05	0.99	10.40	<0.05
SO ₂	SP	$y = 0.93x + 5.89$	1.06	0.98	0.64	<0.05
Na ⁺	SP	$y = 0.87x + 18.70$	2.19	0.77	-0.39	>0.05
Na ⁺	RxL	$y = 0.63x + 50.40$	2.38	0.73	-0.43	>0.05
Na ⁺	CRT	$y = 1.07x - 7.58$	2.02	0.81	-2.39	<0.05
K ⁺	SP	$y = 1.01x + 0.04$	0.21	0.92	-0.08	<0.05
K ⁺	RxL	$y = 0.97x + 0.08$	0.12	0.97	0.00	>0.05
K ⁺	CRT	$y = 1.02x - 0.16$	0.13	0.97	0.10	<0.05
Cl ⁻	RxL	$y = 0.72x + 32.12$	3.02	0.82	-3.34	<0.05
Cl ⁻	CRT	$y = 0.96x + 3.81$	2.01	0.93	0.97	<0.05
THb	Cell Dyn	$y = 1.01x - 0.97$	0.90	0.93	0.91	<0.05

Large mean biases with statistically significant paired differences were found for pO₂ (OPTI versus SP and OMNI versus SP), Na⁺ (OPTI versus CRT), and Cl⁻ (OPTI versus RxL and OMNI versus CRT). These biases may be clinically significant depending on the types of patient management decisions being considered.

Precision and recovery of the OPTI CCA have been analyzed by Schlebush et al,¹² who used heparinized whole-

blood samples and performed within-run analyses for pCO₂, pO₂, Na⁺, K⁺, and THb. Our precision and recovery results generally are similar to those of Schlebush et al with the exception of the CVs of K⁺ at 3 levels and of pCO₂ at levels II and III, which in our study were lower than those in the study by Schlebush et al. This difference possibly results from the different sample types used. For between-day imprecision and recovery we used the same materials. Our results are similar to

TABLE 5. Correlation Data for the OMNI 9 (n = 61)

Analytes	X	Regression Equation	Sy/x	r	Mean Bias	P Value
pH	SP	$y = 0.99x - 0.1$	0.13	0.99	0.055	<0.05
pCO ₂	SP	$y = 0.97x - 0.40$	1.70	0.98	1.60	<0.05
pO ₂	SP	$y = 0.94x + 6.09$	8.06	0.99	6.89	<0.05
SO ₂	SP	$y = 0.88x + 11.26$	1.00	0.98	0.54	<0.05
Na ⁺	SP	$y = 0.68x + 42.57$	2.28	0.68	1.05	<0.05
Na ⁺	RxL	$y = 0.47x + 71.52$	2.49	0.60	1.02	<0.05
Na ⁺	CRT	$y = 1.04x - 3.82$	1.50	0.88	-0.95	<0.05
K ⁺	SP	$y = 1.12x - 0.41$	0.16	0.96	-1.01	>0.05
K ⁺	RxL	$y = 1.04x - 0.21$	0.12	0.98	0.07	<0.05
K ⁺	CRT	$y = 1.10x - 0.53$	0.07	0.99	0.16	<0.05
Cl ⁻	RxL	$y = 0.65x + 34.91$	3.77	0.73	1.10	<0.05
Cl ⁻	CRT	$y = 0.89x + 6.16$	2.95	0.84	5.41	<0.05
Ca ⁺⁺	SP	$y = 1.08x - 0.03$	0.09	0.84	-0.06	<0.05
THb	Cell Dyn	$y = 0.92x + 0.47$	0.81	0.93	0.39	<0.05
Hct	SP	$y = 0.95x + 2.97$	1.81	0.97	-1.41	<0.05
Glucose	SP	$y = 1.08x - 0.95$	0.69	0.99	0.17	>0.05
Glucose	RxL	$y = 1.08x - 0.56$	0.82	0.98	-0.20	<0.05
Lactate	SP	$y = 0.76x + 0.69$	0.42	0.98	0.12	>0.05
Urea	RxL	$y = 1.01x + 0.15$	0.46	0.99	-0.22	<0.05

Hct indicates hematocrit; THb, total hemoglobin.

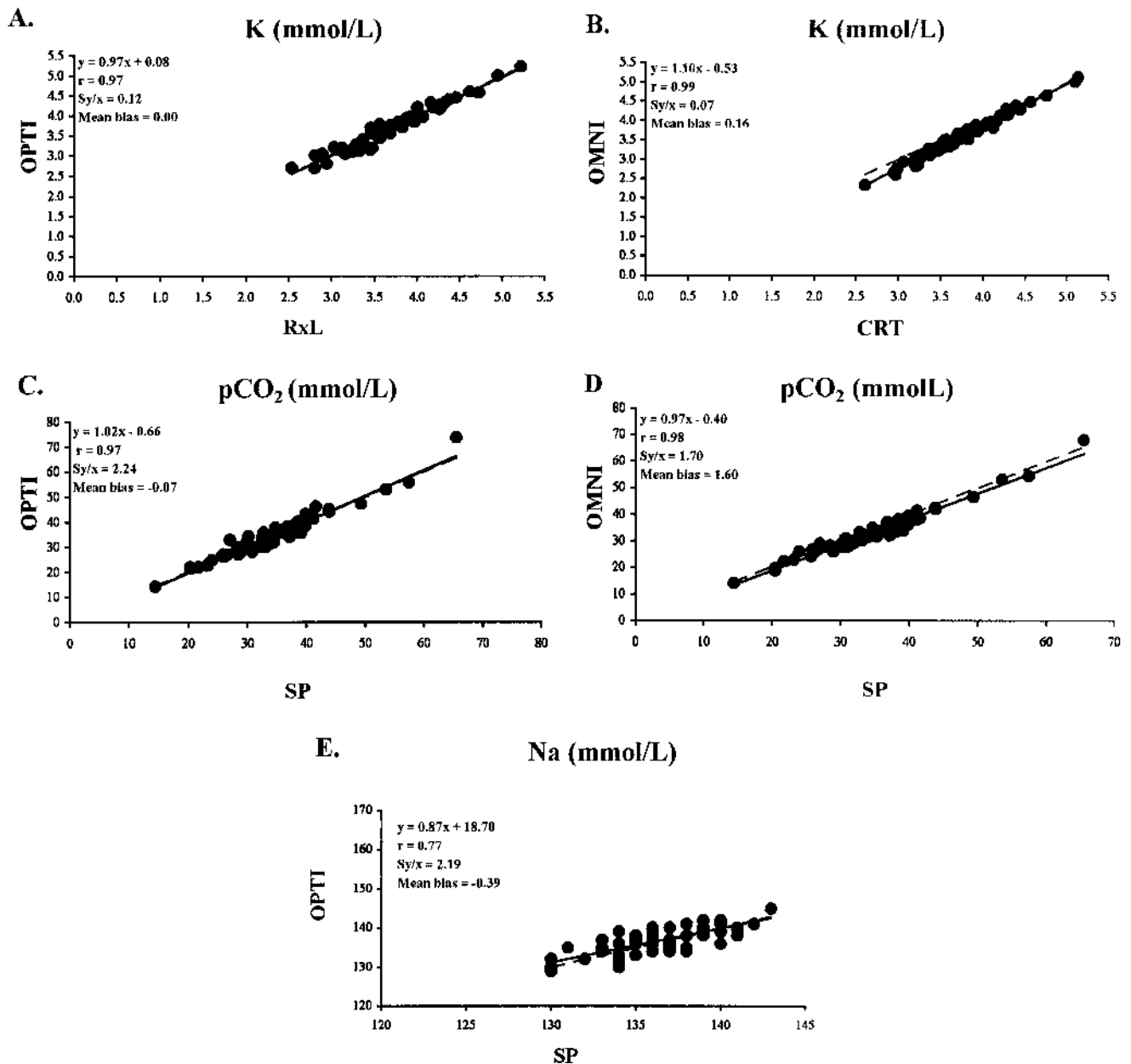


FIGURE 2. Examples of correlative data from study instruments. See text for explanation of data. (A–D) Wide analyte ranges and high values of *r*, the correlation coefficient. (E) Narrow range and poor correlation.

Schlebusch et al study with the exception of K^+ . For pCO_2 , our study showed the CVs of all levels were lower than those reported by Schlebusch et al. Our correlation results were similar to those of Schlebusch et al for pH, pCO_2 , K^+ , and THb, with the exception of pO_2 and Na^+ (see Figs. 4 and 6 in Schlebusch et al¹²).

The OMNI 9 uses electrochemical biosensors to measure metabolites (glucose, lactate, and urea). The measurement principle is based on analyte oxidation following diffusion from the whole-blood sample to the enzyme layer. Kost et al¹⁵

have evaluated the precision of glucose and lactate measurements with whole-blood trilayer biosensors by using three levels of control material. CVs of glucose were less than 2.98%, and CVs of lactate were less than 3.94% for within-day and between-day. Our results were similar to those of Kost et al's study, except that between-day CVs of glucose and lactate (levels II and III) were more than 5%.

Performance evaluation of POCT analyzers is an essential first step in the selection of appropriate instruments for POCT applications. Advantages of point-of-care analyzers in-

clude decreased therapeutic turnaround time (TTAT) and immediate decision support for clinicians managing critically ill patients.¹⁶ Although POCT is common in the United States, it is not used frequently in Thailand. Handheld glucose meters represent the most common form of POCT seen in wards and outpatient clinics in Thai hospitals. We have critical care analyzers in our laboratory in the same area servicing the emergency unit. Implementation of POCT, such as bedside measurement of blood gases, electrolytes, coagulation factors, and metabolites in Thai hospitals will be challenging and will depend on the situation, budget, and policy of each hospital.

To assure excellent quality of the results and timely information for the physician, connectivity should be implemented in parallel with testing. Connectivity is required for bidirectional communication between POC instruments at all sites and the main laboratory. Connectivity systems may require significant expenditures. The training of laboratory personnel, medical students, and nurses to use POC instruments correctly also represents a challenge. Knowledge about the prevention of medical errors in POCT must be conveyed to personnel before they use POCT systems. Therefore, the anticipated growth of POCT in Thailand will be constrained by these factors. The performance results provided in this study will help facilitate the development of the professional practice of point-of-care and near-patient testing in Thailand.

CONCLUSIONS

The OPTI CCA and OMNI 9 demonstrated good precision with CVs of analytes in within-run and between-day trials within acceptable limits and recovery percentages close to 100%. These analyzers showed acceptable correlation when compared with hospital analyzers (SP, RxL, CRT, and Cell Dyn) currently in use. We found the OPTI CCA easy to use and well suited for low and medium volume tests. The OMNI 9 simultaneously measures several important analytes using one patient sample to conserve blood volume and in our clinical laboratory, is well suited to performing medium and high volume tests for critically ill patients.

The results of our study confirm that both of these POC analyzers can be used with patient samples from critical care, although clinically significant biases in a few analytes raise a cautionary note. We anticipate the growing use of these types of whole-blood analyzers in Thailand in critical care settings,

such as the operating room and intensive care unit. Laboratorians carry the professional responsibility for assuring that these instruments used at the point of care remain accurate and precise, and also that they provide consistent results in relation to other instruments used in the clinical laboratory.

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