

Analytical performance of a portable critical care blood gas analyzer

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Abstract

The portable blood gas analyzer OPTI Critical Care Analyzer was evaluated in comparison to routine laboratory assays using heparinized blood samples of adults and newborns. Within-run imprecision studies were performed with native blood using tonometry to adjust blood gas concentrations. The results obtained show a very close agreement between the OPTI system and the comparison methods for all parameters tested: hemoglobin ($y = 1.00x - 0.2$ g/l, $r = 0.997$, $n = 81$), sodium ($y = 1.13x - 18.7$ mmol/l, $r = 0.951$, $n = 79$), potassium ($y = 1.03x - 0.04$ mmol/l, $r = 0.972$, $n = 79$), pH ($y = 1.03x - 0.29$, $r = 0.958$, $n = 57$), $p\text{CO}_2$ ($y = 1.03x - 1.14$ mm Hg, $r = 0.988$, $n = 57$) and $p\text{O}_2$ ($y = 1.07x - 0.85$ mm Hg, $r = 0.995$, $n = 57$). The coefficients of variation for the within-run imprecision were below 1.1% for sodium and hemoglobin, and below 2.6% for all other parameters, except for $p\text{CO}_2$ with coefficients of variation up to 3.6% at low calibration gas concentrations. Due to this analytical performance and its portability, the OPTI system is well suited for low to medium test frequencies and immediate use in emergency rooms, intensive care or surgery units. © 2001 Elsevier Science B.V. All rights reserved.

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1. Introduction

Blood gases, pH, electrolytes, hemoglobin, beside glucose and coagulation parameters are the most important tests in intensive care and emergency medicine. Whereas glucose monitoring in a point-

of-care setting has been established for a long time, the self-contained blood gas analysis only became possible with the introduction of maintenance-free devices during the last few years [1–7]. Point-of-care blood gas and electrolyte testing reduces pre-analytical errors because it shortens the time between blood sampling and measurement compared to centralized testing. This prompt testing decreases the time for ongoing changes in the concentrations of the constituents in the sample [8,9].

The OPTI Critical Care Analyzer is designed for convenient determination of the concentrations of electrolytes, hemoglobin, blood gases and pH as well as oxygen saturation using a disposable multi-analyte

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cassette. The analytical performance of the OPTI system was investigated vs. routine laboratory assays.

2. Materials and methods

2.1. Test principle of the OPTI Critical Care System

The OPTI Critical Care System (Roche Diagnostics, Roswell, GA, USA) consists of a self-maintained instrument (Fig. 1) and the ready-to-use multi-analyte sensor cassettes (Fig. 2). Calibration, lot number and expiration date information from the sensor cassette is scanned into the OPTI Critical Care Analyzer via the barcode label on the packaging using the on-board bar code reader. The cassette is placed in the sample measurement chamber, where it is incubated and automatically calibrated. Sample testing is performed by placing a syringe in the aspiration port where the sample is automatically aspirated. After a calibration and equilibration time of 150 s, the sensor cassette is measured using optical fluorescence. After measurement, the sensor cassette is removed and discarded.

2.2. Method comparisons

The comparison experiments for hemoglobin and electrolytes were performed vs. Cell Dyn (Abbott Laboratories, Abbott Park, IL, USA) and EFOX flame photometer (Eppendorf, Hamburg, Germany) using 50 heparinized venous blood samples from adults and 31 umbilical cord blood samples from newborns. For blood gas analyses, 57 heparinized arterial blood samples from adults were analyzed in parallel with the Corning 178 analyzer (Bayer Diagnostics, Munich, Germany). No data was excluded for method comparison regression analysis.

2.3. Imprecision studies

The within-run imprecision study was performed with heparinized blood samples. The blood gas concentrations were adjusted by tonometry using three different calibration gases. The number of repeats per series was 10.

The day-to-day imprecision and recovery was determined by using the controls of the system, OPTI-Check Multianalyt Control (Roche Diagnostics). Two different lots of OPTI cassettes were used within a 2-month period. The number of measurement days was 8.



Fig. 1. OPTI Critical Care System: analyzer.

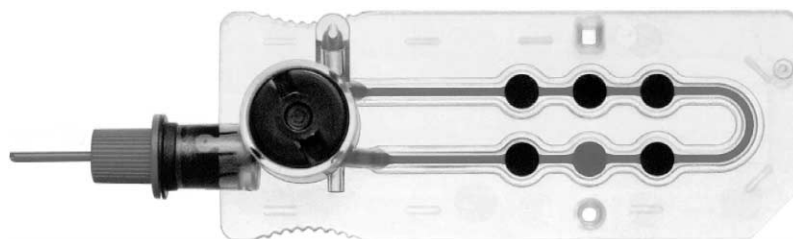


Fig. 2. OPTI Critical Care System: test cassette.

2.4. Acceptance study

A standardized questionnaire was used to determine the acceptance of the system by each of five technicians who worked with the system.

3. Results and discussion

3.1. Imprecision

The within-run imprecision results using heparinized blood samples and tonometry for the blood gas analyses, and day-to-day imprecision results us-

ing OPTI-Check multianalyte controls are shown in Tables 1 and 2. All the coefficients of variation for a 10-fold determination were below 2.6% with the exception of $p\text{CO}_2$, where the low level calibration gas resulted in a CV of 3.6%. For sodium and hemoglobin, the CV was below 1.1%. Imprecision is regarded as very satisfactory for potassium using blood samples. Using the OPTI-Check controls, 2 out of 10 results for potassium were recognized as outliers and excluded. After our evaluation, the potassium sensor of the test cassette has been redeveloped. The new potassium sensor gave an improved imprecision data in preliminary experiments (data not shown). Excellent imprecision was obtained for the other parameters.

Table 1
Within-run imprecision using heparinized blood

Parameter	OPTI		Comparison Method		
	\bar{X}	CV (%)	Analyzer	\bar{X}	CV (%)
Hemoglobin	18.5 g/dl	0.6	Abbott Cell Dyn	18.5 g/dl	1.0
	16.0 g/dl	0.9		15.9 g/dl	0.6
	10.0 g/dl	1.1		10.4 g/dl	0.7
Sodium	140.7 mmol/l	0.7	Eppendorf EFOX	142.9 mmol/l	0.4
	141.1 mmol/l	0.5		143.5 mmol/l	0.4
	140.4 mmol/l	0.4		142.3 mmol/l	0.3
Potassium	4.09 mmol/l	1.8	Eppendorf EFOX	3.92 mmol/l	0.7
	3.66 mmol/l	2.3		3.40 mmol/l	0.7
	5.12 mmol/l	2.6		5.21 mmol/l	1.5
$p\text{CO}_2^a$	67.4 mm Hg	1.8	Corning 178	66.8 mm Hg	1.8
	43.7 mm Hg	3.3		43.0 mm Hg	1.4
	22.1 mm Hg	3.6		21.6 mm Hg	1.1
$p\text{O}_2$	45.4 mm Hg	2.4	Corning 178	45.0 mm Hg	0.8
	104.3 mm Hg	1.9		103.2 mm Hg	1.1
	280.2 mm Hg	1.0		282.7 mm Hg	1.2

CV = coefficient of variation.

^aBlood gas concentration adjusted by tonometry.

Table 2
Day-to-day imprecision and recovery using OPTI-Check Multianalyt Control

Parameter	Control level	Target value	\bar{X}	CV	Recovery (%)
Hemoglobin	I	19.9 g/dl	20.5 g/dl	0.4%	103.0
	II	14.5 g/dl	14.8 g/dl	0.7%	102.1
	III	9.5 g/dl	9.8 g/dl	1.3%	103.2
Sodium	I	116 mmol/l	116.1 mmol/l	1.1%	100.1
	II	141 mmol/l	143.8 mmol/l	0.6%	102.0
	III	158 mmol/l	161.8 mmol/l	1.1%	102.4
Potassium	I	2.6 mmol/l	2.65 mmol/l	6.0%	101.9
	II	4.6 mmol/l	4.73 mmol/l	2.2%	102.8
	III	5.9 mmol/l	5.86 mmol/l	3.5%	99.3
pH	I	7.17	7.18	SD 0.008	100.1
	II	7.39	7.39	SD 0.004	100.0
	III	7.57	7.56	SD 0.009	99.9
$p\text{CO}_2$	I	74 mm Hg	74.8 mm Hg	3.0%	101.3
	II	46 mm Hg	47.0 mm Hg	3.1%	102.2
	III	22 mm Hg	22.6 mm Hg	4.5%	102.9
$p\text{O}_2$	I	67 mm Hg	74.7 mm Hg	2.1%	111.5
	II	100 mm Hg	109.2 mm Hg	2.4%	109.2
	III	148 mm Hg	157.8 mm Hg	2.7%	106.6

$N = 8$ days (within a 2-month period); each day single determination; two different lots of OPTI cassettes. \bar{X} = mean value, CV = coefficient of variation, SD = standard deviation.

3.2. Method comparison

Figs. 3–8 show the results of the regression analyses using the Bablok–Passing procedure.

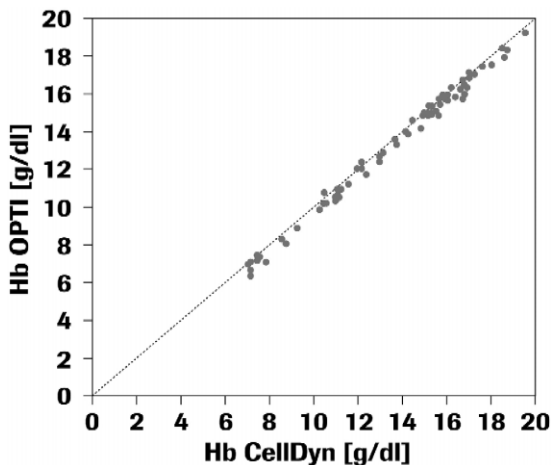


Fig. 3. Method comparison hemoglobin OPTI vs. hemoglobin Abbott Cell Dyn. $y = 1.00x - 0.2$ g/l (Bablok–Passing regression); $r = 0.997$; median of relative differences: -1.4% ; $Sy.x = 0.201$; $n = 81$.

3.2.1. Hemoglobin

Very good agreement for a wide range of samples from 7 to 20 g/dl was achieved, using samples from adults and also umbilical cord blood from newborns (Fig. 3).

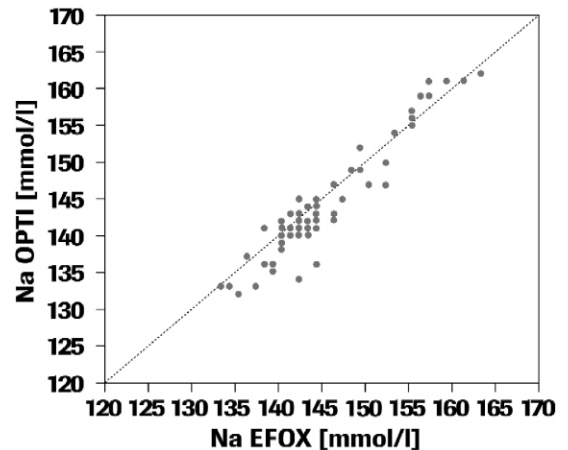


Fig. 4. Method comparison sodium OPTI vs. sodium Eppendorf EFOX. $y = 1.13x - 18.7$ mmol/l (Bablok–Passing regression); $r = 0.951$; median of relative differences: -0.7% ; $Sy.x = 1.565$; $n = 79$.

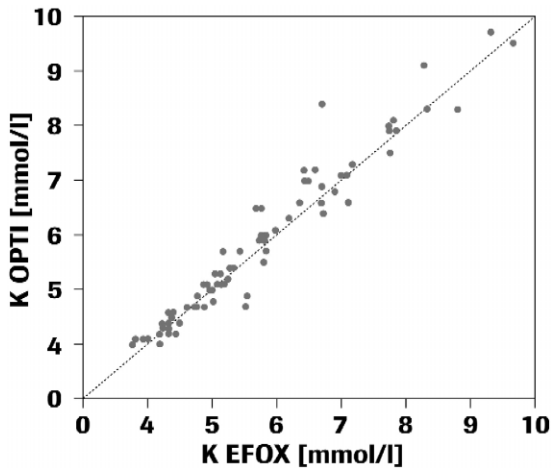


Fig. 5. Method comparison potassium OPTI vs. potassium Eppendorf EFOX. $y = 1.03x - 0.04$ mmol/l (Bablok–Passing regression); $r = 0.972$; median of relative differences: +2.7%; $Sy.x = 0.247$; $n = 79$.

3.2.2. Electrolytes

For sodium, good agreement vs. the EFOX flame photometer was demonstrated. The relative median difference between both assays is with -0.7% small (Fig. 4). The performance vs. the Radiometer ABL 505 analyzer (data not shown) was even better, with $r = 0.964$ and $y = 1.10x - 13.3$ mmol/l. Scattering is also reduced in the comparison vs. the ISE assay ($Sy.x$ 1.34 vs. 1.57). For potassium, a very good calibration is evident from Fig. 5. For umbilical cord

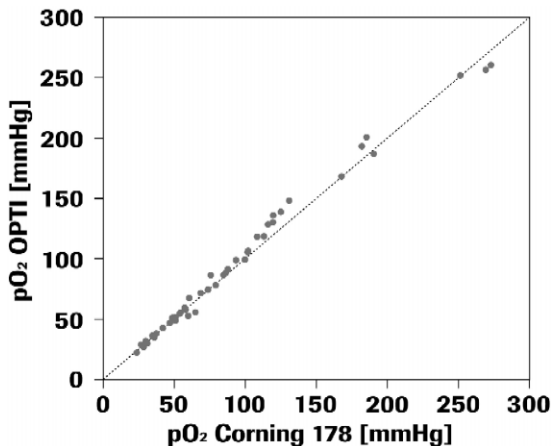


Fig. 6. Method comparison oxygen OPTI vs. oxygen Corning 178. $y = 1.07x - 0.85$ mm Hg (Bablok–Passing regression); $r = 0.995$; median of relative differences: +5.5%; $Sy.x = 4.342$; $n = 57$.

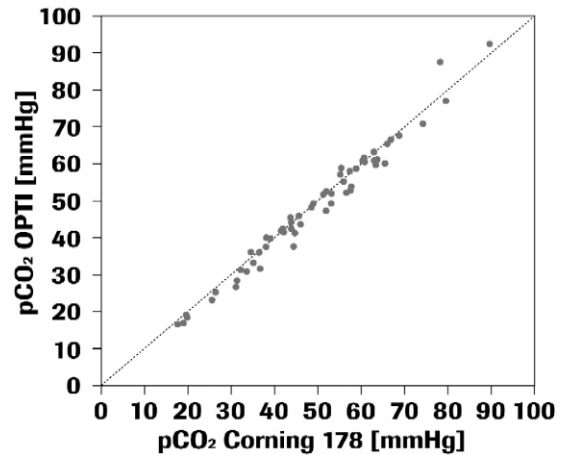


Fig. 7. Method comparison carbon dioxide OPTI vs. carbon dioxide Corning 178. $y = 1.03x - 1.14$ mm Hg (Bablok–Passing regression); $r = 0.988$; median of relative differences: +0.5%; $Sy.x = 1.820$; $n = 57$.

samples, the scattering in the comparison experiment was slightly wider (data not shown) without any consequences for clinical use.

3.2.3. Blood gases and pH

Very good agreement over a wide measurement range, with slightly higher results for OPTI was obtained for oxygen. For pCO_2 , a very close agreement between OPTI and the Corning 178 comparison was found. For the comparison of pH, an inter-

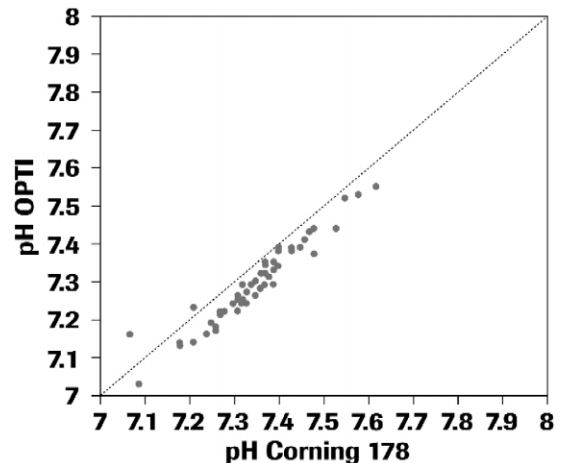


Fig. 8. Method comparison pH OPTI vs. pH Corning 178. $y = 1.03x - 0.29$ (Bablok–Passing regression); $r = 0.958$; median of relative differences: -0.7% ; $Sy.x = 0.021$; $n = 57$.

cept of -0.29 can be seen, but nevertheless, with a relative median difference of -0.7% between the two systems, a high agreement was obtained and there is also a good correlation between the analyzers.

An acceptance study with five operators showed that OPTI was well accepted. It was preferred over two other point-of-care blood gas systems.

4. Conclusion

Overall, the OPTI Critical Care Analyzer showed convincing analytical performance results in imprecision testing and method comparison experiments. With its proven operator convenience, the OPTI Critical Care Analyzer is well suited for medium test frequencies and immediate use in emergency rooms and intensive care or surgery units.

References

- [1] Chance JJ, Li DJ, Sokoll LJ, Silberman MA, Engelstad ME, Nichols JH, Liu X, Mohammad AA, Petersen JR, Okorodudu AO. Multiple site analytical evaluation of a portable blood gas/electrolyte analyzer for point of care testing. *Crit Care Med* 2000;28:2081–5.
- [2] Jacobs E, Nowakowski M, Colman N. Performance of Gem Premier blood gas/electrolyte analyzer evaluated. *Clin Chem* 1993;39:1890–3.
- [3] Lindemans J, Hoefkens P, van Kessel AL, Bonnay M, Kulpmann WR, van Suijlen JD. Portable blood gas and electrolyte analyzer evaluated in a multiinstitutional study. *Clin Chem* 1999;45:111–7.
- [4] Murthy JN, Hicks JM, Soldin SJ. Evaluation of i-STAT portable clinical analyzer in a neonatal and pediatric intensive care unit. *Clin Biochem* 1997;30:385–9.
- [5] Wahr JA, Lau W, Tremper KK, Hallock L, Smith K. Accuracy and precision of a new, portable, handheld blood gas analyzer, the IRMA. *J Clin Monit* 1996;12:317–24.
- [6] Woo J, McCabe JB, Chauncey D, Schug T, Henry JB. The evaluation of a portable clinical analyzer in the emergency department. *Am J Clin Pathol* 1993;100:599–605.
- [7] Zaloga GP, Roberts PR, Black K, Santamauro JT, Klase E, Suleiman M. Hand-held blood gas analyzer is accurate in the critical care setting. *Crit Care Med* 1996;24:957–62.
- [8] Müller-Plathe O, Heyduck S. Stability of blood gases, electrolytes and haemoglobin in heparinized whole blood samples: influence of the type of syringe. *Eur J Clin Chem Clin Biochem* 1992;30:349–55.
- [9] Liss HP, Payne CP. Stability of blood gases in ice and at room temperature. *Chest* 1993;103:1120–2.