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Analitički učinak analizatora Gem® Premier™ 4000 – usporedno istraživanje**Analytical performance of the Gem® Premier™ 4000 – a comparison study**Snježana Hrabrić Vlah¹, Štefica Dvornik, Dino Grdović

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Sažetak

Uvod: Cilj ovog istraživanja bio je usporediti analizator za pretrage uz bolesnika (engl. *point-of-care testing*, POCT) Gem® Premier™ 4000 s referentnim analizatorima. Posebna je pažnja posvećena metodi mjerenja koncentracije tHb/HCT na analizatorima za POCT.

Materijali i metode: Usporedili smo analitički učinak analizatora Gem® Premier™ 4000 s učincima analizatora Ciba Corning 865, Gem® Premier™ 3000 i Dimension RxL, kod određivanja koncentracije parametara acido-bazičnog statusa (pH, pCO₂, pO₂), elektrolita, metabolita, hemoglobina i hematokrita. Za analizator Gem® Premier™ 4000 izračunate su nepreciznosti unutar serije i iz dana u dan. 200 uzoraka pune krvi je analizirano u razdoblju od 30 dana.

Rezultati: Dobiveni su zadovoljavajući rezultati ispitivanja nepreciznosti unutar serije za sve analite (CV ≤ 4,89%), osim za pO₂ (CV = 14,66%) te nepreciznosti iz dana u dan za sve parametre (CV ≤ 4,41%) osim za laktat (1. razina: CV = 8%, 2. razina: CV = 6,59%). Korelacija s usporednim metodama bila je zadovoljavajuća, koeficijenti korelacije za većinu parametara nalazili su se između vrijednosti 0,9458-0,9948, osim za natrij čiji je koeficijent korelacije bio r = 0,86350. Koeficijenti korelacije za hemoglobin bili su izvrsni, r = 0,9923 (Gem® Premier™ 4000 u usporedbi s Ciba Corning 865) i r = 0,9759 (Gem® Premier™ 4000 u usporedbi s Gem® Premier™ 3000). Regresijska analiza po Passing-Babloku pokazala je dobru podudarnost rezultata koncentracija analita, osim kod natrija (Gem® Premier™ 4000 u usporedbi s Ciba Corning 865; y = 34,7500 + 0,7500x) i hemoglobina (Gem® Premier™ 4000 u usporedbi s Gem® Premier™ 3000; y = 23,6923 + 0,8308x).

Zaključak: Rezultati analiza dobiveni usporednim mjerenjima analita između ispitivanog analizatora i referentnih analizatora bili su sukladni. Metoda za određivanje hemoglobina na analizatoru Gem® Premier™ 4000 u potpunosti je sukladna sa metodom na analizatoru Ciba Corning 865, na kojemu se također tHb određuje kooksimetrijom.

Glavne riječi: pretrage uz bolesnika; Gem® Premier™ 4000; hemoglobin

Abstract

Objective: The aim of this study was to compare a new point-of-care testing (POCT) Gem® Premier™ 4000 analyzer with reference analyzers. Special attention was given to the technology of measuring the concentration of hemoglobin and hematocrit on POCT analyzers.

Materials and methods: Analytical performance of the Gem® Premier™ 4000 was compared with Ciba Corning 865, Gem® Premier™ 3000 and Dimension RxL analyzers for pH, pCO₂, pO₂, electrolytes, metabolites and for hemoglobin/hematocrit. Within-run and between-run imprecisions have been determined for the Gem® Premier™ 4000 analyzer. In the period of 30 days, 200 whole blood samples were analyzed.

Results: Satisfactory results were obtained for within-run imprecision for all study analytes (CV ≤ 4.89%), except for pO₂ (CV = 14.66%) and for between-run imprecision for all parameters (CV ≤ 4.41%) except for lactate (Level I: CV = 8%, Level II: CV = 6.59%). The correlation with the comparative methods was satisfactory, correlation coefficients were between 0.9458-0.9948 for most parameters, except for sodium (r = 0.8635). For hemoglobin, correlation coefficients were excellent, r = 0.9923 (Gem® Premier™ 4000 vs. Ciba Corning 865) and r = 0.9759 (Gem® Premier™ 4000 vs. Gem® Premier™ 3000). Passing Bablok regression analysis of analyte concentrations showed good compatibility except for sodium (Gem® Premier™ 4000 vs. Ciba Corning 865; y = 34.7500 + 0.7500x) and hemoglobin (Gem® Premier™ 4000 vs. Gem® Premier™ 3000; y = 23.6923 + 0.8308x).

Conclusions: Results of analyses obtained by the comparative measurement of analytes on Gem® Premier™ 4000 and reference analyzers were compatible. In determining hemoglobin concentration, Gem® Premier™ 4000 is completely comparable with Ciba Corning 865 analyzer, both analyzers using the same co-oximetry method.

Key words: point of care testing; Gem® Premier™ 4000; hemoglobin

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Uvod

Gem® Premier™ 4000 (Inc. Lexington, MA, SAD) je novi analitički sustav dizajniran za pretrage uz bolesnika (engl.

Introduction

Gem® Premier™ 4000 (Inc. Lexington, MA, USA) is a new analytical system designed for point-of-care testing

point-of-care testing, POCT), koji se nedavno pojavio na tržištu. Pojam POCT označava biokemijsko testiranje izvan kliničkih laboratorija, kod operacija, na odjelu intenzivne njege, na odjelu hitne službe i slično (1). POCT nudi brze rezultate te brzo i učinkovito zbrinjavanje bolesnika (2,3). Cilj ovog istraživanja bio je usporediti POCT analizator Gem® Premier™ 4000 s referentnim analizatorima koji su do tada korišteni za testiranje uz bolesnika, a prije njegove instalacije i puštanja u rad (u operacijskoj dvorani). Uporaba analizatora za POCT važna je za brže i pouzdanije donošenje kliničkih odluka prije operacijskih postupaka (kod transfuzije, praćenja acido-bazične ravnoteže i koncentracije glukoze te kod poremećaja disanja). Uporabom analizatora za POCT izostaje vrijeme potrebno za dostavu uzoraka u središnji laboratorij te se u laboratoriju smanjuje broj uzoraka krvi za određivanje vrijednosti parametara kao što su pH, pCO₂, pO₂, elektroliti, metaboliti i hemoglobin/hematokrit (tHb/HCT) (4).

Posebna je pažnja posvećena metodi mjerenja koncentracije tHb/HCT na analizatorima za POCT. Postoje dva tipa mjernih metoda: mjerenje HCT konduktometrijom te izračunavanje koncentracije tHb (Gem® Premier™ 3000) te mjerenje koncentracije tHb kooksimetrijom te izračunavanje HCT (Ciba Corning 865). Uređaj Gem® Premier™ 4000 koristi metodu kooksimetrije te je naš cilj bio otkriti koja je metoda točnija i pouzdanija za mjerenje koncentracije tHb. Za kliničare su koncentracije tHb važne u donošenju odluka o transfuziji krvi.

Materijali i metode

U ovom smo istraživanju usporedili analitički učinak analizatora Gem® Premier™ 4000 s učincima analizatora Corning 865 (Bayer Corporation, SAD), Gem® Premier™ 3000 (Inc. Lexington, MA 02421, SAD) i Dimension RxL (Dade Behring Inc, Newark, DE, SAD) u razdoblju od 30 dana u Kliničkom bolničkom centru Rijeka. Analizatori su, s izuzetkom Dimension RxL, bili postavljeni u operacijskoj dvorani te je njima rukovalo osoblje laboratorija.

Tablica 1. prikazuje analitičke metode analizatora Gem® Premier™ 4000 i usporedne metode ostalih referentnih analizatora. Vrijednosti pH, pCO₂ i elektrolita izmjerene su potenciometrijom, a vrijednosti pO₂, glukoze i laktata amperometrijom. Koncentracija tHb određena je kooksimetrijom, a HCT je izračunan prema formuli $HCT\% = 3,0 \times tHb$.

Ukupno je 200 uzoraka pune arterijske krvi analizirano na analizatoru Gem® Premier™ 4000 i referentnim analizatorima Ciba Corning 865 i Gem® Premier™ 3000 (analiti: pH, pCO₂, pO₂, K, Na, glukoza, tHb, HCT). Od 200 uzoraka, u 130 je dodatno određena i koncentracija laktata i glukoze. Kod određivanja koncentracije glukoze, uzorci plazme (Liheparin) analizirani su na analizatoru Dimension RxL kao referentnom analizatoru. U istraživanju su korišteni uzorci

(POCT), an analyzer that has appeared on the market lately. The term POCT designates biochemical testing out of a clinical laboratory, in surgical wards, intensive care units, emergency departments, etc. (1). POCT provides rapid findings and effective triage of patients (2,3).

The aim of this study was to compare a new Gem® Premier™ 4000 analyzer with those reported for reference POCT analyzers used until then, before its installation in a decentralized location (in the operating room). The use of a POCT analyzer is important to make fast and reliable clinical decisions while the patient is subjected to operation treatment (regarding transfusion, acid-base management, ventilation and glucose management). In addition, POCT analyzers eliminate time delay due to the transport of samples to the central laboratory and reduce the number of blood samples to measure parameters such as pH, pCO₂, pO₂, electrolytes, metabolites and hemoglobin/hematocrit (tHb/HCT) (4).

Special attention was given to technology of tHb/HCT concentration measurement on POCT analyzers. There are two types of technology for tHb/HCT measurement. Some POCT analyzers measure HCT using a technology called conductivity and calculate tHb (Gem® Premier™ 3000). An instrument like Ciba Corning 865 measures tHb using the technology called co-oximetry and calculates HCT. Gem® Premier™ 4000 instrument uses co-oximetry technology, and we wanted to find out which method is more accurate and more reliable for the measurement of tHb concentration. For clinicians, concentrations of tHb are significant for decision about blood transfusion.

Materials and methods

In this study, the analytical performance of the Gem® Premier™ 4000 was compared with the Ciba Corning 865 (Bayer Corporation, USA), Gem® Premier™ 3000 (Inc. Lexington, MA 02421, USA) and Dimension RxL (Dade Behring Inc, Newark, DE, USA) analyzers during the period of 30 days in the Rijeka Clinical Hospital Center, Rijeka, Croatia. These analyzers, except for Dimension RxL, were placed in the operating room and laboratory staff used them in their work.

Table 1 shows analytical methods of the Gem® Premier™ 4000 analyzer and comparable methods of other reference analyzers. pH, pCO₂ and electrolytes were measured by potentiometry, pO₂, glucose and lactate by amperometry. tHb concentrations were measured by co-oximetry and HCT was calculated ($HCT\% = 3.0 \times tHb$).

A total of 200 whole arterial blood samples were analyzed on the Gem® Premier™ 4000 analyzer and on Ciba Corning 865 and Gem® Premier™ 3000 (analytes: pH, pCO₂, pO₂, K, Na, glucose, tHb, HCT), as reference analyzers. In addition, 130 of those blood samples were analyzed for lactate and glucose. In the case of glucose, plasma sam-

TABLICA 1. Analiti i metode na analizatoru Gem® Premier™ 4000 u usporedbi s metodama referentnih analizatora**TABLE 1.** Analytes and methods on Gem® Premier™ 4000 analyzer vs. comparative methods of other examined analyzers

Analytes	Analytical method Gem® Premier™ 4000	Comparison method	Analyzer
pH	Potentiometry	Potentiometry	Ciba Corning 865 Gem® Premier™ 3000
pCO ₂	Potentiometry	Potentiometry	Ciba Corning 865 Gem® Premier™ 3000
pO ₂	Amperometry	Amperometry	Ciba Corning 865 Gem® Premier™ 3000
Glucose	Amperometry	Hexokinase method Amperometry	Dimension RxL Gem® Premier™ 3000
Sodium	Direct Potentiometry	Direct Potentiometry	Ciba Corning 865 Gem® Premier™ 3000
Potassium	Direct Potentiometry	Direct Potentiometry	Ciba Corning 865 Gem® Premier™ 3000
Lactate	Amperometry	Amperometry	Gem® Premier™ 3000
HCT	Calculation HCT=3,0*tHb	HCT=2.941*tHb Conductometry	Ciba Corning 865 Gem® Premier™ 3000
tHb	CO-Oximetry	CO-Oximetry Calculation Hb=0.31*HCT	Ciba Corning 865 Gem® Premier™ 3000

krvi odraslih bolesnika kojima je tijekom operacije trebalo odrediti vrijednosti pH, pCO₂, pO₂, elektrolita, metabolita i tHb/HCT te stoga nije bilo potrebe za dodatnim vađenjem krvi. Uzorci pune krvi izvađeni su u štrcaljke s Li-heparinom kao antikoagulantom (BD Preset™, Plymouth, Velika Britanija) te su analizirani istodobno na svim analizatorima odmah nakon vađenja. Nakon što je uzorak bio ubačen u ispitivani Gem Premier 4000 analizator, mjehurić zraka stvoren kod aspiracijskog postupka bio je eliminiran, a uzorak je zatim bio postavljen na drugi analizator. Kako bi se odredila koncentracija glukoze, heparinizirani uzorci krvi centrifugirani su 10 min na 3.500 okr./min, a plazma je analizirana na analizatoru Dimension RxL.

Nepreciznost u seriji procijenjena je višestrukim (10 puta) određivanjem vrijednosti pH, pCO₂, pO₂, elektrolita, metabolita, tHb i HCT na dva uzorka pune krvi od različitih bolesnika, na jednom s niskom, a drugom s visokom koncentracijom.

Nepreciznost iz dana u dan procijenjena je tijekom 10 dana određivanjem koncentracije istog analita na dva komercijalna kontrolna uzorka s dvije razine koncentracije (Rapid QC Complete Level 1 and Level 2, Bayer HealthCare LLC, MA, SAD) jednom dnevno.

ples (Li-heparin) were analyzed on the Dimension RxL as a reference analyzer. The blood samples that were used in the study were collected from adult patients for whom determination of pH, pCO₂, pO₂, electrolytes, metabolites and tHb/HCT was requested during operations so that no additional blood sampling was required. Whole blood samples were collected in Li-heparin syringes (BD Preset™, Plymouth, U.K.) and analyzed immediately upon collection on all analyzers simultaneously. After having been injected into the Gem® Premier™ 4000, the bubble generated by the aspiration process was eliminated and the sample was injected into another analyzer. As for determinations of glucose, heparinized blood samples were centrifuged (10 min/3,500rpm) and plasma was analyzed on Dimension RxL analyzer.

Within-run imprecision was assessed by multiple (10 times) concentration determinations of pH, pCO₂, pO₂, electrolytes, metabolites, tHb and HCT in two different patient whole blood samples of low and high concentrations, respectively.

During the 10 days, between-day imprecision was assessed by determination of the same analyte concentration in two commercial control samples of two concentration levels (Rapid QC Complete Level 1 and Level 2, Bayer HealthCare LLC, MA,USA) once a day.

Statistička analiza

Statistička analiza izvedena je računalnim programom MedCalc® (MedCalc 9.3.3.0, Mariakerke, Belgija). U svrhu procjene nepreciznosti izračunate su aritmetička sredina (X), standardna devijacija (SD) i koeficijent varijacije (CV). Korelacija je izražena Pearsonovim koeficijentom korelacije (r) uz 95%-tni interval pouzdanosti za svaku pretragu. Za izračun je korištena regresijska analiza po Passing-Babloku (5). Naši kriteriji prihvatljivosti bili su: CV < 5% za nepreciznost, koeficijent korelacije > 0,95 za procjenu stupnja podudarnosti rezultata.

Rezultati

Za određivanje vrijednosti pH, pCO₂, pO₂, elektrolita, metabolita, koncentracije tHb i HCT, nepreciznost unutar serije procijenjena je temeljem rezultata 10 uzastopnih određivanja vrijednosti analita na dvije razine koncentracije različitih uzoraka (1. i 2. razina) (Tablica 2.). Rezultati ispitivanja nepreciznosti unutar serije bili su zadovoljavajući za sve analite (CV ≤ 4,89 %) osim za pO₂ (CV = 14,66 %). Nepreciznost iz dana u dan procijenjena je mjerenjem analita u dva komercijalna kontrolna uzorka 10 dana uzastopce

Statistical analysis

Statistical analysis was performed with MedCalc® (MedCalc 9.3.3.0, Mariakerke, Belgium). In order to determine imprecision, the arithmetical mean (X), standard deviation (SD) and coefficient of variation (CV %) were calculated. Correlation was expressed by Pearson's correlation coefficient (r) with calculation (95%) of confidence interval (CI) for each of the investigated analytes. Passing and Bablok regression analysis (5) of results was used for the calculation.

Our acceptance criteria were: CV < 5% for imprecision, correlation coefficient r > 0.95 for assessment of the level of correlation of results.

Results

For pH, pCO₂, pO₂, electrolytes, metabolites, tHb and HCT, within-run imprecision was determined on the basis of results of 10 successive measurements at two concentration levels of different samples (levels I and II) (Table 2). Results of the within-run imprecision study were satisfactory for all analytes (CV ≤ 4.89%), except for pO₂ (CV = 14.66%). Between-run imprecision was

TABLICA 2. Rezultati procjene nepreciznosti unutar serije i iz dana u dan

TABLE 2. Results of within-run and between-run imprecisions

Analytes	Unit	Level	Within-run imprecision			Between-run imprecision		
			X	SD	CV	X	SD	CV
pH		I	7.42	0.01	0.10	7.34	0.01	0.09
		II	7.67	0.02	0.21	7.54	0.00	0.06
pCO ₂	kPa	I	4.25	0.07	1.66	5.31	0.14	2.58
		II	2.34	0.07	2.99	2.94	0.08	2.87
pO ₂	kPa	I	57.74	8.47	14.66	14.97	0.66	4.41
		II	26.03	1.15	4.42	6.51	0.27	4.12
Glucose	mmol/L	I	5.38	0.06	1.18	4.93	0.19	3.83
		II	5.41	0.11	2.03	2.36	0.10	4.09
Sodium	mmol/L	I	138	0.84	0.61	131	0.82	0.62
		II	142	0.32	0.22	154	0.79	0.51
Potassium	mmol/L	I	3.64	0.07	1.92	4.83	0.05	1.00
		II	4.30	0.00	0.00	6.69	0.14	2.17
Lactate	mmol/L	I	/	/	/	0.63	0.05	8.00
		II	3.58	0.18	4.89	2.28	0.15	6.59
HCT	%	I	0.34	0.01	1.57	0.30	0.01	2.12
		II	0.18	0.00	1.77	0.32	0.01	1.58
tHb	g/L	I	111	0.82	0.74	99	2.22	2.23
		II	59	0.63	1.08	105	1.01	0.97

X – mean; SD – standard deviation; CV – coefficient of variation; Level I – control sample Rapid QC Complete Level 1; Level II - control sample Rapid QC Complete Level 2

(Tablica 2.). Nepreciznost iz dana u dan bila je zadovoljavajuća za sve parametre (CV ≤ 4,41%), s iznimkom laktata (1. razina: CV = 8,0%, 2. razina: CV = 6,59 %).

Naše je istraživanje provedeno usporedbom analizatora Gem® Premier™ 4000 s referentnim analizatorima (Dimension RxL, Ciba Corning 865 and Gem® Premier™ 3000). Tablica 3. prikazuje rezultate usporedbe uzoraka na ispitivanom analizatoru i referentnim analizatorima s izračunanim Pearsonovim koeficijentima korelacije (r). Dobiveni koeficijenti pokazuju dobru korelaciju za većinu parametara (0,9458-0,9948) osim za natrij (Gem® Premier™ 4000 u usporedbi s Ciba Corning 865; r = 0,8635). Koeficijenti korelacije za tHb bili su izvrsni, r = 0,9923 (Gem® Premier™ 4000 u usporedbi s Ciba Corning 865) i r = 0,9759 (Gem® Premier™ 4000 u usporedbi s Gem® Premier™ 3000).

Tablica 4. prikazuje rezultate usporedbe koncentracija analita u uzorcima analiziranih regresijskom analizom po Passing-Babloku. Rezultati dobiveni regresijskom analizom pokazuju dobru podudarnost rezultata između ispitivanog analizatora i referentnih analizatora, osim za natrij (Gem® Premier™ 4000 u usporedbi s Ciba Corning 865; $y = 34,7500 + 0,7500x$) i tHb (Gem® Premier™ 4000 u usporedbi s Gem® Premier™ 3000; $y = 23,6923 + 0,8308x$).

assessed by measuring analytes in two commercial controls for 10 successive days (Table 2). Between-run imprecision was satisfactory for all parameters (CV ≤ 4.41 %), with exception of lactate (Level I: CV = 8.0 %, Level II: CV = 6.59 %).

Our study of the Gem® Premier™ 4000 analyzer was conducted by comparison with reference (Dimension RxL, Ciba Corning 865 and Gem® Premier™ 3000) analyzers. The results of comparison studies of the Gem® Premier™ 4000 analyzer and reference analyzers are shown in Table 3, where Pearson's correlation coefficients (r) are calculated. Correlation coefficients showed good correlation for most parameters (0.9458-0.9948), except for sodium (Gem® Premier™ 4000 vs. Ciba Corning 865; r = 0.8635). Correlation coefficients of tHb were excellent, r = 0.9923 (Gem® Premier™ 4000 vs. Ciba Corning 865) and r = 0.9759 (Gem® Premier™ 4000 vs. Gem® Premier™ 3000).

Results of compared determination of analyte concentrations in samples processed by Passing Bablok regression analyses are presented in Table 4. Results of the regression analysis showed good compatibility between Gem® Premier™ 4000 and reference analyzers, except for sodium (Gem® Premier™ 4000 vs. Ciba Corning 865; $y = 34.7500 + 0.7500x$) and tHb (Gem® Premier™ 4000 vs. Gem® Premier™ 3000; $y = 23.6923 + 0.8308x$).

TABLICA 3. Pearsonovi koeficijenti korelacije

Analyte	Gem® Premier™ 4000 vs. comparison methods	N	r	95% CI
pH	Ciba Corning 865	200	0.9768	0.9695-0.9824
	Gem® Premier™ 3000	200	0.9785	0.9717-0.9837
pCO ₂	Ciba Corning 865	200	0.9466	0.9300-0.9594
	Gem® Premier™ 3000	200	0.9604	0.9480-0.9699
pO ₂	Ciba Corning 865	200	0.9728	0.9641-0.9793
	Gem® Premier™ 3000	200	0.9525	0.9377-0.9639
Glucose	Dimension RxL	130	0.9948	0.9927-0.9963
	Gem® Premier™ 3000	200	0.9923	0.9898-0.9941
Sodium	Ciba Corning 865	200	0.8635	0.8235-0.8950
	Gem® Premier™ 3000	200	0.9458	0.9290-0.9588
Potassium	Ciba Corning 865	200	0.9534	0.9389-0.9646
	Gem® Premier™ 3000	200	0.9857	0.9811-0.9892
HCT	Ciba Corning 865	200	0.9906	0.9876-0.9929
	Gem® Premier™ 3000	200	0.9729	0.9643-0.9794
tHb	Ciba Corning 865	200	0.9923	0.9899-0.9942
	Gem® Premier™ 3000	200	0.9759	0.9683-0.9817
Lactate	Gem® Premier™ 3000	130	0.9833	0.9765-0.9882

TABLE 3. Pearson's correlation coefficients

TABLICA 4. Rezultati regresijske analize po Passing-Babloku

TABLE 4. Results of Passing Bablok regression analysis

Analyte	Gem® Premier™ 4000 vs. comparison methods	N	Regression analysis	Slope (b) 95% CI	Intercept (a) 95% CI
pH	Ciba Corning 865	200	$y = -1.2333 + 1.1667x$	1.1250-1.2000	-1.4800-(-0.9256)
	Gem® Premier™ 3000	200	$y = -0.9262 + 1.1250x$	1.0833-1.1667	-1.2350-(-0.6187)
pCO ₂	Ciba Corning 865	200	$y = -0.3000 + 1.0000x$	1.0000-1.0833	-0.6750-(-0.3000)
	Gem® Premier™ 3000	200	$y = -0.3000 + 1.0000x$	0.9333-1.0000	-0.3000-0.02667
pO ₂	Ciba Corning 865	200	$y = 0.6065 + 0.9948x$	0.9710-1.0149	-0.0791-1.2667
	Gem® Premier™ 3000	200	$y = -8.2500 + 1.3125x$	1.2581-1.3750	-10.0188-(-6.4758)
Glucose	Dimension RxL	130	$y = -0.0607 + 1.0143x$	1.0000-1.0455	-0.2227-0.0000
	Gem® Premier™ 3000	200	$y = 0.0000 + 1.0000x$	0.9825-1.0000	0.0000-0.1219
Sodium	Ciba Corning 865	200	$y = 34.7500 + 0.7500x$	0.6667-0.8182	25.7273-46.3333
	Gem® Premier™ 3000	200	$y = -1.0000 + 1.0000x$	1.0000-1.0000	-1.0000-(-1.0000)
Potassium	Ciba Corning 865	200	$y = -0.2000 + 1.0000x$	1.0000-1.0000	-0.2000-(-0.2000)
	Gem® Premier™ 3000	200	$y = -0.2174 + 1.0435x$	1.0000-1.0625	-0.3000-0.0000
HCT	Ciba Corning 865	200	$y = 0.0100 + 1.0000x$	1.0000-1.0000	0.0100-0.0100
	Gem® Premier™ 3000	200	$y = 0.0686 + 0.8571x$	0.8261-0.8947	0.0592-0.0763
tHb	Ciba Corning 865	200	$y = 1.000 + 1.0000x$	1.0000-1.0127	-0.4747-1.0000
	Gem® Premier™ 3000	200	$y = 23.6923 + 0.8308x$	0.8000-0.8571	21.2857-26.6000
Lactate	Gem® Premier™ 3000	130	$y = 0.0000 + 1.0000x$	1.0000-10000	0.0000-0.0000

Rasprava

Prema rezultatima prikazanim u Tablici 2., nepreciznosti unutar serije i iz dana u dan bile su zadovoljavajuće za sve parametre (CV ≤ 4,89 %), osim za pO₂ gdje je nepreciznost unutar serije bila nešto viša (CV = 14,66%). Manja nepreciznost iz dana u dan od nepreciznosti unutar serije za pO₂ očekivana je zbog višestrukog otvaranja štrcaljke tijekom uzorkovanja za ispitivanje nepreciznosti unutar serije. Prethodno određeni kriterij za nepreciznost iz dana u dan nije bio zadovoljavajući za laktat (1. razina: CV = 8,0 %, 2. razina: CV = 6,59 %). Pearsonov koeficijent korelacije pokazao je dobru korelaciju za većinu parametara (0,9458-0,9948), osim za natrij (Gem® Premier™ 4000 u usporedbi s Ciba Corning 865; r = 0,8635). Rezultati regresijske analize pokazali su dobru podudarnost rezultata ispitivanog analizatora i referentnih analizatora, osim za natrij (Gem® Premier™ 4000 u usporedbi s Ciba Corning 865; $y = 34,7500 + 0,7500x$). Budući da je Ciba Corning 865 stariji tip analizatora POCT, pretpostavljamo da je njegova elektroda za određivanje koncentracije natrija istrošena. To bi mogao biti razlog neprihvatljivih rezultata za natrij. Posebna je pozornost posvećena rezultatima usporedbe metoda za određivanje koncentracija tHb na ispitivanom novom analizatoru i referentnim analizatorima, budući da je određivanje koncentracije tHb vrlo važno pri donošenju odluka o transfuziji krvi kod operacija. Postoje dva

Discussion

On the basis of the results presented in Table 2, within-run and between-run imprecisions were satisfactory for all parameters (CV ≤ 4.89 %), except for pO₂ where within-run imprecision was slightly higher (CV = 14.66%). Better results for between-run imprecision for pO₂ than for within-run imprecision are expected due to multiple opening of syringe during sampling in within-run imprecision testing. The present criteria of between-run imprecision were not acceptable for lactate (Level I: CV = 8.0 %, Level II: CV = 6.59 %). Pearson's correlation coefficients showed good correlation for most parameters (0.9458-0.9948), except for sodium (Gem® Premier™ 4000 vs. Ciba Corning 865; r = 0.8635). Results of the regression analysis showed good compatibility between Gem® Premier™ 4000 and reference analyzers, except for sodium (Gem® Premier™ 4000 vs. Ciba Corning 865; $y = 34.7500 + 0.7500x$). Ciba Corning 865 is the older type of POCT analyzer and we supposed that the electrode for the sodium was almost exhausted. This may be the reason for some unacceptable results for sodium.

Special attention was given to results of comparison of methods for determining the concentration of tHb between the new analyzer and reference analyzers, because tHb values are important to make decisions regarding blood transfusion during operation. There are two types

tipa metoda mjerenja tHb/HCT (4). Analizator Gem® Premier™ 3000 mjeri HCT konduktometrijom te izračunava koncentraciju tHb ($tHb = 0,31 \times HCT$). Drugi slični analizatori (Gem® Premier™ 4000 i Ciba Corning 865) određuju koncentraciju tHb kooksimetrijom te računaju HCT ($HCT = 0,30 \times tHb$ i $HCT = 0,2941 \times HCT$). Koeficijent korelacije za tHb bio je izvanredan ($r = 0,9923$, Gem® Premier™ 4000 u usporedbi s Ciba Corning 865), kao i rezultat regresijske analize ($y = 1,0000 + 1,0000x$, Gem® Premier™ 4000 u usporedbi s Ciba Corning 865), budući da oba analizatora određuju koncentraciju tHb kooksimetrijom. Međutim, kod usporedbe ispitivanog analizatora i analizatora Gem® Premier™ 3000, koeficijent korelacije za tHb bio je dobar ($r = 0,9759$), no rezultat regresijske analize bio je neprihvatljiv ($y = 23,6923 + 0,8308x$, Gem® Premier™ 4000 u usporedbi s Gem® Premier™ 3000). Čak i da su pokazatelji korelacije unutar dozvoljenih granica, ta bi dva mjerenja i dalje pokazivala neslaganje zbog različitih rezultata regresijske analize. Najvjerojatnije je razlog tome razlika u metodama određivanja koncentracije tHb između ta dva analizatora (Gem® Premier™ 4000 i Gem® Premier™ 3000). Metoda za određivanje tHb na analizatoru Gem® Premier™ 4000 u potpunosti je sukladna sa metodom na analizatoru Ciba Corning 865, na kojemu se također tHb određuje kooksimetrijom (6).

Rezultati ispitivanja analitičkog učinka analizatora Gem® Premier™ 4000 pokazuju da je prihvatljiv za svakodnevnu provedbu pretraga uz bolesnika (7,8) te da se može koristiti na mjestima izvan središnjeg laboratorija.

Zahvala

Zahvaljujemo se društvu Ventus-Medical d.o.o. Zagreb za opskrbu uređajima i reagensima u svrhu analitičke procjene analizatora Gem® Premier™ 4000.

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of technology for tHb/HCT measurement (4). Gem® Premier™ 3000 analyzer measures HCT using a technology called conductivity and calculates tHb ($tHb = 0.31 \times HCT$). Other similar instruments (Gem® Premier™ 4000 and Ciba Corning 865) measure tHb using the technology called co-oximetry and calculate HCT ($HCT = 0.30 \times tHb$ and $HCT = 0.2941 \times HCT$). Correlation coefficient for tHb was excellent ($r = 0.9923$, Gem® Premier™ 4000 vs. Ciba Corning 865), as well as the result of the regression analysis ($y = 1.0000 + 1.0000x$, Gem® Premier™ 4000 vs. Ciba Corning 865), because both of them measure concentrations of tHb by co-oximetry. However, correlation coefficient for tHb was good ($r = 0.9759$, Gem® Premier™ 4000 vs. Gem® Premier™ 3000), but the result of the regression analysis was unacceptable ($y = 23.6923 + 0.8308x$, Gem® Premier™ 4000 vs. Gem® Premier™ 3000), when tHb was calculated. Even if the correlation factors are within permitted limits, two measurements can still show discrepancy due to different regression analysis. The most probable reason for that is the difference between methods for determining concentrations of tHb between two analyzers (Gem® Premier™ 4000 and Gem® Premier™ 3000). In determining tHb concentration, Gem Premier 4000 is completely comparable with Ciba Corning 865 analyzer, both analyzers using the same co-oximetry method (6).

The results of analytical performance of the Gem® Premier™ 4000 analyzer show that it is acceptable for daily application in the POCT (7,8), and the analyzer can be installed in decentralized locations.

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