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Evaluation of the i-STAT Blood Gas Analysis System in Cardiovascular Surgery

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Abstract: It is crucial to analyze the blood samples correctly and fast in open heart surgery. Because of that, the reliability of point of care testing (POCT) analysis systems is an essential point for the clinician. This study aimed to investigate the compatibility of the parameters measured with the i-STAT blood gas analyzer and the conventional blood gas analyzer Rapid Point 500 (Siemens Healthcare Diagnostics, USA) in patients who underwent cardiovascular surgery. This clinical study included fifty patients undergoing coronary artery bypass surgery. Fifty whole blood samples were portioned and measured on the i-STAT and RP500 laboratory analyzers — the compatibility between pH, pCO_2, pO_2, Hb, Na^+, K^+, iCa $^{2+}$ and glucose values investigated. There was a good correlation between the i-STAT analyzer with the RP500 analyzer, except Hb and Na^+. Also, all parameters except for Hb and ionized calcium were found to be within acceptable range regarding clinical decision limits. It is essential that the point-of-care devices give accurate results as well as quick results. For this reason, we think that the point of care devices should be subject to external and internal quality control programs, users should be trained regularly, and feedback studies should be done.
Keywords: Blood gas analysis; Point of care testing; Hand-held portable analysis;Coronary artery bypass surgery; Operating room

INTRODUCTION

Blood gas analysis (BGA) is one of the most important tests used in emergency services, intensive and critical care units. Short turn around times is known to improve clinical outcomes by accelerating the decision-making process and patient care. The need for rapid laboratory test results leads to improve point of care testing (POCT) analysis systems as they are easy to use and cost effective. (Jatlow P. 2013, Parvin CA et al. 1996, Kilgore ML et al 1999, Price CP 2002)

Hand-held portable BGA systems are routinely used in some hospitals to provide more rapid, effective and also reliable results especially in critical care units (Nichols JH et al. 2000, Chin Pin Yeo et al. 2011, Dascombe BJ et al. 2007). The i-STAT (Abbott Point of Care, East Windsor, NJ, USA) is one of the portable BGA analysis systems(Chin Pin Yeo et al. 2011). Sediame S et al. studied 92 routine blood gas samples of physiologically normal patients and found that results of i-STAT portable devices were reliable in comparison to conventional laboratory blood gas analyzer. Jacobs E et al. evaluated the performance of the i-STAT Portable Clinical Analyzer and found that the results of operator technique provided reliable results. (Sediame S et al. 1999, Jacobs E et al. 1993).

To our knowledge, there are only a few studies performed with critically ill patients. Oyaert M et al. evaluated the analytical performance of a new cartridge type blood gas analyzer GEM Premier 5000 (Werfen) for pH, partial carbon dioxide pressure, and partial oxygen pressure determination. They emphasized that the evaluated device was suitable for both POCT and laboratory use (Oyaert M et al. 2018).

Lewis T C et al. studied 24 blood gas measurements including pH, partial pressure of oxygen and partial pressure of carbon dioxide to 5043 m. The samples were analyzed using an Abbott i-STAT blood gas analyzer and G3+ cartridges. They found that it is useful for both research and therapeutic measurements in remote, rural and wilderness medicine (Lewis T C et al. 2018).

In our study, we aimed to investigate the compatibility of the parameters measured with the i-STAT blood gas analyzer and the conventional blood gas analyzer Rapid Point 500 (Siemens Healthcare Diagnostics, USA) in patients who underwent cardiovascular surgery.

MATERIALS AND METHODS

Whole blood from patients undergoing coronary artery bypass cases (n=50) collected and analyzed between January 2015 and January 2016. The patients were undergoing CABG with a beating heart or having a cardiac or non-cardiac simultaneous operation not included in this study. Fifty whole blood samples were portioned and measured on the i-STAT and RP500 laboratory analyzers. The evaluation of the i-STAT and Rapidpoint 500 laboratory analyzers were performed using 50 randomly collected samples with PICO50 lithium-balanced heparin whole blood syringe (Radiometer, Denmark) from CABG cases. Two simultaneous blood gas samples were taken from each patient at any time. Thus, a total of 100 samples were collected from 50 patients.

Patients were informed about the study preoperatively, and their written consent obtained from the volunteer patients. One of the samples were first analyzed using the i-STAT in operation room, and the other sample was managed to reach laboratory by staff to perform the analyze with Rapidpoint 500 (Siemens Healthcare Diagnostics, USA).

This process took approximately 2–3 min for each sample. Results of Rapidpoint 500 determined via a calibration curve which is instrument-specifically generated by one-point (every 30 minutes) or 2-point calibration (every 2 hours). Results of i-STAT determined after calibration for each sample. Precision was determined using internal quality control samples, 20 runs performed in a day in duplicate for within-run precision and two runs per day in duplicate each for 20 days performed for between-day precision. Two levels of internal quality control materials are used for both devices every 8 hours a day. The laboratory has an external quality control program attendance that the materials are studied once a month — the compatibility between pH, pCO_2, pO_2, Hb, Na^+, K^+, iCa^{2+} and glucose values investigated.

The i-STAT point-of-care laboratory system uses a single-use disposable cartridge containing chemically sensitive biosensors. CG8+cartridge has a biosensor that consists of amperometric, potentiometric and conductometric circuits. The measurement of pH, pCO_2, Na^+, K^+, ionized (iCa2+) performed with potentiometric ion-selective electrode (ISE) measurement; the amperometric electrodes used for the measurement of pO_2 and glucose. The measurement of hematocrit (Hct) was performed with conductometric analysis.

Hemoglobin (Hb) is automatically calculated using the formula: Hb (g/dL) =Hct (% PCV) x 0.34.i-STAT Cartridges stored in the refrigerator at +4°C and before use, the sealed packaging was opened and left in the room for 5 minutes. The results are available in 2 minutes.

Laboratory testing performed on the Rapidpoint 500 (Siemens Healthcare Diagnostics, USA) for blood gas and electrolyte measurement. RP500 blood gas analyzer cartridges use the potentiometric measurement of pH, pCO_2 Na^+, K^+, and iCa^{2+}. The amperometric electrodes used for measuring pO2 and glucose. Hemoglobin (Hb) measured by the co-oximetry method. Rapid Point 500 blood gas analyzer cartridges were kept in the room temperature (15-30 °C) until use. Every sample saved until the final output. Both devices were kept side-by-side to preserve the equality of the environmental factors when the analysis performed.

For each sample, calibrations of devices, automatic sample integrity, and quality controls performed before an operation.

Within-day and between-day precision studies were performed with the RP500 system. The i-STAT precision studies were calculated according to the data provided by the manufacturer.Duplicate measurements were done in method comparison studies. The study was approved by the Local Ethics Committee of Bozok University Faculty of Medicine and conducted according to the revised Declaration of Helsinki (1998).

The findings of this study were analyzed SPSS 18. The conformity of continuous variables to normal distribution was tested with the Kolmogorov–Smirnov test. The descriptive statistics of continuous variables were expressed as mean ± standard deviation for normal distributions. Linear regression analysis was performed for calculating bias (mean difference) and illustrated using Bland-Altman plots with the differences in parameter values between the methods plotted aganist their means. Total allowable error (TE_A) and desirable bias based on within and between biological variations for each analytes were used (Ricos C et al 2014). Mean Bias was assessed using the formula: mean difference (%)=[(test tube mean-reference tube mean)/ reference tube mean x 100](Ricos C, 2014).The statistical signifiance was calculated using pearson's two-tailed t-test. P-value of <0.05 was considered statistically significant.Paired t-test and Wilcoxon test were used for parametric and nonparametric tests respectively:95% CI – confidence intervals of 95%.

RESULTS AND DİSCUSSİON

The results of patient samples obtained from i-STAT and the reference device RP500 were shown in Table 1. The correlation cofficients (R) between the i-STAT and RP500 were >0.89 for each parameter,with the exception of Hb and Na^+ (0.31, 0.57 respectively).The acquired resultsof parameters from Bland-Altman plots of the the i-STAT and RP500are shown inFigure 1.Statistically significant differences werefound for Hb(p=0.028), pH, pCO_2, pO_2, Na^+, K^+, $Ca^{2+}$and glucose(all parameters p<0.001) between i-STAT and RP500.

The between-day and within-day precision of RP500 were shown in Table 2 and Table 3. The CV % of all parameters of RP500 were < 2.42 .The precision values of i-STAT were shown in Table 4.

The blood gas parameters showed significant biases for pCO_2, Hb,Na^+, iCa^{2+}andglucose parametres(mean bias-3.57% desirable bias±1.8%,mean bias14.18% desirable bias±1.84%, mean bias-1.73% desirable bias±0.23%,mean bias-2.67% desirable bias±0.6%, mean bias-2.17% desirable bias±1.8%) respectively (Table 1).

Lower and upper limits of clinical insignificant difference calculated based on total allowable error (TEa) in RP500 parameters were shown in Table 5, i-STAT parameters were within the indicated limits, with the exception of Hb and iCa^{2+} (Table 5).
In the present study, we compared the results of electrolytes, pH, blood gases, Hb and metabolites in whole blood measured bythe i-STAT analyzer (Abbott Point of Care, East Windsor, NJ, USA) andconventional laboratoryblood gas analyzer (Rapid Point 500, Siemens Healthcare Diagnostics, USA). Also our study compared the correlation between the i-STAT and RP500. These two analyzersshowedhigh correlation (R>0.89) except Na^+ (R=0.57) and Hb (R=0.31).

In a study the analysers of i-STAT and Central Laboratory were compared and there were similar correlation coefficients with the results ofour study(Na^+R=0.56)(Chin Pin Yeo et al 2011).These findings were in contrast to the previously reported excellent results (R=0.84–0.99) between the epocdevice and the i-STAT(Stotler BA,Kratz A 2013,Steinfelder -Vischer J et al 2008,Papadea C et al 2002). In terms of Hb results, we found bad correlation (R=0.31) however other studies showed better correlation results (Luukkonen AA et al 2015,Leino A, Kurvinen K 2011).

Although there were low data between two analyzers in terms of the significance of the mean bias, some studies detected the difference of bias based on the biological variaton database and the external quality control data (Luukkonen AA et al 2015). Significant differences in Hb, pCO_2, glucose values were determined according to the desirable biological variaton database. Despite the absence of desirable bias , the data was evaluated based on the bias value from external quality results and a significant difference was detected.

Table 1. Correlation statisticis between RP500 and i-STAT

	pH	$p0_2$	$pC0_2$	Hb	Na^+	K^+	Ca^{+2}	Glucose
Unit		mmHg	mmHg	g/dL	mmol/L	mmol/L	mmol/L	mg/dL
Slope#	1,02x (-0,94~ 0,53)	1,046x (0,97~ 1,11)	1,003x (0,90~ 1,10)	0,13x (0,015~ 0,25)	0,969x (-48,91~ 62,37)	0,992x (0,93~ 1,05)	1,080x (0,92~ 1,24)	1,020x (0,98~ 1,05)
y-intercept#	-0,202 (0,93~ 1,13)	-13,19 (-21,93~ -4,45)	1,234 (-2,35~ 4,81)	9,22 (7,58~ 10,87)	6,727 (0,56~ 1,37)	0,014 (-0,23~ 0,25)	-0,052 (0,92~ 1,24)	0,340 (-6,72~ 7,40)
RP500	7,45** (7.22~7.60)	93,95** (29~425)	37,25** (27.1~60.8)	10,93** (5.4~10.3)	139,54±6.89 *	4,02±0.64 *	1,12±0.10 *	176,98** (101~359)
i-STAT	7,44** (7.20~7.54)	102,46** (27.5~358.4)	35,92** (23.9~61.1)	12,48** (7.8~16.03)	137,12±4.05 *	4,05±0.63 *	1,09±0.08 *	173,22** (95~348)
Agreement mean¥	0,011 (0,003~ 0,018)	-8,50 (- 13,9~3,10)	1,32 (0,64~2)	-1,55 (-2,98~ -0,11)	2,42 (0,81~4,03)	-0,02 (-0,06~ -0,01)	0,04 (0,02~0,05)	3,76 (1,25~6,26)
Mean Bias (%)	-0,013	9,50	-3,57	14,18	-1,73	0,74	-2,67	-2,17
Desirable bias (%)**	-	-	±1,8	±1,84	±0,23	±1,81	±0,6	±1,8
Acceptance limit₸	±0,11	±12,91	±1,79	-	±0,54	±0,66	±2,58	±0,07
R	0,95	0,97	0,94	0,31	0,57	0,97	0,89	0,99
p-value*	<0,001	<0,001	<0,001	0,028	<0,001	<0,001	<0,001	<0,001
Range of results	7,20~7,60	27,5~425	23,9~61,1	5,4~16,03	128~178	2,8~5,8	0,85~1,42	95~359
N	50	50	50	50	50	50	50	50

*p-value was calculated by pearson's two tailed correlation test.**Mean Bias was assessed using the formula: mean difference (%) = [(test tube mean - reference tube mean) / reference tube mean x 100]. Desirable bias based on within and between biological variations (11). . *Mean±SD; **Median (min-max):Paired t-test and Wilcoxon test were used for parametric and nonparametric tests respectively:95% CI – confidence intervals of 95%.

Table 2. Precision for between-day of RP500 system

Parameter	Level 1 Mean	SD	CV%	Level 2 Mean	SD	CV%
pH	7,12	-		7,31	-	
$p0_2$ (mmHg)	148,41	1,48	0,99	102,57	1,52	1,48
$pC0_2$(mmHg)	69,99	1,69	2,42	42,62	0,73	1,72
Hb(g/dL)	18,09	0,07	0,40	13,9	0,047	0,33
Na^+ (mmol/L)	118,65	0,37	0,31	142,86	0,29	0,20
K^+(mmol/L)	3,26	0,006	0,21	5,30	0,02	0,38
iCa^{+2}(mmol/L)	1,65	0,012	0,75	1,29	0,006	0,53
Glucose(mg/dL)	189,6	1,26	0,66	94,4	0,84	0,89

Table 3. Precision for within-day of RP500 system

Parameter	Level 1 Mean	SD	CV%	Level 2 Mean	SD	CV%
pH	7,11	0,003	0,04	7,30	0,002	0,02
pO_2 (mmHg)	151,9	0,48	0,31	103,78	0,93	0,90
pCO_2(mmHg)	71,52	0,31	0,43	43,26	0,30	0,71
Hb(g/dL)	18	-	-	13,85	0,05	0,38
Na^+ (mmol/L)	118,5	0,2	0,16	142,09	0,15	0,17
K^+(mmol/L)	3,23	0,013	0,40	5,28	0,04	0,78
iCa^{+2}(mmol/L)	1,66	0,004	0,26	1,31	0,004	0,78
Glucose(mg/dL)	191,2	1,78	0,93	94,7	0,82	0,86

Table 4. The precision values of i-STAT

	Level 1			Level 2		
Parameter	Mean	SD	CV%	Mean	SD	CV%
pH	7.165	0.005	0.08	7.656	0.003	0.04
pO_2 (mmHg)	65.1	3.12	4.79	146.5	6.00	4.10
pCO_2(mmHg)	63.8	1.57	2.5	19.6	0.40	2
Hb (g/dL)	10.2	0.44	1.5	16.66	0.50	1.0
Na^+ (mmol/L)	120.0	0.46	0.4	160.0	0.53	0.3
K^+(mmol/L)	2.85	0.038	1.3	6.30	0.039	0.6
iCa^{+2}(mmol/L)	1.60	0.017	1.1	0.84	0.012	1.4
Glucose (mg/dL)	41.8	0.68	1.6	289	2.4	0.8

In a study comparing the results of the reference method with i-STAT from patients undergoing cardiopulmonary bypass and patients in intensive care units, they reported a significant difference for pO_2 values (Stotler BA, Kratz A. 2013). In another study researchers found that the mean biases of pO_2 were statistically significant (Steinfelder-Visscher J et al 2008). In our study we did not find any difference in terms of pO_2 values but significant difference was found for pCO_2, Hb, Na^+, iCa^{2+} and glucose parameters according to desirable mean, based on the acceptable bias data from OneWorld Accuracy External Quality program (Table 1).

Table 5. Comparison of results obtained from i-STAT device within the Clin.Low and Clin.Up calculated based on TE_A% of reference RP500

	TE_A, %	RP500 Clin.Low- Clin.Up	i-STAT
pH	-	7,45 -	7,44
$p0_2$ (mmHg)	-	93,95 -	102,46
$pC0_2$ (mmHg)	±5,7	37,25 35,13-39,37	35,92
Hb (g/dL)	±4,19	10,93 10,48-11,38	12,48
Na^+ (mmol/L)	±0,73	139,54 138,53-140,55	137,12
K^+ (mmol/L)	±5,61	4,02 3,8-4,24	4,05
iCa^{+2} (mmol/L)	±2	1,12 1,10-1,14	1,09
Glucose (mg/ dL)	±5,5	176,98 167,25-186,71	173,22

TE_A: Total allowable error.(11)Based on theseTE_AClin.Low: lower limit of clinically insignificant difference and Clin.Up: upper limit of clinically insignificant difference were calculated.

Hb levels in i-STAT calculated via Hct measured by the conductometry system. Hct analysis has been shown in many studies that it methodically led to interference (Stott RA et al. 1995). The low protein concentration leads to low Hb values due to the significant negative bias in Hct measurement. Also, the reduction of the total conductivity in the electrolytes and colloid-containing infusions affects the result (Stott RA et al. 1995).

We observed a quite high mean difference in calculated Hb(%14)between the i -STAT and the Rapid Point 500 analyzer (Table 1).In case of measuring Hb levels lower than real levels may cause unnecessary intraoperative blood transfusion and a volume overload which can result with serious complications such as intraoperative cardiac insufficiency, hemodynamic instability. And in case of measuring it higher than normal levels and deficient blood transfusion would result with inadequate tissue oxygenation.

In the study comparing three different blood gas analyzers (EPoC, RL1265, and RP500) they found the significant mean difference in Hb values measured with the three analyzers, similar to the results of our study (Luukkonen AA et al. 2015). Also, abnormal electrolyte levels may cause incorrect Hb results as shown in the study used samples from patients undergoing CABG. They found a decrease in the conductivity of samples of these patients and they suggest that the decrease could affect the conductometric measurement of Hb (Steinfelder-Vischer J, 2008). The variation of Hb results of our study could be derived from the altered conductivity of the samples of patients undergoing CABG.

One of the most affected parameters of preanalytical factors (such as air contamination, low volume or drug use (propofol, thiopental sodium) is pCO_2. The significant difference of pCO_2 values could be attributed to the fact that it is easily affected by preanalytical errors.

In a study, they found that all parameters except lactate, Hb, Na^+, and pCO_2 were within acceptable limits according to TEa (Luukkonen AA et al. 2015). Similarly, in our study, all parameters, except Hb and iCa^{2+} were found to be within the indicated limits according to TEa.

One of the limitations of our study was our results can be only limited to a particular patient group. Also, studies with larger sample groups could provide more information as we had a smaller sample group size.

CONCLUSION

In conclusion, according to our results, there was a good correlation between the i-STAT analyzer with the RP500 analyzer, except Hb and Na+. Also, all parameters except for Hb and ionized calcium were found to be within acceptable range regarding clinical decision limits. It is essential that the point-of-care devices give accurate results as well as quick results. For this reason, we think that the point of care devices should be subject to external and internal quality control programs, users should train regularly, and feedback studies should be doing.

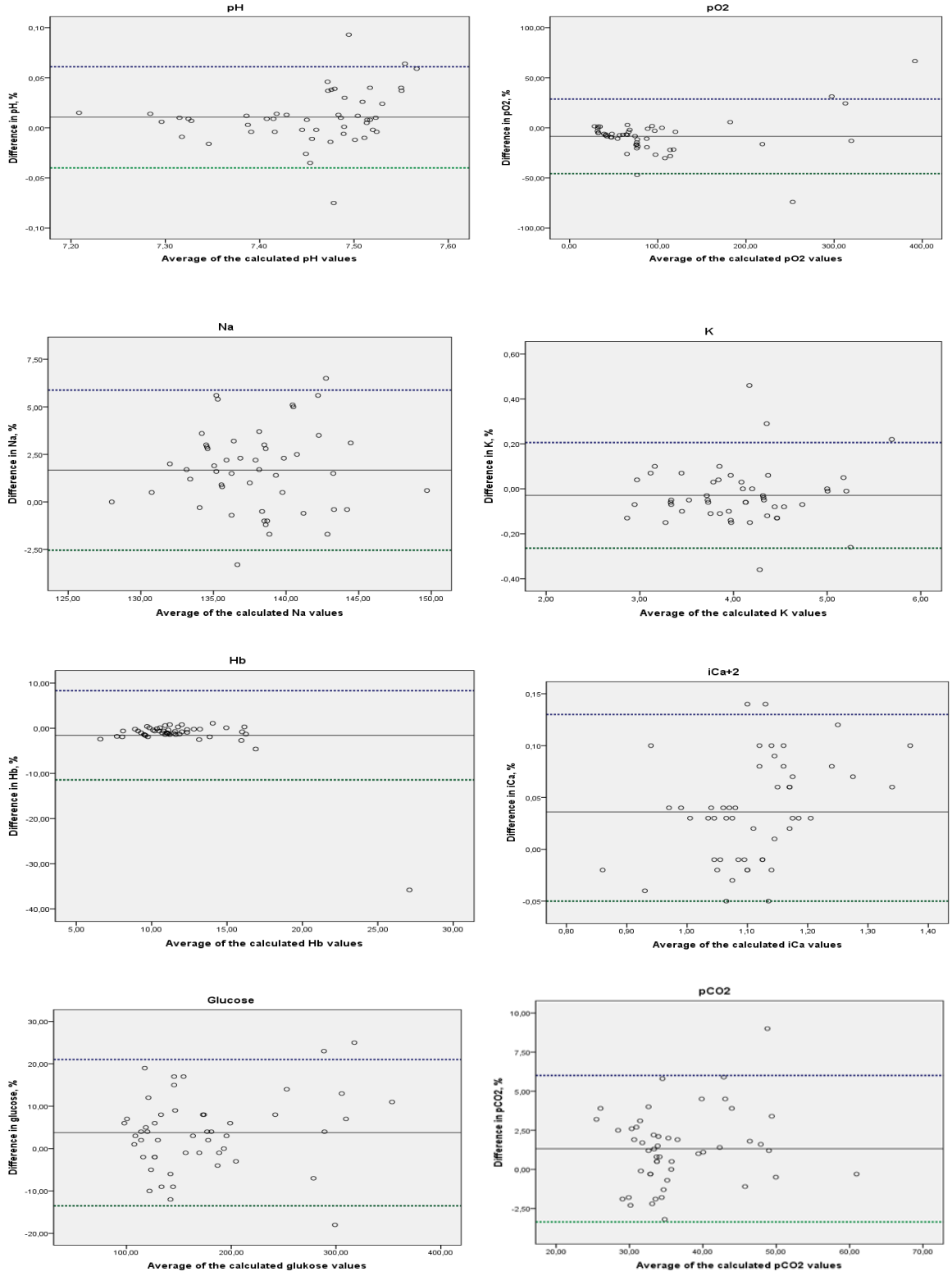

Figure1 :Bland-Altman plots for the comparison of RP500 and i-STATresults. The y-axis represents the difference between RP500 and the comparison method i-STAT (RP500 – i-STAT), and the x-axis represents the average of RP500 and i-STAT values. Horizontal line sare drawn at themean difference (blue), at the mean difference ±1.96 SD (95% confidence intervals) of the differences (green dotted line).

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