DOI: 10.5152/eajem.2018.07078

Manuscript Type: Research Article

Title: Comparison of Hgb, Htc, Na, and K Levels Measured by Blood Gases Analyzer and Laboratory Auto-Analyzer in Different ph Stages

Running Head: Reliability of Results Blood Gases Analyzer

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Cite this article as: Çorbacıoğlu ŞK, Emektar E, Çevik Y, Dağar S, Şencanlar Çetiner H, Özbek MA, et al. Comparison of Hgb, Htc, Na, and K Levels Measured by Blood Gases Analyzer and Laboratory Auto-Analyzer in Different ph Stages. Eurasian J Emerg Med 2018; DOI: 10.5152/eajem.2018.07078

Submitted: 21.05.2018

Accepted: 28.06.2018

Abstract

Aim: In this study, primary aim was detecting whether blood gases analyzer (BGA) is reliable or not in daily practice by comparing of Na+, K, Hgb, and Htc levels measured by BGA and laboratory auto-analyzer (LAA). Secondary aim was whether BGA is reliable or not in daily practice by comparing of Na, K, Hgb, and Htc levels measured by BGA and LAA in different pH stages.

Materials and Methods: This study screened electronic data and file records of all patients who admitted to ED with any complaint during the study period, retrospectively. Patients who had results of venous blood gases and routine laboratory taken at the same time were included this study. For each parameters, agreements and correlations between results of BGA and LAA were evaluated Bland-Altman test and Spearmen Correlation test, respectively and r-value higher than 0.80 was considered a strong correlation.

Results: Finally, laboratory results of 1374 patients were evaluated for statistically analyses. When evaluated correlations between results of BGA and LAA, it was found that there was only strong correlation for K ($p<0.001$, $r=0.83$). When assessed agreements between results of BGA and LAA, the mean difference were found as 0.02±6.1 for sodium, 0.3±0.44 for potassium, -0.5±1.6 for hemoglobin, and -0.6±5 for hematocrit.

Conclusion: Whereas there is strong correlation and relatively acceptable-good agreement for K measurement, there is no strong correlation and good agreement for other measurements – including Na, Hgb, and Htc. In addition, we found that these results did not change according the different pH stages.

Keywords: Blood gases analysis, venous blood gases, potassium, sodium, hemoglobin, hematocrit

Introduction

In patients who have life-threatening conditions (trauma or medical) in emergency departments (EDs) or intensive care unites (ICUs), to decide appropriate management way, it is needed that routine laboratory results - especially sodium (Na^+), potassium (K^+), hemoglobin (Hgb), and hematocrit (Htc) - are measured quickly and reliably. However, these laboratory results are measured by laboratory auto-analyzer (LAA) in routine practice and this method is time consuming. Therefore, in today, many physicians increasingly prefer more blood gases analyzer (BGA) addition to routine laboratory analyses and they decide how their patients manage (1, 2).

As opposed to this, it is known that there are measurement differences between results of laboratory auto-analyzer and blood gases analyzer (3, 4). However, results of previously studies, which about how reliable these differences are for using in daily practice, are controversial (4-7). Therefore, we believe that new-further studies on this topic are needed.

The aims of this study were detecting whether BGA is reliable or not in daily practice by comparing of Na^+, K^+, Hgb, and Htc levels measured by BGA and LAA and whether BGA is reliable or not in daily practice by comparing of Na^+, K^+, Hgb, and Htc levels measured by BGA and LAA in different pH stages.

Materials and Methods

This retrospective study was conducted with patients who admitted to emergency department (ED) of a training and research hospital and who had venous blood gases and routine laboratory results taken at the same time between January 2016 and March 2016. The local ethics committee approved the study.

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Study Population and Data Collection

This study screened electronic data and file records of all patients who admitted to ED with any complaint during the study period, retrospectively. Patients older than 18 years who had results of venous blood gases and routine laboratory taken at the same time were included this study. Patients who have lack of one or more parameters in VBG or LAA, who had hemolysis in routine laboratory, who was younger than 18 years, who have treated with any intravenous transfusion before the sampling, and who did not have results venous blood gases and routine laboratory taken at the same time were excluded from this study. Before the study period, three researchers, who were emergency physicians, were trained to collect data from the hospital data-registration system.

To measure VBG, venous blood samples were obtained with heparinized syringes (PICO70 Arterial Blood Sampler - Radiometer Medical AsP, Brønshøj, Denmark) as bedside in our ED and analyzed by bedside BGA (Techno Medica, GASTAT-1800 series pH/Blood Gas Analyzer, St. Ingbert, Germany). During the study period, BGA was calibrated four times a day. The other venous blood samples, after venous blood samples were obtained, were sent to core laboratory of hospital for whole blood count by hematology analyzer (The Abbott Cell-Dyn 3700 Hematology Analyzer, IL, USA) and analyzing biochemistry tests by LAA with ion-selective electrode diluted (indirect ISE) method (The ARCHITECT c8000 Clinical Chemistry Analyzer, IL, USA - Material used in the ARCHITECT c8000 Clinical Chemistry Analyzer was 2P32 ICT sample Diluent [ICTD5] kit). During the study period, core laboratory determined the calibration time as 24-hours intervals for hematology and biochemistry analyzers according to the manufacturers' instructions. Two levels of controls (normal and abnormal) were to be run every 8 hours and following calibration. The imprecision of the ICT assays for serum samples were as follows: sodium $\leq$ 1.5% and potassium $\leq$ 2.7%. The all blood samples were transferred from ED to core laboratory with pneumatic system in the first half hour. Finally, collected data from the

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hospital data-registration system - including pH, Na^+, K^+, Hgb, and Htc values were recorded the study form by three researchers.

Statistical analysis

Statistical analyses were performed using SPSS version 16.0 (Chicago,IL, USA).The Shapiro-Wilk test was used to assess the normal distribution of all parameters. Non-parametric data were expressed as median values and inter-quartiler range (IQR) (25-75%). For each parameters (Na^+, K^+, Hgb, and Htc), correlations between results of BGA and LAA were evaluated Spearmen Correlation test and r-value higher than 0.80 was considered a strong correlation. Finally, agreements between results of BGA and LAA were assessed by Bland-Altman test with 95%CI limits of agreement.

Results

In the study period, a total of 1562 patients who have both VBG and routine laboratory results were screened, retrospectively. One hundred twenty three of all patients who have lack of one or more parameters in VBG and sixty-five of all patients who had hemolysis in routine laboratory were excluded from this study. Finally, laboratory results of 1374 patients were evaluated for statistically analyses. The median age of patients were 59 (IQR25 - 75%: 36 - 75) and 790 patients (57%) were female. Demographic and clinical characteristics of patients were presented table-1. Results of VBG and routine laboratory of all patients were presented table-2.

When evaluated correlations between results of BGA and LAA, it was found that there was strong correlation for K^+ ($p<0.001$, $r=0.83$) and there were moderate-high correlations for Hgb ($p<0.001$, $r=0.79$) and for Htc ($p<0.001$, $r=0.78$). In contrast, there was poor correlation for Na^+ ($p<0.001$, $r=0,46$) (Figure 1). However, when assessed agreements between results of BGA and LAA, the mean difference were found as (mean±SD) 0.02±6.1*mmol/L* for sodium, 0.3±0.44*mmol/L* for potassium, -

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0.5±1.6g/dL for hemoglobin, and -0.6±5% for hematocrit. After Bland-Altman analyses it was found that although there was relatively acceptable-good agreement for potassium measurements, there was poor agreement for sodium, hemoglobin, and hematocrit measurements for clinical using (Figure 2).

In addition, in this study, agreements between values of VBG and routine laboratory were evaluated in different pH stages. A totally 835 of all patients had normal pH range (7.35-7.45), 336 patients had acidosis pH (<7.35), and 203 patients had alkalosis pH (>7.45). Similar to results of the analysis in which all samples were included, after Bland-Altman analysis in different pH stages, it was found that there was relatively acceptable agreement for potassium measurement, there was poor agreement for sodium, hemoglobin, and hematocrit measurements (Table 3).

Discussion

The results of this study showed that in measurements by BGA and LAA, whereas there is strong correlation and relatively acceptable-good agreement for K^+ measurement, there is no strong correlation and good agreement for other measurements - including Na^+, Hgb, and Htc. In addition, we found that these results did not change according the different pH stages.

For potassium and sodium measurement

As known, quickly and reliably measurements of K^+ and Na^+ are crucial in non-traumatic medical critical illness. For example, early detection of hypernatremia or hyponatremia in patients with acute altered mental status can be life-saving. Similarly, early detection of hypokalemia or especially hyperkalemia can be crucial for decision of hemodialysis and prevention of life-threatening ventricular dysrhythmia (8-9). In this study, we found that there is no strong correlation for sodium between BGA and LAA. In addition, when evaluated agreement limits for Na+, we found quite wide

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range of agreement limits as -11.9 to 11.9. We believe that this wide range is not acceptable for daily practice in ED. Similar to our results, there are some studies in the literature. For example, in Dr. Solak's study was conducted 2257 patients, evaluated agreements Na^+ results were measured by BGA and biochemistry auto-analyzer (BAA) in different stages of sodium level - including hyponatremia, eunatremia, and hypernatremia. And also, it has been reported that there is poor correlation and significant differences of measurements between LAA and BAA (10). In another study, which evaluated agreements of Na^+ and K^+ results were measured by LAA and BGA, was conducted by Budak et al. with 1105 test samples, it was found that wide range agreements limits (mean diff: 4.94, LoA: -0.97 to 10.85) for sodium similar to our result (11). In contrast to results of these studies, in different two studies were conducted Zhang et al. and Uysal et al, they have found narrower agreements limits for Na^+ measurements (mean diff: 3.0, LoA: -1.2 to 7.3 and mean diff: -1.63, LoA: -6.63 to 3.37, respectively) (5, 12). Of course, interpretation of results Blant-Altman is very subjective and can be change in different clinical scenarios. However, we believe that even in the study which has best agreement limit values, these values were distributed over relatively wide range. Therefore, we believe that sodium results measured by BGA is not enough reliable for using in ED practice and physicians should be aware risk of bias in using BGA for Na^+ measurements.

In contrast to Na^+ measurements, we found that there is strong correlation for potassium (K^+) between BGA and LAA. And also, when evaluated agreement limits for K^+, we found relatively acceptable-good agreement (-0.5 to 1.22). In the literature, there are studies which have similar findings to our findings for potassium. However, these similar results were discussed with different perspectives by authors of these studies. For example, in the study was conducted by Uysal et al. with 1094 patients, they aim to investigate correlation and agreement of some results measured by BGA and core laboratory analyzer. They reported that there is strong correlation (r=0.82) and acceptable-good agreement for K^+ measurements (mean: -0.46, LoA: -1.34 to 0.42). However, they

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warned that these results measured by BGA must be validated by core LA (5). Similarly, in another study was conducted by Budak et al., agreement limit for K^+ was found as -0.5 to 1.1 and authors concluded that K^+ results obtained using BGA and LAA cannot be interchangeably in clinical practice (11). Contrarily, although Zhang et al. in their study found that similar agreement limits for K^+ measurements as -0.29 to 1.16, they concluded that K^+ results measured by BGA was reliable (12). We believe that these different perspectives can cause that optimal agreement limits are subjective and can change in different clinical scenarios. However, we think that at least if potassium results of BGA are normal range, it can be reliable for exclusion of mortal hyperkalemia or hypokalemia with these agreements limits. Thus, we believe that measurements K^+ by BGA can be helpful in managements of patients in ED practice.

For hemoglobin and hematocrit measurements

In patients with hemorrhage (traumatic or non-traumatic), early evaluation of Hgb and Htc levels is crucial because current guidelines stated that detected low initial Hgb/Htc values could be indicator for severe bleeding (13). Therefore, at the beginning of this study, we thought that measurements of Hgb and Htc values by BGA could be useful for assessment of hemorrhagic stage in early period of trauma management in ED. However, in this study, we found that there is no strong correlation and unacceptable agreement limits for Hgb and Htc measurements in clinical ED practice. Similar to our results, in their study, Uysal et al. found that unacceptable-wide agreements limits for Hgb and Htc measurments by BGA and LAA (mean diff. of Hgb: -0.03, LoA: -2.23 to 1.71 and mean diff. of Htc: -2.19, LoA: -8.75 to 4.36) (5). Similarly, in another study was conducted by Kozacı et al. with 100 patients' laboratory results, some laboratory results - including Hgb and Htc measured by BGA and standard automatic devices in core laboratory were compared. Although they reported there are high correlations between measurements by BGA and core laboratory analyzer for Hgb and Htc

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measurements, agreements limits for Hgb and Htc values as mean diff:-0.1, Loa -4.2 to 3.9 and mean diff: -1.5, LoA: -13.9, respectively (14). And also, although they concluded that BGA measurements for Hgb and Htc values could facilitate in management of patients with active bleeding based on high correlation in their results, we believe that agreements limits in their study were very wide for using clinical practice in ED, similar to our results. Contrast to findings of these studies, in the study of Zhang et al., narrower agreements limits for Hgb measurements was reported as mean diff: 0.1, LoA: -1.8 to 1.9 and they concluded that Hgb values measured by BGA was reliable (12). Consequently, despite presence of different results and opinions in the literature, we think that especially initial Hgb and Htc values measured by BGA were not reliable in management of patients with hemorrhage. However, when considered that there are relatively high (r:0.78 and 0.79) correlation between BGA and LAA for Hgb and Htc measurements, serial measurements of Hgb and Htc by BGA could be useful and helpful for prediction of severe bleeding.

Study limitations

In this study, there were three important limitations. First, because all data were analyzed retrospectively, standardization of obtaining venous blood gases may not have been adequate enough. Similarly, although calibration of these BGA devices performed daily in routine practice, daily calibration's standardization may not have been adequate enough. In addition, our study groups were heterogeneous and consisted of various disease groups (medical, trauma, etc.). However, we believe that results with these limitations may be more compatible with real-life. Second, we analyzed only venous blood samples not arterial samples. Third, we did not analyze triglyceride and total protein levels of patients. Because of using indirect ISE in Na^+ and K^+ measurements, we could not evaluate potential affect of triglyceride and total protein levels on measurements of Na^+ and K^+. If this study did not have these limitations, more appropriate results might have been founded.

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Conclusion

In conclusion, our results showed that there is strong correlation between measurements by BGA and LAA for K^+ values; however, there is no strong correlation for Na^+, Hgb, and Htc values. In addition, when considered agreements limits, whereas relatively acceptable agreements limits were found for K^+ values, agreements limits of Na^+, Hgb, and Htc values were found as unacceptable for using in clinical ED practice.

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Table 1. Demographic and clinical characteristics of patients.

Age (years) *median (IQR25%-75%)*	59 (36-75)
Sex	
• Male	584 (43%)
• Female	790 (57%)
Comorbidities	
• Ischemic heart disease	181 (13%)
• Diabetes mellitus	282 (20%)
• Hypertension	399 (29%)
• Chronic obstructive pulmonary disease	155 (11%)
• Congestive heart failure	66 (7.2%)
• Chronic renal failure	36 (2.6%)
• Other	40 (2.9%)
Final Diagnosis of Patients	
• Acute abdomen	101 (7.3%)
• Acute coronary syndrome	98 (7.1%)
• Acute kidney injury	74 (5.3%)
• Soft tissue problems	75 (5.4%)
• Intoxication	96 (6.9%)
• Acute diabetes mellitus complications	48 (3.4%)
• Primer headache	68 (4.9%)
• Altered mental status	62 (4.5%)
• Peripheral vertigo	44 (3.2%)
• Syncope	52 (3.7%)
• Stroke	78 (5.6%)
• Non-specific abdominal pain	194 (14%)
• Primer epilepsy	30 (2.1%)
• Infection disease	182 (13.2%)
• Gastrointestinal hemorrhage	34 (2.4%)
• Psychiatric disorder	17 (1.2%)
• Moderate-severe trauma	121 (8.8%)

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Table 2. Venous blood gases and routine laboratory results of patients

	Venous Blood Gases	Routine Laboratory Results
• **Sodium** *(mmol/L)*	137 ± 7.1	137 ± 4.1
• **Potassium** *(mmol/L)*	3.8 ± 0.7	4.2 ± 0.6
• **Hemoglobin** *(g/dL)*	13.4 ± 2.5	12.8 ± 2.1
• **Hemotocrit** *(%)*	39.4 ± 7.4	38.8 ± 5.8
• **pH**	7.38 ±0.07	-

Table 3. Mean and mean difference of Na, K, Hgb and Htc levels in VBG and routine laboratory with agreement limits according to Bland-Altman analyses

pH stage		VBG *mean±SD*	Routine Laboratory *mean±SD*	MD *mean±SD*	Agreement limits with 95%
Normal range *(7.35 - 7.45)* **n:835**	• **Na** (mmol/L)	137±6.6	137±3.9	0.26±5.8	-11.1 to 11.6
	• **K** (mmol/L)	3.8±0.6	4.1±0.5	0.3±0.4	- 0.4 to 1.08
	• **Hgb** (g/dL)	13.5±2.4	13±2	-0.5±1.5	- 3.4 to 2.4
	• **Htc** (%)	36.6±7.1	39.1±5.4	-0.4±4.7	- 9.6 to 8.8
Acidosis *<7.35* **n:336**	• **Na** (mmol/L)	140±7.6	137±4.9	-2.4±5.8	-13.7 to 8.9
	• **K** (mmol/L)	4.2±0.8	4.5±0.8	0.3±0.5	- 0.6 to 1.2
	• **Hgb** (g/dL)	13.2±2.6	12.6±2.2	-0.6±1.8	- 4.1 to 2.9
	• **Htc** (%)	38.9±7.7	38.1±6.5	-0.7±5.0	- 10.5 to 9.1
Alkalosis *>7.45* **n:203**	• **Na** (mmol/L)	133±6.1	136±3.9	3.1±5.8	- 8.2 to 14.4
	• **K** (mmol/L)	3.6±0.6	4.0±0.5	0.4±0.3	- 0.1 to 0.9

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	• **Hgb** (g/dL)	13.5±2.6	12.8±2.1	-0.6±1.8	- 4.1 to 2.9
	• **Htc** (%)	39.6±7.9	38.3±6.2	-1.2±5.8	-12.5 to 10.1

VBG: venous blood gases; MD: mean difference; Hgb: hemoglobin; Htc: hemotocrit; SD: standard deviation

Figure 1.

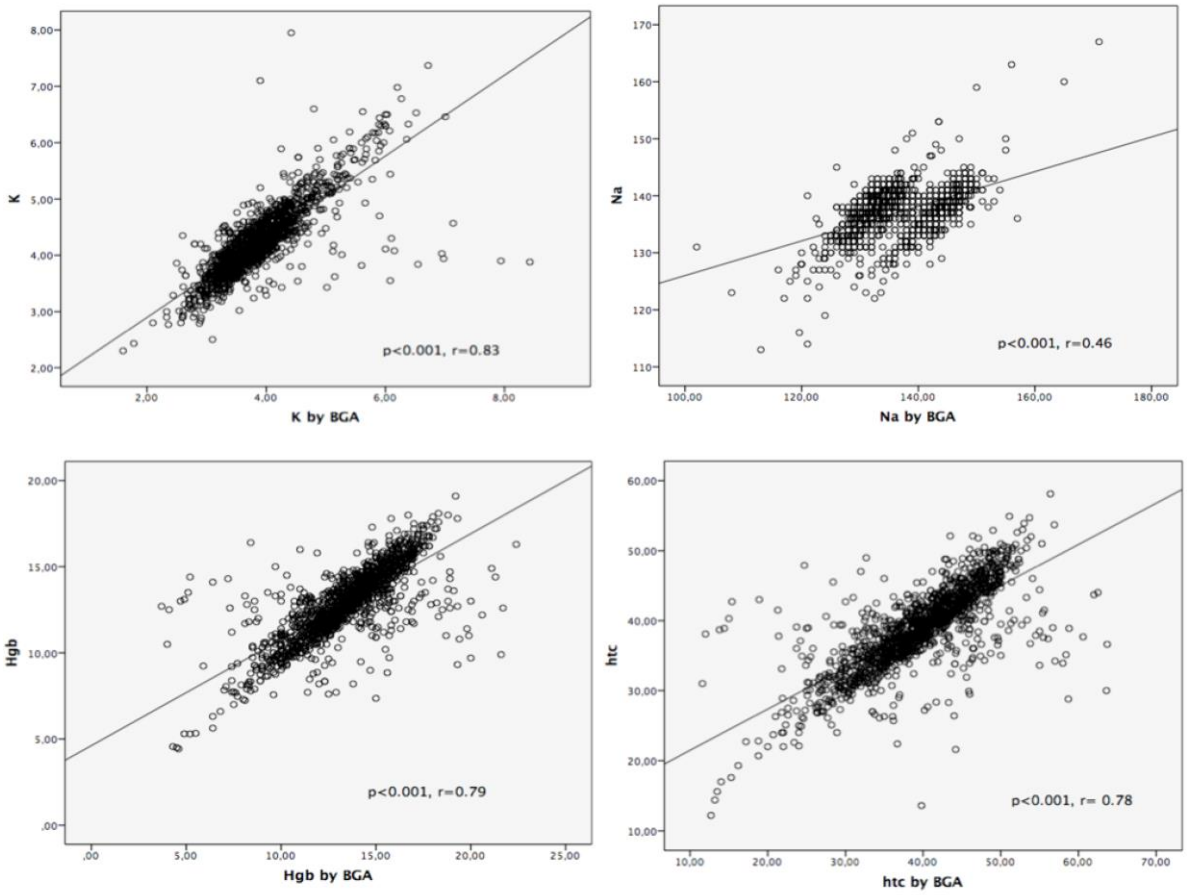

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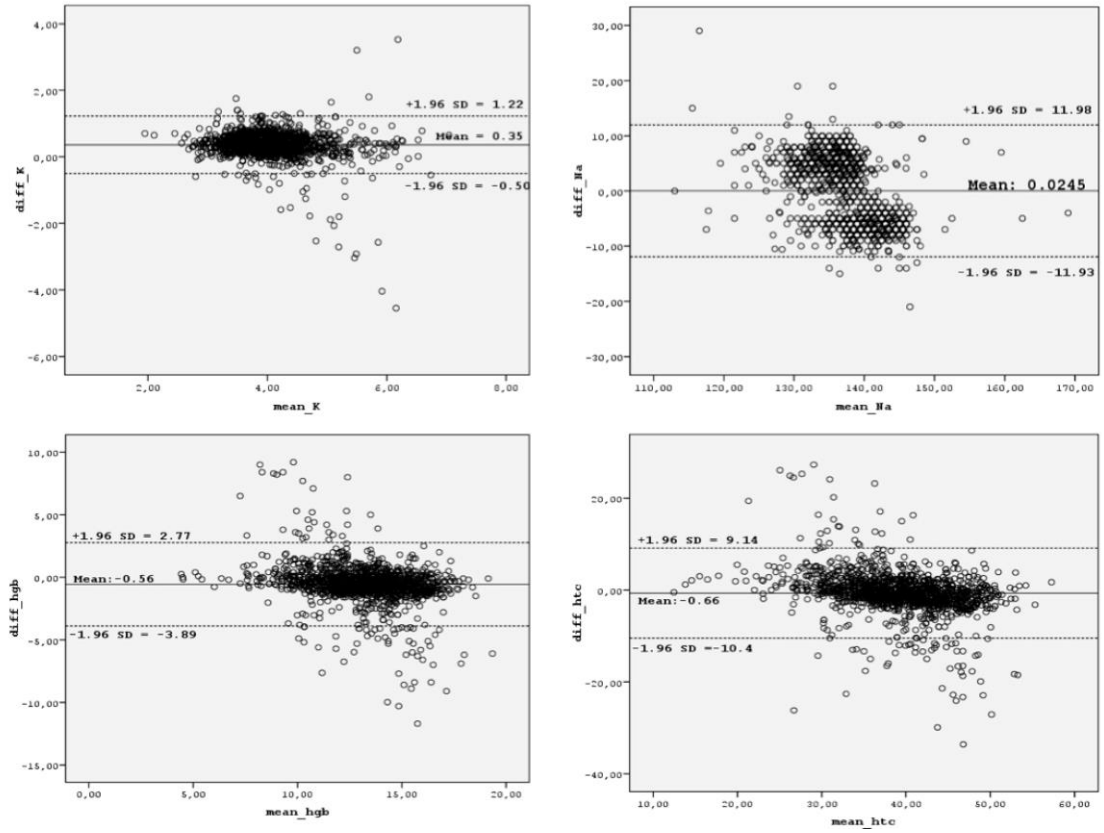
Figure 2.



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