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PERFORMANCE EVALUATİON OF THE MEASUREMENT OF COMPLETE BLOOD COUNT PARAMETERS BETWEEN MİNDRAY BC 6000 AND BT PRO 2401 HEMATOLOGY ANALYZERS

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Abstract

Objective: Today, different trademarks of Hematology Analyzers have been used in blood analysis and but the compatibility of these devices with each other is unknown. In this study, the aim was to investigate the agreement between the results of complete blood count parameters values with BC 6000 hematology analyzer (Mindray, China) and BT PRO 2401 hematology analyzer (Izmir, Turkey).

Materials and Methods: This prospective study was included in 51 EDTA-anticoagulated samples submitted to our biochemistry laboratory for routine testing of CBC(complete blood cell). Statistical correlations CBC parameters values, analyzed in each analyzer as a single analysis from each sample were evaluated using two-way random intraclass correlation coefficient (ICC) and regression analysis. We compared the accuracy and precision of CBC count methods; i.e. BC-6000 Plus (optical (O) and impedance (I))and BT PRO 2401 (optical (O) and impedance (I)).

Results: There was agreement between the two devices in Wbc, Neu, Mon, Neuperc, Lymperc, Monperc, Hct, Mcv, Mch, RdwSD, Plt, Mpv and pct parameters as intraclass correlation coefficient (ICC) <90. However we found disagreement in Bas, Eos, Eosper, Basper, Rbc, Hgb,Mchc hemoglobin, RdwCV and Pdw measurements between Mindray and Bt-pro 2401 (ICC >90).

Conclusion: In terms of white blood cells and neutrophil analysis which suggests that they can be used interchangeably, perfect agreement between them. However, instruments did not ensure satisfactory interchangeability and did not facilitate a

substitution of one analyzer by another.

Key Words: BT PRO 2401, BC-6000, Complete blood count parameters, performance evaluation, hematology analyzer.

Introduction:

Complete blood count (CBC) is a important assessment to detect any pathology reflected in the blood stream, so the validation of results

from any hematology analyzer becomes an item of special importance especially for reflecting the quality of laboratory results and directly influencing patients‟ clinical conduct (1). Complete blood count (CBC) analysis is performed for the analysis of abnormalities within the white blood cells (WBC), red blood cells (RBC), neutrophile (NO), lymphocyte (LYM) and platelets (PLT) of peripheral blood. Modern automated laboratory hematology analyzers allow the measurement of over 30 different hematological parameters useful in the diagnostic and clinical interpretation of patient symptoms (2–5). Although automated analyzers use the most advanced technologies for the performance of white blood cell differentiation, manual microscopy remains the most reliable and reference method for WBC evaluation, when performed by an expert microscopist (5).

Complete blood cell count (CBC) and leukocyte differential count (LDC) among analyzers generally have quite good but not perfect agreement. However, in various situations, precise automated measurement is difficult or not possible (eg, immature cells, platelet clumps), and microscopy is triggered by the respective “flags” in the laboratory results. Therefore, the objective of modern hematology laboratories is to optimize the number of samples for which further, accepted expensive action (eg, microscopic smear review) is needed while minimizing the number of false-negative results(6).

In this study, we aim was to investigate the agreement between the results of complete blood count parameters values with BC 6000 hematology analyzer (Mindray, China) and BT PRO 2401 hematology analyzer (Izmir, Turkey).

Materials and Methods:

Specimens

We included in this study 51 EDTA-anticoagulated samples submitted to our biochemistry laboratory for routine testing of CBC. Each sample were performed within 2 h of the diagnostic test, specimens were transported between laboratory at room temperature time of transport was shorter than 15 min. All samples were analyzed in both devices at once and the results were recorded.

Instruments

The Mindray BC-6000 (Mindray Bio-Medical Electronics Co., Ltd, Shenzhen, China) provides classification of white blood cells based on the size of cells, their granularity, and content of nucleic acid. Nucleated red blood cells (NRBC) are counted separately and basophils are counted in selected channels. The fluorescent stain allows the differentiation of reticulocytes (RET) on various levels of maturation. The equipment enables the measurement of hemoglobin concentrations in reticulocytes (RetHgb) and mean reticulocyte volume (MRV). The instrument provides the measurement of 54 different diagnostic and research parameters. BC-6000 can load up to 50 samples at a time and offers a throughput of up to 110 tests per hour. It requires less sample volume as well as reagent consumption. For a CBC+DIFF test with NRBC result, BC-6000 only requires 80μL of whole blood and 35 μL of capillary blood (7).

The BT PRO 2401(Izmir, Turkey) analyzes complete blood count based Helium-Neon Laser Light Scatter. The instrument provides the measurement of 27 different diagnostic and research parameters. The throughput is 110 tests per hour. It determines the existence of NRBC and warns the user. Besides with 4 angle laser technology. It eliminates the interfering effect of the clumbes clumbed clots and debris with NRBC.

WBC monitoring system gives a warning for osmanit fragile cells(8).

Statistical Analysis

Compliance between the evaluators was performed using Intraclass Correlation (ICC).

In regression analysis, there are two types of linearity in variables and coefficients (linearity in parameters). The state of linearity in variables means that the value of each variable in the model is one; indicates a linear functional relationship between dependent and independent variables. Similarly, in coefficients, linearity is the exponent of all coefficient values in the model and the existence of a linear functional relationship between the dependent variable and the coefficient values.

$$Y_i = \beta_0 + \beta_1 X_i + e_i \quad (1)$$

An example of a model is that both the coefficients and the variables are linear.

$$Y_i = \beta_0 + \beta_1 X^2{}_i + e_i \quad (2)$$

The coefficients are also linear, but the variables are examples of nonlinear models.

$$Y_i = \beta_0 + \sqrt{\beta_1} X_i + e_i \quad (3)$$

Variables are linear, while coefficients are examples of nonlinear models.

Simple linear regression model

The regression model examines the causality relationship between a single independent variable and a dependent variable.

$$Y_i = \beta_0 + \beta_1 X_i + e_i \quad (4)$$

Multiple regression model

Models developed for multiple regression analysis resemble simple linear regression models, with the exception of more terms, and can be used to examine straightforward, more complex relationships. For example, suppose that the average time E (y) needed to fulfill the data-processing task increases as the use of computers increases and we think that the relationship is curve-linear. To model the deterministic $E(y) = \beta_0 + \beta_1 X_1$ component, the following quadratic model can be used instead of the straight-line model.

$$E(y) = \beta_0 + \beta_1 X_1 + \beta_2 X_1^2 \quad (5)$$

For example, the first-order model;

$$E(y) = \beta_0 + \beta_1 X_1 + \beta_2 X_2 \quad (6)$$

(x1, x2) -plane. For our example (and for many real-life applications), we expect a slope on the response surface and use a second-order model to model the relationship.

$$E(y) = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_1 X_2 + \beta_4 X_1^2 + \beta_5 X_2^2 \quad (7)$$

All the models written up to now are called generic linear models, because E (y) is a linear function of unknown parameters. The following model is not linear.

$$E(y) = \beta_0 e^{-\beta_1 x} \quad (8)$$

Because E (y) is not a linear function of unknown model parameters.

Semi-parametric regression models

Semi-parametric regression models are models in which the dependent variable can be parameterized in relation to some explanatory variables, but not easily related to some other explanatory variable or variables. In the semi-parametric model, linear parametric components form the parametric part of the model whereas both parametric and non-linear components form the non-parametric part of the model. This model is a special case of additive regression models (Härdle et all 2004), which allows easier interpretation of the effect of each variable and generalizes standard regression methods. In addition, the semi-parametric model is a model in which the dependent variable is linear with some explanatory variables but not linear with other specific independent variables.

Parametric Methods;

Linear: $\hat{y} = b_0 + b_1 x$ (9)

Inverse: $\hat{y} = b_0 + (\frac{b_1}{t})$ (10)

Quadratic: $\hat{y} = b_0 + b_1 x + b_{11} x^2$ (11)

Cubic: $\hat{y} = b_0 + b_1 x + b_{11} x^2 + b_{111} x^3$ (12)

Semi-Parametric Methods;

Logarithmic:$\hat{y} = b_0 + (b_1 Ln\,(t))$ (13)

Power:$\hat{y} = b_0 + b_1 x\ or Ln(y) = Ln(b_0) + (b_1 Ln\,(t))$ (14)

Compound: $\hat{y} = b_0 + b_{11}^2 x\ or Ln(y) = Ln(b_0) + (b_1 Ln\,(t))$ (15)

S-curve:$\hat{y} = e^{(b_0 + \frac{b_1}{t})} or\ Ln(\hat{y}) = b_0 + (\frac{b_1}{t})$ (16)

Growth: $\hat{y} = e^{(b_0 + b_1 t)} or\ Ln(\hat{y}) = b_0 + (b_1 t)$ (17)

Exponential: $\hat{y} = b_0 e^{(b_1 t)} or\ Ln(\hat{y}) = Lnb_0 + (b_1 t)$ (18)

$$E(y) = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + ... + \beta_k X_k \qquad (19)$$

(Farebrother 1976, Rao and Toutenburg 1995, Robinson 1988)

Statistical analysis was performed with Microsoft Excel (Microsoft Corporation, Redmond, WA), SPSS 25 (IBM Inc., Chicago, IL, USA) and MedCalc Software, Ostend, Belgium

A comparison of results obtained by automated analysis of 52 anticoagulated blood samples from patients were performed on both instruments.

There is no agreement between the two devices according to the If intraclass correlation coefficient values <90. If intraclass correlation coefficient values > 90, there is agreement between the two devices. Compliance between various variables ICC (intraclass correlation coefficient (ICC)) values were calculated and detailed information about the compatibility of the performances was obtained as shown (Table 1). There was agreement between the two devices in Wbc, Neu, Mon, Neuperc, Lymperc, Monperc, Hct, Mcv, Mch, RdwSD, Plt, Mpv and pct parameters as shown in Table 1 (ICC > 90). We found disagreement in Bas, Eos, Eosper, Basper, Rbc, Hgb,Mchc hemoglobin, RdwCV and pdw measurements between Mindray and Bt-pro 2401 shown in Table 1 (ICC <90).

Results:

Table 1. ICC values and confidence intervals (%95) of the hemogram parameters measured on both devices

	ICC	%95LOWER(ICC)	%95UPPER(ICC)	p
Wbc*-Wbc**	0,99	0,998	0,999	0,001
Neu*-Neu**	0,99	0,999	0,999	0,001
Lym*-Lym**	0,99	0,988	0,999	0,001
Mon*-Mon**	0,94	0,889	0,966	0,001
Eos*-Eos**	0,66	0,391	0,814	0,001
Bas*-Bas**	0,076	-0,67	0,489	0,396
Neuperc* -Neuper**	0,94	0,897	0,969	0,001
Lymperc*-Lymper**	0,99	0,993	0,998	0,001
Monper*-Monper**	0,85	0,734	0,919	0,001
Eosper*-Eosper**	0,51	0,113	0,728	0,009
Basper*-Basper**	0,016	-0,778	0,456	0,478
Rbc*-Rbc**	0,306	-0,254	0,616	0,112
Hgb*-Hgb**	0,277	-0,307	0,6	0,14
Hct*-Hct**	0,989	0,979	0,994	0,001
Mcv*-Mcv**	0,99	0,982	0,995	0,001
Mch*-Mch**	0,99	0,914	0,974	0,001
Mchc*-Mchc**	0,57	0,225	0,763	0,003
RDWCV*-RDWCV**	0,88	0,79	0,936	0,001
RDWSD*-RDWSD**	0,91	0,854	0,955	0,001
Plt*-PLT**	0,9	0,821	0,945	0,001
MPV*-MPV**	0,79	0,631	0,887	0,001
Pdw*-Pdw**	0,3	-0,256	0,615	0,113
Pct*-Pct**	0,93	0,885	0,965	0,001

*: BT-pro24 results, **:BC-6000 results ICC: intraclass correlation coefficient, Wbc:White Blood Cells, Neu: neutrophil,Lym: lymphocytes, Mon: monocytes, Eosperc: eosinophil percentage, Basperc: basophil percentage, Rbc:red blood cells, Hgb: hemoglobin, Hct: hematocrit, Mcv:mean corpurcular volume, Mch: mean corpuscular hemoglobin, Mchc: Mean corpuscular hemoglobin concentration RDWCV: Red cell distribution width - coefficient of variation , RDWSD:Red cell distribution width standard deviation, Plt:Platalet, Mpv: Mean Platelet Volume, Pdw: Platelet Distribution Width, Pct:

plateletcrit. Parameters with significant difference between two analyzer in the same samples with ICC < 90.

Table 2. Results of univariate parametric and semi-parametric regression models

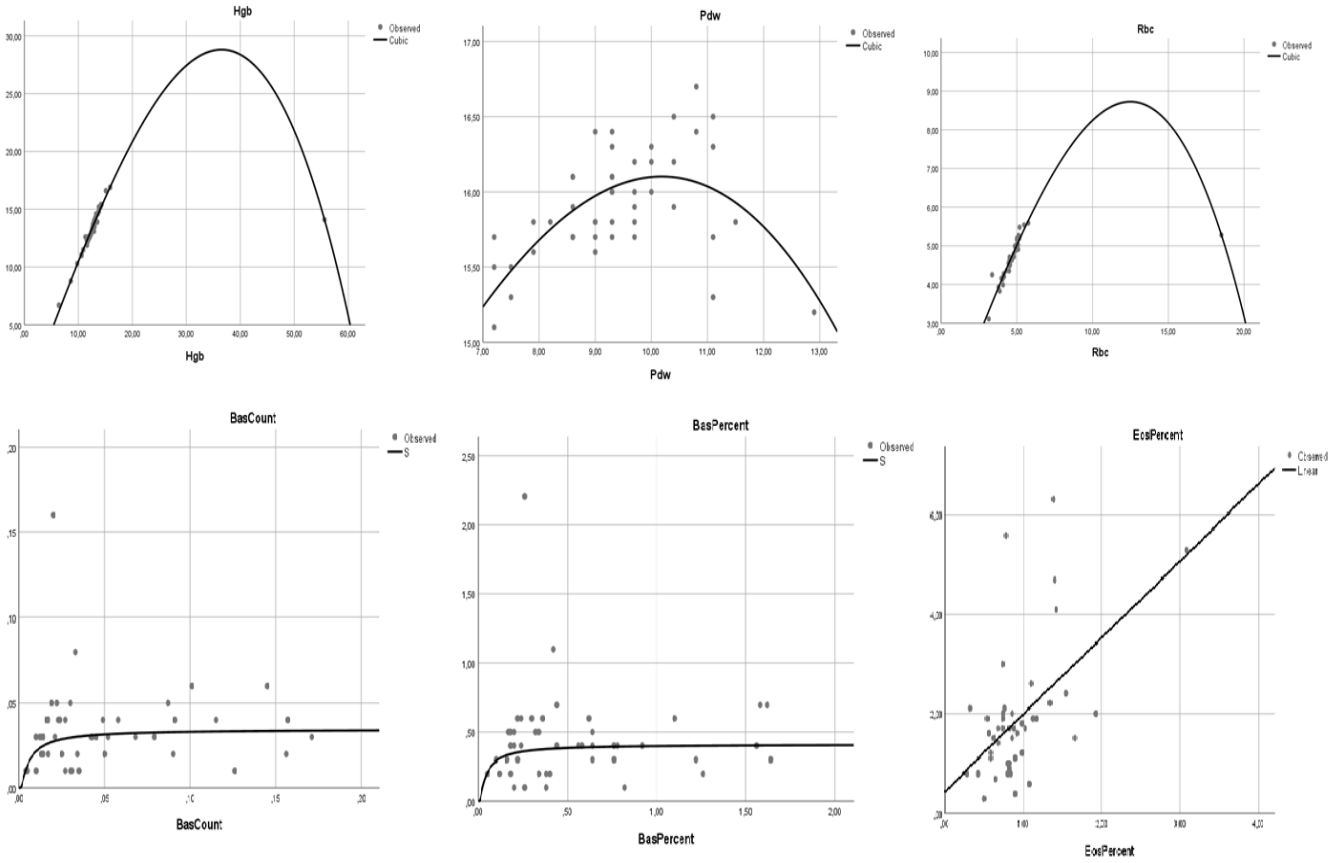
			Summary Model				Estimation of parameters						
	Methods												
		R^2, %	F	df 1	df 2	p	Constant	b1	b2	b 3			
WBC*-WBC**	Quadratic	0,996	5512,982	1	43	0,001	0,835	0,86	0,004				
Neu*-Neu**	Linear	0,997	13116,3	1	44	0,001	-0,229	1,006					
Lym*-Lym**	Linear	0,96	1061,105	1	44	0,001	-0,073	1,014					
Mon*-Mon**	Cubic	0,909	139,629	3	42	0,001	-0,22	2,002	-1,65	0,528			
Eos*-Eos**	Cubic	0,405	9,512	3	42	0,001	0,034	1,79	-5,87	15,64			
Bas*-Bas**	S	0,124	6,245	1	44	0,016	-3,365	-0,005					
Neuperc* -Neuper**	Cubic	0,966	393,862	3	42	0,001	48,937	-1,731	0,048	0			
Lymper*-Lymper**	Linear	0,987	3279,383	1	44	0,001	-0,25	1,029					
Monper*-Monper**	Cubic	0,669	28,31	3	42	0,001	-7,925	4,367	-0,45	0,017			
Eosper*-Eosper**	Linear	0,297	18,558	1	44	0,001	0,441	1,544					
Basper*-Basper**	Cubic	0,045	0,666	3	42	0,578	0,216	1,541	-2,46	1,011			
Rbc*-Rbc**	Cubic	0,906	207,696	2	43	0,001	0,139	1,03	0	-0			
Hgb*-Hgb**	Cubic	0,979	994,449	2	43	0,001	-1,769	1,256	0	0			
Hct*-Hct**	Cubic	0,961	342,038	3	42	0,001	30,348	-1,386	0,065	0			
Mcv*-Mcv**	S	0,978	1937,981	1	44	0,001	5,399	-78,376					
Mch*-Mch**	Quadratic	0,922	253,797	2	43	0,001	-50,83	4,922	-0,07				
Mchc*-Mchc**	Inverse	0,171	9,049	1	44	0,004	50,908	-578,74					
RDWCV*-RDWCV**	Quadratic	0,903	199,519	2	43	0,001	67,745	-7,825	0,276				
RDWSD*-RDWSD**	Linear	0,749	131,063	1	44	0,001	-2,589	1,043					
Plt*-PLT**	S	0,81	187,471	1	44	0,001	6,532	-188,33					
MPV*-MPV**	Inverse	0,562	56,362	1	44	0,001	20,391						
Pdw*-Pdw**	Cubic	0,424	15,844	2	43	0,001	9,508	0,971	0	-0			
Pct*-Pct**	Cubic	0,862	87,424	3	42	0,001	-0,017	1,79	-1,18	-0,8			

*: BT-pro24 results, **:BC-6000 results ICC: intraclass correlation coefficient, Wbc:White Blood Cells, Neu: neutrophil,Lym: lymphocytes, Mon: monocytes, Eosperc: eosinophil percentage, Basperc: basophil percentage, Rbc:red blood cells, Hgb: hemoglobin, Hct: hematocrit, Mcv:mean corpurcular volume, Mch: mean, corpuscular hemoglobin, Mchc: Mean corpuscular hemoglobin concentration RDWCV: Red cell distribution width - coefficient of variation , RDWSD:Red cell distribution width standard deviation, Plt:Platalet, Mpv: Mean Platelet Volume, Pdw: Platelet Distribution Width, Pct: plateletcrit

Table. 2 has shown that estimation of hemogram parameters measurements were performed with different regression models. There was high degree of compliance between the two devices in Wbc, Neu, Lym, Mon, Eos, Neuperc, Lymperc, Rbc, Hgb, Hct Mcv, Mch, RdwCV, parameters as shown in Table 2.

There was quite low compliance in Eos, Bas, Eosperc ,Mchc, Mpv, Pdw and Pct measurements between Mindray BC 6000 and Bt-pro 2401 shown in Table 2. There was moderate compliance in Monperc, RdwSD and Plt measurements between Mindray BC 6000 and Bt-pro 2401 shown in Table 2. Wbc, Neu, Lym, Mon, Neuperc, Lymperc, Monperc, Rbc, Hgb, Hct, Mcv, Mch, RdwCV, RdwSD and plt mesurements, the parameters can be calculated more accurately with the desired curve estimation (R^2>0,50). We observe the best compliance is among at Wbc and Neu measurements because R^2 values are almost close to 100. When the estimation equations for univariate methods are examined, Quadratic or Cubic models give higher R^2 value, unlike the use of continuous linear models (Table 2, Figure1-6).

Figure 1-6. Curve Estimates of Hgb, Pdw, Rbc, Bas Count, Bas percent, Eospercent



Hgb: hemoglobin, Pdw: Platelet Distribution Width, Rbc:red blood cells, Bascount: basophil count Basperc: basophil percentage, Eosperc: eosinophil percentage

Discussion:

The results of analyses performed by an automated hematology analyzer should be as reliable as possible for every type of sample, including specimens with leucopenia, thrombocytopenia, or anemia. Based on the results obtained for white blood cell differentiation and the presence of pathologies of either red blood cells or platelets, basophils, monocytes, lymphocytes a decision is made regarding manual microscopic peripheral blood analysis. Consequently, the information from a hematology analyzer should leave no doubts, since manual verification of the obtained result is labor-intensive and time-consuming(9). In our study, we evaluated the agreement of CBC results obtained from two different automated analyzers which use their own principles in the differentiation of leukocytes and red blood cells at different stages of maturation. The Mindray BC-6000 use fluorescence and light scattering, The BT PRO 2401 use Helium-Neon Laser Light Scatter.

The correlation between the two devices is based on the intraclass correlation coefficient (ICC). In some publications, the correlation coefficient above 0.90 was interpreted as being very good (10), while others were found to be moderate complience between 0.90-0.95 (11). In the ICC analysis we conducted to examine the compatibility of the two devices in our study, Wbc, Neu, Lym, Hct, Mcv and Mch are found the ICC = 0.99, 0.99,0.99,0.98,0.99 and 0,99 respectly. Accordingly, these parameters compatibility between the two devices appears to be very good. Mon, Neuperc, RdwSD, Plt and Pct are found ICC values 0.94, 0.94, 0.91, 0.90 and 0.93 respectly. For these parameters compatibility between the two devices are moderate complience. However, for Bas, Eos, Eosper, Basper, Rbc, Hgb, Mch, RdwCV and Pdw are found ICC values 0,07, 0,66, 0.51, 0.02, 0.31, 0.28, 0.57,0,88 and 0.30 respectly. That means that for these parameters compatibility between two devices are incompatible.

A similarly poor level of agreement was indicated by Tan et al. (12). That the smallest

level of agreement between different analyzers was in terms of basophil and basophil and Eosper count was also indicated by Meintker et al. (13), where this was explained by a falsely increased basophil count in the presence of atypical lymphocytes and blasts.

Not till the basophil count and eosinophils count increases significantly, which may be indicative for allergies or falsely gated blasts, is their number not clinically relevant.

Jo et al. showed substantially higher agreement for Rbc, Mch, Hgb and Pdw between BC-6800 and LH750 (14) and Meintker et al. indicated extremely good accordance for hemoglobin concentration measured with Sapphire, Advia 120, XE-2100 and DxH 800 (13). But in our study we couldn't find good agreement for for these parameters. We think that these results can be attributed to differences in technology and calibration between the 2 instrument systems for these parameters.

We also made regression models between hemogram parameters. The relationship between variables must be examined with functional regression models. We have found highest R^2 values in Wbc and Neu. These values almost almost close to 100. That tells to us that we can use these two devices interchangeably according to these values.

As a coclusion, the usefulness and capability of the two analyzers were comparable overall. In terms of white blood cells and neutrophil analysis which suggests that they can be used interchangeably, perfect agreement between them. BC 6000 and BT-PRO2401 analyzers competently performs the WBC differential and screens appropriately for morphologically abnormal samples. An efficiency rate of >80% means the laboratory will properly identify abnormal specimens for follow-up but will not be burdened with excessive numbers of unnecessary manual differentials.

The crucial factor, which could have a determinant role in deciding about the usage of a specific hematology analyzer in a biochemistry hospital laboratory, could be the volume of sample, anticoagulant type and quality of tubes needed for effective analysis.

Collectively, we can state that results were not transferable between the two studied analyzers. The main conclusion of our study is that samples from one patient should be analyzed with the same laboratory instrument, because possible changes in hematological parameters, when using different analyzers, could not be noticed and properly interpreted.

The limitation of our study is that we did not analyze bias for each instrument. Due to small volume of samples, that were analyzed with two different instruments, there was no possibility to repeat analysis with every analyzer one more time. Thus, we cannot analyze the Bland–Altman plots to estimate each analyzer repeatability.

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