Evaluation of the LABGEO PT10 Point-Of-Care Testing Device: Comparison of Analyte Measurements in Capillary Whole Blood and Lithium Heparin Whole Blood Samples With Those in Central Laboratory

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Background: Point-of-care (POC) testing device has been widely used because of its rapid availability of results making diagnosis and management as early as possible. Capillary blood can reduce the difficulty of obtaining samples compared to venous blood and allows the prompt testing results. In this study, we evaluated the usefulness of capillary blood in Samsung LABGEO PT10. Methods: Fifty-one patients and 18 healthy adults aged between 20 and 65 were enrolled and their capillary and venous blood samples were collected. Venous blood samples were split into lithium heparin (LiHep) tube and serumseparating tube. Measurements using capillary blood and LiHep whole blood were performed in LABGEO PT10. Serum was used for measurement by Toshiba 2000FR NEO in central laboratory. Results: In comparison between measurements in LABGEO PT10 using capillary

and LiHep whole blood, the slope ranged between 0.9289 and 1.0471, correlation coefficients (R^2) were over 0.95 except albumin, high-density lipoprotein, and total protein. Comparison of measurements in capillary and LiHep whole blood using LABGEO PT10 with those in the central laboratory revealed that the slope ranged between 0.6433 and 1.1364 for capillary whole blood and 0.6255 and 1.1602 for LiHep whole blood except alkaline phosphatase. For most of analytes, R2 were over 0.95. Conclusion: Measurements in LABGEO PT10 using capillary blood was well correlated with those in LABGEO PT10 using LiHep whole blood and also with in the central laboratory. In conclusion, capillary blood provides reliable measurements and can be trustfully used in LABGEO PT10. J. Clin. Lab. Anal. 00:1-© 2016 Wiley Periodicals, Inc. 11. 2016.

Key words: Analytic chemistry technique; capillary blood; POCT; point-of-care testing

Abbreviations

POCT point-of-care test

ALP alkaline phosphatase

ALT alanine aminotransferase

AST aspartate aminotransferase

GGT γ-glutamyl transferase

HDL high-density lipoprotein

TG triglyceride

BUN blood urea nitrogen

LiHep lithium heparin

LDL low-density lipoprotein

CLSI Clinical and Laboratory Standards Institute

CLIA Clinical Laboratory Improvement Amendments

INTRODUCTION

Point-of-care test (POCT) devices do not require special techniques for the collection of blood, transportation to a central laboratory, and sample processing (1). Consequently, results can be obtained

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immediately, enabling on-the-spot patient management and improving patient care. Over the last few decades, advances in technology have led to the widespread availability of a wide range of POCT devices such as pregnancy tests, blood glucose tests, tools for arterial blood gas analysis, and electrolyte tests (2, 3). However, to date, only a few POCT devices capable of performing comprehensive chemical tests simultaneously, for evaluation of the overall health status of the patient, have been developed (4, 5) although 60–70% of tests performed in the laboratory comprise clinical chemistry tests for liver function, renal function, glucose levels, and lipid profile analysis (6).

The Samsung LABGEO PT10 (Samsung Electronics, Suwon, Korea), which has been introduced to the market recently, assesses the following 14 analytes: alkaline phosphatase (ALP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), y-glutamyl transferase (GGT), total protein, total bilirubin (TBIL), albumin, glucose, total cholesterol (TC), high-density lipoprotein (HDL), triglyceride (TG), creatinine, amylase (AMY), and blood urea nitrogen (BUN). Moreover, this device is capable of analyzing the aforementioned analytes in several different types of samples, including plasma, serum, and whole blood. A previous study demonstrated that the LABGEO analyzer provides comparable measurements of analytes in lithium heparin (LiHep) whole blood, plasma, and serum samples (2, 7). However, measurements using capillary whole blood were not evaluated previously. Therefore, in this study, we compared measurements of analytes in capillary whole blood and LiHep whole blood using the LABGEO PT10 with those performed in the central laboratory to validate the comparability of capillary whole blood in the LABGEO PT10.

MATERIALS AND METHODS

Instrument and cartridge

The LABGEO PT10 analyzer weighs 13.5 kg, with dimensions of 344 mm (width) × 293 mm (depth) × 390 mm (height). The analyzer features a graphic color liquid crystal display (LCD) module with a touch-sensitive screen and built-in thermal printer module. This instrument enables convenient quality control (QC) via its QC and self-diagnosis modes; furthermore, as each cartridge lot is calibrated during manufacture, only minimal training of laboratory personnel is required. The Samsung LABGEO PT Biochemistry test 15, which is a dedicated cartridge for the device, simultaneously evaluates the levels of 14 analytes (albumin, ALP, ALT, AST, TBIL, glucose, GGT, total protein, TC, HDL, TG, creatinine,

amylase, and BUN), as well as that of low-density lipoprotein (LDL), which is calculated using a formula. The cartridge consists of sample input and analyzer modules; a glass fiber filter installed within the sample input module filters red blood cells from the sample. The filtrate is then transferred to the analyzer module, where it reacts with a pre-dried reagent to emit light at a specific wavelength, which is captured to measure the quantity of analytes. When 70 µl of sample is injected into the cartridge, results of analysis may be obtained in approximately 7 min.

Blood sample collection and measurement

Capillary blood and venous blood samples were obtained from 51 patients and 18 healthy adults aged between 20 and 65 years. The present study was reviewed and approved by the Chungnam National University Hospital institutional review board (IRB number: 2015-01-013). All participants provided written informed consent. Capillary blood was used for analyte measurement by LABGEO PT 10 immediately after collection. Venous blood samples were collected in serum-separating tubes and LiHep tubes; the former

TABLE 1. Linear Regression Analysis, Bias, and % Bias Between Analyte Measurements in Capillary Whole Blood and Venous Whole Blood Samples Using the LABGEO PT10

		Capillary whole blood vs. LiHep whole blood				
Analytes	Range	Slope	Intercept	R^2	Bias	% Bias
ALB (g/dl)	2.3-4.9	0.9628	0.2287	0.8185	0.1	1.4
HDL (mg/dl)	19–128	1.0132	1.4198	0.9287	2.1	4.0
TP (g/dl)	4.7 - 8.0	0.9289	0.5799	0.6016	0.2	2.5
Glucose (mg/dl)	41–434	1.0091	6.4876	0.9786	7.6	7.0
TC (mg/dl)	68-468	1.0194	0.7674	0.9746	4.0	2.4
BUN (mg/dl)	5.3–96.3	1.0014	0.0331	0.9978	0.1	0.7
TG (mg/dl)	34-452	1.0471	-0.1892	0.9689	7.2	4.4
ALT (U/l)	6-494	0.9441	0.7725	0.9960	-2.2	-0.7
AST (U/l)	9-241	0.9798	0.8488	0.9961	1.8	5.1
ALP (U/l)	34-419	1.0244	1.6469	0.9953	9.1	2.8
TBIL (mg/dl)	0.18-4.45	1.0039	0.0093	0.9889	0.1	1.6
GGT (U/l)	5-1171	0.9883	2.5117	0.9984	1.2	2.8
AMY (U/l)	9-164	1.0155	0.0106	0.9971	1.2	1.6
Creatinine (mg/dl)	0.4–22.7	1.0037	-0.0862	0.9979	-0.08	-0.89

LiHep, lithium heparin; ABL, albumin; HDL, high-density lipoprotein; TP, total protein; TC, total cholesterol; BUN, blood urea nitrogen; TG, triglyceride; ALT, alanine aminotransferase; AST, aspartate aminotransferase; ALP, alkaline phosphatase; TBIL, total bilirubin; GGT, γ-glutamyl transferase; AMY, amylase.

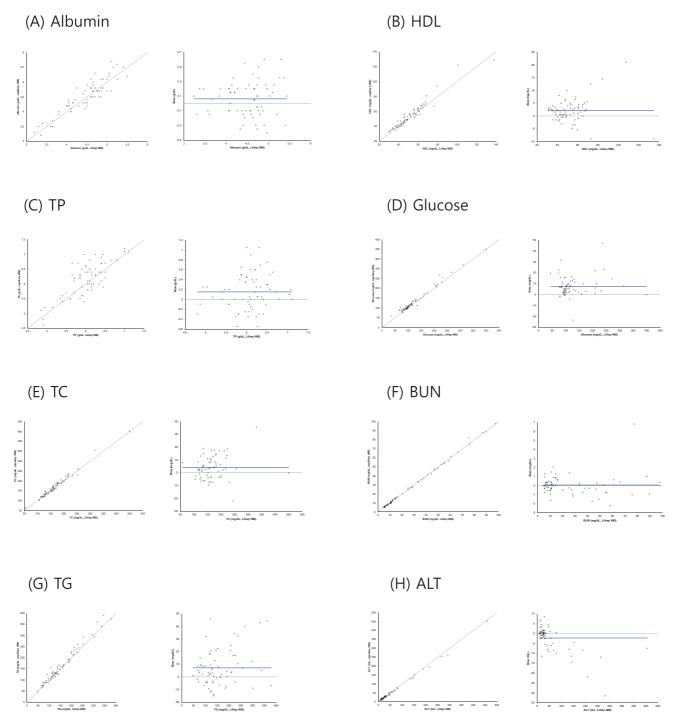


Fig. 1. Scatter plots displaying linear regression data and Bland-Altman bias plots for capillary whole blood and LiHep whole blood analysis performed using the LABGEO PT10 analyzer. (A) Albumin, (B) HDL, (C) TP, (D) Glucose, (E) TC, (F) BUN, (G) TG, (H) ALT, (I) AST, (J) ALP, (K) TBIL, (L) GGT, (M) AMY, (N) Creatinine.

were centrifuged and the serum was used for measurement using a Toshiba 2000FR NEO (Toshiba Medical System Co., Tokyo, Japan) analyzer, in duplicate, in a central laboratory. The whole blood sample collected in LiHep tubes was used for measurement of analytes

by the Samsung LABGEO PT10 analyzer, in duplicate. All analyses performed using the LABGEO PT10 analyzer and the Toshiba 2000FR NEO analyzer were completed within 30 min and 2 hr of sample collection, respectively.

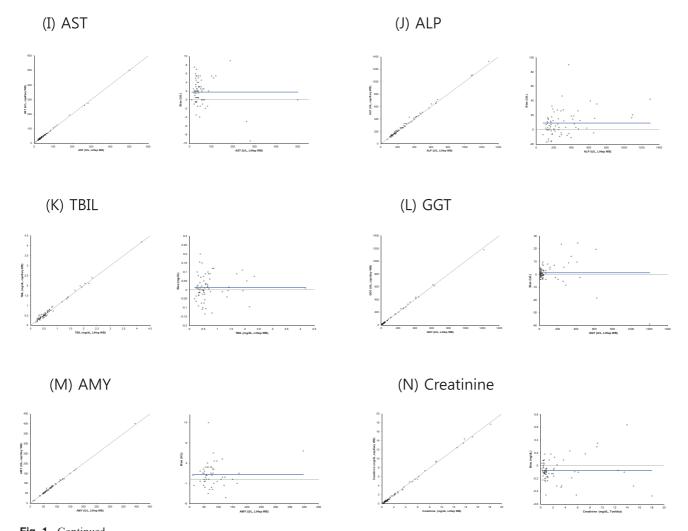


Fig. 1. Continued

Results obtained from the analysis of the following combinations of samples were analyzer, (b) LiHep whole blood samples, using the LABGEO PT10 analyzer and the Toshiba 2000FR NEO analyzer, and (c) capillary whole blood using the LABGEO PT10 analyzer and the Toshiba 2000FR NEO analyzer. The correlation in each comparison was evaluated according to the Clinical and Laboratory Standards Institute (CLSI) EP9A guidelines (8).

Statistical analysis

Analyse-it software (version 2.30 Excel 12+; Microsoft, Leeds, United Kingdom) was used for linear regression analysis. The slope, intercept, correlation coefficient (R^2), bias, and percent (%) bias were also calculated. Bland–Altman plots were constructed for visual comparison of the correlation

between measurements of whole blood samples as performed using the LABGEO PT10 analyzer and the Toshiba 2000FR NEO analyzer at the central laboratory.

RESULTS

Comparison between analytical results for capillary whole blood and LiHep whole blood samples using the LABGEO PT10 analyzer

The slope derived for the comparison of capillary whole blood and LiHep whole blood analyses, using the LABGEO PT10, ranged from between 0.9289 and 1.0471 and the correlation coefficient (R^2) was over 0.95, except for albumin, HDL, and total protein. The % bias ranged from -0.89% to 7.0% for all analytes (Table 1 and Fig. 1).

TABLE 2. Linear Regression, Bias, and % Bias Between Measurements of Capillary Whole Blood Using the LABGEO PT10 and Analyzer and the Toshiba 2000FR NEO Analyzer at the Central Laboratory

Results for capillary whole blood analysis performed using the LABGEO PT10 analyzer vs. those obtained using the Toshiba 2000FR NEO analyzer at the central laboratory

Analytes	Range	Slope	Intercept	R^2	Bias	% Bias
ALB (g/dl)	2.3-4.9	0.8493	1.2243	0.7868	0.6	16.0
HDL (mg/dl)	19–128	0.8409	14.3240	0.8375	6.8	17.2
TP (g/dl)	4.7 - 8.0	0.6433	1.7370	0.6209	-0.7	-10.6
Glucose (mg/dl)	41–434	0.9825	7.9022	0.9744	5.7	5.2
TC (mg/dl)	68-468	0.9717	-2.5186	0.9645	-7.6	-4.4
BUN (mg/dl)	5.3–96.3	1.0695	-2.6823	0.9970	-0.9	-12.0
TG (mg/dl)	34-452	0.7644	38.6340	0.9303	0.1	7.8
ALT (U/l)	6-494	0.7946	8.3324	0.9796	-2.9	15.2
AST (U/l)	9-241	1.1364	13.1430	0.9876	16.3	54.0
ALP (U/l)	34-419	3.2515	-12.1030	0.9800	213.0	120.6
TBIL (mg/dl)	0.18-4.45	0.9050	-0.0905	0.9674	-0.2	-22.8
GGT (U/l)	5-1171	1.0196	0.8433	0.9982	3.0	6.5
AMY (U/l)	9-164	1.0044	1.2450	0.9856	1.6	3.2
Creatinine (mg/dl)	0.4–22.7	0.8792	0.1798	0.9761	-0.16	-12.9

ABL, albumin; HDL, high-density lipoprotein; TP, total protein; TC, total cholesterol; BUN, blood urea nitrogen; TG, triglyceride; ALT, alanine aminotransferase; AST, aspartate aminotransferase; ALP, alkaline phosphatase; TBIL, total bilirubin; GGT, γ-glutamyl transferase; AMY, amylase.

Comparison between analyte measurements of capillary whole blood samples performed using the LABGEO PT10 analyzer and the Toshiba 2000FR NEO analyzer at the central laboratory

The slope derived from the comparison of analytical results for the capillary whole blood samples, obtained using the LABGEO PT10 analyzer and the Toshiba 2000FR NEO analyzer at the central laboratory, ranged from between 0.6433 and 1.1364 for all analytes except ALP; the R^2 of glucose, TC, BUN, ALT, AST, ALP, TBIL, GGT, AMY, and creatinine was over 0.95. The % bias ranged from -22.8% to 54.0% for all analytes except ALP (Table 2 and Fig. 2).

Comparison between analyte measurements of LiHep whole blood samples performed using the LABGEO PT10 and analyzer and the Toshiba 2000FR NEO analyzer at the central laboratory

The slope obtained for the comparison of analyte measurements in LiHep whole blood samples, using

the LABGEO PT10, and in serum samples, using the Toshiba 2000FR NEO analyzer at the central laboratory, ranged from 0.6255 to 1.1602 for each analyte except ALP. The R^2 values for glucose, TC, BUN, ALT, AST, ALP, TBIL, GGT, AMY, and creatinine were over 0.95. The % bias ranged from -25.6% to 44.2% for all analytes except ALP (Table 3 and Fig. 3).

DISCUSSION

Point-of-care test devices have traditionally been used for the measurement of a single analyte; however, recent advances in technology have led to the development of POCT analyzers capable of the simultaneous measurement of multiple analytes, resulting in a growth in the potential range of applications of these devices. Despite the numerous advantages of POCT analyzers, these devices have not been widely adopted in primary care in many countries mainly due to clinicians' concerns regarding test accuracy, limited utility, and over-reliance on tests (9, 10).

Many analytical studies evaluating point-of-care testing devices have mainly relied on the use of venous blood samples, which requires the collection of blood by a phlebotomist; only a small number of studies have comparatively analyzed the utility of POCTs and capillary blood sampling, although the latter would be of greater practical use in primary care clinics (11-13). Moreover, as only a small number of instruments are capable of performing several biochemical tests simultaneously, the application of POCTs for evaluation of patients' overall health status in primary care settings has been limited (4, 12).

In order to evaluate the utility of capillary blood analysis by the LABGEO PT10 device, results obtained from the analysis of capillary whole blood samples using this analyzer were compared with those obtained using the Toshiba 2000FR NEO at the central laboratory. Moreover, relatively few studies to date have used capillary whole blood samples, whereas numerous studies have reported evaluations using LiHep whole blood; therefore, we compared results obtained from the analysis of LiHep whole blood samples using the LABGEO PT 10 analyzer to those obtained at the central laboratory results in order to enable comparisons with data from other studies. Overall, the correlation coefficients between the results of analysis of capillary whole blood and LiHep whole blood samples, obtained using the LABGEO PT10, were very high, and the bias measured via Bland-Altman analysis was minimal (Table 1 and Fig. 1). Therefore, we concluded that the analytical results for the two types of whole blood samples, obtained using the LABGEO PT10 analyzer, did not

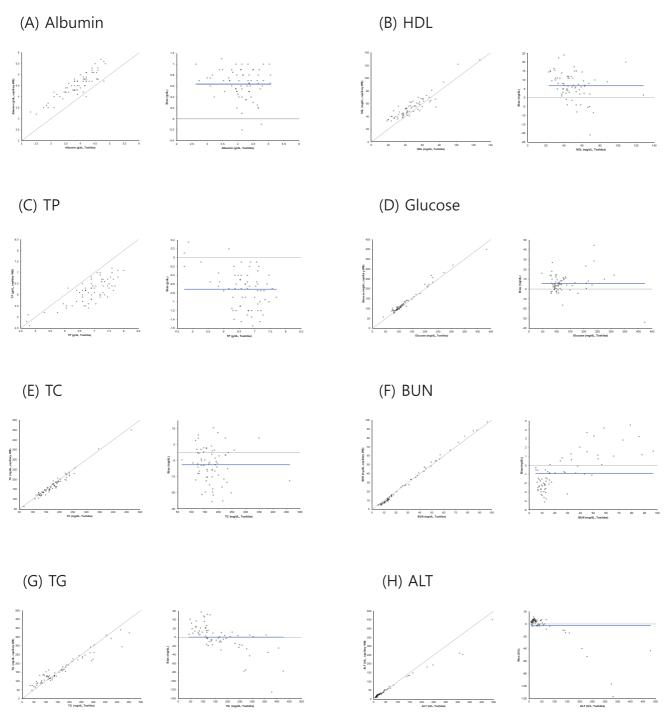


Fig. 2. Scatter plots displaying linear regression data and Bland–Altman bias plots of capillary whole blood analysis by the LABGEO PT10 analyzer and the Toshiba 2000FR NEO analyzer at the central laboratory. (A) Albumin, (B) HDL, (C) TP, (D) Glucose, (E) TC, (F) BUN, (G) TG, (H) ALT, (I) AST, (J) ALP, (K) TBIL, (L) GGT, (M) AMY, (N) Creatinine.

differ significantly. Moreover, when the results of analysis of capillary whole blood and LiHep whole blood samples, obtained using the LABGEO PT10 device, were each compared with those obtained at the central laboratory, similar patterns were observed except for a slightly larger bias for the comparison of capillary blood

analysis performed using the LABGEO PT10 device with that performed at the central laboratory. For most analytes in both the capillary as well as LiHep whole blood samples, measurements obtained using the LABGEO PT10 showed high correlation with those obtained at the central laboratory and the %

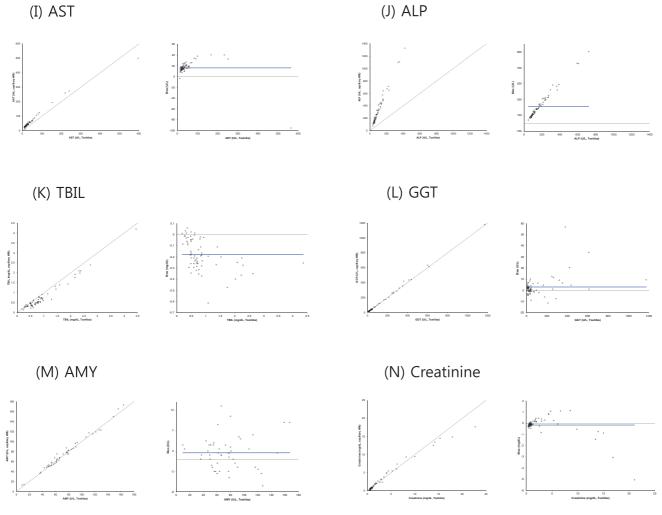


Fig. 2. Continued

bias satisfied the Clinical Laboratory Improvement Amendments (CLIA) criteria. However, the % bias for the results for albumin, total protein, and AST exhibited a deviation from the CLIA acceptance criteria when compared with those obtained at the central laboratory. With regard to these analytes, as the analytical results for the present samples tended to lie within a relatively specific range with low values, evaluation using samples with a wider distribution would be necessary in future studies. Particularly, the slope was 3 in comparison of the measurements using LABGEO PT10 with those in central laboratory. On ALP activity, Japan Society of Clinical Chemistry (JSCC) method is known to show three times larger values than the International Federation of Clinical Chemistry (IFCC) method (14). Thus, our finding was attributed to the differences between the test methods, IFCC method used by central laboratory and JSCC method used by LABGEO PT10.

In case of glucose, the coefficient of correlation between the results for capillary whole blood and serum analysis was found to be far higher $(R^2 = 0.9744; y = 0.98x + 7.9)$ than that obtained in previous studies (0.47 for pediatric patients and 0.77 for patients in intensive care units) (12, 13). The analytical results for capillary blood samples showed a mean bias of 5.2% compared with those obtained at the central laboratory, which is consistent with the fact that glucose levels measured in capillary blood are usually higher than those measured in venous blood. Only 4.5% of all measurements of LiHep whole blood samples and 19.4% of those of capillary whole blood deviated from the CLIA 88 requirement of $\pm 10\%$; therefore, in terms of accuracy, the performance of the LABGEO PT10 analyzer was superior to that of the Piccolo Xpress Chemistry Analyzer or i-Stat chem8 (4, 12, 15). However, it is known that blood glucose measurements in capillary samples

TABLE 3. Linear Regression, Bias, and % Bias Between Analyte Measurements in LiHep Whole Blood Samples Using the LABGEO PT10 Analyzer and the Toshiba 2000FR NEO Analyzer at the Central Laboratory

Results for LiHep whole blood analysis performed using the LABGEO PT10 analyzer vs. those obtained using the Toshiba 2000FR NEO analyzer at the central laboratory

Range						
	Slope	Intercept	R^2	Bias	% Bias	
2.3–4.9	0.8227	1.2660	0.8361	0.6	14.2	
19-128	0.8108	13.6480	0.8607	4.6	12.4	
4.7 - 8.0	0.6255	1.7064	0.8420	-0.9	13.3	
41–434	0.972	1.6086	0.9923	-1.9	-1.8	
68-468	0.9447	-1.6013	0.9707	-11.5	-6.9	
5.3-96.3	1.0668	-2.6787	0.9969	-1.0	-13.2	
34-452	0.7215	38.4750	0.9377	-7.0	2.7	
6-494	0.8421	7.9883	0.9844	-0.6	15.1	
9-241	1.1602	10.4920	0.9902	14.5	44.2	
34-419	3.1734	-13.3480	0.9841	203.9	98.3	
0.18-4.45	0.8959	-0.0944	0.9664	-0.2	-25.6	
5-1171	1.0311	-1.6241	0.9986	1.8	3.4	
9-164	1.0100	-0.2677	0.9894	0.5	1.5	
0.4-22.7	0.8767	0.2627	0.9800	-0.09	-5.0	
	2.3-4.9 19-128 4.7-8.0 41-434 68-468 5.3-96.3 34-452 6-494 9-241 34-419 0.18-4.45 5-1171 9-164	2.3-4.9	2.3-4.9 0.8227 1.2660 19-128 0.8108 13.6480 4.7-8.0 0.6255 1.7064 41-434 0.972 1.6086 68-468 0.9447 -1.6013 5.3-96.3 1.0668 -2.6787 34-452 0.7215 38.4750 6-494 0.8421 7.9883 9-241 1.1602 10.4920 34-419 3.1734 -13.3480 0.18-4.45 0.8959 -0.0944 5-1171 1.0311 -1.6241 9-164 1.0100 -0.2677	2.3-4.9 0.8227 1.2660 0.8361 19-128 0.8108 13.6480 0.8607 4.7-8.0 0.6255 1.7064 0.8420 41-434 0.972 1.6086 0.9923 68-468 0.9447 -1.6013 0.9707 5.3-96.3 1.0668 -2.6787 0.9969 34-452 0.7215 38.4750 0.9377 6-494 0.8421 7.9883 0.9844 9-241 1.1602 10.4920 0.9902 34-419 3.1734 -13.3480 0.9841 0.18-4.45 0.8959 -0.0944 0.9664 5-1171 1.0311 -1.6241 0.9986 9-164 1.0100 -0.2677 0.9894	2.3-4.9 0.8227 1.2660 0.8361 0.6 19-128 0.8108 13.6480 0.8607 4.6 4.7-8.0 0.6255 1.7064 0.8420 -0.9 41-434 0.972 1.6086 0.9923 -1.9 68-468 0.9447 -1.6013 0.9707 -11.5 5.3-96.3 1.0668 -2.6787 0.9969 -1.0 34-452 0.7215 38.4750 0.9377 -7.0 6-494 0.8421 7.9883 0.9844 -0.6 9-241 1.1602 10.4920 0.9902 14.5 34-419 3.1734 -13.3480 0.9841 203.9 0.18-4.45 0.8959 -0.0944 0.9664 -0.2 5-1171 1.0311 -1.6241 0.9986 1.8 9-164 1.0100 -0.2677 0.9894 0.5	

LiHep, lithium heparin; ABL, albumin; HDL, high-density lipoprotein; TP, total protein; TC, total cholesterol; BUN, blood urea nitrogen; TG, triglyceride; ALT, alanine aminotransferase; AST, aspartate aminotransferase; ALP, alkaline phosphatase; TBIL, total bilirubin; GGT, γ-glutamyl transferase; AMY, amylase.

from critically ill patients are less accurate owing to hypoperfusion and the hypermetabolic state of these patients, especially within the hypoglycemic range. Therefore, additional evaluation for these patient groups is required (13).

The ability of a creatinine meter to report results comparable to those obtained at a routine laboratory is extremely important as a lack of accuracy may impact patient safety (16). However, creatinine measurement in whole blood is challenging due to the complexity of the specimen matrix and disease state (17). Compared with the results of a previous study in which LiHep whole blood samples were used, LABGEO PT10 showed a higher coefficient of correlation and lower bias, with the exception of data obtained using a Radiometer ABL800 FLX analyzer (14, 18). However, the bias worsened when capillary whole blood was analyzed, which is expected to result in a decrease in the sensitivity of detection of the estimated glomerular filtration rate (eGFR) to lower than $60 \text{ ml/min}/1.73 \text{ m}^2$.

Few instruments available in the market provide liver function panels or lipid panel analysis; therefore, studies evaluating these devices are scarce. As expected, the detected levels of total protein were higher in LiHep whole blood than serum; this was attributed to the consumption of coagulation factors and fibrinogen during clotting (19). Correlation coefficients for liver function tests were similar to those reported by previous studies that compared measurements of LiHep whole blood, performed using the Abbott Piccolo Xpress, to those obtained in a central

laboratory (19, 20). However, when the % bias was compared, the data for amylase and GGT showed lower bias while those for the remaining analytes (AST, ALT, ALP, albumin, and total protein) showed higher bias than in other studies (19, 20). In particular, when analyses were performed using whole blood samples, the data for AST exhibited a significant bias that exceeded the CLIA 88 requirement. Therefore, caution must be exercised when analyzing AST levels in whole blood, and improvements are required in order to resolve this limitation.

In terms of the lipid panel, correlation with data obtained at the central laboratory was good regardless of specimen type. The results obtained satisfied the National Cholesterol Education Program (NCEP) criteria (21), which specify TC levels of lower than $\pm 3\%$ and TG and HDL levels of lower than $\pm 5\%$, when LiHep whole blood samples were analyzed. These results demonstrated the adequacy of the LABGEO PT10 device for use in screening programs for the early detection of lipid disorders. However, this was not the case when capillary whole blood was analyzed; in particular, the bias for HDL levels in capillary whole blood was significant, despite the CLIA 88 criteria being satisfied.

In the near future, with improved outpatient management and patient monitoring in the home environment, the number of patients that require inpatient care and the duration of hospitalization are predicted to decrease (22). Moreover, in addition to the current POC monitoring of glucose levels in diabetes, the monitoring of chronic diseases using

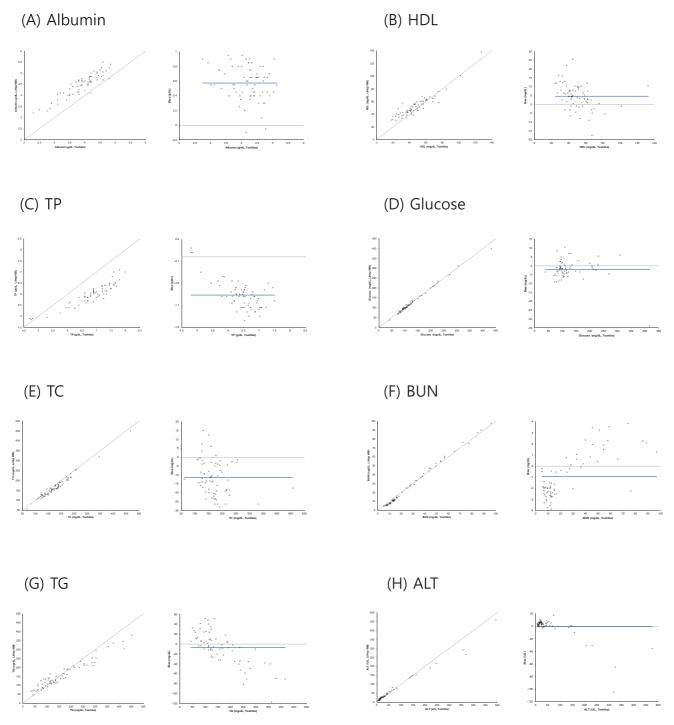


Fig. 3. Scatter plots displaying linear regression data and Bland-Altman bias plots for analysis of LiHep whole blood samples performed using the LABGEO PT10 analyzer and the Toshiba 2000FR NEO analyzer at the central laboratory. (A) Albumin, (B) HDL, (C) TP, (D) Glucose, (E) TC, (F) BUN, (G) TG, (H) ALT, (I) AST, (J) ALP, (K) TBIL, (L) GGT, (M) AMY, (N) Creatinine.

POCT devices is expected to increase with the growing availability of suitable analyzers (3). The LAB-GEO PT10 chemistry analyzer, which is capable of performing several biochemical analyses simultaneously, generates results within 7 min, is potentially

extremely useful when prompt medical decisions are required as well as for the diagnosis and monitoring of chronic diseases in primary care settings where the availability of instruments and technicians is limited. Furthermore, as this device only requires a very

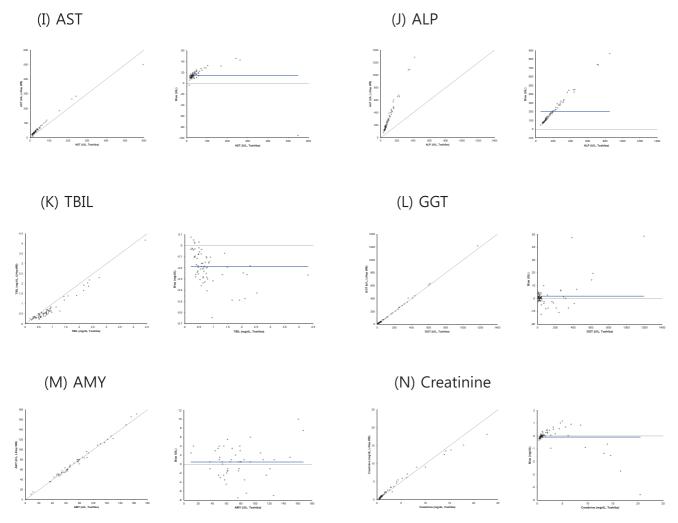


Fig. 3. Continued

small blood sample for analysis, it is ideal for use with newborns and pediatric patients with small blood volumes.

In conclusion, good correlation was observed between analytical measurements of capillary whole blood and LiHep whole blood samples using the LAB-GEO PT10 chemistry analyzer. In addition, these results showed a high correlation with measurements obtained at the central laboratory. Our findings indicate that capillary whole blood may be reliably sampled for clinical chemistry analyses using the LABGEO PT10 device.

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