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Evaluation of the Performance of LABGEO PT Hepatic Test 9

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Background: The Samsung LABGEO PT Hepatic Test 9 (Samsung electronics, Korea) was developed as a point-of-care (POC) testing device. The levels of 9 analytes, namely, albumin, AST, ALT, alkaline phosphatase, gamma-glutamyl transferase, glucose, total bilirubin, direct bilirubin, and total protein, could be evaluated simultaneously by using 70 μL of whole blood, plasma, or serum samples. In this study, we assessed the performance of the Samsung LABGEO PT Hepatic Test 9.
Methods: The precision and linearity of the test were evaluated according to the CLSI EP5-A2 and CLSI EP6-A guidelines, respectively. Correlational analyses between Samsung LABGEO PT Hepatic Test 9 and Cobas 8000 modular analyzer (Roche, Switzerland) were carried out as per the CLSI EP9-A2 guidelines. Additionally, the results between 3 different specimen types, whole blood, plasma, and serum samples obtained from the same individual were compared to evaluate the matrix effect.
Results: The total imprecision at both low and high levels of the 9 analytes was within 10% and in the clinically important concentration range for all test items, all obtained results were linear. We compared the above results with those obtained using Cobas 8000 and a good correlation was observed with a correlation coefficient of more than 0.975 for all 9 analytes. Simple linear regression analyses between the 3 different specimen types indicated that there was no statistically significant difference ($P < 0.001$).
Conclusions: The Samsung LABGEO PT Hepatic Test 9 showed good precision and linearity when compared to established assays for 9 clinical test items and could be useful in cases where the POC testing is required.

Key Words: Samsung LABGEO PT Hepatic Test 9, Precision, Linearity, Method comparison, Specimen type

Introduction

As point-of-care (POC) testing is a convenient testing method that neither requires specimen to be transferred to a central lab after it has been collected nor needs specimen to undergo a preliminary processing as centrifuging, it potentially reduces turnaround time (TAT) [1].

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Since physicians or nurses conduct point-of-care tests themselves, POC tests have the advantage of producing readily available results, which then may be utilized for diagnosing and/or treating the patients promptly. Therefore, use of POC tests is on the rise [2-4]. On the other hand, disadvantages of POC tests include the limited spectrum of conductible tests and the difficulty of quality control as the tests are conducted by non-laboratory personnel [5]. At present, pregnancy test, blood glucose test, and arterial blood gas and electrolyte test are routinely conducted at point of care, while the use of POC tests in infectious diseases, cardiovascular disorders, and drug overdose cases are gradually increasing.

The recently developed Samsung LABGEO PT Hepatic Test 9 (Samsung Electronics, Korea) can be used easily on Samsung LABGEO PT10 (Samsung Electronics), a dedicated point-of-care testing system. Samsung LABGEO PT Hepatic Test 9 is capable of testing serum, plasma, or whole blood specimen for the nine items of albumin, alkaline phosphatase (ALP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, glucose, gamma-glutamyl transferase (γ-GT), and total protein simultaneously.

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The purpose of this study is to evaluate the performance of Samsung LABGEO PT Hepatic Test 9 including precision, linearity, and method comparison of nine test items, and to compare whole blood, plasma, and serum specimens in order to evaluate the matrix effect by specimen type.

Subject and Method

1. Equipment and Reagents

A Samsung LABGEO PT10 system and Samsung LABGEO PT Hepatic Test 9 cartridges were used, and tests were conducted in accordance with the manufacturer's guidelines. Samsung LABGEO PT10 is a point-of-care testing system designed for easy clinical chemistry assays using 70 μL of blood specimen, whether it be whole blood, plasma, or serum. An integrated QC mode enables the user to conduct quality control, and, like usual POC testing systems, the manufacturer calibrates each and every cartridge lot, making it unnecessary for the user to conduct additional procedures. The system is designed to provide a touchscreen interface for controlling the majority of test procedures. Samsung LABGEO PT Hepatic Test 9 can simultaneously conduct nine general chemistry tests using whole blood, plasma, or serum specimen. The manufacturer's guideline dictates that specimen is to be placed in a dedicated container, i.e. a lithium heparin tube. Once specimen is injected into the cartridge and test is initiated, the result of nine test items are produced in approximately seven minutes. When test is completed, a sound plays, and the test results are displayed on screen; a paper printout of the results is also produced.

The following methods are employed for the nine test items: Albumin is measured by using the dye binding-bromcresol purple (BCP) method; AST and ALT by using the colorimetric method; ALP by using the JSCC-EAE method; total and direct bilirubins by using the enzymatic bilirubin oxidase method; blood glucose by using the glucose dehydrogenase method; GGT by using the IFCC method; and total protein by using the Biuret method.

2. Precision

Precision was evaluated by using BIO-RAD Liquid Assayed Multiqual Level 1 and Level 3 (Bio-Rad Laboratories Inc., Hercules, CA, USA), in accordance with the Clinical and Laboratory Standards Institute (CLSI) EP5-A2 Guidelines [6]. Each concentration was measured by two duplications per session, twice a day over a period of 20 days. The b.i.d. examinations were conducted in the morning and the afternoon of the day, with at least two hours of interval between each session. The measurement results were used to calculate the within-run coefficient of variation (CV), between-run CV, between-day CV, and total CV.

3. Linearity

The linearity was evaluated by using Validate GC Linearity Test Set (Marine Standard Company, Windham, ME, USA), in accordance with the CLSI EP6-A Guidelines [7]. Validate is a liquid substance designed for calibration and linearity testing; it was approved by the United States Food and Drug Administration. It consists of substances with five different concentrations, with each concentration consisting of identical intervals. With Validate, it is not necessary to dilute or mix specimens. Also, since Validate is in liquid form, it can be used directly without pre-processing the specimen.

For each of the nine test items, five concentrations, ranging from low to high concentration, were measured four times each by taking into consideration the analytical measurement range provided by the manufacturer. Polynomial regression analyses were conducted on the measurement results to obtain the best-fit polynomial. If the best-fit polynomial displays first-order linearity, linearity is deemed to be maintained within the range; if the polynomial does not display first-order linearity, linearity is deemed to exist within the range if the relative nonlinearity at all concentrations is 2.5% or less.

4. Method Comparison

Correlation was evaluated in accordance with the CLSI EP9-A2 Guidelines [8]. Cobas 8000 modular analyzer (Roche diagnostics, Switzerland), which is the testing equipment currently being used in the clinical laboratory, was used as the reference testing equipment. Specimens were collected from 60 patients, so that the specimens include concentrations that are inside and outside the measurable range. Each of the two testing systems was used to obtain a set of two measurements, the averaged value of which was then used to calculate the regression equation and the coefficient of correlation (r) between the two testing methods. The standards of College of American Pathologists and Clinical Laboratory Improvement Amendments (CLIA) were used as the total allowable error. Correlation was deemed to exist if the coefficient of correlation was 0.975 or higher.

5. Correlation by Specimen Type

To evaluate the correlation by specimen type, a modified CLSI EP14-A2 [9] was employed to take a set of two measurements from each of the serum, plasma, and whole blood specimens that were taken from each patient of a 40-patient group. To identify the difference among whole blood, plasma, and serum specimens that were collected from a patient, the specimens were collected in both the lithium heparin tubes and the serum separating tube (SST).

70 μL of the whole blood specimen collected in the lithium heparin tube was injected into the prepared cartridge, and the test was initiated. While the test of whole blood specimen was in progress, the lithium heparin tube and the serum separating tube were centrifuged at 3,000g for 10 minutes. After preparing the lithium heparinized plasma that was obtained by centrifuging and the serum, the plasma and serum specimens were tested in turn when testing of whole blood specimen was completed.

Cartridges from the same lot were used for measurements; specimens from the same patients were tested on the same equipment. Simple linear regression analyses were conducted on the results of measuring each specimen, in order to obtain the coefficient of determination and the P value.

6. Statistical Analysis

Statistical analysis was conducted by using EP Evaluator Release 10 (David G. Rhoads Assoc., Kennett square, PA, USA), Analyse-it Standard Edition 2.26, SPSS version 13.0 (SPSS Inc., Chicago, IL, USA).

Result

1. Precision

Table 1 shows the mean, standard deviation, within-run coefficient of variation (CV), between-run CV, between-day CV, and total CV for each test item. The evaluation of precision revealed that, for the five items of albumin, AST, blood glucose, total bilirubin, and total protein, the total coefficients of variation are 5% or less at both level 1 and level 3. For the three items of ALP, GGT, and direct bilirubin, the total CVs are 5% or less at level 3, and 5-10% at level 1. For ALT, the total CV was 5.1% at level 1, and 5.5% at level 3.

2. Linearity

The best-fit polynomial for all nine test items displayed first-order linearity, and their coefficients of determination (R^2) were 0.99 or higher (Table 2, Fig 1). Linearity was observed in all test items within clinically significant concentration range.

Table 1. Precision profiles of Samsung LABGEO PT Hepatic Test 9

Analytes (unit)	Level	Mean	SD	Within-run	Between-run	Between-day	Total	CLIA criteria for acceptance performance (%)
ALB (g/dL)	1	2.73	0.09	3.0	1.1	0.4	3.2	10
	3	4.89	0.17	2.9	0.0	1.8	3.4	
AST (U/L)	1	46.39	2.25	4.2	0.0	2.4	4.8	20
	3	256.30	8.68	2.5	0.6	2.2	3.4	
ALT (U/L)	1	19.27	0.98	4.4	2.6	0.0	5.1	20
	3	151.55	8.30	3.4	4.3	0.0	5.5	
ALP (U/L)	1	100.39	7.07	5.3	4.6	0.6	7.0	30
	3	723.75	24.69	2.6	2.2	0.0	3.4	
GGT (U/L)	1	22.85	1.81	6.5	3.9	2.2	7.9	NA
	3	132.78	3.06	2.1	0.0	0.8	2.3	
GLU (mg/dL)	1	57.69	0.88	1.2	0.8	0.5	1.5	10
	3	363.24	6.26	1.3	1.2	0.0	1.7	
TBIL (mg/dL)	1	0.66	0.02	3.7	0.8	1.5	4.1	20
	3	7.21	0.10	1.3	0.4	0.5	1.4	
DBIL (mg/dL)	1	0.47	0.03	8.3	0.0	3.3	8.9	20
	3	3.74	0.17	4.1	0.0	1.5	4.4	
TP (g/dL)	1	4.58	0.11	1.9	0.7	1.1	2.4	10
	3	6.28	0.20	2.8	0.0	1.4	3.2	

Abbreviations: SD, standard deviation; CV, coefficient of variation; CLIA, Clinical Laboratory Improvement Amendments; ALB, albumin; AST, aspartate aminotransferase; ALT, alanine aminotransferase; ALP, alkaline phosphatase; GGT, γ-glutamyl transferase; GLU, glucose; TBIL, total bilirubin; DBIL, direct bilirubin; TP, total protein; NA, not applicable.

Table 2. Linearity of Samsung LABGEO PT Hepatic Test 9

Analytes (unit)	Linear range specified by the manufacture	Test range	Observed linear range	Slope	Intercept	R^2
ALB (g/dL)	1.0–7	0.8–5.3	0.8–5.3	0.9896	0.0269	0.9999
AST (U/L)	10–500	0.0–398.1	0.0–398.1	1.0190	-9.9463	0.9995
ALT (U/L)	10–700	0.0–390.6	0.0–390.6	1.0338	0.5266	0.9995
ALP (U/L)	20–2000	0.0–655.1	0.0–655.1	0.9962	-5.9407	0.9999
GGT (U/L)	10–1500	0.0–1161.7	0.0–1161.7	1.0074	-8.3447	0.9996
GLU (mg/dL)	10–400	3.5–409.5	3.5–409.5	0.9826	2.2947	0.9999
TBIL (mg/dL)	0.1–30	0.1–29.8	0.1–29.8	1.0280	0.4970	0.9991
DBIL (mg/dL)	0.1–16	0.3–24.1	0.3–24.1	1.0600	-0.6405	0.9995
TP (g/dL)	2.0–11	2.3–11.1	2.3–11.1	0.9926	0.0138	0.9995

Abbreviations: R^2, coefficient of determination; ALB, albumin; AST, aspartate aminotransferase; ALT, alanine aminotransferase; ALP, alkaline phosphatase; GGT, γ-glutamyl transferase; GLU, glucose; TBIL, total bilirubin; DBIL, direct bilirubin; TP, total protein.

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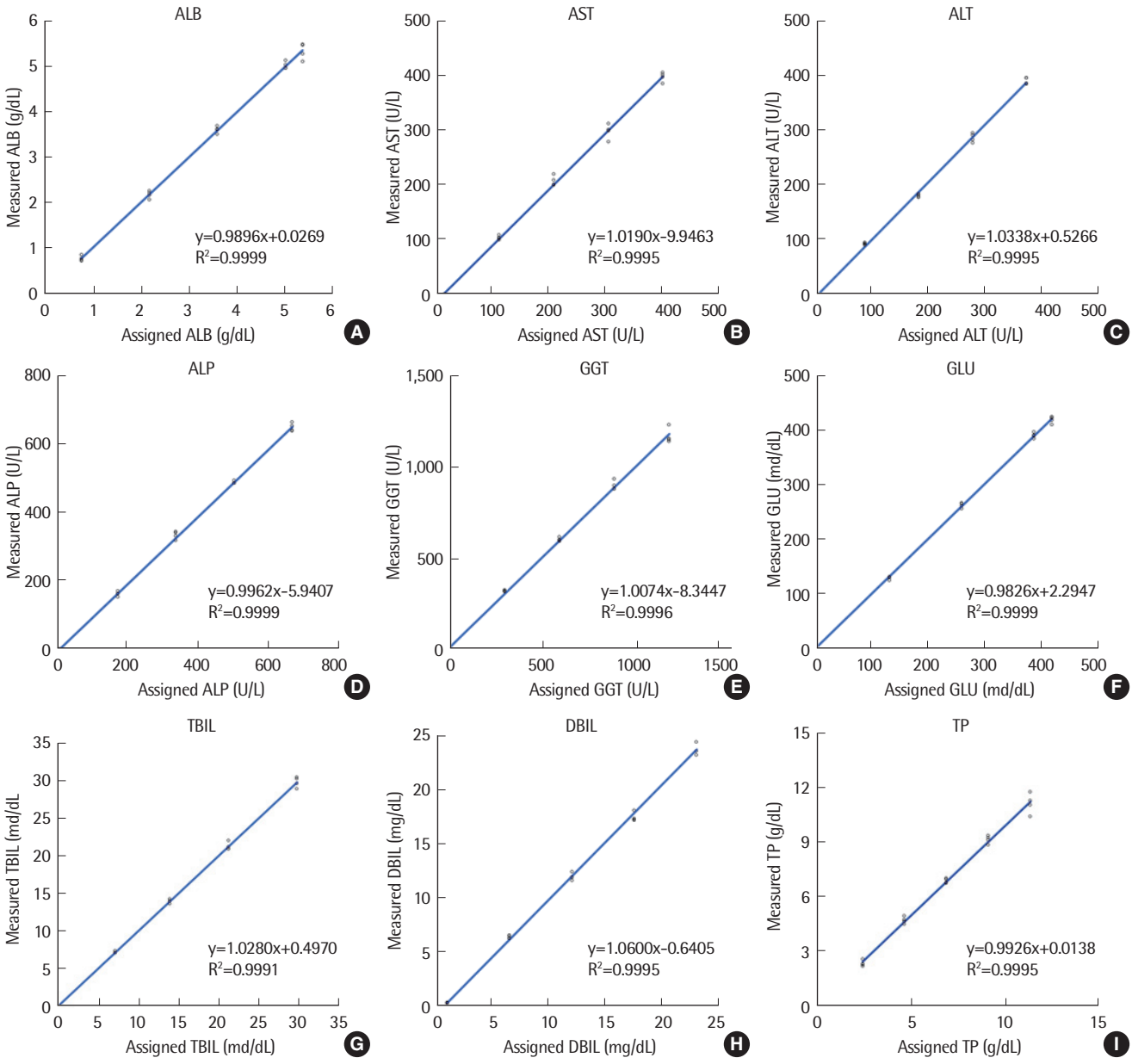

Fig. 1. Linearity of Samsung LABGEO Hepatic Test 9. (A) ALB, albumin; (B) AST, aspartate aminotransferase; (C) ALT, alanine aminotransferase; (D) ALP, alkaline phosphatase; (E) GGT, γ-glutamyl transferase; (F) GLU, glucose; (G) TBIL, total bilirubin; (H) DBIL, direct bilirubin; (I) TP, total protein.

3. Method Comparison

The slopes of correlation equation with the reference testing equipment were within the range of 0.958-1.024, and the coefficients of correlation for all nine test items were 0.975 or higher, which indicates a close correlation (Fig 2).

4. Correlation by Specimen Type

For the eight test items except albumin, the coefficients of determination between whole blood and plasma, between whole blood and serum, and between plasma and serum were 0.95 or higher, and were all statistically significant (Table 3). For albumin, the coefficients of determination was 0.8986 when comparing whole blood and plasma specimens, and the correlation slope was 0.897 when comparing whole blood and serum specimens, which are relatively low but statistically significant nonetheless.

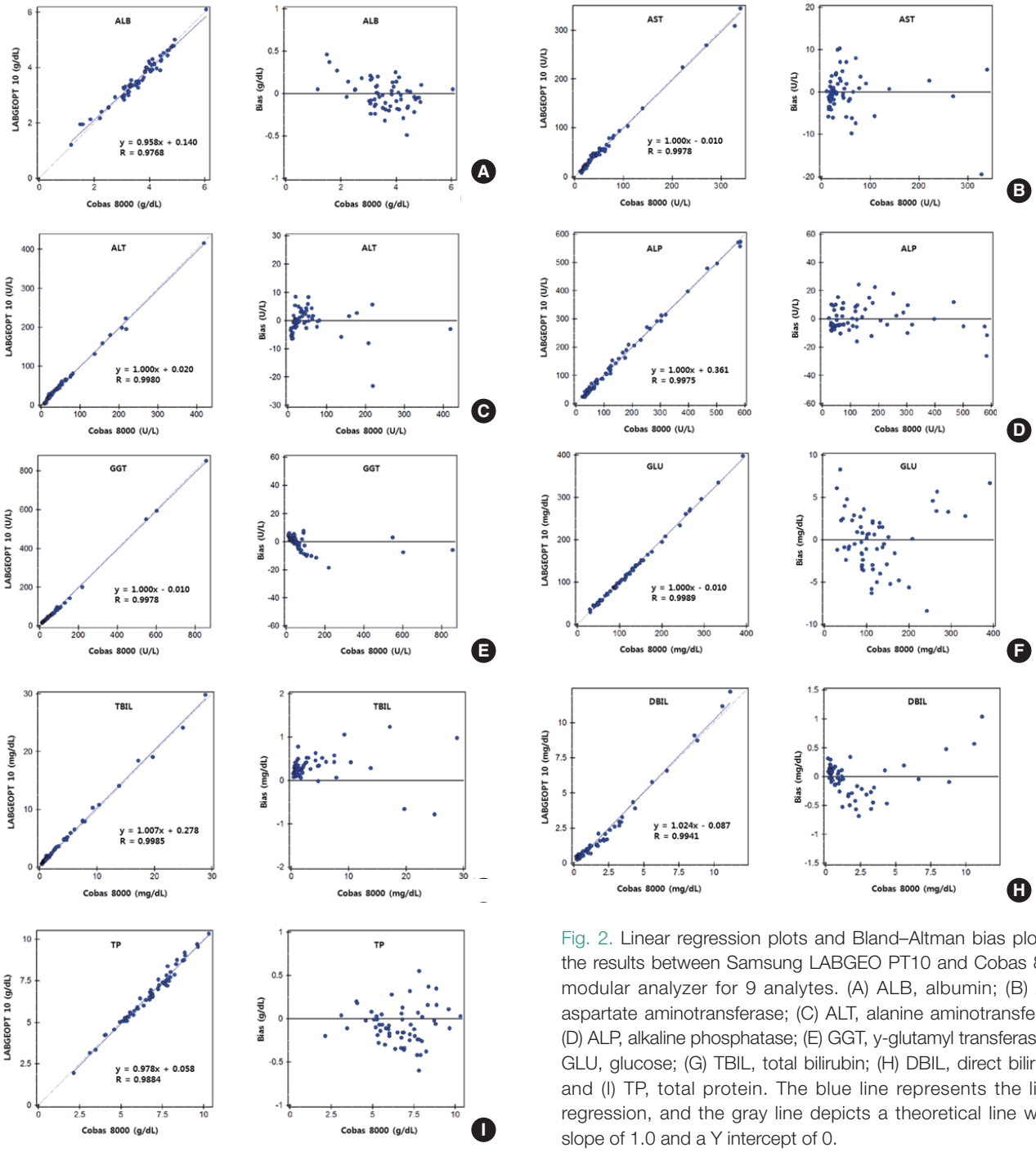

Fig. 2. Linear regression plots and Bland–Altman bias plots of the results between Samsung LABGEO PT10 and Cobas 8000 modular analyzer for 9 analytes. (A) ALB, albumin; (B) AST, aspartate aminotransferase; (C) ALT, alanine aminotransferase; (D) ALP, alkaline phosphatase; (E) GGT, y-glutamyl transferase; (F) GLU, glucose; (G) TBIL, total bilirubin; (H) DBIL, direct bilirubin; and (I) TP, total protein. The blue line represents the linear regression, and the gray line depicts a theoretical line with a slope of 1.0 and a Y intercept of 0.

Consideration

This study evaluated the performance of Samsung LABGEO PT Hepatic Test 9 in the areas of test precision, linearity, and correlation with the existing equipment; the correlations between whole blood, plasma, and serum specimens were analyzed to evaluate the matrix effect by type of specimen.

In the evaluation of precision, the total coefficients of variation for all nine test items satisfied the standards of precision for general chemistry tests that are proposed by the CLIA [10].

For high-concentration substances, the total coefficients of variation for eight test items except ALT were less than 5%; for low-concentration substances, the total coefficients of variation for ALP, GGT, and direct bilirubin were 5-10%.

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Table 3. Simple linear regression analysis of 3 different specimen types by using Samsung LABGEO PT Hepatic Test 9

Analytes	Whole Blood vs. Plasma			Plasma vs. Serum			Plasma vs. Serum		
	Slope (95% CI)	R^2	*P*	Slope (95% CI)	R^2	*P*	Slope (95% CI)	R^2	*P*
ALB	0.959 (0.961–1.056)	0.8986	<0.001	0.897 (0.815–0.979)	0.9180	<0.001	0.929 (0.856–1.002)	0.9401	<0.001
AST	1.005 (0.975–1.036)	0.9913	<0.001	1.038 (0.999–1.078)	0.9860	<0.001	1.033 (0.998–1.069)	0.9887	<0.001
ALT	1.049 (1.020–1.079)	0.9925	<0.001	1.014 (0.989–1.039)	0.9944	<0.001	0.966 (0.937–0.996)	0.9911	<0.001
ALP	1.001 (0.987–1.016)	0.9982	<0.001	1.029 (1.004–1.053)	0.9953	<0.001	1.028 (1.014–1.042)	0.9984	<0.001
GGT	1.007 (0.996–1.018)	0.9991	<0.001	1.017 (1.007–1.027)	0.9992	<0.001	1.01 (1.002–1.018)	0.9995	<0.001
GLU	0.998 (0.979–1.014)	0.9971	<0.001	1.005 (0.977–1.032)	0.9927	<0.001	1.003 (0.978–1.028)	0.9941	<0.001
TBIL	0.991 (0.985–0.997)	0.9996	<0.001	1.002 (0.994–1.010)	0.9994	<0.001	1.011 (1.003–1.019)	0.9995	<0.001
DBIL	1 (0.989–1.010)	0.9991	<0.001	1.007 (0.992–1.021)	0.9984	<0.001	1.007 (0.998–1.017)	0.9993	<0.001
TP	1.07 (1.013 –1.128)	0.9729	<0.001	1.023 (0.962–1.084)	0.9660	<0.001	0.952 (0.905–0.998)	0.9767	<0.001

Abbreviations: CI, confidence interval; R^2, coefficient of determination; ALB, albumin; AST, aspartate aminotransferase; ALT, alanine aminotransferase; ALP, alkaline phosphatase; GGT, γ-glutamyl transferase; GLU, glucose; TBIL, total bilirubin; DBIL, direct bilirubin; TP, total protein.

Considering that Samsung LABGEO PT Hepatic Test 9 is a point-of-care testing system, all nine test items can be judged to possess superior precision.

In the evaluation of linearity, all test items were proven to possess superior linearity in clinically significant range of concentration. For blood glucose, total bilirubin, direct bilirubin, and total protein, linearity was proven for the concentrations that fall within, or are higher than, the range of linearity that is proposed by the manufacturer.

However, for albumin, AST, ALT, ALP, and GGT, linearity was proven only within a limited range, because commercially available substances for evaluating linearity do not cover the entire range of concentration that is proposed by the manufacturer.

For test items other than total protein, there were differences between the testing method of Samsung LABGEO PT Hepatic Test 9 and that of Cobas 8000; however, the evaluation of correlation revealed that the coefficients of correlation for all test items exceed the acceptable minimum of 0.975, which indicates superior correlation. Coefficient of correlation for albumin was 0.9768, which is relatively lower than those for other test items; this could be interpreted as the difference between testing methods. Samsung LABGEO PT Hepatic Test 9 measures albumin by using dye binding-BCP method, while Cobas 8000 uses dye binding-brom-cresol green (BCG) method to measure albumin. Albumin binds to both BCP and BCG with high affinity.

However, since BCG binds to α1- globulin and α2-globulin as well as to albumin, BCG tends to measure the concentration of albumin higher than BCP does [11, 12]. The evaluation of correlation in this study also found that Cobas 8000, which uses BCG, measured albumin concentration higher than Samsung LABGEO PT Hepatic Test 9, which uses BCP, by an average concentration of 0.011 g/dL; this is attributable to the difference in methods.

While there is no difference in bilirubin, cholesterol, or creatinine concentration between serum and plasma, some test items may measure concentration differently for each type of specimen [13].

Items whose plasma and serum concentrations differ include calcium, chloride, lactate dehydrogenase, and total protein; the concentration of total protein, for example, is known to be higher in plasma than in serum by 4% [13]. On the other hand, albumin, ALP, AST, and glucose are present in greater concentration in serum than in plasma by 1.3%, 1.6%, 0.9%, and 5.1% respectively [13]. In the comparison between whole blood, plasma, and serum specimens in this study, total bilirubin and direct bilirubin produced results that are almost identical regardless of the type of specimen, while the comparison between serum (y axis) and plasma (x axis) specimens for total protein showed higher concentration in plasma, with a correlation slope of 0.952. In the comparison between plasma and serum specimens for AST and glucose, serum concentrations were higher than plasma concentrations on average, with correlation slopes of 1.033 and 1.003 respectively.

These findings are consistent with known facts. Concentration of albumin was the highest in whole blood specimen and the lowest in serum. Since serum is plasma minus fibrinogen, the concentration of albumin should be higher in serum than in plasma in theory. This study yielded plasma concentration of albumin that is higher than serum concentration by 0.1 g/dL on average. However, it is hardly a significant difference considering potential errors that may occur during measurements.

Therefore, it is the judgment of the authors that Samsung LABGEO PT Hepatic Test 9 possesses superior correlations in the comparisons between whole blood, plasma, and serum specimens. In conclusion, the evaluation of the performance of Samsung LABGEO PT Hepatic Test 9 determined that it provides superior precision and inter-systemic correlation, and displays linearity within clinically significant range. The Samsung LABGEO PT Hepatic Test 9 cartridges were developed to be used with Samsung LABGEO PT10, a dedicated point-of-care testing system. Since tests can be performed using whole blood specimens, pre-processing of specimen such as centrifuging is not necessary, which makes testing more convenient; a touchscreen interface makes it easy to control the system after placing the specimen. In addition, the results of nine test items are produced within seven minutes, which makes the system suitable for use in such diverse patient care environments as primary healthcare organizations, emergency rooms, intensive care units, outpatient settings, etc.

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Abstract

Background: Samsung LABGEO PT Hepatic Test 9 (Samsung Electronics, Korea) was designed as a point-of-care test for nine items of albumin, AST, ALT, ALP, GGT, glucose, total bilirubin, direct bilirubin, and total protein in serum, plasma, or whole blood specimen. This study is intended to evaluate the performance of Samsung LABGEO PT Hepatic Test 9.

Method: In accordance with the CLSI Guidelines, the nine general chemistry test items were evaluated for precision, linearity, and correlation with existing testing equipment.

In addition, to evaluate the matrix effect by type of specimen, the nine items were measured and compared using the whole blood, plasma, and serum specimens collected from the same patient. A Cobas 8000 modular analyzer (Roche, Switzerland) was used to evaluate the correlation with existing equipment.

Result: Total precision of the nine test items in both low and high concentrations was within 10%, and all test items displayed linearity within clinically significant range. In the evaluation of correlation with existing equipment, all nine test items displayed superior correlation, with coefficients of correlation of 0.975 or higher.Simple linear regression analyses between whole blood, plasma, and serum specimens produced statistically significant correlations for all nine test items.

Conclusion: We found Samsung LABGEO PT Hepatic Test 9 to possess superior precision, linearity, and correlation with existing equipment in nine general chemistry test items, and believe that it will serve as a useful tool in environments where point-of-care testing is required.

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