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Comparative Evaluation of Mobilab: A Portable Biochemistry Analyzer for Enhanced Healthcare

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Abstract: ***Accurate diagnosis is a fundamental element of any health system. The World Health Organization (WHO), highlights diagnostic tools as essential for addressing non-communicable diseases (NCDs), the leading cause of global health-related disability. Diagnosing these chronic noncommunicable diseases relies on biochemical tests, but in low-income settings, inadequate laboratory infrastructure and the long distances to healthcare facilities pose major barriers to timely diagnosis and care. Mobilab, a portable battery-operated comprehensive solution developed by Centre for Nanotechnology, IIT Guwahati in collaboration with M/S Primary Healthtech Private Limited, addresses the need for rapid and convenient diagnostics. Mobilab consists of several integrated portable battery-operated components: Mobicube (an external incubator), an Android smartphone installed with the Mobilab Connect application and an Analyzer that provide rapid analysis for several biochemical parameters when connected via an OTG cable to the android smartphone. The system also contains Mobimix for automated and uniform mixing of samples and reagents along with Mobifuge to separate serum from blood sample. Besides this, a micropipette is included for aspirating accurate volume of sample and reagents. The analyzer is also equipped with IoT (Internet of Things) connectivity for real-time data transmission and can determine multiple parameters, bringing diagnostics directly to door step. This study aimed to evaluate the diagnostic accuracy of Mobilab analyzer by comaparing its result with those of established biochemistry autoanalyzer, Siemens Dimension EXL 200 and hematology analyzer, Beckman Coulter DxH 900 at GNRC Hospital, North Guwahati. The testing and comparision was performed for thirteen parameters: Glucose (GLU), Total Bilirubin (TBIL), Albumin (ALB), Total protein (TP), Cholesterol (CHOL), Triglyceride (TGL), Uric Acid (UA), Creatinine (CRE), Hemoglobin (HB), Urea (UREA), Aspartate aminotransferase (AST) and Alanine aminotransferase (ALT) with 100-plus samples. The comparitive analysis was performed by statistical methods such as Passing & Bablok regression, Bland-Altman plots and Paired t-test. The findings indicate Mobilab's potential to accurately diagnose multiple health parameters. Routine uses of Mobilab may provide significantly enhanced healthcare delivery in resource-limited settings, improving access to timely diagnostics and care.***

Keywords: mobilab, non-communicable diseases, biochemistry parameter, biochemistry parameter, method comparison, non-communicable diseases, portable biochemistry analyzer

1. Introduction

Accurate and efficient assessment of various disease conditions is a crucial part of clinical disease management to provide best possible patient care in a health system. Globally, chronic noncommunicable diseases such as liver, heart, kidney diseases and diabetes, are leading causes of death, contributing to a significant burden of global mortality. [1,2] In 2023, cardiovascular diseases, including heart disease and stroke, remained the leading causes of global death, accounting for approximately 19.05 million annual fatalities. Chronic kidney disease (CKD) also significantly impacts global health, with millions suffering from various stages of the disease, particularly those related to diabetes. According to WHO report, diabetes was responsible for around 1.5 million deaths with an additional 460,000 deaths attributed to diabetic nephropathy in 2019. Liver disease, primarily caused due to cirrhosis, viral hepatitis and liver cancer, was responsible for over 2 million deaths globally (https://www.who.int/news-room/fact-sheets/detail/diabetes). Routine monitoring of liver enzymes, renal function markers and glucose levels allows for the early detection of diseases like liver dysfunction, chronic kidney disease, cardiovascular problems and diabetes. Early detection of these diseases will help to curb the disease progression since many of these disorders progress silently, with little or no symptoms until they reach an advanced stage. Laboratory medicine is mostly dependent on fully automated biochemistry analyzer as automation leads to reduction in result variation and error of analysis. However, most of the peripheral health care systems or primary healthcare center in developing countries are not facilitated with these fully automated analyzers due to the exorbitant expense, infrastructural, logistical barriers and skilled person. [3,4] This highlights the necessity of accessible healthcare at the doorstep, signifying a shift from costly, bulky, fully-automated analyzers to more user-friendly and versatile point-of-care testing (POCT) devices. These devices can be used directly at patients' bedsides or outpatient clinics and can also be easily deployed for clinical biochemistry in remote and resource-constrained areas. If the POCT device based biochemical reporting of routine parameters have comparable and dependable results to that of the auto analyzers, they can be an efficient alternative in primary healthcare setups to provide quality biochemistry laboratory services. This transition would shorten the time between sample acquisition and analysis (turnaround time) and also lower the cost of tests making it affordable for patients, government and private organizations, thereby facilitating cost-effective and accessible quality healthcare. [1]

In response to these challenges, the Center for Nanotechnology, IIT Guwahati, in collaboration with M/S Primary Healthtech Private Limited has developed Mobilab, which is a portable clinical chemistry analyzer. The analyzer

of Mobilab is connected to a smartphone installed with an Mobilab Connect application developed in a vernacular language for real-time data transmission and capable of determining multiple parameters. Its compact, portable, user-friendly features make it appropriate for meeting healthcare demands in resource-constrained areas.

This study evaluates the efficiency of Mobilab analyzer, focusing on thirteen vital biochemical parameters: Glucose (GLU), Albumin (ALB), Triglyceride (TGL), Cholesterol (CHOL), Uric Acid (UA), Creatinine (CRE), Total Bilirubin (TBIL), Low-density Lipoprotein-Cholesterol (LDL-C), Total Protein (TP), Hemoglobin (HB), Urea (UREA), Aspartate aminotransferase (AST), and Alanine aminotransferase (ALT). All these tests are approved by the Central Drugs Standard Control Organization (CDSCO), ensuring their clinical validity and compliance with regulatory standards. CRE, UREA and UA are important markers used to assess kidney function as elevated levels of creatinine and uric acid in the blood can indicate issues with kidney function, as the kidneys may not be effectively clearing them. [26] AST, ALT, ALB, TP and TBI evaluation help to determine the area of hepatic injury and the elevation pattern can help organize a differential diagnosis. [27] Likewise, CHOL, TGL and LDL-C provide important insights into the overall cardiovascular health, as elevated levels are linked to a higher risk of heart disease. [28] Blood glucose testing is the primary method for diagnosing diabetes, prediabetes and gestational diabetes and determination of hemoglobin levels is critical for assessing overall health and diagnosing various medical conditions like anemia, sickle cell anemia, thalassemia and also evaluating nutritional deficiency in an individual. [29, 30] The analytical test results of twelve parameters were compared with those of the fully recognized automated analyzers, SDE clinical chemistry analyzer while that of Hemoglobin (HB) test results compared with BC DxH 900 Hematology Analyzer at GNRC hospital, North Guwahati.

2. Materials and Methods

2.1 Materials

The reagent kits for all parameters were purchased from Agappe (Kerala, India). A GLU reagent kit (GOD-PAP method [19]) with Ref No.: 51406001. A TBIL reagent kit (Modified DMSO/Diazo method [23]) with Ref no.: 51003003. An ALB reagent kit (Bromocresol Green Method [28]) with Ref no.: 51415003. A TP reagent kit (Direct Biuret method [29]) with Ref no.: 51013002. A CHOL reagent kit (CHOD-PAP method [14]) with Ref no.: 51403002. A TGL reagent kit (GPO-PAP method [15]) with Ref no.: 51410002. A UA kit (Uricase PAP method [17]). A CRE reagent kit (Enzymatic method [25]) with Ref no.: 51420003. An LDL-C Direct with Calibration reagent kit (Selective Solubilization Method [26]) with Ref no.: 51415003. A HB reagent kit (Cyanmethemoglobin method [20,21]) with Ref No.: 51011001. A UREA reagent kit (Urease/GLDH method [32]) with Ref no.: 51412002. An AST reagent kit (IFCC recommended method [34]) with Ref no.: 51408003. An ALT reagent kit (IFCC recommended method [34]) with Ref no.: 51409003. 4 mL polystyrene cuvettes were purchased from Axibio (France), a device Mobilab (M/S Primary Healthtech Private Limited, India), Mobimix -a mixer device (M/S Primary Healthtech Private Limited, India), an Android smartphone (Redmi 9A, Xiaomi) and a micro-USB OTG cable. 0.9% NaCl, Liquid Assayed Multiqual control serum Level 1 (LOT NO. 45931) and Level 3 (LOT NO. 45933) were purchased from Bio-Rad (California, United States) to assess the analytical sensitivity, linearity and precision for all the test parameters on the Mobilab device. The UV-Vis Spectrophotometer LABMAN LCD LMSP-UV1900 (India) was selected as the reference for determining linearity in Mobilab.

2.2 Methods

In this study, over 100 samples were tested for each parameter using Mobilab analyzer to ensure its comprehensive assessment. Figure 1. (i) presents a closed view of Mobilab, which measures 53.34 cm in length and 35.56 cm in height. Figure. 1 (ii) shows opened view of Mobilab consisting of: (1) Mobicube, a portable battery-operated external incubator that regulates temperature to incubate multiple samples simultaneously during the test (2) an Android Smartphone which is installed with the "Mobilab Connect" application (3) Analyzer, a device that measures all biochemical parameters. It is portable, battery operated and digitally connected through an OTG cable to the android smartphone (4) Mobimix, a portable and battery-operated device used for automated uniform mixing of sample and reagent (5) Micropipette used for aspirating the required volume of the reagent and sample (6) Mobifuge, a portable and battery-operated centrifuge that separates serum from blood. The quantitative measurement using Mobilab is conducted according to the following steps: a. A precise volume of reagent is pipetted into a test cuvette and inserted into the Analyzer, for the initial base reading. b. The sample is added to the cuvette and subjected to a uniform mixing in a mixing device, Mobimix c. The sample containing cuvette is then reinserted into the Analyzer. It measures the absorbance of the products formed at the end of every reaction or during the reaction by applying the Beer-Lambert law. [21] d. The final result is calculated and a digital test report is generated by the Android application. This process of quantitative measurement by Mobilab is illustrated in the schematic diagram, Figure 2.

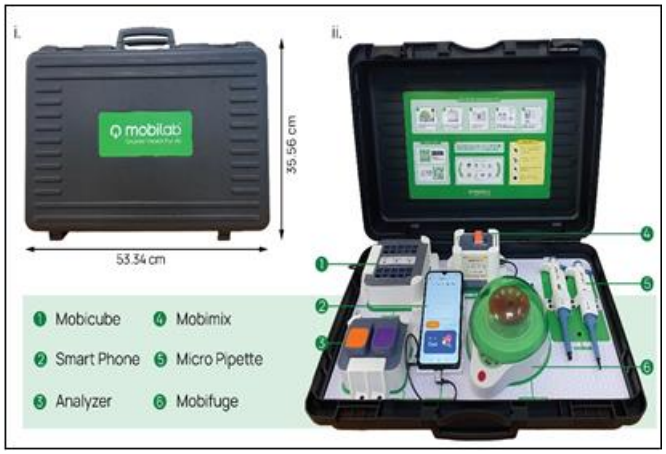

Figure 1: (i) Closed view of Mobilab with a length of 53.34 cm and height of 35.56 cm. ii) Opened view of Mobilab consisting of (1) Mobicube, a portable battery-operated external incubator that regulates temperature to incubate

multiple samples simultaneously during the test (2) An Android Smartphone which is installed with the "Mobilab Connect" application (3) Analyzer, a device that measures all biochemical parameters. It is portable, battery operated and digitally connected through an OTG cable (4) Mobimix, a portable and battery-operated device used for automated uniform mixing of sample and reagent (5) Micropipette used for aspirating the required volume of the reagent and sample (6) Mobifuge, a portable and battery-operated centrifuge that separates serum from blood.

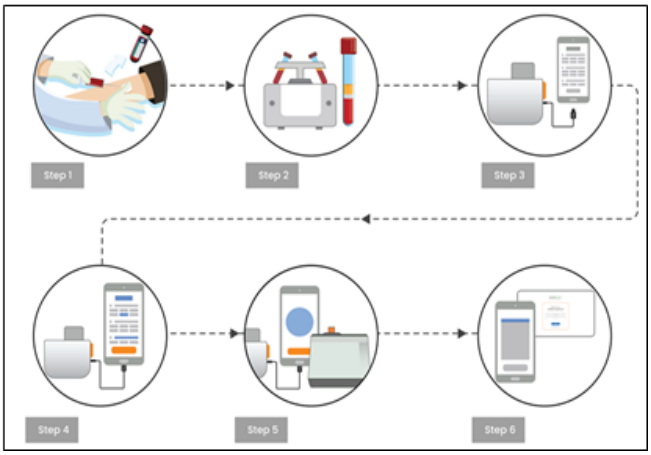

Figure 2: An elaborate breakdown of how Mobilab operates, divided into six sequential steps. Step-1: Venous blood collection; Step-2: Serum separation by centrifugation; Step-3: Mobilab device connection to the phone using an OTG cable; Step-4: Initiate the test by clicking on 'start test' followed by filling in the patient details and choosing the preferred tests; Step 5: Follow the instructions presented in the app and mix the sample with the corresponding reagent using the Mobimix; Step-6: Immediately after completion of the test, digital report is generated.

2.3 Sample collection

Samples were obtained from GNRC Hospital, North Guwahati, following the approval of study protocols from the hospital authority. Serum samples retained after patient testing were examined for biochemistry parameters using the SDE 200 clinical chemistry analyzer and whole blood samples were assessed for hemoglobin content using the BC DxH 900 Hematology Analyzer. Collection and transportation of samples to our laboratory adhered to the clinical guidelines and regulations set forth by the ethical committee of the institute. Patient confidentiality was strictly maintained throughout the study. Samples were stored at 4°C, subjected to no more than two freeze/thaw cycles before assessment. Reference ranges for CHOL, TGL, UA, CRE, LDL-C, GLU, TBIL, ABL, TP, UREA, AST, ALT and HB were considered as outlined in **Table 1.**

Table 1: Methods of detection and reference ranges for different parameters used at GNRC Hospital, Guwahati and Mobilab

Test Name	*Analytical Method – GNRC*	*Analytical Method – Mobilab*	*Reference range (Adult)*
Cholesterol	Cholesterol Oxidase method [14]	CHOD-PAP method[a] [14]	0-200 mg/dL
Triglyceride	GPO-POD method [15]	GPO-PAP method[b] [15]	30 - 150 mg/dL
Uric Acid	Uricase, UV method [16]	Uricase PAP method [17]	2.6 – 7.2 mg/dL
Glucose	Hexokinase method [18]	GOD-PAP method[c] [19]	74-106 mg/dL
Hemoglobin	Spectrophotometric method	Cyanmethemoglobin method [20] [21]	13-17 g/dL (Male) 12 - 15 g/dL (Female)
Total Bilirubin	Jendrassik-Grof method [22]	Modified DMSO /Diazo method[d] [23]	0.2 – 1.0mg/dL
Creatinine	Alkaline picrate method [24]	Enzymatic method [25]	0.55 – 1.30 mg/dL
Low Density Lipoprotein-Cholesterol	Friedewald method [30]	Selective Solubilization Method [26]	0-100 mg/dL
Albumin	Bromocresol Purple Method [27]	Bromocresol Green Method [28]	3.4 - 5 g/dL
Total Protein	Biuret method [29]	Direct Biuret method [29]	6.4 - 8.2 g/dL
Urea	Urease, UV Method (BUN) [32]	Urease / GLDH Method[e] [32]	7-18 mg/dL
Aspartate aminotransferase	UV with P5P (Pyridoxal 5'-phosphate) Method [33]	IFCC recommended Method[f] [34]	15-37 U/L
Alanine aminotransferase	UV with P5P (Pyridoxal 5'-phosphate) Method [33]	IFCC recommended Method[f] [34]	14-63 U/L

a) CHOD-PAP = Cholesterol oxidase-phenol-aminophenazone method; b) GPO-PAP = Glycerol-3-phosphate oxidase-phenol-aminophenazone method; c) GOD-PAP = Glucose oxidase-peroxidase coupled method; d) DMSO = Dimethyl sulfoxide; e) GLDH = Glutamate dehydrogenase; f) IFCC = International Federation of Clinical Chemistry and Laboratory

2.4 Performance comparison

The study compared Mobilab's method, analytical sensitivity, linearity, repeatability and performance with SDE 200, an automated clinical chemistry analyzer and BCDxH 900, a Hematology analyzer, which were used at GNRC Hospital.

This evaluation covered CHOL, TGL, UA, CRE, LDL-C, GLU, TBIL, ABL, TP, UREA, AST, ALT and HB parameters, confirming Mobilab's suitability for producing reliable point-of-care results. The methods employed for this performance comparison are briefly outlined below:

2.4.1 Method comparison

This evaluation was done with respect to the analytical method used in GNRC hospital with SDE clinical chemistry analyzer and BC DxH 900 Hematology analyzer. The study involved statistical analysis such as: Passing & Bablok Regression analysis, Bland-Altman plot and t-Test to determine the degree of agreement between the analytical methods used in the established auto analyzers and Mobilab. The analytical methods used to compare both the analyzers for each of the 13 tests is described under the following headings.

(a) Passing & Bablok Regression

Passing and Bablok regression analysis is a statistical technique enabling the estimation of agreement between analytical methods and potential systematic biases between them. This method is non-parametric and robust to variations in error distribution and the presence of outliers in the data. Proper application of Passing and Bablok regression requires data with continuous distribution and linear relationships between measurements obtained from two analytical methods. The findings are shown as an equation, regression line and scatter plot, in which the slope denotes proportionate measurement error and the intercept denotes a constant. The 95% Confidence Intervals (CI) for both intercept and slope evaluate if their values significantly deviate from 0 and 1, respectively. [5]

(b) Bland-Altman Plot

A Bland-Altman plot is an effective method to visually represent the relationship between two paired variables measured on the same scale. Unlike formal hypothesis testing, it examines the phenomenon without conducting statistical tests, thereby not providing the same level of error in decision-making about the variables. [6] The plot is constructed by plotting the differences between paired data from two variables (Auto-analyzer of GNRC hospital and Mobilab device) against the average of these readings. The mean difference line is accompanied by ± 2SD lines, representing the Confidence Interval (CI). This plot aids in identifying outliers, evaluating agreement and detecting any systematic bias in the data.

(c) Paired t-test

Another statistical method involves determining the p-value. A significance threshold of 0.05 is established to identify significant disparities between the devices. If the p-value is greater than 0.05, the null hypothesis is accepted, suggesting no substantial distinction between the actual and reference devices. Conversely, if the p-value is less than 0.05, the alternate hypothesis is accepted, indicating a significant difference between the devices. [7]

2.4.2 Method validation

(a) Linearity Test

Linearity plays a pivotal role in ensuring the credibility of any analytical process. In this study, Mobilab was tested across a wide range of concentrations to assess its ability to detect varied concentration levels of the specified parameters. The concentration range for each test parameter on Mobilab (y-axis) were subsequently juxtaposed against those on the UV-spectrophotometer (x-axis). This assessment highlights Mobilab's capability and consistency in maintaining linearity across a range of concentrations. [22]

(b) Analytical Sensitivity

This clinical aspect highlights how well an analytical technique can accurately and dependably identify lower levels of test substances. The current research clarifies the concepts of Limit of Blank (LOB) and Limit of Detection (LOD) for these substances, which define the method's sensitivity. LOB refers to the concentration detected by the device even when there is no substance present. It is established by repeatedly measuring samples without the substance to establish a baseline. Conversely, LOD indicates the lowest concentration of the substance that can be consistently and accurately detected through multiple repetitions. Determining the LOB and LOD provides insights into Mobilab's precision and reliability in detecting test substances and the parameters being investigated. [10]

(c) Precision test

The intra-day precision assessment of all thirteen test parameters has been consistently conducted using Liquid Assayed Multiqual control serum from Bio-Rad: Level 1 (L1) and Level 3 (L3) for 20 consecutive runs. Mobilab's intra-day precision is evaluated under identical conditions for all test parameters to examine the consistency of the study by calculating the coefficient of variation (CV%). A lower coefficient of variation (CV%) indicates that Mobilab results exhibit higher precision in the precision study for these test parameters. Therefore, conducting an intra-day precision study helps to better understand the accuracy of Mobilab's test results when repeatedly analyzing the same substance at identical concentrations. [11]

(d) Performance Metrices

Performance metrics were calculated to gauge the accuracy of the proposed device, encompassing sensitivity, specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV) and Diagnostic Accuracy (DA). As shown in the Table 2, the calculation was done with following test results: True Positive (TP), True Negative (TN), False Negative (FN) and False Positive (FP). The specificity was calculated to identify how often Mobilab correctly detect the absence of a condition. PPV (Positive Predictive Value) assessed the proportion of true positive results accurately identified by Mobilab out of all the positive test results.

NPV (Negative Predictive Value) measured the proportion of true negative results correctly identified by Mobilab among all negative outcomes. DA is computed to ascertain the total count of true positives and true negatives identified among all test outcomes. [23]

Table 2: The tabular illustration of the performance metrices and their respective formulas to calculate diagnostic accuracy for the Mobilab device

		Siemens Dimension EXL 200		
		Positive	Negative	
Mobilab	Positive	True Positive (TP)	False Positive (FP)	Positive Predictive Value (PPV) $\frac{TP}{(TP+FP)} \times 100$
	Negative	False Negative (FN)	True Negative (TN)	Negative Predictive Value (NPV) $\frac{TN}{(FN+TN)} \times 100$
		Sensitivity $\frac{TP}{(TP+FN)} \times 100$	Specificity $\frac{TN}{(TN+FP)} \times 100$	Diagnostic Accuracy (DA) $\frac{TP+TN}{(TP+FN+FP+TN)} \times 100$

3. Results & Discussion

In this study, we investigated the clinical performance of the portable clinical chemistry analyzer, Mobilab with the goal

of assessing its practicality and diagnostic accuracy. The study involved testing 100-plus samples for each parameter individually, employing meticulously designed experimental setups. For every parameter, diagnostic method was compared followed by determination of analytical sensitivity, linearity, and intra-day precision studies were conducted and evaluated performance metrics. The findings deliberated upon for each parameter (CHOL, TGL, UA, CRE, LDL-C, GLU, TBIL, ALB, TP, UREA, AST, ALT and HB) highlight the device's effectiveness in early detection of NCDs, aiming to enhance individuals' health conditions.

3.1 Method Comparison

3.1.1 Passing & Bablok Regression

As shown in Table 3 and Figure S1, for thirteen parameters— CHOL, TGL, UA, CRE, LDL-C, GLU, TBIL, ALB, TP, UREA, AST, ALT and HB—the slope and intercept values of the device for the specified tests fall within the 95% Lower Confidence Limit (LCL) and 95% Upper Confidence Limit (UCL). This provides strong evidence in favor of accepting the null hypothesis. However, in the case of ALB, the slope and intercept values for the specified test do not fall within the 95% Lower Confidence Limit (LCL) and 95% Upper Confidence Limit (UCL). This indicates that our null hypothesis cannot be accepted. The reason for the failure of Passing Bablok regression is the difference in methods: Mobilab used the Bromocresol Green (BCG) method, while GNRC hospital used the Bromocresol Purple (BCP) method. As an alternative approach, a paired t-test was performed, which is commonly used in clinical chemistry for comparing two methods (Table 3).

3.1.2 Bland-Altman Plot

Based on the findings shown in Table 3 and /Figure S2, we can conclude that insignificant bias indicates the agreement between measurements obtained from Mobilab and those from the comparative measuring technique. The mean bias between the device used in GNRC hospital and Mobilab was 0.15 mg/dL for GLU, -0.05 g/dL for HB, 0.03 mg/dL for TBIL, -0.03 g/dL for ALB, 0.02 g/dL for TP, -0.33 mg/dL for CHOL, 0.05 mg/dL for UA, -0.22 mg/dL for TGL, -0.02 mg/dL for CRE, -0.72 mg/dL for LDL-C, 7.48 mg/dL for UREA, -0.09 U/L for AST and 0.66 U/L. Nearly all sample points were within the 95% confidence interval (±2 SD), except for 4 points for GLU, 2 points for HB, 3 points for TBIL, 2 points for ALB, 3 points for TP, 10 points for CHOL, 3 points for UA, 3 points for TGL, 4 points for CRE, 4 points for LDL-C, 3 points for UREA, 11 points for AST and 6 points for ALT which were likely due to random analytical error. Bland-Altman analysis further confirmed the overall agreement between the two methods.

3.1.3 Paired t-test

Table 3 depicts the mean values of GLU, TBIL, ALB, TP, CHOL, TGL, UA, CRE, LDL-C, UREA, AST, ALT and HB that are statistically similar between both the methods used in GNRC hospital and Mobilab. This is corroborated by the Pearson correlation analysis, where the values for GLU (0.99), HB (0.99), TBIL (0.79), ALB (0.99), TP (0.94), CHOL (0.98), TGL (0.99), UA (0.99), CRE (0.95), LDL-C (0.98), UREA (0.99), AST (0.99) and ALT (0.99) are close to 1. This suggests a strong relationship between the results obtained from Mobilab and those from GNRC hospital. The paired t-test for the Mobilab device yielded a p-value greater than the chosen significance level of 0.05 for all tested parameters (0.98 for GLU, 0.64 for HB, 0.99 for TBIL, 0.99 for ALB, 0.46 for TP, 0.95 for CHOL, 0.98 for TGL, 0.88 for UA, 0.74 for CRE, 0.88 for LDL, 0.99 for UREA, 0.98 for AST and 0.83 for ALT). These results strongly support the null hypothesis, indicating that the test outcomes from Mobilab are comparable to those obtained at GNRC hospital.

Table 3: Summary of Method Comparison study for all parameters assessed between Mobilab and SDE 200 for GLU, TBIL, ALB, TP, CHOL, UA, TGL, CRE, LDL-C, UREA, AST, ALT and BCDxH 900 for HB

Method Comparison	*Passing Bablok Plot*			*Bland Altman plot*		*t-test*
	Slope	*Intercept*	*$R^{2a)}$*	*Bias*	*LOA[b)]*	*p-value*
Glucose	0.98	2.12	0.99	0.15 mg/dL	-14.16 to 14.45 mg/dL	0.89
Total Bilirubin	0.99	0.01	0.99	0.03 mg/dL	-0.87 to 0.93 mg/dL	0.66
Albumin	0.77	0.83	0.89	-0.03 g/dL	-0.39 to 0.33 g/dL	0.20
Total Protein	1.01	-0.14	0.88	0.02 g/dL	-0.53 to 0.57 g/dL	0.63
Hemoglobin	1.03	-0.26	0.95	-0.05 g/dL	-1.09 to 0.99 g/dL	0.48
Cholesterol	0.98	1.56	0.96	-0.33 mg/dL	-16.21 to 15.56 mg/dL	0.95
Uric Acid	1.03	-0.19	0.97	0.05 mg/dL	-0.61 to 0.71 mg/dL	0.88
Triglyceride	0.98	1.56	0.99	-0.22 mg/dL	-14.28 to 13.84 mg/dL	0.98
Creatinine	0.97	0.01	0.89	-0.02 mg/dL	-0.24 to 0.21 mg/dL	0.74
Low Density Lipoprotein-C	0.96	2.69	0.95	-0.72 mg/dL	-13.88 to 12.45 mg/dL	0.88
Urea	0.99	0.09	0.99	7.48 mg/dL	-6.09 to 6.09 mg/dL	0.99
Aspartate Aminotransferase	0.99	0.15	0.99	-0.09 U/L	-7.80 to 7.62 U/L	0.98
Alanine Aminotransferase	1.04	-1.07	0.98	0.66 U/L	-5.98 to 7.31 U/L	0.83

[a)] R^2=Coefficient of determination; [b)] LOA=Limit of assay

3.2 Method Validation

3.2.1 Linearity test

The graph (Figure S3) and Table 4 indicates that all data points (concentrations) ranging from 64.68 mg/dL to 850.13 mg/dL for GLU, 4 g/dL to 16.6 g/dL for HB, 0.99 mg/dL to 21.95 mg/dL for TBIL, 1.45 g/dL to 6.95 g/dL for ALB, 1.35 g/dL to 19.12 g/dL for TP, 40 mg/dL to 587 mg/dL for CHOL, 30 mg/dL to 759 mg/dL for TGL, 2 mg/dL to 23 mg/dL for UA, 0.34 mg/dL to 24.16 mg/dL for CRE, 8.41 mg/dL to 267.41 mg/dL for LDL-C, 17.7 mg/dL to 144.3 mg/dL for Urea, 31.2 U/L to 273.6 U/L for AST and 53.4 U/L to 208.2 U/L for ALT align along a straight line. This suggests that the Mobilab device provides accurate results across a wide range of concentrations for all parameters.

Table 4: Summary of Linearity in the Method Validation study for all parameters compared Between Mobilab and SDE 200 for GLU, TBIL, ALB, TP, CHOL, UA, TGL, CRE, LDL-C, UREA, AST, ALT and BCDxH 900 for HB

Method Validation (Linearity Study)	Slope	Intercept	$R^{2a)}$	Linearity
Glucose	0.95	6.69	1	upto 850.13 mg/dL[b)]
Total Bilirubin	0.95	0.16	1	upto 21.95 mg/dL[b)]
Albumin	1.04	-0.15	1	upto 6.95 g/dL[c)]
Total Protein	0.99	0.09	1	upto 19.12 g/dL[c)]
Hemoglobin	1.01	0.07	0.99	upto 16.6 g/dL[c)]
Cholesterol	1.01	-2.69	1	upto 587 mg/dL[b)]
Uric Acid	0.99	0.03	1	upto 23 mg/dL[b)]
Triglyceride	1.01	-16.08	0.99	upto 759 mg/dL[b)]
Creatinine	1.01	0.02	0.99	upto 24.16 mg/dL[b)]
Low Density Lipoprotein-C	1.05	-2.36	0.99	upto 267.41 mg/dL[b)]
Urea	2.14	-4.86	0.99	upto 144.3 mg/dL[b)]
Aspartate Aminotransferase	1.09	-2.89	0.99	upto 273.6 U/L[d)]
Alanine Aminotransferase	1.07	-2.76	0.99	upto 208.2 U/L[d)]

[a)] R^2=Coefficient of determination; [b)] mg/dL=milligram per deciliter; [c)] g/dL=gram per deciliter; [d)] Units per liter

3.2.2 Analytical sensitivity

The limit of blank (LOB) for GLU is 1.55 mg/dL, TBIL is 0.06 mg/dL, ALB is 0.01 g/dL, TP is 0.20 g/dL, CHOL is 0.34 mg/dL, TGL is 3.79 mg/dL, UA is 0.22 mg/dL, CRE is 0.24 mg/dL, LDL-C is 1.12 mg/dL, Urea is 4.30 mg/dL, AST is 9.60 U/L and ALT is 22.8 U/L indicating that any concentration below this value for respective parameter is indistinguishable from background noise. The limit of detection (LOD) for GLU is 2.45 mg/dL, for TBIL is 0.1 mg/dL, for ALB is 0.02 g/dL, for TP is 0.35 g/dL, for CHOL is 1.4 mg/dL, for TGL is 5.87 mg/dL, for UA is 0.28 mg/dL, for CRE is 0.33 mg/dL, for LDL-C is 2.09 mg/dL, for Urea is 7.88 mg/dL, for AST is 28.35 U/L and for ALT is 31.44 U/L. This indicates that the device can reliably detect concentrations as low as the LOD value for each respective parameter (Table 5). Analytical sensitivity for HB could not be performed due to the unavailability of control whole blood.

Table 5: Summary of Analytical Sensitivity in the Method Validation study for all parameters compared between Mobilab and SDE 200 for GLU, TBIL, ALB, TP, CHOL, TGL, UA, CRE, LDL-C, UREA, AST and ALT

Method Validation (Analytical Sensitivity)	*LOB[a)]*	*LOD[b)]*
Glucose	1.55 mg/dL	2.45 mg/dL[c)]
Total Bilirubin	0.06 mg/dL	0.1 mg/dL[c)]
Albumin	0.01 g/dL	0.02 g/ dL[d)]
Total Protein	0.20 g/dL	0.35g/ dL[d)]
Cholesterol	0.34 mg/dL	1.4 mg/dL[c)]
Triglyceride	3.79 mg/dL	5.87 mg/dL[c)]
Uric Acid	0.22 mg/dL	0.28 mg/dL[c)]
Creatinine	0.24 mg/dL	0.33 mg/dL[c)]
Low Density Lipoprotein-C	1.12 mg/dL	2.09 mg/dL[c)]
Urea	4.30 mg/dL	7.88 mg/dL[c)]
Aspartate Aminotransferase	9.60 U/L	28.35 U/L[e)]
Alanine Aminotransferase	22.8 U/L	31.44 U/ L[e)]

a) Limit of Blank; b) LOD=Limit of Detection; c) mg/dL=milligram per deciliter; d) g/dL=gram per deciliter; e) Units per liter

3.2.3 Precision test

Using Level 1 and Level 3 Bio-Rad control serum over 20 repeats, the coefficient of variation (CV%) is of approximately 2.26% and 2.7%, respectively for GLU test, 3.9% and 2.56% respectively for TBIL test, 2.03% and 1.69% respectively for ALB test, 2.73% and 1.31% respectively for TP, 3.59% and 2.90% respectively for Urea, 3.73% and 2.71% respectively for AST and 4.94% and 2.94% respectively for ALT. Intraday precision test was done with whole blood sample (Sample 1 and Sample 2) which yielded a CV% of 2.61% and 2.73% respectively for HB. These findings indicate a high level of precision suggesting consistent and reliable test outcomes (Table 6).

Table 6: Summary of Intra Day Precision in the Method Validation study for all parameters compared Between Mobilab and SDE 200 for GLU, TBIL, ALB, TP CHOL, TGL, UA, CRE, LDL-C, UREA, AST and ALT and BCDxH 900 for HB

Method Validation (Intra Day Precision)	*% Control Level1*	*% Control Level3*
Glucose	2.26	2.7
Total Bilirubin	3.9	2.56
Albumin	2.03	1.69
Total Protein	2.73	1.31
Cholesterol	2	2.48
Triglyceride	2.75	3.3
Uric Acid	1.43	3.29
Creatinine	2.66	2.92
Low Density Lipoprotein-C	2.44	2.12
Urea	3.59	2.90
Aspartate Aminotransferase	3.73	2.71
Alanine Aminotransferase	4.94	2.94
Method Validation (Intra Day Precision)	*Sample 1*	*Sample 2*
Hemoglobin	2.61%	2.73%

3.2.4 Performance Metrices

The Mobilab analyzer demonstrates 92.31% sensitivity for GLU, 94.44% for TBIL, 85.71% for ALB, 70.27% for TP, 87.50% for CHOL, 95% for TGL, 96.97% for UA, 77.78% for CRE, 91.67% for LDL-C, 97.18% for UREA, 93.51% for AST, 92.86% for ALT and 97.37% for HB indicating its ability to correctly identify these parameters in true positive cases. The Specificity of the Mobilab analyzer is 81.25% for GLU, 100% for TBIL, 100% for ALB, 87.30% for TP, 98.20% for CHOL, 98.51% for TGL, 88.52% for UA, 89.04% for CRE, 100% for LDL-C, 91.67% for UREA, 95.90% for AST, 97.46% for ALT and 91.67% for HB indicating its ability to correctly identify true negative cases for these parameters. PPV of 84.21% for GLU, 100% for TBIL, 100% for ALB and 76.47% for TP, 91.30% for CHOL, 97.44% for TGL, 82.05% for UA, 72.41 for CRE,

100% for LDL-C, 95.83% for UREA, 93.51% for AST, 81.25% for ALT and 97.37% for HB implies that the device predicted a respective mentioned positive value for each parameter. NPV implies that the device predicts true negative values correctly by 90.70% for GLU, 98.80% for TBIL, 94.68% for ALB and 83.33% for TP, 97.32% for CHOL, 97.06% for TGL, 98.18% for UA, 91.55% for CRE, 98.92% for LDL-C, 94.29% for UREA, 95.90% for AST, 99.14% for ALT and 91.67% for HB of the time. DA of 87% for GLU, 99% for TBIL, 95.97% for ALB, 81% for TP, 96.30% for CHOL, 97.20% for TGL, 91.49% for UA, 86% for CRE, 99.04% for LDL-C, 95.33% for UREA, 94.97% for AST, 96.97% for ALT and 96% for HB implies that out of 100 times, the device predicted 87 times for glucose, 99 times for TBIL, 96 times for ALB, 81 times for TP, 96 times for CHOL, 97 times for TGL, 91 times for UA, 86 times for CRE, 99 times for LDL-C, 95 times for UREA, 95 times for AST, 97 times for ALT and 96 times for HB correctly (Table 7).

Table 7: Summary of Performance Metrices in the Method Validation study for all parameters compared Between Mobilab and SDE 200 for GLU, TBI, ALB, TP, CHOL, TGL, UA, CRE, LDL-C, UREA, ALT, AST and BCDxH 900 for HB

Method Validation (Performance Metrices)	*Sensitivity (%)*	*Specificity (%)*	*Diagnostic accuracy (%)*
Glucose	92.31	81.25	87
Total Bilirubin	94.44	100	99
Albumin	85.71	100	95.97
Total Protein	70.27	87.30	81
Hemoglobin	97.37	91.67	96
Cholesterol	87.50	98.20	96.30
Triglyceride	95	98.51	97.20
Uric Acid	96.97	88.52	91.49
Creatinine	77.78	89.04	86
Low density lipoprotein-C	91.67	100	99.04
Urea	97.18	91.67	95.33
Aspartate Aminotransferase	93.51	95.90	94.97
Alanine Aminotransferase	92.86	97.46	96.97

4. Conclusion

This comparative study was conducted to assess performance of Mobilab analyzer by comparing its results with that of a fully automated analyzer at GNRC Hospital. Thirteen vital parameters including GLU, TBIL, ALB, TP, CHOL, TGL, UA, CRE, LDL-C, UREA, AST, ALT and HB were analyzed with the chemistry analyzer SDE 200 and Hematology analyzer BCDxH 900, demonstrating good agreement with Mobilab analyzer. However, some outliers were observed which were attributed to hemolyzed samples and manual errors. To evaluate the repeatability of Mobilab analyzer, we performed 20 runs of two concentrations of control serum for each parameter except hemoglobin where whole blood samples were used. Results revealed acceptable coefficient of variation (CV%< 5%), indicating good precision and consistency. Furthermore, we calculated sensitivity, specificity, PPV, NPV and DA for Mobilab, revealing its reliability and consistency in diagnosing various parameters. Our findings suggest that Mobilab has the potential to accurately diagnose multiple parameters in both human serum and whole blood, providing real-time digital patient data that can significantly improve community healthcare, particularly in resource-constrained areas. The rapid diagnostics, portability and ease of use of devices like Mobilab enable timely decision-making, especially in settings where laboratory facilities are limited. By facilitating early diagnosis and intervention, Mobilab can ultimately reduce healthcare costs by minimizing clinic visits and hospitalizations while optimizing resource utilization for better overall healthcare outcomes.

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