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Evaluation of Portable Clinical Chemistry Analyzer-'Mobilab' for Comprehensive Assessment of Liver, Heart, and Kidney Functions Using Human Blood / Serum Samples

Sahil Jagnani[1], Anuj Kumar Baruah[2], Ankit Chowdhury[3]

[1]Department of Chemistry, M/S Primary Healthtech Private Limited, C-Block, Sector 6, Noida, Uttar Pradesh- 201301, India
Email: *sahil[at]mobilab.in*

[2]Medical Section, Indian Institute of Technology Guwahati Hospital, Guwahati, Assam-781039, India
Email: *akb[at]iitg.ac.in*

[3]Department of Chemistry, M/S Primary Healthtech Private Limited, C-Block, Sector 6, Noida, Uttar Pradesh- 201301, India
Email: *ankit[at]mobilab.in*

Abstract: ***Non-communicable diseases (NCDs) are rising in developing nations, emphasizing the urgent need for affordable and accessible diagnostic tools. This study focuses on validating Mobilab, an IoT (Internet of Things) enabled, battery operated, point-of-care testing (POCT) device created by Indian Institute of Technology (IIT) Guwahati's Centre for Nanotechnology in collaboration with M/S Primary Healthtech Private Limited., which intends to meet the diagnostic needs of the resource limited population. To evaluate its efficacy, Mobilab was compared with the recognized and established auto-analyzer Selectra ProS by ELITech Group, present at IIT Guwahati Hospital (IITGH), Guwahati. The clinical trial involved the assessment of seven biochemical parameters-Creatinine (CRE), Uric Acid (UA), Cholesterol (CHOL), Triglycerides (TGL), Total Bilirubin (TBIL), Glucose (GLU), and Hemoglobin (HB) which are essential for evaluating the functions of Liver, Heart, and Kidney. Total 30-plus human blood/serum samples were tested, with comparisons made to determine Mobilab's analytical sensitivity, linearity, precision, and overall performance. The statistical analyses were used to measure agreement between the two systems, including Passing-Bablok regression, Bland-Altman analysis, and paired t-tests. The findings revealed a high level of consistency and accuracy across all parameters, confirming Mobilab's stability and reliability. These results demonstrate Mobilab's potential to improve NCD diagnostics and expand healthcare access in resource-limited settings.***

Keywords: Point-of-care testing (POCT), Diagnostic Accuracy, Passing-Bablok Regression, Bland-Altman plot, Paired t-test

1. Introduction

Non-communicable diseases (NCDs) account for approximately two-thirds of global deaths, with cardiovascular diseases, cancer, diabetes, and chronic respiratory illnesses being the most significant contributors [1]. The growing prevalence of NCDs in low- and middle-income countries (LMICs) has played a key role in the rising global burden. Notably, the likelihood of premature death from NCDs is higher in LMICs compared to wealthier nations [2]. In regions like Sub-Saharan Africa, where infectious diseases remain dominant, NCDs are projected to become the leading cause of death by 2030 [3,4].

People with NCDs often face difficulties in receiving an accurate diagnosis and the necessary resources for managing their conditions. In LMICs, disparities related to social, geographic, and economic factors further limit access to healthcare services [5,6]. Many patients with NCDs also struggle with the financial burden of healthcare. At the primary care level, there is frequently a lack of trained medical personnel and limited healthcare infrastructure. Furthermore, laboratory services are hampered by inadequate testing equipment and a shortage of supplies, even for basic clinical chemistry tests recommended by the World Health Organization [7]. As a result, patients are often referred to higher-level healthcare facilities or private laboratories for proper diagnosis and treatment. These obstacles contribute to higher rates of illness and reduced quality of life for those affected [8].

Point-of-care testing (POCT) devices are diagnostic instruments designed for clinical chemistry assessments, providing user-friendly functionality and delivering quick, precise results in just a few minutes at the patient's location [9]. These tools are essential for both the diagnosis and management of NCDs directly at the point of care. Multiparameter POCT devices can perform several tests simultaneously, allowing for a more comprehensive evaluation of a patient's health while conserving time and resources by reducing the need for multiple separate laboratory tests [10]. POCT devices can be utilized in various environments, including rural and remote regions. The implementation of POCT devices represents a promising strategy to alleviate the burden of NCDs and improve access to diagnostic and monitoring services at the primary healthcare level [11,12].

Mobilab is a portable, IoT enabled, battery-operated clinical chemistry analyzer designed to address the key challenges outlined earlier. It is controlled via a smartphone-based Android app, which facilitates the collection, analysis, and reporting of medical data while allowing for transmission to remote laboratory technicians. Mobilab measures multiple parameters, providing a cost-effective solution for delivering accurate real-time patient information. It requires minimal maintenance and offers quicker turnaround times compared to traditional methods. These attributes make it particularly

suitable for healthcare delivery in resource-constrained areas. This study emphasizes Mobilab's clinical effectiveness, especially in analyzing seven crucial diagnostic parameters vital for the early detection of NCDs and improving overall health outcomes.

Creatinine (CRE) and Uric acid (UA) are vital markers used in kidney function tests, offering significant insights into kidney health. Cholesterol (CHOL), and Triglycerides (TGL) are critical indicators of cardiovascular health, with high levels associated with an increased risk of heart disease. Total bilirubin (TBIL) is also crucial for assessing liver health. Glucose (GLU) and Haemoglobin (HB) diagnose and manage conditions such as diabetes and anaemia [12-14]. This study aims to detail the methodology and develop a framework for implementing the multiparameter POCT device to assist in the diagnosis of NCDs. The analytical performance of Mobilab has been assessed by comparing its results to those obtained from the fully automated Selectra ProS auto-analyzer for all parameters

2. Materials and Methods

2.1 Materials

The materials used in this study were obtained and used by following the manufacturer's protocol without any modifications. The kits employed in the research were obtained from Agappe, India. A CHOL reagent kit (CHOD-PAP method), REF no. 51403002 [15]; a TGL reagent kit (GPO-PAP method), REF no. 51410002 [16]; a CRE reagent kit (Enzymatic method), REF no. 51420003 [17]; UA reagent kit (Uricase-PAP method), REF no. 51413002 [18], and a TBIL reagent kit (Modified DMSO/Diazo Method) REF no. 51003002 [19], GLU reagent kit (GOD-PAP Method), REF no. 51406001 [20]; and HB reagent kit (Cyanmethemoglobin Method), REF no. 51011001 [21] were used. For the study, 4 mL disposable polystyrene cuvettes supplied by VOLVEX were utilized. The experiments were conducted using a Mobilab device, a Mobimix mixer, an Android smartphone (Redmi 9A, Xiaomi), and a micro-USB OTG cable. NaCl (0.9%) solution was used in this study. BIO-RAD Liquid Assayed Multiqual Control Serum Level 1 (L1) (Lot No. 45931) and Control serum Level 3 (L3) (Lot No. 45933) serums were used to evaluate the analytical sensitivity, precision, and linearity of the tested parameters on the Mobilab device. The UV-Vis Spectrophotometer (LABMAN LCD LMSP-UV1900) was used as the reference instrument for determining the linearity in Mobilab. We have performed daily runs on the Mobilab device using the prepared control serums for each selected parameter. The tools utilized for Passing-Bablok regression, Bland-Altman analysis, and paired t-tests include Python, and R programming.

2.2 Sample Collection

The serum samples utilized in this clinical validation study were obtained from IITGH in North Guwahati, following approval of the study design and experimental protocols by the hospital authority. These samples consisted of retained serum from patients at IITGH, which were tested using the Selectra ProS analyzer in compliance with clinical guidelines and the ethical regulations set forth by the institute's committee. Throughout this process, no personal information about the patients was disclosed. The tests were performed for seven biomarkers: Creatinine (CRE), Uric Acid (UA), Cholesterol (CHOL), Triglycerides (TGL), Total Bilirubin (TBIL), Glucose (GLU), and Hemoglobin (HB). More than 30 samples were collected for each biomarker. The reference ranges for CRE, UA, CHOL, TGL, TBIL, GLU, and HB were aligned with the standard ranges employed at IITGH to ensure consistency and accuracy throughout the study, as outlined in **Table 1**.

Table 1: Techniques and reference ranges in assays for two different analyzers

Biomarkers	Analytical Method (Selectra ProS auto-analyzer)	Analytical Method (Mobilab Device)	Reference range (mg/dL)
CRE	Enzymatic Method	Enzymatic Method	0.5-1.6
UA	Uricase-PAP methodology (Enzymatic)	Uricase-PAP methodology (Enzymatic)	2.5-7.2
CHOL	CHOD-CSE methodology (Enzymatic)	CHOD-PAP methodology (Enzymatic)	0-200
TGL	GPO-PAP methodology (Enzymatic)	GPO-PAP methodology (Enzymatic)	35-165
TBIL	Malloy-Evelyn method	Modified DMSO/ Diazo Method	0.2-1.2
GLU	GOD-PAP Method	GOD-PAP Method	70-110
HB	Photometric	Cyanmethemoglobin Method	12-18

CHOD-POP = cholesterol oxidase (CHOD) and phenol aminophenazone (PAP), GPO-PAP = Glycerol-3-phosphate oxidase (GPO) and phenol aminophenazone (PAP), mg/dL = milligrams per deciliter

2.3 Sample Preparation

The procedure for testing CRE, UA, CHOL, TGL, TBIL, GLU, and HB with the Mobilab POCT device involves two primary steps: first, obtaining base and standard readings, followed by readings of patient samples.

Step-1: Base Reading and Standard Reading

For the testing of CHOL, TGL, and UA, 1 mL of reagent was added to a cuvette, followed by the addition of 10 µL of standard for CHOL and TGL, and 25 µL for UA. The mixture was then blended using the Mobimix and incubated at 37°C for 5 minutes before obtaining the standard reading. For CRE testing, 900 µL of Reagent 1 (R1) was combined with 300 µL of Reagent 2 (R2) in a cuvette, incubated for 5 minutes at 37°C, and a base reading was recorded. Subsequently, 900 µL of R1 and 20 µL of the standard were added to a new cuvette, followed by 300 µL of R2, and incubated for another 5 minutes before the standard reading was taken. For HB, 2.5 mL of deionized water was added to the cuvette, and a base reading was taken. In the same cuvette, 1 mL of standard HB was added and run in the analyzer and standard reading was taken. To perform the test for GLU, 1 mL of the reagent was added to the cuvette. Insert the cuvette into the analyzer to take a base reading. Once the base reading is recorded, add 10 µL of the standard GLU into the reagent in the same cuvette. Mix the contents uniformly using the Mobimix device for 10 seconds. After

mixing, incubate the cuvette at 37°C for 10 minutes in the incubator. Finally, insert the cuvette back into the analyzer to take the standard reading. For TBIL, 1000µl reagent was taken in a fresh cuvette and 50µl patient sample was added and mixed uniformly in Mobimix followed by base reading was taken in the analyzer.

Step-2: Patient Sample Reading

To test CHOL, TGL, and UA, a new cuvette is prepared with 1 mL of reagent, to which 10 µL of the patient sample is added for CHOL and TGL, and 25 µL for UA. After mixing with the Mobimix, the cuvette is incubated at 37°C for 5 minutes before taking the readings. For CRE, 900 µL of Reagent 1 (R1) is added to a fresh cuvette, along with 20 µL of the patient sample. The mixture is thoroughly mixed and incubated at 37°C for 5 minutes, after which 300 µL of Reagent 2 (R2) is added. Following mixing and an additional 5min incubation, the cuvette is placed in the analyzer to obtain readings for CRE. To perform the HB test, the blood sample was taken in an EDTA vial. Then, take a fresh cuvette and add 2.5 mL of the HB reagent. Insert the cuvette into the analyzer to record the base reading. After this, 10 µL of whole blood was added into the same cuvette. The cuvette was Placed in the Mobimix device and mixed the contents uniformly for 3 minutes at fast mode. Finally, the cuvette was inserted back into the analyzer to take the sample reading. For GLU test, 1 mL of the reagent was added to the cuvette. Insert the cuvette into the analyzer to take a base reading. Once the base reading is recorded, add 10 µL of serum into the reagent in the same cuvette. Mix the contents uniformly using the Mobimix device for 10 seconds. After mixing, incubate the cuvette at 37°C for 10 minutes in the incubator. Finally, insert the cuvette back into the analyzer to take the standard/patient sample reading. For TBIL, after taking the base reading, 20 µl Activator was added to the same cuvette with reagent and sample followed by uniform mixing in Mobimix. The cuvette was incubated at 30°C for 5 minutes in the analyzer followed by insertion of the cuvette again in the analyzer to take the sample reading.

2.4 Description of Mobilab Analyzer

The Mobilab analyzer measures 93.26 mm in length, 56.99 mm in width, and 98.07 mm in height, weighing 312 g, as shown in [**Fig. 1(a) (i-iv)**]. The steps for performing quantitative measurements with Mobilab analyzer are as follows: (a) A specific volume of reagent is pipetted into a test cuvette, which is then placed in the device for an initial baseline reading. (b) The sample is added to the cuvette and mixed uniformly using the Mobimix device, as depicted in [**Fig. 1(b) (i-iv)**]. (c) After uniform mixing, the cuvette with the sample is reinserted into Mobilab analyzer, which measures the absorbance of the reaction products at each step using the Beer-Lambert law. (d) The final result is calculated, and a digital test report is generated through an Android application.

2.5 Sample Testing Procedure

The testing process begins with the collection of venous blood. After the sample is collected, it is centrifuged to separate the serum. The Mobilab device is then connected to

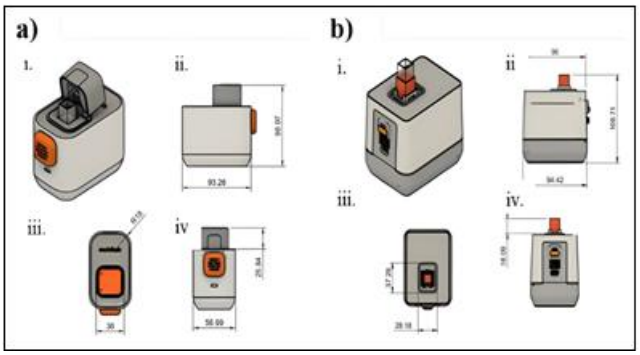


Figure 1: Description of Mobilab device and Mobimix (a) Isometric view of the Mobilab analyzer: (i) Overview of the device, highlighting the data port for smartphone connectivity, the cuvette compartment, and its enclosure, **(ii)** Side view, showing Mobilab's dimensions: 93.26 mm in length, 56.99 mm in width, and 98.07 mm in height, **(iii)** Top view, illustrating the cap, which measures 38 mm in both length and width. **(iv)** front view, featuring the ambient sensor, **(b) Isometric view of the Mobimix mixer: (i)** Overview of Mobimix, showing the On/Off switch, cuvette holder, mode switch, and charging port, **(ii)** Side view, detailing Mobimix's length, which ranges from 90 mm to 94.42 mm, and a height of 108.71 mm, **(iii)** Top view, with the cuvette holder measuring 37.28 mm in length and 28.18 mm in width **(iv)** Front view, emphasizing the On/Off switch, mode switch, and charging port

a smartphone via an OTG cable. To start the test, "start test" is selected in the app, followed by entering the patient's information and selecting the required tests (CRE, UA, CHOL, TGL, TBIL, GLU, and HB). The app guides the user to mix the serum sample with the appropriate reagent using the mixer (Mobimix). Once the test is complete, the system automatically generates a digital report. The blood testing process includes **Step 1:** Collection of venous blood by venepuncture method, **Step 2:** Separation of serum using a portable battery-operated centrifuge, **Step 3:** Connecting the Mobilab device (analyzer) to an Android phone via OTG cable, **Step 4:** Initiating the test by following the app instructions, **Step 5:** Mixing the sample with the reagent as per the app's guidance, and **Step 6:** Final report generation after test completion.

3. Methodology of Comparison

3.1 Performance Matrices

3.1.1 Diagnostic Accuracy

Diagnostic accuracy assesses a test's ability to correctly detect the presence of a condition when it is present and confirm its absence when it is not. The diagnostic accuracy of the Mobilab device was calculated as the percentage of correctly identified samples out of the total samples tested. The calculation was performed using Eq. (1), as shown below.

$$Diagnostic\ Accuracy = \frac{TP+TN}{TP+TN+FP+FN} \times 100 \quad \ldots\ldots\ldots \text{Eq (1)}$$

3.1.2 Sensitivity

Sensitivity measures the proportion of individuals with a disease who test positive, out of all those who actually have

the disease, regardless of their test outcomes. The sensitivity of the Mobilab device was calculated using the true positive and false negative values for each parameter. Refer to Eq. 2 for the sensitivity calculation. Equation used for calculating the diagnostic accuracy, as outlined below.

$$Sensitivity = \frac{TP}{TN + FP} X\,100 \quad \text{..... Eq. (2)}$$

3.1.3 Specificity

Specificity refers to the proportion of healthy individuals who test negative, out of the total number of people without the disease, regardless of their test outcomes. The specificity of the Mobilab device was determined using the true negative and false positive values for each parameter [22,23]. Equation (3) was used to calculate the diagnostic accuracy, as shown below.

$$Specificity = \frac{TN}{TN + FP} X\,100 \quad \text{..... Eq. (3)}$$

Sensitivity and specificity were calculated using the test results: True Positive (TP), True Negative (TN), False Positive (FP), and False Negative (FN). These values were determined based on the test's reference range, as shown below. The test results from IITG Hospital were used as the actual values, and the following definitions were applied:

Patient: Individuals who test positive for the disease (those with values outside the reference range)
Healthy: Individuals who test negative for the disease (those with values within the reference range)
True Positive (TP): The count of cases accurately identified as patients
False Positive (FP): The count of cases inaccurately identified as patients
False Negative (FN): The count of cases inaccurately identified as healthy
True Negative (TN): The count of cases accurately identified as healthy

3.2 Performance Comparison

The comparative study evaluated the methodology, analytical sensitivity, linearity, repeatability, and overall performance of Mobilab with the Selectra ProS auto-analyzer, which is a fully automated device used at IITGH, Guwahati. This assessment focused on the parameters CRE, UA, CHOL, TGL, TBIL, GLU, and, HB. The findings demonstrated the Mobilab analyzer's capability to provide reliable and accurate results at the point of care. Below is a concise summary of the performance comparison methods employed in this study:

3.2.1 Passing-Bablok Regression

The Passing-Bablok regression (P-B Regression) is a robust statistical method used to assess the agreement and potential bias between different analytical techniques. This non-parametric approach is resilient to error distribution and outliers, requiring continuous data that aligns with a linear regression line. The regression equation comprises an intercept, representing a constant, and a slope, which indicates proportional measurement error. Confidence intervals of 95% for both the intercept and slope help determine whether their values significantly differ from zero (for the intercept) and one (for the slope) merely by chance. This assessment enables conclusions about method agreement and identifies the need for any corrective actions. The null hypothesis (H_0) posits that the slope equals zero, implying no significant relationship between the two methods. In contrast, the alternative hypothesis (H_1) indicates that if the slope is approximately equal to one, there exists a significant correlation between the two methods [24].

3.2.2 Bland-Altman Plot

A Bland-Altman plot (B-A Plot) is an effective tool for visualizing the relationship between two paired variables on the same scale. This plot is created by graphing the difference between the two variables (the Selectra ProS auto-analyzer and Mobilab analyzer) against the average of their readings. The mean difference is represented by a line, along with lines indicating ± 2 standard deviations (SD) that define the confidence interval (CI). The B-A Plot aids in detecting outliers, assessing agreement, and uncovering any systematic bias within the data [25,26].

3.2.3 Paired t-test

A paired t-test is a statistical method used to compare the means of two related data sets. The objective of this test is to determine whether the means of these connected data sets differ significantly. In research articles, this test is commonly employed to analyze related data sets. In a paired t-test, there are two hypotheses: The Null Hypothesis (H_0) and the Alternative Hypothesis (H_1). The Null Hypothesis posits that there is no significant difference between the means of the two groups. Conversely, the Alternative Hypothesis suggests that a significant difference exists between the population means, which is unlikely to arise from sampling error or chance.

A significance level of 0.05 is set as the threshold for determining significant differences between the devices. If the p-value exceeds 0.05, the null hypothesis is accepted, indicating no significant difference between the actual and reference devices. On the other hand, if the p-value is less than 0.05, the alternative hypothesis is accepted, signifying a significant difference between the two devices [27,28].

4. Error Segments and Clinical Laboratory Improvement Amendments (CLIA) Compliance

4.1 Error Segment

In POCT devices, error segments are specific aspects of the device's operation, data processing, or result interpretation where errors or deviations from anticipated performance may arise. Identifying these segments is essential for diagnosing and addressing issues that could affect the accuracy and reliability of test results.

4.2 Clinical Laboratory Improvement Amendments (CLIA)

POCT devices must adhere to strict regulations that guarantee their accuracy, reliability, and promptness in clinical environments. According to CLIA, devices intended

for diagnostic use must undergo validation of their analytical performance. Identifying and resolving error segments is essential for achieving CLIA compliance, as it ensures that the device consistently delivers accurate and reliable results in diverse testing settings.

5. Results and Discussion

This study provides a clinical comparison of the POCT device, Mobilab, to evaluate its clinical utility and diagnostic accuracy. A total of 30-plus samples for each parameter were retested using a well-designed experimental framework. For every parameter, the diagnostic method was validated, analytical sensitivity and linearity were examined, and performance metrics were assessed. The findings for each parameter (CRE, UA, CHOL, TGL, TBIL, GLU, and HB) are discussed in detail, emphasizing the device's effectiveness in the early detection of NCDs.

5.1 Creatinine (CRE)

5.1.1 Performance Matrices

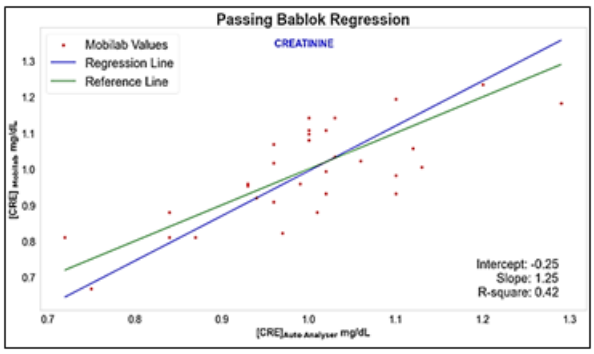
The specificity was measured at 94.29%, indicating that the device correctly identifies 100% of true negative cases. The negative predictive value (NPV) of 100% shows that the device effectively detects all true negative instances. Overall, Mobilab achieves a diagnostic accuracy of 100% for CRE detection, as detailed in **Table 2**. Sensitivity and Positive Predicted Values are nil because we have zero samples of true positive, false positive, and False negative cases.

5.1.2 Performance Comparison

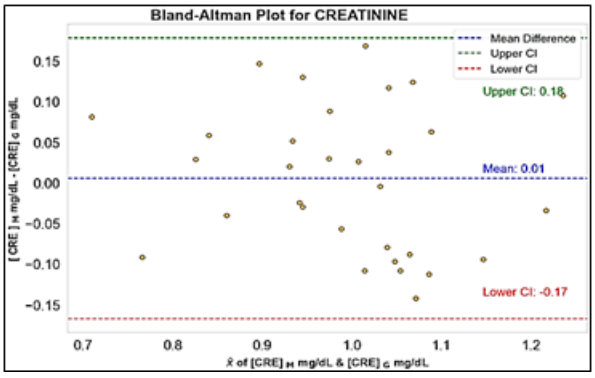
A method comparison was performed to evaluate the CRE test results from Mobilab about those from the Selectra ProS auto-analyzer present at IITGH using P-B Regression. In this analysis, the x-axis represents the results from the ProS auto-analyzer, while the y-axis displays the corresponding results from Mobilab [**Fig. 2(a) Table 2**]. The analysis yielded a slope of 1.25, an intercept of -0.25, and a correlation coefficient (R^2) of 0.42, indicating a strong linear correlation between the two testing methods. Additionally, a B-A plot was created [**Fig. 2(b) Table 2**], revealing a mean bias of 0.01 and a narrow limit of agreement (LOA) ranging from -0.17 mg/dL to 0.18 mg/dL. The results from the paired t-test indicate that the means (0.99 for both methods) and variances (0.01 for Selectra ProS auto-analyzer and 0.02 for Mobilab) of the two testing methods are statistically similar, as evidenced by the Pearson correlation value and p-value. The Pearson correlation coefficient of 0.74, which is close to 1, suggests a strong relationship between the results from Mobilab and the auto analyzer present at IITGH. Furthermore, the p-value of 0.73 for the Mobilab device is greater than the selected significance level of 0.05, providing strong evidence to accept the null hypothesis, and confirming that the test results from the IITGH assay and the Mobilab assay are equivalent. (**Table 2**).

5.1.3 Error Segments and CLIA

The summary in **Table 2** indicates that most sample errors for CRE fall within the CLIA limit of 10%. Samples that exceed this limit are likely attributed to erroneous samples (hemolyzed) or manual errors.



(a)



(b)

Figure 2: Method comparison between Mobilab and ProS auto-analyzer, in terms of CRE as a test parameter: (a) Passing-Bablok regression analysis plot: The CRE concentration measured in patient serum is plotted on the x-axis as $[CRE]_G$ (mg/dL) from ProS auto-analyzer and on the y-axis as $[CRE]_M$ (mg/dL) from Mobilab. The reference line is green, and the regression line is blue. The red dots indicate the values obtained from the Mobilab analyzer. The regression analysis results in intercepts = -0.25, slope =1.25, **(b)** Bland-Altman plot for interrater agreement analysis: The difference in the measurement of CRE in two devices (Mobilab and ProS auto-analyzer) are plotted on the y-axis as $\Delta([CRE]_M - [CRE]_G)$ (mg/dL) and average of measurement from both the devices are plotted on the x-axis as (x of $[CRE]_M$ (mg/dL) & $[CRE]_G$ (mg/dL). Limits of Agreement (mean) are shown as dotted blue lines, upper limit (green line) = 0.18 and lower limit (red line) = -0.17 with 95% confidence intervals, mean of differences or bias represented as a solid line with 95% confidence interval

Table 2: Summary of the CRE Comparison Study: Method Comparison Between Mobilab and Vitros ProS auto-analyzer, Performance comparison, Performance matrices, and Error segments

Performance Comparison of Creatinine								
Passing-Bablok Regression			Bland-Altman Plot		t-test			
Slope	Intercept	R2	Bias (mg/dL)	LOA (mg/dL)	p-value			
1.25	-0.25	0.42	0.01	-0.17 to 0.18	0.7328			
Performance Matrices								
TP	TN	FP	FN	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Diagnostic Accuracy (%)
0	-	0	0	-	100	-	100	100
Error Segments (Allowable error = 10%)								
Avg Error (%)	≤ 5%	5-10%	10-15%	15-20%	>20%	Total		
7.74	-	-	-	-	-	31		

Correlation Coefficient (R^2), True positive (TP), True negative (TN), False positive (FP), False negative (FN), Positive Predictive Value (PPV), Negative Predictive Value (NPV).

5.2 Uric Acid (UA)

5.2.1 Performance Matrices

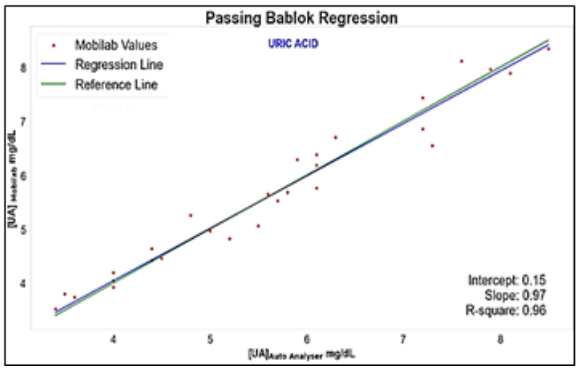
The performance metrics for UA demonstrated a sensitivity of 80% and a specificity of 96%. The positive predictive value (PPV) of 80% indicated that the device correctly identified positive cases in 80% of instances, while the negative predictive value (NPV) of 96% reflected its accuracy in detecting true negative cases. With an overall diagnostic accuracy of 93.33%, the device accurately measured UA concentrations in 93 out of 100 cases. These results highlight a strong correlation between the test outcomes of the Selectra ProS auto-analyzer and the Mobilab device (**Table 3**).

5.2.2 Performance Comparison

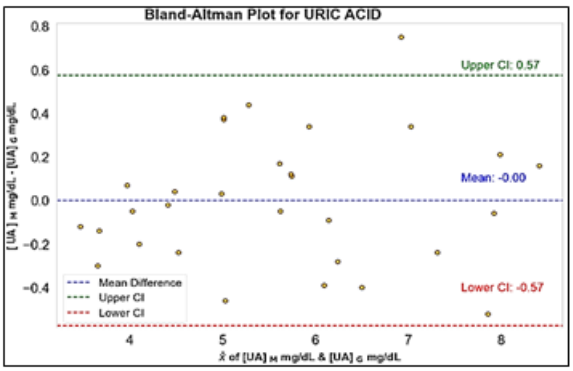
A method comparison study was performed to evaluate the agreement between Mobilab and the Selectra ProS auto-analyzer for UA measurements, using the P-B regression plot [**Fig. 3(a) Table 3**]. The plot produced a slope of 0.97 and an intercept of 0.15, indicating a strong correlation between the two methods. The B-A plot [**Fig. 3(b) Table 3**] further supported this, showing a mean bias of 0.00 mg/dL, with limits of agreement (LOA) from -0.57 to 0.57 mg/dL, suggesting good concordance between results. Most sample points fell within the 95% confidence interval (±2 SD) except for 1 data point. B-A plot analysis confirmed the overall agreement between the two methods. According to the paired t-test results, the mean values (5.62 for both Selectra ProS auto-analyzer and Mobilab) and variances (2.06 and 1.97, respectively) of the two methods are statistically similar. This is further supported by the Pearson correlation coefficient of 0.98, which is close to 1, indicating a strong relationship between the results from Mobilab and the Selectra ProS auto-analyzer present at IITGH. The paired t-test for the Mobilab device yielded a p-value of 0.98, which is higher than the chosen significance level of 0.05, providing strong evidence to accept the null hypothesis, confirming no significant difference between the two methods (**Table 3**).

5.2.3 Error Segments and CLIA

The error segment analysis revealed that most sample errors were within the CLIA limit of 10% for UA. Samples exceeding this limit were likely influenced by manual errors or the presence of hemolyzed samples. This consistency confirmed that the device delivered accurate and reliable results across various testing environments (**Table 3**).



(a)



(b)

Figure 3: Method comparison between Mobilab and Selectra ProS auto-analyzer, in terms of UA as a test parameter: (a) Passing-Bablok regression analysis plot: The UA concentration measured in patient serum is plotted on the x-axis as [UA]G (mg/dL) from Selectra ProS auto-analyzer and on the y-axis as [UA]M (mg/dL) from Mobilab. The reference line is green, and the regression line is blue. The red dots indicate the values obtained from Mobilab. The regression analysis results in intercepts = 0.15, slope = 0.97, (b) Bland–Altman plot for interrater agreement analysis: The difference in the measurement of UA in two devices (Mobilab and Selectra ProS auto-analyzer) are plotted on the y-axis as Δ([UA]M - [UA]G) (mg/dL) and average of measurement from both the devices are plotted on the x-axis as (x of [UA]M (mg/dL) & [UA]G (mg/dL). Limits of Agreement (mean) are shown as dotted blue lines, upper limit (green line) = 0.57 and lower limit (red line) = -0.57

with 95% confidence intervals, mean of differences or bias represented as a solid line with 95% confidence interval.

Table 3: Summary of the UA Comparison Study: Method Comparison Between Mobilab and Selectra ProS auto-analyzer, Performance comparison, and Error segments

Performance Comparison of Uric Acid								
Passing-Bablok Regression				Bland-Altman Plot		t-test		
Slope		Intercept	R^2	Bias (mg/dL)		LOA (mg/dL)		p-value
0.97		0.15	0.96	0.00		-0.57 to 0.57		0.9854
Performance Matrices								
TP	TN	FP	FN	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Diagnostic Accuracy (%)
4	24	1	1	80	96	80	96	93.33
Error Segments (Allowable error = 10%)								
Avg Error (%)	≤ 5%	5-10%	10-15%	15-20%	>20%	Total		
4.21	19	10	1	0	0	30		

Correlation Coefficient (R^2), True positive (TP), True negative (TN), False positive (FP), False negative (FN), Positive Predictive Value (PPV), Negative Predictive Value (NPV).

5.3 Cholesterol (CHOL)

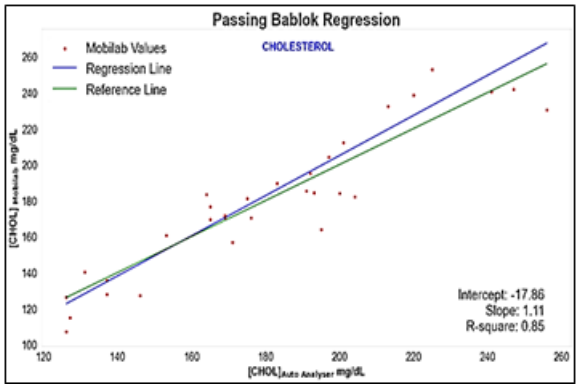
5.3.1 Performance Matrices

The Mobilab device demonstrated a sensitivity of 87.50%, accurately identifying all true positive cases. Its specificity was 95.65%, indicating that it correctly recognized 95.65% of true negative cases. The positive predictive value (PPV) of 87.50% showed that the device correctly predicted positive results 87.50% of the time, while the negative predictive value (NPV) of 95.65% confirmed the device's consistent accuracy in predicting true negative results. With an overall diagnostic accuracy of 93.55%, the device made correct predictions in 93 out of 100 cases. **Table 4** presents the performance metrics for CHOL.

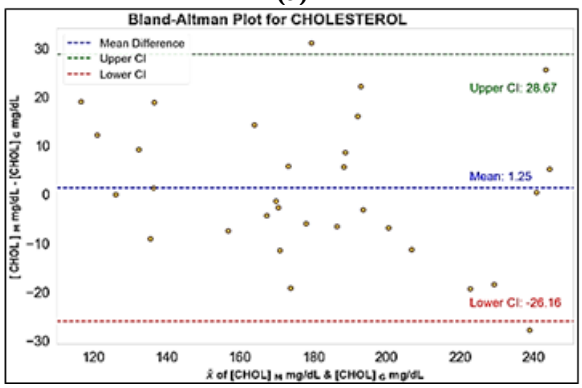
5.3.2 Performance Comparison

The P-B regression for CHOL test results from Mobilab, compared to the Selectra ProS auto analyzer present at IITGH, produced a slope of 1.11, an intercept of -17.86, and a correlation coefficient (R^2) of 0.85 [**Fig. 4(a) Table 4**]. These values fall within the 95% Lower Confidence Limit (LCL) and Upper Confidence Limit (UCL), providing strong support for the null hypothesis (intercept ≈ 0 and slope ≈ 1). The B-A plot analysis revealed a mean bias of 1.25 mg/dL, with limits of agreement (LOA) ranging from -26.16 to 28.67 mg/dL [**Fig. 4(b) Table 4**]. Most sample points were within the 95% confidence interval (±2SD) except for 2 data points, further confirming a strong agreement between the two methods. The paired t-test results showed that the mean values (180.48 for Selectra ProS auto-analyzer and 179.23 for Mobilab) and variances (1292.06 and 1554.51, respectively) for the two methods are statistically similar. This is further supported by the Pearson correlation coefficient of 0.93, indicating a strong correlation between the results of Mobilab and the auto analyzer present at IITGH. The paired t-test for the Mobilab device yielded a p-value of 0.62, which is greater than the chosen significance level of 0.05, providing strong evidence to accept the null hypothesis, confirming no significant difference between the two methods. (**Table 4**).

The results indicate that most samples fall within the CLIA limit of 10% for cholesterol. The few samples exceeding this limit are likely attributable to factors such as hemolysis or manual handling errors. The average and percentage error parameters are presented in **Table 4**.



(a)



(b)

Figure 4: Method comparison between Mobilab and Selectra ProS auto-analyzer, in terms of CHOL as a test parameter. (a) Passing-Bablok regression analysis plot: The CHOL concentration measured in patient serum is plotted on the x-axis as $[CHOL]_G$ (mg/dL) from Selectra ProS auto-analyzer and on the y-axis as $[CHOL]_M$ (mg/dL) from Mobilab. The reference line is green, and the regression line is blue. The red dots indicate the values obtained from Mobilab. The regression analysis results in intercepts = 0.15, slope = 1.11, **(b)** Bland–Altman plot for interrater agreement analysis: The difference in the measurement of CHOL in two devices (Mobilab and Selectra ProS auto-analyzer) are plotted on the y-axis as $\Delta([CHOL]_M - [CHOL]_G)$ (mg/dL) and average of measurement from both the devices are plotted on the x-axis as (x of $[CHOL]_M$ (mg/dL) & $[CHOL]_G$ (mg/dL). Limits of Agreement (mean) are shown as dotted blue lines, upper limit (green line) = 28.67 and lower limit (red line) = -26.16 with 95% confidence intervals, mean of differences or bias represented as a solid line with 95% confidence interval.

Table 4: Summary of the CHOL Comparison Study: Method Comparison Between Mobilab and Selectra ProS auto-analyzer, Performance comparison, and Error segments

Performance Comparison of Cholesterol								
Passing-Bablok Regression				Bland-Altman Plot		t-test		
Slope		Intercept	R^2	Bias (mg/dL)		LOA (mg/dL)		p-value
1.11		-17.86	0.85	1.25		-26.16 to 28.67		0.6268
Performance Matrices								
TP	TN	FP	FN	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Diagnostic Accuracy (%)
7	22	1	1	87.50	95.65	87.50	95.65	93.55
Error Segments (Allowable error = 10%)								
Avg Error (%)		≤ 5%	5-10%	10-15%		15-20%	>20%	Total
6.28		15	10	4		2	0	31

5.4 Triglyceride (TGL)

5.4.1 Performance Matrices

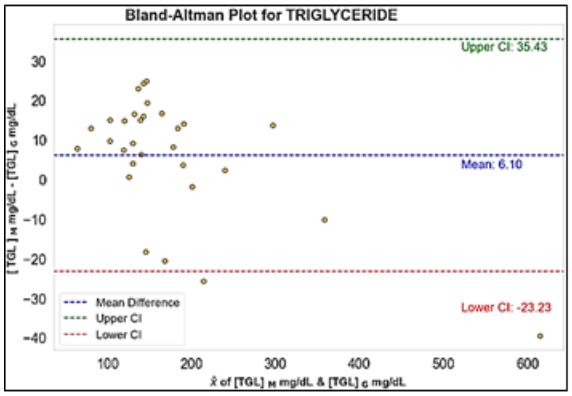
The device demonstrated a sensitivity of 90%, correctly identifying true positive cases 90% of the time. It achieved 95.24 % specificity, accurately detecting all true negative cases. With an impressive positive predictive value (PPV) of 90%, the device consistently predicts true positive results. Likewise, a negative predictive value (NPV) of 95.24% indicates that the device accurately identifies true negative results 95.24% of the time. Overall, the device has a diagnostic accuracy of 93.55%, making correct predictions in 93 out of 100 cases. **Table 5** presents the performance metrics for TGL.

5.4.2 Performance Comparison

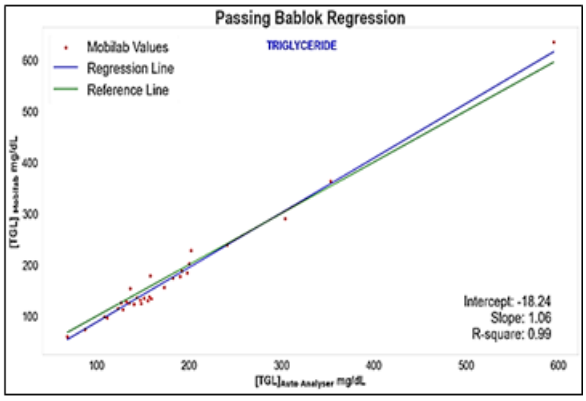
The P-B regression for TGL test results from Mobilab, compared to the corresponding TGL concentrations from the Selectra ProS auto-analyzer present at IITGH, yielded a slope of 1.06, an intercept of -18.24, and a correlation coefficient of 0.99 [**Fig. 5(a) Table 5**]. These findings indicate a strong correlation and high level of agreement between the two methods. The B-A plot analysis revealed a mean bias of 6.10 mg/dL, with limits of agreement (LOA) ranging from -23.23 to 35.43 mg/dL [**Fig. 5(b) Table 5**]. Most sample points fell within the 95% confidence interval (±2 SD) except for 1 point. This deviation is likely due to manual errors or the presence of hemolyzed samples. The paired t-test results indicated that the means (178.06 for Selectra ProS auto-analyzer and 171.96 for Mobilab) and variances (9550.41 and 1148.53, respectively) of the two methods are statistically similar. This is further supported by the Pearson correlation coefficient of 0.98, which is close to 1, suggesting a strong relationship between the results from Mobilab and the auto analyzer present at IITGH. The paired t-test for the Mobilab device yielded a p-value of 0.04, which is less than the chosen significance level of 0.05, indicating no significant difference between the two methods. (**Table 5**).

5.4.3 Error Segments and CLIA

The summary in **Table 5** shows that most sample errors fall within the CLIA limit of 15% for triglycerides. Samples exceeding this limit are likely due to manual errors or the presence of hemolyzed samples.



(a)



(b)

Figure 5: Method comparison between Mobilab and Selectra ProS auto-analyzer, in terms of TGL as a test parameter: (a) Passing-Bablok regression analysis plot: The TGL concentration measured in patient serum is plotted on the x-axis as $[TGL]_G$ (mg/dL) from Selectra ProS auto-analyzer and on the y-axis as $[TGL]_M$ (mg/dL) from Mobilab. The reference line is green, and the regression line is blue. The red dots indicate the values obtained from Mobilab. The regression analysis results in intercepts = -18.24, slope =1.06, **(b)** Bland–Altman plot for interrater agreement analysis: The difference in the measurement of TGL in two devices (Mobilab and Selectra ProS auto-analyzer) are plotted on the y-axis as $\Delta([TGL]_M - [TGL]_G)$ (mg/dL) and the average of measurement from both the devices are plotted on the x-axis as (x of $[TGL]_M$ (mg/dL) & $[TGL]_G$ (mg/dL). Limits of Agreement (mean) are shown as dotted blue lines, upper limit (green line) = 35.43 and lower limit (red line) = -23.23 with 95% confidence intervals, mean of differences or bias represented as a solid line with 95% confidence interval.

Table 5: Summary of the TGL Comparison Study: Method Comparison Between Mobilab and Selectra ProS auto-analyzer, Performance comparison, and Error segments

Performance Comparison of Triglycerides								
Passing-Bablok Regression						Bland-Altman Plot		t-test
Slope			Intercept	R^2		Bias (mg/dL)	LOA (mg/dL)	p-value
1.06			-18.24	0.99		6.10	-23.23 to 35.43	0.0363
Performance Matrices								
TP	TN	FP	FN	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Diagnostic Accuracy (%)
9	20	1	1	90	95.24	90	95.24	93.55
Error Segments (Allowable error = 10%)								
Avg Error (%)		≤ 5%		5-10%	10-15%	15-20%	>20%	Total
8.55		12		7	6	4	2	31

Correlation Coefficient (R^2), True positive (TP), True negative (TN), False positive (FP), False negative (FN), Positive Predictive Value (PPV), Negative Predictive Value (NPV).

5.5 Total Bilirubin (TBIL)

5.5.1 Performance Metrics

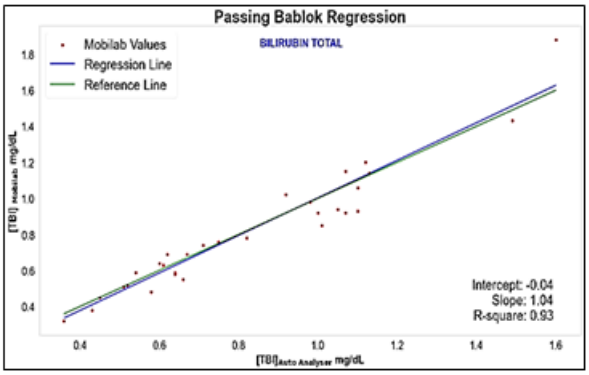
The performance metrics for TBIL demonstrate a sensitivity of 100% and a specificity of 100%. A positive predictive value (PPV) of 100% indicates that the device correctly identifies positive cases consistently. Similarly, the negative predictive value (NPV) of 100% confirms that the device accurately detects true negative cases without error. With a diagnostic accuracy of 100%, the device measures TBIL concentrations correctly in all 100 instances. These statistical measures confirm a strong agreement between the results from the Selectra ProS auto-analyzer and the Mobilab device, as detailed in **Table 6**.

5.5.2 Performance Comparison

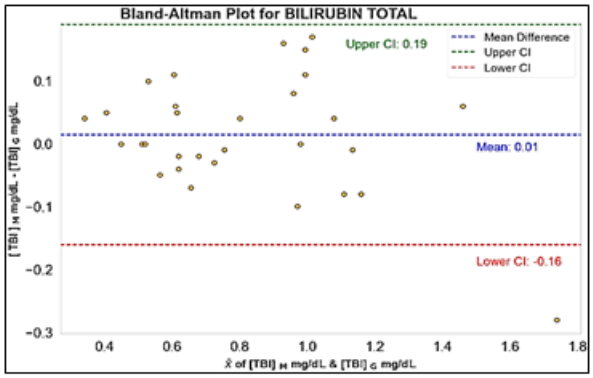
A comparative study was conducted to evaluate the agreement between Mobilab and the Selectra ProS auto-analyzer present at IITGH for TBIL using the P-B regression plot [**Fig. 6(a) Table 6**]. The analysis yielded a slope of 1.04, an intercept of -0.04, and a correlation coefficient of 0.93, providing strong evidence to support the acceptance of the null hypothesis. The B-A plot analysis [**Fig. 6(b) Table 6**] indicated a low mean bias of 0.01 mg/dL, with limits of agreement (LOA) ranging from -0.16 to 0.19 mg/dL, demonstrating a narrow range and good concordance between the two techniques. The paired t-test results indicate that the means (0.83 for Selectra ProS auto-analyzer and 0.81 for Mobilab) and variances (0.10 and 0.11, respectively) of the two methods are statistically similar. This is further supported by a Pearson correlation coefficient of 0.96, which is close to 1, suggesting a strong relationship between the results from Mobilab and the auto analyzer at IITGH. The paired t-test for the Mobilab device yielded a p-value of 0.39, which exceeds the chosen significance level of 0.05, providing strong evidence to accept the null hypothesis, indicating no significant difference between the two methods used by Mobilab and IITGH (**Table 6**).

5.5.3 Error Segments and CLIA

The summary in **Table 6** indicates that most sample errors are within the CLIA limit of 20% for TBIL. Samples that exceed this limit are likely attributed to manual errors or the presence of hemolyzed samples.



(a)



(b)

Figure 6: Method comparison between Mobilab and Selectra ProS auto-analyzer, in terms of TBIL as a test parameter: (a) Passing-Bablok regression analysis plot: The TBIL concentration measured in patient serum is plotted on the x-axis as $[TBIL]_G$ (mg/dL) from Selectra ProS auto-analyzer and on the y-axis as $[TBIL]_M$ (mg/dL) from Mobilab. The reference line is green, and the regression line is blue. The red dots indicate the values obtained from Mobilab. The regression analysis results in intercepts = -0.04, slope = 1.04, **(b)** Bland-Altman plot for interrater agreement analysis: The difference in the measurement of TBIL in two devices (Mobilab and Selectra ProS auto-analyzer) are plotted on the y-axis as $\Delta([TBIL]_M - [TBIL]_G)$ (mg/dL) and average of measurement from both the devices are plotted on the x-axis as (x of $[TBIL]_M$ (mg/dL) & $[TBIL]_G$ (mg/dL). Limits of Agreement (mean) are shown as dotted blue lines, upper limit (green line) = 0.19 and lower limit (red line) = -0.16 with 95% confidence intervals, mean of differences or bias represented as a solid line with 95% confidence interval.

Table 6: Summary of the TBIL Comparison Study: Method Comparison Between Mobilab and Selectra ProS auto-analyzer, Performance comparison, and Error segments

Performance Comparison of Total Bilirubin								
Passing-Bablok Regression						Bland-Altman Plot		t-test
Slope			Intercept	R^2		Bias (mg/dL)	LOA (mg/dL)	p-value
1.04			-0.04	0.93		0.01	-0.16 to 0.19	0.3958
Performance Matrices								
TP	TN	FP	FN	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Diagnostic Accuracy (%)
2	28	0	0	100	100	100	100	100
Error Segments (Allowable error = 10%)								
Avg Error (%)		≤ 5%		5-10%	10-15%	15-20%	>20%	Total
7.88		11		8	6	5	0	30

Correlation Coefficient (R^2), True positive (TP), True negative (TN), False positive (FP), False negative (FN), Positive Predictive Value (PPV), Negative Predictive Value (NPV).

5.6 Glucose (GLU)

5.6.1 Performance Metrics

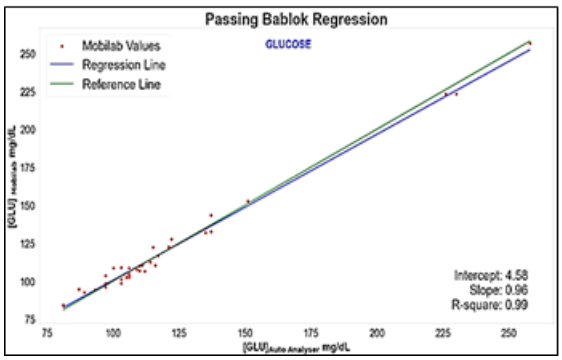
In the analysis of LDL samples, the device demonstrated a sensitivity of 93.33%, indicating its effectiveness in accurately detecting positive cases. With a specificity of 95%, it correctly identifies 95% of true negative cases. The positive predictive value (PPV) of 93.33% signifies that the device accurately detects 93.33% of true positive cases, while the negative predictive value (NPV) of 95% indicates reliable identification of true negative instances. Overall, Mobilab achieves a diagnostic accuracy of 94.29% for LDL detection, as detailed in **Table 7**.

5.6.2 Performance Comparison

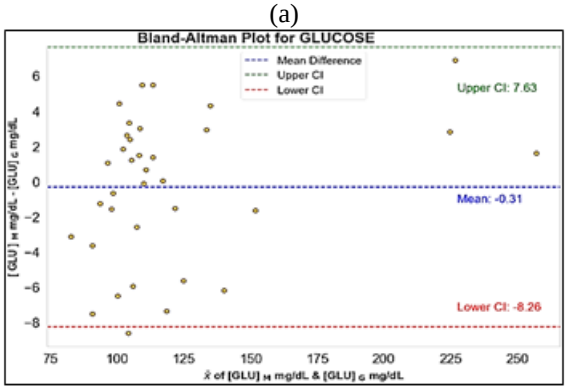
A method comparison study was conducted to evaluate the agreement between Mobilab and the Selectra ProS auto-analyzer for LDL using the P-B regression plot [**Fig. 7(a) Table 7**]. The analysis yielded a slope of 0.96, an intercept of 4.58, and a correlation coefficient of 0.93, indicating a strong correlation between the two methods. Further evaluation with the B-A plot [**Fig. 7(b) Table 7**] revealed a low mean bias of -0.31 mg/dL, with limits of agreement (LOA) ranging from -8.26 to 7.63 mg/dL, demonstrating good concordance between the methods. The paired t-test results indicate that the means (120.23 for Selectra ProS auto-analyzer and 120.54 for Mobilab) and variances (1569.00 and 1474.24, respectively) of the two methods are statistically similar. This is further supported by a Pearson correlation coefficient of 0.99, which is very close to 1, suggesting a strong relationship between the results from Mobilab and the Selectra ProS auto-analyzer present at IITGH. The aired t-test for the Mobilab device yielded a p-value of 0.65, which exceeds the chosen significance level of 0.05, providing strong evidence to accept the null hypothesis (**Table 7**).

5.6.3 Error Segments and CLIA

The data presented in **Table 7** indicate that most sample errors are within the CLIA limit of 8% for GLU. Samples exceeding this limit are likely attributed to erroneous factors, such as hemolyzed samples or manual errors.



(a)



(b)

Figure 7: Method comparison between Mobilab and Selectra ProS auto-analyzer, in terms of GLU as a test parameter: (a) Passing-Bablok regression analysis plot: The GLU concentration measured in patient serum is plotted on the x-axis as $[GLU]_G$ (mg/dL) from Selectra ProS auto-analyzer and on the y-axis as $[GLU]_M$ (mg/dL) from Mobilab. The reference line is green, and the regression line is blue. The red dots indicate the values obtained from Mobilab. The regression analysis results in intercepts = 4.58, slope = 0.96, **(b)** Bland-Altman plot for interrater agreement analysis: The difference in the measurement of GLU in two devices (Mobilab and Selectra ProS auto-analyzer) are plotted on the y-axis as $\Delta([GLUL]_M - [GLU]_G)$ (mg/dL) and an average of measurement from both the devices are plotted on the x-axis as (x of $[GLU]_M$ (mg/dL) & $[GLU]_G$ (mg/dL). Limits of Agreement (mean) are shown as dotted blue lines, upper limit (green line) = 7.63 and lower limit (red line) = -8.26 with 95% confidence intervals, mean of differences or bias represented as a solid line with 95% confidence interval.

Table 7: Summary of the GLU Comparison Study: Method Comparison Between Mobilab and Selectra ProS auto-analyzer, Performance comparison, and Error segments

Performance Comparison of Glucose								
Passing-Bablok Regression						Bland-Altman Plot		t-test
Slope			Intercept	R^2		Bias (mg/dL)	LOA (mg/dL)	p-value
0.96			4.58	0.99		-0.31	-8.26 to 7.63	0.6541
Performance Matrices								
TP	TN	FP	FN	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Diagnostic Accuracy (%)
14	19	1	1	93.33	95	93.33	95	94.29
Error Segments (Allowable error = 10%)								
Avg Error (%)		≤ 5%		5-10%	10-15%	15-20%	>20%	Total
2.96		30		5	0	0	0	35

Correlation Coefficient (R^2), True positive (TP), True negative (TN), False positive (FP), False negative (FN), Positive Predictive Value (PPV), Negative Predictive Value (NPV).

5.7 Hemoglobin (HB)

5.7.1 Performance Metrics

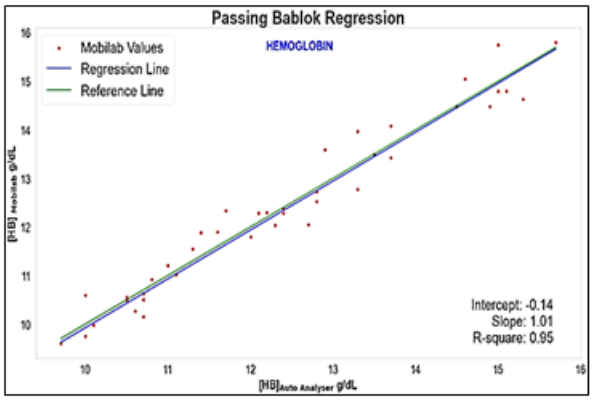
The Mobilab device demonstrated a sensitivity of 94.12%, meaning it accurately identified all true positive cases. Its specificity was 95.83%, indicating that it correctly detected 95.83% of true negative cases. A positive predictive value (PPV) of 94.12% suggests that the device accurately predicted positive results in 94.12% of cases. The negative predictive value (NPV) OF 95.83% confirmed the device's consistency in identifying true negative cases. Overall, with a diagnostic accuracy of 95.83%, the device correctly predicted 95 out of 100 cases. **Table 8** details the device's performance metrics for HB.

5.7.2 Performance Comparison

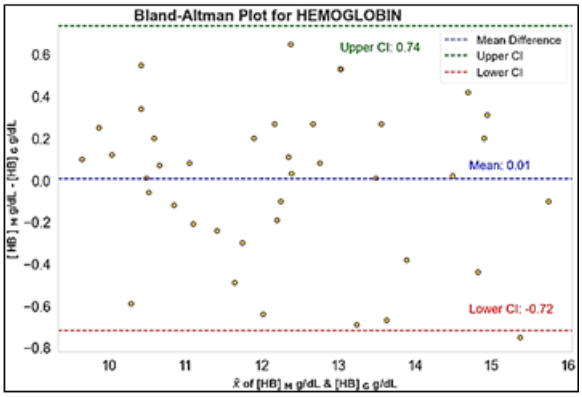
The P-B regression for HB test results in Mobilab, compared to the Selectra ProS auto-analyzer present at IITGH, yielded a slope of 1.01, an intercept of -0.14, and a correlation coefficient of 0.95 [**Fig. 8(a) Table 8**]. Both values fall within the 95% Lower Confidence Limit (LCL) and Upper Confidence Limit (UCL), providing strong support for the null hypothesis (intercept ≈ 0 and slope ≈ 1). B-A plot analysis indicated a mean bias of 0.01 mg/dL, with limits of agreement (LOA) ranging from -0.72 to 0.74 mg/dL [**Fig. 8(b) Table 8**]. Most sample points were within the 95% confidence interval (±2SD) except for 1 data point, confirming the strong agreement between the two methods. The paired t-test results show that the mean values (12.39 for Selectra ProS auto-analyzer and 12.38 for Mobilab) and variances (2.91 and 2.98, respectively) of the two methods are statistically similar. This is further supported by a Pearson correlation value of 0.98, indicating a close relationship between the results of the Mobilab device and the auto analyzer present at IITGH. With a p-value of 0.89, which is greater than the chosen significance level of 0.05, there is strong evidence to accept the null hypothesis, confirming that the test results from both the IITGH assay and the Mobilab device are comparable. (**Table 8**).

5.7.3 Error Segments and CLIA

The analysis indicates that most cholesterol test samples fall within the HB limit of 4%. The few samples that exceed this threshold are likely due to errors such as manual handling mistakes or the presence of hemolyzed samples. Detailed average and percentage error metrics are provided in



(a)



(b)

Figure 8: Method comparison between Mobilab and Selectra ProS auto-analyzer, in terms of HB as a test parameter: Passing-Bablok regression analysis plot: The HB concentration measured in patient serum is plotted on the x-axis as $[HB]_G$ (mg/dL) from Selectra ProS auto-analyzer and on the y-axis as $[HB]_M$ (mg/dL) from Mobilab. The reference line is green, and the regression line is blue. The red dots indicate the values obtained from Mobilab. The regression analysis results in intercepts = -0.14, slope = 1.01, **(b)** Bland-Altman plot for interrater agreement analysis: The difference in the measurement of HB in two devices (Mobilab and Selectra ProS auto-analyzer) are plotted on the y-axis as $\Delta([HB]_M - [HB]_G)$ (mg/dL) and an average of measurement from both the devices are plotted on the x-axis as (x of $[HB]_M$ (mg/dL) & $[HB]_G$ (mg/dL). Limits of Agreement (mean) are shown as dotted blue lines, upper limit (green line) = 0.74 and lower limit (red line) = -0.72 with 95% confidence intervals, mean of differences or bias represented as a solid line with 95% confidence interval.

Table 8: Summary of the HB Comparison Study: Method Comparison Between Mobilab and Selectra ProS auto-analyzer, Performance comparison, and Error segments

Performance Comparison of Hemoglobin								
Passing-Bablok Regression						Bland-Altman Plot		t-test
Slope			Intercept	R^2		Bias (mg/dL)	LOA (mg/dL)	p-value
1.01			-0.14	0.95		0.01	-0.72 to 0.74	0.8950
Performance Matrices								
TP	TN	FP	FN	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Diagnostic Accuracy (%)
16	23	1	1	94.12	95.83	94.12	95.83	95.12
Error Segments (Allowable error = 10%)								
Avg Error (%)		≤ 5%	5-10%	10-15%		15-20%	>20%	Total
2.40		34	7	0		0	0	41

Correlation Coefficient (R2), True positive (TP), True negative (TN), False positive (FP), False negative (FN), Positive Predictive Value (PPV), Negative Predictive Value (NPV).

6. Conclusion

This study highlights the clinical use of the Mobilab POCT device, which incorporates IoT technology and operates via a smartphone interface. Its performance was evaluated against the standard and established Selectra ProS auto-analyzer using retained samples from IITGH. Key analytes, including Triglycerides (TGL), Cholesterol (CHOL), Uric Acid (UA), Creatinine (CRE), Total Bilirubin (TBIL), Glucose (GLU), and Hemoglobin (HB), were measured, showing a strong correlation with the results of Selectra ProS auto-analyzer present at IITGH. A few discrepancies were noted, likely due to hemolyzed samples or manual errors. To evaluate repeatability, 20 trials were conducted with two concentrations for each biomarker using Bio-Rad control serum Levels 1 and 3. The device demonstrated a high precision in the measurements. Diagnostic accuracy was further assessed by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy (DA), confirming the device's reliability in measuring analytes. Overall, Mobilab proves to be a promising POCT device, delivering accurate results for multiple serum parameters, generating real-time digital patient data, and providing affordable, accessible healthcare solutions to a broad and diverse population.

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Author Profile

Corresponding cum First Author: Sahil Jagnani. Sahil is a PhD student in the Centre for Nanotechnology, IIT Guwahati. Sahil completed his B.Tech degree from Department of Chemical Engineering, IIT Guwahati in 2013. He is dedicated to developing innovative healthcare solutions, with a particular focus on market driven IOT enabled- point-of-care testing (POCT) devices. Sahil has been instrumental in creating the portable blood testing device, a ground-breaking device designed to diagnose chronic non-communicable and has publication in IEEE Journal for Flexible Electronics (J Flex). This technology aims to make early disease detection more accessible and affordable, addressing significant gaps in healthcare delivery

Second Author: Dr. Anuj Kumar Baruah: Dr. Anuj Kumar Baruah is a senior medical professional with an MD in Internal Medicine. He serves as the Chief Medical Officer (NFSG) and Head of Section (HOS) at the Indian Institute of Technology Guwahati. With extensive experience in clinical internal medicine, Dr. Baruah has been instrumental in managing institutional healthcare systems and contributing to research in medical diagnostics and public health.

Third Author: Ankit Chowdhury. Ankit is a distinguished Prime Minister's Research Fellow and a dedicated PhD student at the Centre for Nanotechnology, IIT Guwahati. He earned his Bachelor of Design degree from IIT Guwahati's Department of Design in 2019. His research primarily revolves development of point of care testing devices for low resource settings. Ankit's contributions to the field are highlighted his publications in prestigious journals, including the IEEE Journal for Flexible Electronics (J Flex). His dedication to research have made significant impacts in the field, fostering advancements in portable diagnostic devices and contributing to the scientific community.