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Performance Evaluation Of Mobilab: A Portable Biochemistry Analyzer For Hba1c Testing In Point-Of-Care Diagnostics

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Abstract : This study has been undertaken to compare the clinical performance of the Siemens Dimension EXL 200 and the portable biochemistry analyser Mobilab for HbA1c determination. Accessible and affordable diagnostic methods are required due to the rising incidence of diabetes, particularly in environments with low resources. Mobilab provides a portable point-of-care testing substitute that promotes early detection and efficient illness treatment. 52 whole blood samples were drawn from patients at GNRC Medical in North Guwahati. The Siemens Dimension EXL 200 and Mobilab were used to determine the patients' HbA1c levels. To evaluate method agreement and device performance, statistical analyses were conducted, including Bland-Altman plots, diagnostic accuracy computations, sensitivity, specificity, and Passing & Bablok regression. With a Passing & Bablok regression slope of 0.9735 (95% CI: 0.6047–1.0500) and an intercept of 0.1869 (95% CI: -0.3375–0.9029), Mobilab showed a significant correlation with the reference technique. 95% of data points fell within the permissible ranges, according to Bland-Altman analysis, which revealed a mean bias of -0.0004%. Mobilab demonstrated its dependability in measuring HbA1c with a sensitivity of 95.65%, specificity of 93.10%, and total diagnostic accuracy of 94.23%. With excellent concordance with recognised clinical analysers, Mobilab offers a precise, portable, and affordable substitute for HbA1c testing. It is a promising tool for diabetes monitoring and management, facilitating early diagnosis and better patient outcomes because of its capacity to be implemented in environments with low resources.

Keywords: *HbA1c, Portable Biochemistry Analyzer, Point-of-Care Testing, Diagnostic Accuracy, Diabetes Management*

1. Introduction

Over 400 million people worldwide suffer from diabetes, a fast-expanding global health concern (International Diabetes Federation, 2019). A prolonged undiagnosed and untreated condition of diabetes leads to kidney failure, neuropathies, and cardiovascular illnesses, it significantly increases morbidity and mortality (World Health Organization, 2016). To avoid these problems, blood glucose levels must be properly monitored and managed (American Diabetes Association, 2020).

HbA1c testing provides a long-term evaluation of glycaemic control by representing average blood sugar levels over two to three months rather than a single time point, therefore, it is favoured over glucose level tests (Sacks et al., 2011). HbA1c is more convenient and dependable than fasting glucose testing because it is not impacted by transient variations and does not necessitate fasting (American Diabetes Association, 2022). Despite the fact that HbA1c testing is crucial for both diagnosing and treating diabetes, conventional testing methods rely on large, automated laboratory analysers, which makes them unavailable in resource-constrained environments (Kumar et al., 2017). This leads to a substantial gap in diabetes care, particularly in remote and underserved areas with inadequate laboratory infrastructure.

In order to address this issue, IIT Guwahati collaborated with Primary Healthtech Private Limited to develop the portable biochemistry analyser Mobilab, which offers a battery-operated, portable, and cost-effective biochemistry analyser for measuring HbA1c. By enabling early detection and timely therapies, the gadget was created to simplify point-of-care testing, which will enhance patient outcomes and diabetes management

		Siemens Dimension EXL 200		
		Positive	*Negative*	
Mobilab	*Positive*	True Positive **(TP)**	False Positive **(FP)**	Positive Predictive Value **(PPV)**
	Negative	False Negative **(FN)**	True Negative **(TN)**	Negative Predictive Value **(NPV)**
		Sensitivity **TP / (TP+FN) × 100.**	Specificity **TN / (TP+FP) × 100**	Diagnostic Accuracy (DA) **TP + TN / (TP+FN+FP+TN) × 100**

This study aims to evaluate the accuracy of the Siemens Dimension EXL 200, a high-performance clinical analyser, with the clinical performance of Mobilab in measuring HbA1c levels. To ensure statistical rigour in assessing Mobilab's performance, the study uses Bland-Altman analysis and Passing & Bablok regression to evaluate method agreement and bias (Passing and Bablok, 1983, Bland and Altman, 1986). According to the study's premise, Mobilab is a good substitute for point-of-care diagnostics since it can measure HbA1c with an accuracy that is on par with that of conventional laboratory analysers.

This study fills a critical gap in diabetes diagnosis by bridging the gap between laboratory-based testing and practical accessibility. Mobilab has the potential to transform diabetes screening and monitoring if it turns out to be accurate and dependable, especially in low-resource environments where early diagnosis is frequently postponed. This project intends to improve diabetes care and patient outcomes globally by offering a portable and reasonably priced diagnostic tool.

2. Materials and Methods

2.1 Study Design and Ethical Approval

This study was a cross-sectional clinical validation conducted at GNRC Medical Lab, North Guwahati. Ethical approval was obtained from the GNRC Hospital Ethics Committee in compliance with the Helsinki Declaration (2013). Informed consent was obtained from all adult participants, and assent was collected from children above seven years, as per national guidelines.

Table 1: The tabular illustration of the performance metrices and their respective formulas to calculate Sensitivity, Specificity, and Diagnostic Accuracy for the Mobilab device

2.2 Selection and Description of Participants

Fifty-two whole blood samples were collected from patients undergoing routine diabetes monitoring. Inclusion criteria were individuals diagnosed with diabetes or at risk of diabetes, irrespective of age and

gender. Exclusion criteria included hemolyzed, lipemic, and degraded samples, as well as samples stored beyond 24 hours post-collection.

2.3 Analytical Methods and Device Details

HbA1c measurement was performed using:

(a) Mobilab-Duo (Primary Healthtech Private Limited, Assam, India): A portable clinical chemistry analyzer employing the Latex-Enhanced Immunoturbidimetric (LEiT) method (Jeppsson et al., 2002).

(b) Siemens Dimension EXL 200 (Siemens Healthineers, Erlangen, Germany): A high-performance fully automated clinical analyzer serving as the reference standard.

2.4 Sample Collection and Processing

Blood samples were collected using EDTA vials. The HbA1c reagent used was AGAPPE HbA1c Kit (Agappe Diagnostics Ltd., Kerala, India, REF No. 51835004), following the manufacturer's protocol. Samples were analyzed within twenty-four hours of collection to prevent degradation.

2.5 Statistical Analysis

All statistical analyses were performed using NCSS Statistician tool 2021 version (Kaysville, Utah, USA). The following statistical methods were applied:

(a) Passing & Bablok Regression: Passing & Bablok regression (P-B Regression) is a robust non-parametric statistical method used to evaluate agreement and detect potential bias between analytical methods. It is resistant to variations in error distribution and outliers, making it suitable for method comparison studies. The regression model requires continuous data and assumes a linear relationship, where the intercept indicates a constant measurement bias and the slope represents proportional error. The 95% Confidence Intervals (CI) for the intercept and slope help determine whether their values significantly deviate from 0 and 1, respectively, providing insights into systematic and proportional differences (Bilić-Zulle, 2011).

(b) Bland-Altman Plot: A Bland-Altman plot (B-A Plot) is a powerful visualization tool for assessing agreement between two paired measurement methods on the same scale. It is constructed by plotting the difference between the two methods (SDA and Mobilab) against their average values. The plot includes a mean difference line, flanked by ±2 standard deviation (SD) limits, representing the confidence interval (CI). This approach helps identify outliers, evaluate agreement, and detect any systematic bias between the methods (Bland and Altman, 1986; Mansournia et al., 2020).

(c) Sensitivity, Specificity, and Diagnostic Accuracy: To assess the accuracy of the proposed device, key diagnostic metrics including sensitivity, specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV), and Diagnostic Accuracy (DA) were calculated. These metrics were derived from test outcomes classified as True Positive (TP), True Negative (TN), False Negative (FN), and False Positive (FP) (Dhamnetiya et al., 2021), as presented in Table 1

Sensitivity analysis measured Mobilab's ability to correctly identify the presence of a condition, while specificity analysis evaluated its accuracy in detecting the absence of the condition. PPV determined the proportion of correctly identified positive cases among all positive results, whereas NPV assessed the proportion of true negative cases among all negative instances. Finally, DA represented the overall proportion of correctly classified cases, combining both true positives and true negatives, to provide a comprehensive measure of Mobilab's diagnostic performance (Dhamnetiya et al., 2021).

2.6 Patient Confidentiality

Patient anonymity was strictly maintained, with all samples anonymized and assigned unique codes. No personal identifiers such as names or hospital numbers were recorded in the dataset.

3. Results

3.1 Method Comparison

3.1.1 Passing & Bablok Regression

The Passing & Bablok regression analysis demonstrated a strong correlation between Mobilab and the Siemens Dimension EXL 200. The regression equation yielded a slope of 0.9735 (95% CI: 0.6047–1.0500) and an intercept of 0.1869 (95% CI: -0.3375–0.9029), confirming a high level of agreement between the two devices as shown in the Figure 1 (a). These values indicate that the measurements obtained from Mobilab are statistically comparable to those from the reference analyzer.

(a) **(b)**

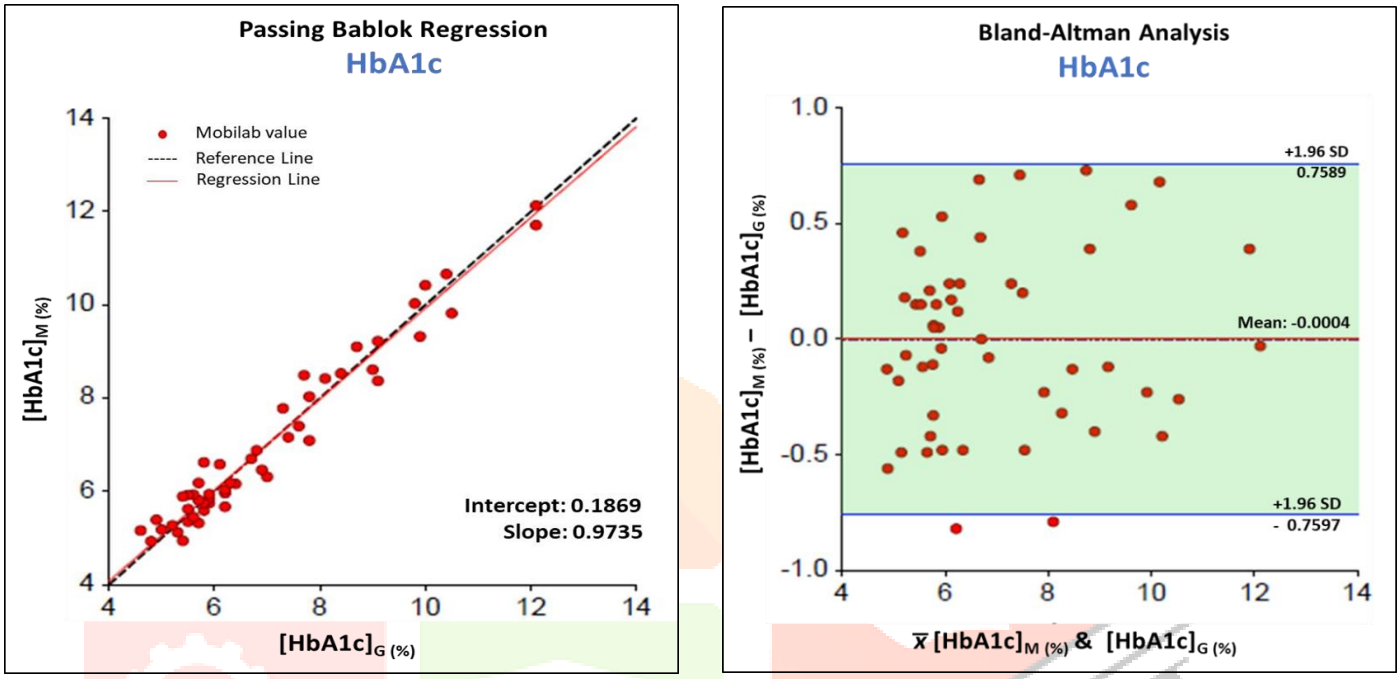

Figure 1: (a) Passing–Bablok regression analysis plot: The HbA1c concentration measured in patient serum is plotted on the x-axis as [HbA1c] G (%) from SDA and on the y-axis as [HbA1c]M (%) from Mobilab. The reference line is shown in black, and the fitted line is in red. Red dots indicate the values obtained from Mobilab. The regression analysis results in intercepts = -0.1869, and slope=0.9735. **(b)** Bland- Altman plot for interrater agreement analysis: Comparison between Mobilab and SDA, in terms of HbA1c as a test parameter. The difference in the measurement of HbA1c in two devices (Mobilab and SDA) are plotted on the y axis as [HbA1c]M (%) – [HbA1c]G (%)] and average of measurement from both the devices are plotted on the x axis as (x of [HbA1c]M (%) & [HbA1c]G (%) . Limits of Agreement are shown as blue lines, upper limit = 0.7589 and lower limit = -0.7597 with 95% confidence intervals, mean of differences or bias (0.0004 %) represented as the red line with 95% confidence interval.

3.1.2 Bland-Altman Analysis

Bland-Altman analysis was conducted to evaluate the systematic bias between the two measurement methods. The mean bias was calculated as -0.0004%, with 95% limits of agreement ranging from -0.7597% to 0.7589%. All but two sample points fell within these limits, indicating strong agreement between the two devices. The presence of two outliers suggests potential random analytical errors rather than systematic deviation as shown in the Figure 1 (b).

3.2 Performance Metrics

The diagnostic performance of Mobilab was assessed using sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy. Mobilab demonstrated high sensitivity (95.65%), confirming its ability to accurately identify true positive cases, and specificity (93.10%), ensuring reliable identification of true negative cases. The positive predictive value (91.67%) and negative

predictive value (96.43%) indicate that Mobilab provides a reliable result. A diagnostic accuracy of 94.23% reinforces its clinical validity for HbA1c measurement as shown in the Table 2.

Table 2: Summary of Performance Metrices in the Method Validation study for HbA1c compared Between Mobilab and SDE 200

Device Metrics	Test Results
Total Sample	52
True Positive	22
True Negative	27
False Positive	2
False Negative	1
Sensitivity	95.65 %
Specificity	93.10 %
Positive Predictive Value	91.67 %
Negative Predictive Value	96.43 %
Diagnostic Accuracy	94.23 %

3.3 Observations

Mobilab demonstrates a strong correlation with the reference analyzer, with only minor variations attributed to random errors. Its high sensitivity and specificity validate its reliability for HbA1c measurement in clinical settings. Additionally, Mobilab's portability and cost-effectiveness make it a valuable tool for point-of-care testing, particularly in resource-limited environments where access to large clinical analyzers is restricted. These findings highlight Mobilab's potential to enhance diabetes screening and management by providing an accessible and efficient alternative for HbA1c testing in underserved areas.

4. Discussion

The study indicates a strong correlation between Mobilab and the Siemens Dimension EXL 200, demonstrating high diagnostic accuracy, sensitivity, and specificity. Mobilab effectively identified both diabetic and non-diabetic cases, reinforcing its potential as a reliable point-of-care testing device (Bland and Altman, 1986; Lenters-Westra and Slingerland, 2014). The results align with previous studies that have evaluated point-of-care HbA1c testing devices, confirming their ability to provide accurate and rapid measurements. However, prior research has also highlighted that some portable analyzers exhibit greater bias when compared to standard laboratory methods [14,15]. The findings of this study confirm that Mobilab maintains a strong agreement with standard laboratory methods, with minimal bias observed in the Bland-Altman analysis. Furthermore, Mobilab’s performance surpasses certain earlier models that reported higher mean biases and lower specificity in similar evaluations (Lenters-Westra and Slingerland, 2014).

The study employed a well-defined methodology with strong statistical rigor, incorporating Passing & Bablok regression and Bland-Altman analysis to ensure robust performance evaluation (Passing and Bablok, 1983; Bland and Altman, 1986). A clinically relevant sample size (n=52) was used, providing reliable data for assessing accuracy and agreement. Conducted in a real-world clinical setting, the study enhances practical applicability, reflecting real-world diagnostic conditions (Klonoff and Kerr, 2021). Additionally, Mobilab’s portability and cost-effectiveness make it a promising alternative for resource-limited settings, where access to conventional analyzers is restricted (World Health Organization, 2011). However, the study was limited to a single clinical site, necessitating further validation across multiple centres to establish broader applicability. Moreover, only a single brand of reagent was used, which may impact generalizability when different reagents are employed (Little et al., 2008). While Mobilab demonstrated high agreement with the reference analyzer,

minor variations in precision due to handling and sample processing could influence results (Sacks et al., 2011).

The findings of this study support the integration of Mobilab into clinical workflows for HbA1c testing, particularly in remote and resource-constrained settings (Klonoff and Kerr, 2021; World Health Organization, 2011). The strong agreement between Mobilab and the Siemens Dimension EXL 200 suggests that the device can serve as a viable alternative for laboratory-based HbA1c testing, improving accessibility and facilitating early diabetes diagnosis (Sacks et al., 2011).

This study contributes to the growing body of evidence supporting the role of portable biochemistry analyzers in decentralizing diagnostic testing. The ability to perform HbA1c testing at the point of care can lead to earlier interventions, reduced patient burden, and improved glycaemic control monitoring (Nathan et al., 2008). Additionally, the adoption of Mobilab in primary healthcare settings could enhance diabetes management programs by allowing immediate clinical decisions without delays associated with centralized laboratory testing (Klonoff and Kerr, 2021).

Future studies should explore the long-term performance and stability of Mobilab in diverse clinical environments. A larger, multi-centre validation study would further strengthen confidence in the device's diagnostic capabilities. Additionally, evaluating its integration with telemedicine and digital health platforms could maximize its impact on diabetes care (American Diabetes Association, 2022).

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