Research Article

# Comparative performance analysis of three point-of-care glucose testing devices against a central laboratory reference method

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**Keywords**

Point-of-care testing, Glucose monitoring, Analytical accuracy, Hexokinase method, ISO 15197

**Abstract**

**Background:** Point-of-care testing (POCT) glucose systems are widely used in clinical practice due to their rapid turnaround time and operational convenience. However, concerns remain regarding their analytical agreement with laboratory reference methods, particularly in relation to accuracy and potential clinical impact.

**Methods:** This cross-sectional analytical study included 196 adult outpatients at Dr. Soetomo General Academic Hospital, Surabaya, Indonesia. Capillary blood glucose was measured using three POCT devices (StatStrip, Accu-Chek Inform II, and Rightest), while venous plasma glucose was analyzed using a hexokinase-based reference method (Alinity C). Analytical performance was evaluated using correlation analysis, Bland–Altman plots, Passing–Bablok regression, and ISO 15197 accuracy criteria.

**Results:** All POCT devices demonstrated strong correlations with the reference method ($r = 0.967–0.982$; $p < 0.001$). StatStrip showed a small negative bias (−2.89 mg/dL; $p = 0.003$), while Accu-Chek Inform II exhibited a larger deviation (−7.80 mg/dL; $p < 0.001$). In contrast, Rightest showed no statistically significant bias (−0.14 mg/dL; $p = 0.870$) and demonstrated the closest agreement with the reference method. Agreement analysis confirmed minimal systematic and proportional bias for Rightest, whereas Accu-Chek Inform II showed wider variability. ISO 15197 evaluation indicated the highest accuracy for Rightest and lower compliance for Accu-Chek Inform II, particularly at glucose levels <200 mg/dL.

**Conclusion:** Although all POCT systems showed strong correlations with the reference method, clinically relevant differences in analytical agreement and accuracy were identified. Rightest demonstrated the best overall performance. These findings highlight the importance of evaluating agreement beyond correlation and support the use of POCT primarily for glucose monitoring rather than definitive diagnosis.

**Background**

The American Diabetes Association (ADA) defines diagnostic and prediabetic criteria based on blood glucose levels in conjunction with the presence or absence of clinical symptoms [1,2]. Glycemic assessment can be performed either in a central laboratory or through point-of-care testing (POCT), which refers to diagnostic methods designed for use in close proximity to the patient [1,3,4]. POCT platforms offer several advantages over conventional central laboratory testing, including faster turnaround times and reduced specimen volume requirements [5]. Point-of-care glucose testing is a diagnostic technology that enables rapid, automated, efficient, and cost-effective detection of blood glucose levels [6–9]. These devices are widely utilized across various healthcare settings, including hospitals, emergency departments, outpatient clinics, intensive care units (ICUs), and ambulatory services [6,7]. Continuous improvements in analytical performance have been reported; however, POCT glucose meters have not yet gained universal acceptance for diagnostic use [10,11].

POCT glucose meters are used in both inpatient and outpatient settings, although their clinical applications may differ. In outpatient or ambulatory care, glucometers are commonly used for routine glucose monitoring and diabetes self-management. In hospital settings, particularly in emergency departments and intensive care units, POCT systems facilitate rapid clinical decision-making for glycemic control. However, critically ill patients often present physiological conditions such as anemia, hypotension, or drug interference that may affect POCT accuracy. Therefore, many clinical guidelines recommend that POCT glucose measurements obtained in hospitalized patients be interpreted cautiously and verified using laboratory methods when clinically indicated.

POCT systems typically analyze whole blood samples, whereas reference laboratory methods measure glucose levels in venous plasma. Physiologically, glucose concentration in venous plasma is approximately 10%–15% higher than that in whole blood, due to differences in water content between plasma and red blood cells. Most POCT devices convert whole blood measurements to plasma-equivalent glucose concentrations using correction factors that account for hematocrit levels in order to improve comparability with laboratory methods [12]. Variability in glucose measurements may also depend on the type of blood sample used, such as capillary versus venous blood [13]. According to the Clinical Laboratory Improvement Amendments (CLIA), POCT glucose results should fall within ±10% or 5.4 mg/dL of those obtained using reference laboratory methods [14]. This study aimed to evaluate the analytical performance of three POCT glucose systems StatStrip (Nova Biomedical), Accu-Chek Inform II (Roche Diagnostics), and Rightest (Bionime) by comparing their results with those obtained using the laboratory hexokinase reference method on the Alinity analyzer (Abbott Laboratories).

**Objective**

To evaluate the validity of blood glucose point-of-care testing (POCT) devices StatStrip, Accu-Chek Inform II, and Rightest by comparing their performance to the reference hexokinase methodusing the Alinity analyzer as the standard for glucose measurement.

**Methods**

**Study Design and Setting**

This analytical observational study employed a cross-sectional design and was conducted between August and October 2023 at the Clinical Pathology Laboratory of Dr. Soetomo General Academic Hospital, Surabaya, Indonesia. Data were collected using simple random sampling. The study population consisted of adult outpatients in order to minimize potential physiological interferences commonly observed in critically ill hospitalized patients.

Three point-of-care testing (POCT) glucose systems StatStrip® (Nova Biomedical), Accu-Chek Inform II® (Roche Diagnostics), and Rightest® (Bionime) were evaluated. These devices were selected because they represent commonly used glucose monitoring systems in routine clinical practice, including hospital and outpatient settings in Indonesia, and employ different enzymatic detection principles. StatStrip® utilizes a glucose oxidase–based electrochemical detection system, Accu-Chek Inform II® uses a mutant quinoprotein glucose dehydrogenase (Mut. Q-GDH) enzyme system, and Rightest® operates using a glucose dehydrogenase (GDH) detection method. The reference laboratory measurement was performed using the Alinity C analyzer (Abbott Laboratories), which applies the hexokinase enzymatic method. Ethical approval for this study was obtained from the Ethics Committee of Dr. Soetomo General Academic Hospital. All POCT measurements were performed according to the manufacturers' instructions.

Only outpatient participants were included in this study to minimize potential confounding factors commonly present in critically ill patients, such as severe hematocrit abnormalities, hypoperfusion, vasopressor therapy, or interfering substances. These conditions are known to affect the analytical performance of POCT glucose meters. By focusing on outpatient individuals with relatively stable physiological conditions, the study aimed to evaluate the analytical agreement between POCT devices and the laboratory reference method under controlled clinical circumstances.

**Sample Collection and Procedure**

The study population comprised outpatient individuals undergoing routine blood sampling at the Sampling Unit, 1st Floor, Dr. Soetomo General Hospital, Surabaya. Inclusion criteria were patients aged >18 years who provided written informed consent prior to participation. Capillary blood samples were obtained via single-finger puncture and analyzed immediately using the three POCT glucose meters: StatStrip (Nova), Accu-Chek Inform II (Roche), and Rightest (Bionime). Concurrently, venous blood samples were collected using vacutainer tubes containing sodium fluoride (NaF, gray-top tubes) to inhibit glycolysis. Samples were stored in a small manual cooler box containing a single frozen ice gel pack, which maintained an internal temperature of approximately 6°C to 10°C during transport and prior to analysis, in order to preserve glucose stability. Plasma glucose analysis was conducted within twohours

of sample collection. Prior to testing, venous blood samples were centrifuged to separate the plasma. The resulting plasma was then analyzed for glucose concentration using the Alinity C analyzer (Abbott), which served as the reference standard.

**Results**

This study included 196 participants. The majority were female (110, 56.1%), while males accounted for 86 participants (43.9%). Based on blood glucose levels, 49 participants (25%) had levels <100 mg/dL, 98 (50%) between 100–200 mg/dL, and 49 (25%) >200 mg/dL. The age of participants ranged from 18 to 83 years,with a median of 54 years and a mean of 51.09 ± 12.823 years. Baseline characteristics are summarized in Table 1. Clinically relevant differences were observed between POCT devices and the reference laboratory method (Table 2). StatStrip demonstrated a small but statistically significant negative bias (mean difference −2.89 mg/dL; 95% CI: −4.81 to −0.97; p = 0.003). Accu-Chek Inform II showed a larger negative bias (−7.80 mg/dL; 95% CI: −9.90 to −5.69; p < 0.001), indicating greater deviation from the reference method. In contrast, the Rightest device showed no statistically significant bias (−0.14 mg/dL; 95% CI: −1.80 to 1.52; p = 0.870).

**Table 1**: Demographic Characteristics and Blood Glucose Categories of Respondents.

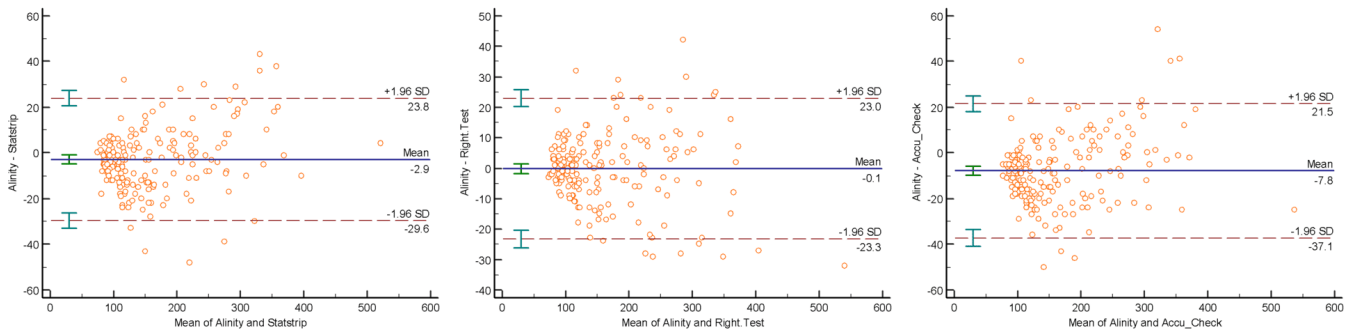
| Category | Frequency | Percentage (%) |
|---|---|---|
| Male | 86 | 43.9 |
| Female | 110 | 56.1 |
| Total | 196 | 100 |
| < 100 mg/dL | 49 | 25 |
| 100-200 mg/dL | 98 | 50 |
| > 200 mg/dL | 49 | 25 |
| Total | 196 | 100 |
| Age (Median [Range]) | 54 (18 - 83) | Mean ± SD: 51.09 ± 12.823 |

**Table 2**: Comparison of Blood Glucose Differences Between StatStrip, Accu-Chek Inform II, and Rightest Against Alinity.

| Variable | Mean Difference | 95% CI of Difference | P (H: Mean = 0) |
|---|---|---|---|
| Alinity vs StatStrip | -2.89 | -4.8131 to -0.9727 | 0.0033 |
| Alinity vs Accu-Chek | -7.80 | -9.9015 to -5.6903 | 0.0001 |
| Alinity vs Rightest | -0.14 | -1.7993 to 1.5238 | 0.8703 |

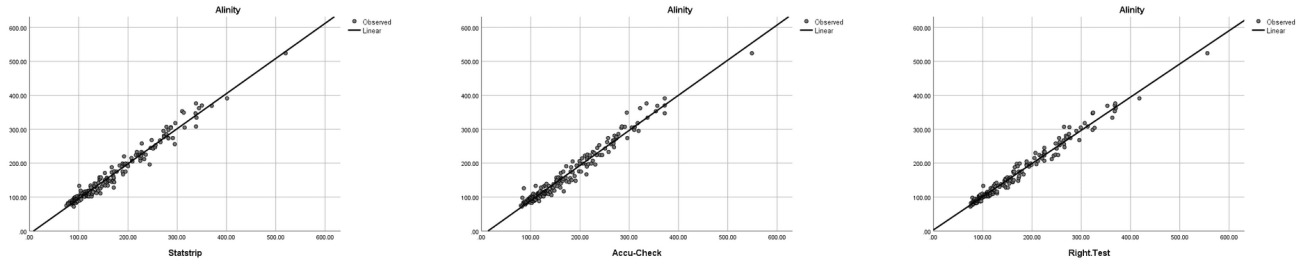
Agreement analysis using Bland–Altman plots demonstrated systematic bias across devices (Figure 1). The Rightest device showed the narrowest limits of agreement, whereas Accu-ChekInform II exhibited wider variability, indicating less consistent agreement with the reference method.

**Figure 1:** Bland - Altman plots comparing glucose measurements between Alinity and StatStrip A, Rightest B, and Accu-Chek C.



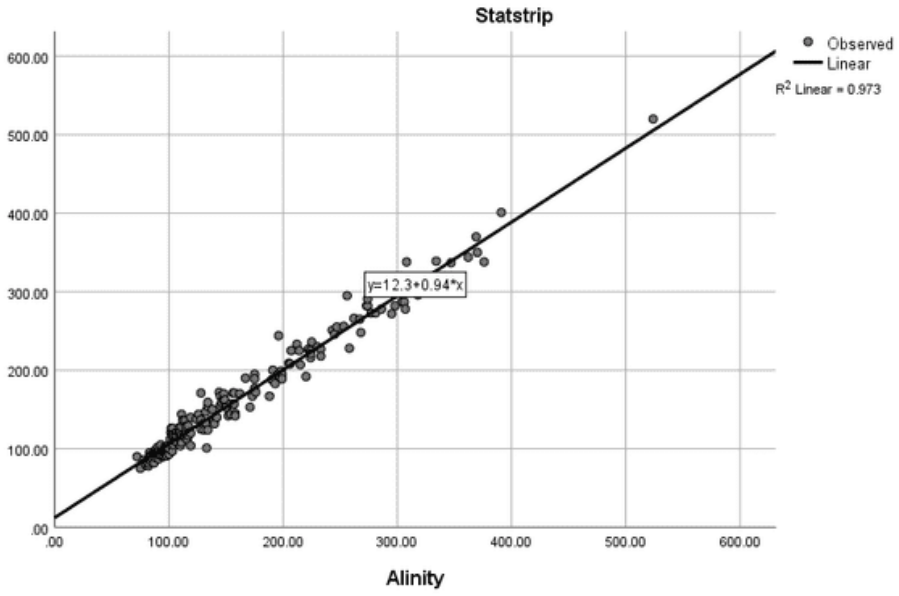
Correlation analysis revealed strong and statistically significant associations between all POCT devices and the reference method (all $p < 0.001$). The highest correlation was observed for the Rightest device ($r = 0.982$), followed by StatStrip ($r = 0.975$) andAccu-Chek Inform II ($r = 0.967$). Scatter plots are presented in Figure 2. However, correlation alone does not imply agreement; therefore, agreement analyses were further performed.

**Figure 2:** Spearman correlation plots comparing glucose measurements between Alinity and StatStrip A, Accu-Chek B, and Rightest C.



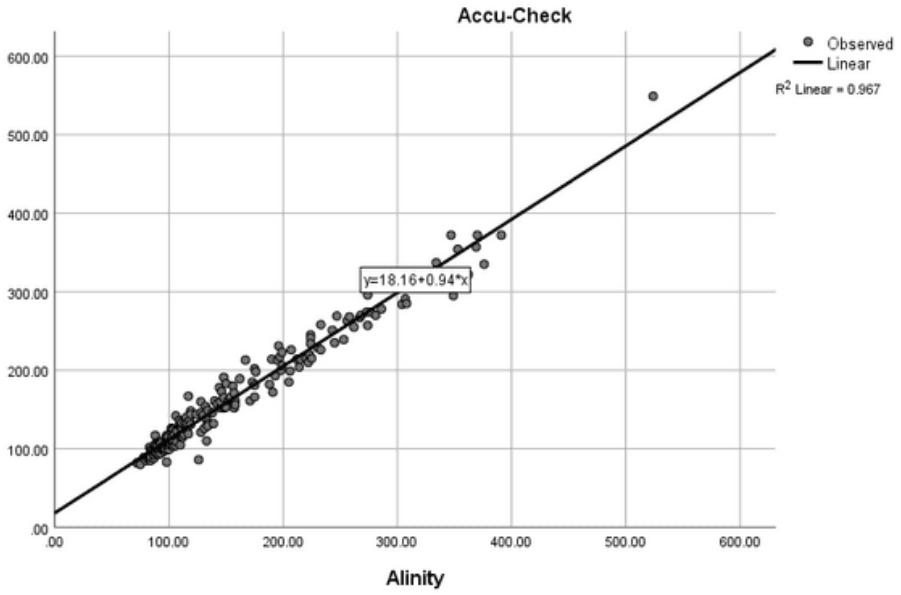

Passing–Bablok regression analysis demonstrated that the Rightest device showed the closest agreement with the reference method, with minimal systematic and proportional bias. In contrast, StatStrip and Accu-Chek Inform II exhibited bothsystematic and proportional deviations, indicating less optimal agreement (Figures 3–5). Detailed regression parameters are provided in the Supplementary Material.

**Figure 3:** Passing–Bablok regression analysis of StatStrip versus Alinity.



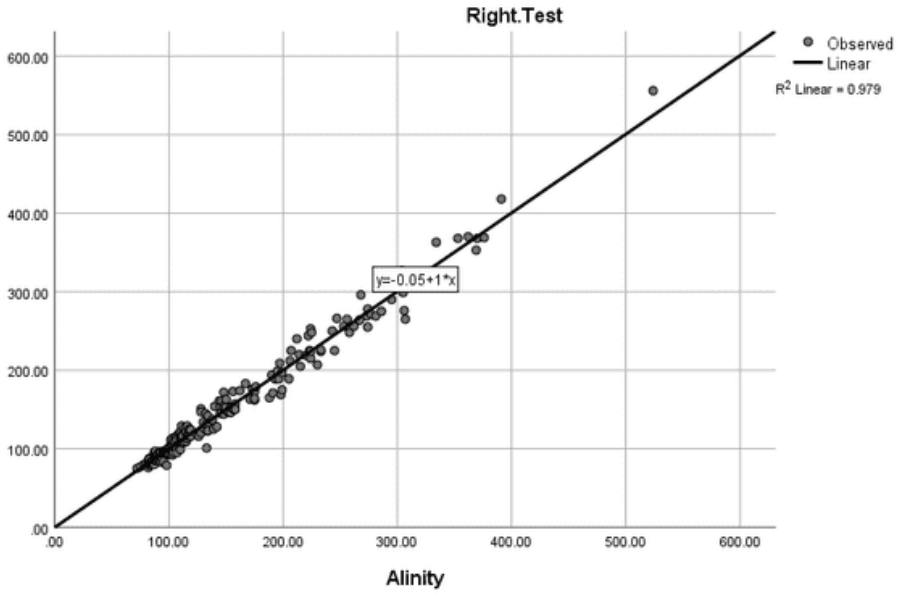

Accu-Chek showed an intercept of 18.158 (95% CI: 13.795 to 22.521) and a slope of 0.935 (95% CI: 0.911 to 0.959),suggesting a greater systematic deviation from the reference method (Figure 4).

**Figure 4:** Passing–Bablok regression analysis of Accu-Chek versus Alinity.




The Rightest device demonstrated an intercept close to zero (−0.055; 95% CI: −3.735 to 3.625) and a slope of 1.001 (95% CI: 0.981 to 1.022), indicating near-perfect proportional agreement with the Alinity analyzer **(**Figure 5).

**Figure 5:** Passing–Bablok regression analysis of Rightest versus Alinity.




Accuracy evaluation based on ISO 15197 criteria demonstrated variability in analytical performance among the devices (Table 3). The Rightest device achieved the highest overall compliance, with accuracy of 98.0% at glucose levels <100 mg/dL, 94.9% at 100–200 mg/dL, and 100% at >200 mg/dL. StatStrip showed good performance at low and high glucose ranges but reducedcompliance in the intermediate range (83.7%). Accu-Chek Inform II demonstrated lower accuracy at glucose levels <200 mg/dL but high compliance at levels >200 mg/dL (98.0%). Additional descriptive statistics, detailed ISO analysis, and full regression results are provided in the Supplementary Material.

**Table 3**: Accuracy of POCT devices based on ISO 15197 criteria.

| Device | <100 mg/dL (%) | 100–200 mg/dL (%) | >200 mg/dL (%) |
|---|---|---|---|
| StatStrip | 98.0 | 83.7 | 98.0 |
| Accu-Chek | 65.3 | 67.3 | 98.0 |
| Rightest | 98.0 | 94.9 | 100 |

## Discussion

This study provides a comprehensive evaluation of the analytical performance of three point-of-care testing (POCT) glucose systems using a standardized laboratory reference method. While all evaluated devices demonstrated strong correlations with the hexokinase-based reference, notable differences in analytical accuracy and bias were observed, highlighting the inherent variability among POCT technologies [10,13,21].

The observed variability in performance is consistent with previous studies demonstrating that device-specific analytical characteristics are influenced by the underlying enzymatic detection principles. Systems based on glucose dehydrogenase (GDH) and its variants are known to be susceptible to certain analytical interferences, whereas glucose oxidase-based systems may be affected by oxygen concentration and sample conditions [23,25]. These methodological differences likely contribute to the variation in agreement observed across devices in this study.

Importantly, the findings underscore that correlation alone does not equate to analytical interchangeability. Despite strong linear associations, clinically relevant biases may persist, particularly at extreme glucose concentrations [10,13]. This has direct implications for patient management, as even small deviations may influence clinical decision-making in glycemic control.

The selection of outpatient participants in this study allowed for a more controlled evaluation of device performance by minimizing confounding factors such as acute physiological instability, medication effects, and critical illness–related alterations commonly encountered in emergency and intensive care settings [22,24]. However, this also highlights the need for caution when extrapolating these findings to inpatient or critically ill populations, where additional variables may further impact measurement accuracy.

POCT glucose devices are widely used across both outpatient and inpatient settings due to their rapid turnaround time and operational convenience [9,24]. Nevertheless, their analytical performance may vary depending on patient condition, particularly in critically ill individuals where factors such as impaired perfusion, altered hematocrit, and oxygenation status can significantly influence results [17,19].

Several known interferences may affect the accuracy of POCT glucose measurements. Variations in hematocrit can lead to either underestimation or overestimation of glucose levels depending on the device technology. Additionally, the presence of reducing substances such as ascorbic acid, galactose, and other endogenous or exogenous compounds may interfere with electrochemical detection systems [2,23]. Oxygen tension and sample handling conditions may further contribute to measurement variability [7].

These factors collectively emphasize the importance of understanding device-specific limitations in clinical practice.

Despite the demonstrated analytical reliability of POCT systems, it is important to emphasize that these devices are not intended for the diagnosis of diabetes. Diagnostic criteria require the use of standardized laboratory-based methods with established traceability and analytical performance [3,20]. POCT glucose measurements are primarily intended for monitoring and immediate clinical decision-making rather than definitive diagnosis.

Overall, these findings reinforce the importance of careful device selection, ongoing quality assurance, and appropriate clinical interpretation when using POCT glucose systems. Integration of POCT technologies with laboratory standards remains essential to ensure accurate and reliable patient care across diverse healthcare settings [21,27].

## Conclusion

This study provides a comparative evaluation of three point-of-care glucose testing (POCT) systems StatStrip, Accu-Chek Inform II, and Rightest against a hexokinase-based laboratory reference method using the Alinity C platform. All evaluated devices demonstrated strong correlations with the reference method, confirming their utility for glucose monitoring in routine clinical practice.

However, clinically relevant differences in analytical agreement and accuracy were observed. Among the evaluated systems, Rightest demonstrated the closest agreement with the reference method, with minimal systematic and proportional bias, whereas StatStrip and Accu-Chek Inform II showed greater analytical variability. These findings highlight that high correlation does not necessarily equate to analytical agreement, emphasizing the importance of comprehensive performance evaluation beyond correlation metrics alone.

Importantly, variability in accuracy across glucose ranges—particularly in intermediate concentrations - suggests that device performance may influence clinical decision-making in specific scenarios. Therefore, POCT glucose systems should be used with an understanding of their analytical limitations and are best positioned as tools for monitoring rather than definitive diagnostic instruments.

Overall, careful device selection, implementation of rigorous quality assurance programs, and appropriate clinical interpretation are essential to ensure safe and effective use of POCT glucose testing. Strengthening the integration between POCT systems and standardized laboratory methods may further improve diagnostic reliability and support optimal glycemic management across diverse healthcare settings.

**Data Availability**

The data supporting the findings of this study are available from the corresponding author upon reasonable request. Access to the data is subject to ethical approval and participant confidentiality regulations.

**Conflict of Interest Statement**

The authors declare that there are no conflicts of interest related to this study.

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**Author Contributions**

All authors contributed to the study conception and design. Data collection and analysis were performed by the authors. The first draft of the manuscript was written by the first author, and all authors critically revised the manuscript for important intellectual content. All authors read and approved the final manuscript.

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**Supplementary Tables**

**Supplementary Table 1:** Descriptive statistics of blood glucose measurements obtained from POCT devices and the reference laboratory method.

| Device | Median (Range) | Mean + SD | CV |
|---|---|---|---|
| Alinity | 128 (72 - 524) | 159.541 + 81.209 | 0.509 |
| StatStrip | 135.5 (75 - 520) | 162.434 + 77.479 | 0.477 |
| Accu-Chek | 141 (80 - 549) | 167.337 + 77.212 | 0.461 |
| Rightest | 125.5 (75 - 556) | 159.679 + 82.158 | 0.515 |

*Abbreviations: SD, standard deviation; CV, coefficient of variation.*

**Supplementary Table 2:** Descriptive analysis of differences (delta values) between POCT devices and the reference method.

| Comparison | Median (Range) | Mean + SD | CV |
|---|---|---|---|
| Alinity vs StatStrip | -3 (-48 to 43) | -2.89 + 13.63 | -4.71 |
| Alinity vs Accu-Chek | -8 (-50 to 54) | -7.80 + 14.95 | -1.92 |
| Alinity vs Rightest | 0.5 (-32 to 42) | -0.14+ 11.80 | -85.59 |

*Negative values indicate higher glucose readings from POCT devices compared to the reference method.*

**Supplementary Table 3:** Normality test of glucose measurements using the Kolmogorov–Smirnov test (n = 196).

| Device | Kolmogorov-Smirnov Value | p-value |
|---|---|---|
| Alinity | 0.171 | <0.001 |
| StatStrip | 0.150 | <0.001 |
| Accu-Chek | 0.145 | <0.001 |
| Rightest | 0.171 | <0.001 |

*All datasets showed non-normal distribution ($p < 0.05$), supporting the use of non-parametric statistical analysis.*

***indicates strong correlation. Spearman's correlation was used due to non-normal data distribution.*

**Supplementary Table 4:** Correlation analysis between POCT devices and the reference method.

| Comparison | Spearman's r | p-value |
|---|---|---|
| StatStrip vs Alinity | 0.975** | <0.001 |
| Accu-Chek vs Alinity | 0.967** | <0.001 |
| Rightest vs Alinity | 0.982** | <0.001 |

**Supplementary Table 5:** Comparative statistical analysis between POCT devices and the reference method.

| Comparison | Median (Range) | Mean | CV | Median | Mean | CV | p-value |
|---|---|---|---|---|---|---|---|
| StatStrip vs Alinity | 128 (72-524) | 159.541 ± 81.21 | 0.509 | 135.5 (75-520) | 162.434 ± 77.48 | 0.477 | <0.001 |
| Accu-Chek vs Alinity | 128 (72-524) | 159.541 ± 81.21 | 0.509 | 141 (80-549) | 167.337 + 77.21 | 0.461 | <0.001 |
| Rightest vs Alinity | 128 (72-524) | 159.541 + 81.21 | 0.509 | 125.5 (75–556) | 159.679 + 82.16 | 0.515 | <0.001 |

*p-values derived from non-parametric comparison tests.*

**Supplementary Table 6:** Analytical accuracy of POCT devices according to ISO 15197:2013 criteria across glucose concentration ranges.

| Category | <100 mg/dL | 100–200 mg/dL | >200 mg/dL | Total |
|---|---|---|---|---|
| Not compliant | 1 (2.0%) | 16 (16.3%) | 1 (2.0%) | 18 (9.2%) |
| Compliant | 48 (98.0%) | 82 (83.7%) | 48 (98.0%) | 178 (90.8%) |

| Category | <100 mg/dL | 100–200 mg/dL | >200 mg/dL | Total |
|---|---|---|---|---|
| Not compliant | 17 (34.7%) | 32 (32.7%) | 1 (2.0%) | 50 (25.5%) |
| Compliant | 32 (65.3%) | 66 (67.3%) | 48 (98.0%) | 146 (74.5%) |

| Category | <100 mg/dL | 100–200 mg/dL | >200 mg/dL | Total |
|---|---|---|---|---|
| Not compliant | 1 (2.0%) | 5 (5.1%) | 0 (0.0%) | 6 (3.1%) |
| Compliant | 48 (98.0%) | 93 (94.9%) | 49 (100%) | 190 (96.9%) |

**StatStrip / Accu-Chek / Rightest**

Accuracy was evaluated according to ISO 15197:2013 criteria, which require that ≥95% of results fall within ±15 mg/dL (forglucose <100 mg/dL) or ±15% (for glucose ≥100 mg/dL) of the reference method.