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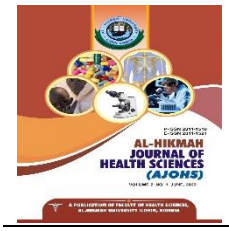

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**Original Article**

# Evaluation of Analytical Performance of Point-of-Care Glucose Monitoring Devices in Aminu Kano Teaching Hospital, Kano, Nigeria

**Idris Yahaya Mohammed[1*], Hassan Maikudi Muhammad[2], Muhammad Ahmad Bello[3], Akeem Olayinka Busari[4]**

[1]Department of Chemical Pathology, Bayero University Kano, Kano State, 700233, Nigeria
[2]Department of Chemical Pathology, Aminu Kano Teaching Hospital, Kano State, 700233, Nigeria
[3]Department of Medical Laboratory Science, Bayero University Kano, Kano State, 700233, Nigeria.
[4]Department of Medical Laboratory Science, Ladoke Akintola University of Technology, Ogbomoso, 210214, Nigeria

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**Corresponding Author**
Dr. Idris Yahaya Mohammed,
Department of Chemical Pathology,
Bayero University Kano PMB 3011,
Kano, Kano State, Nigeria.
*Phone Number:* +2348133394293
*Email:* idrismoore@gmail.com
*Zip code: 700233*

**ABSTRACT**

**Introduction:** Point of care Glucose Monitoring devices (POCGMDs) provide rapid monitoring of glycaemic control in an acceptable range for diabetic patients in both the hospital and outpatient environments. Poorly calibrated and validated POCGMDs are unreliable and potentially dangerous and usage should be regulated. This study evaluated the analytical performance of POCGMDs at Aminu Kano Teaching Hospital, Nigeria where POCGMDs are commonly used.

**Materials and Methods:** The accuracy and precision of the POCGMDs glucose readings utilized in the specialty clinics with the reference method employed by the Abbott C4000 at the Central Laboratory of the Hospital were compared using the ISO 15197:2003 and ISO 15197:2013 standards.

**Results:** Our results showed that Accu-Check active demonstrated an acceptable precision at all levels for repeatability (CV <5%) and reproducibility precision at higher glucose concentrations (i.e. Level 3) whereas Fine Test Auto-coding demonstrated an acceptable precision (CV < 5%) for both repeatability and reproducibility at level 2 and 3 concentrations and failed both at level 1 compared to the reference method. The Mean glucose value for Accu-Chek showed no statistical difference whereas the Fine test auto-coding device showed a statistically significant increase at $P < 0.005$ compared with the reference method. The linear regression revealed that the two POCGMDs statistically at $p < 0.05$ overestimated the glucose concentrations compared to the reference method.

**Conclusion:** This study showed that the two POCGMDs had low precision in comparison to ISO 15197: 2003 and 2013's minimal accuracy requirements, which suggests that their glucose measurement was imprecise. As a result, this study advised employing ISO and ADA criteria for optimal glycaemic control in POCGMDs evaluation and validation to enhance health status.

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**Introduction**

Nigeria is still at the infancy stage of critical care as the services have been affected by low wages, an exodus of manpower, the government's inability to fund hospitals, and corruption which in turn causes high fatality rates (Bolodeoku *et al*., 2020). Intensive care unit's mortality rates have been described as 69.4% in severe head injury patients, 43.5% in medical neurological, 33% and 52% in obstetric patients (Okafor and Aniebue, 2004; Okafor and Onwuekwe, 2004; Osinaike *et al*., 2006; Ohaegbulam *et al*., 2007; Okafor, 2009).

Point of Care Testing (POCT) is the diagnostic testing performed on the patient outside the main Laboratory setting (Bolodeoku *et al*., 2020) with the main goal of reducing the turnaround time to eliminate some steps in the laboratory testing process, such as specimen transport, result distribution, structured specialist sample taking, second-party reading and recording of the result (Plebani, 2009). A survey recently conducted by Bolodeoku *et al*. (2017) showed that Laboratory turn-around times in critical care departments average between 5.12 – 8.33 hours. Interestingly, 20% - 47% of the clinicians received their results less than 2 hours after a request for acute situations and it was concluded that laboratory turnaround times in the critical situation in Nigeria could be improved with the use of point-of-care testing devices (Bolodeoku *et al*., 2020).

Point-of-care tests performed outside the main Laboratory include blood glucose tests, blood cholesterol tests, triglyceride tests, low and high-density lipoprotein tests, and chlamydia tests, amongst others (Adje *et al*., 2016).

During the 1970s, the Point of Care Glucose Monitoring Device (POCGMD) was originally designed for home self-monitoring of blood glucose (SMBG) for diabetes patients to improve glucose control during regular life activities (Rebel *et al*., 2012). However, the ease of use of a POCGMD and its rapid reporting of blood glucose information led to its utilization in the inpatient setting, recognizing that POCGMDs might have certain limitations with this application (Rebel *et al*., 2012). Depending on the specific glucose measurement technique of a POCGMD, the measurements can be influenced by various circumstances. This study thus evaluated the analytical performance of POCGMDs at Aminu Kano Teaching Hospital, Kano, a tertiary institution with multiple usages of POCGMDs in Nigeria.

**Materials and Methods**

**Study Design**

A cross-sectional study was carried out on participants at specialist clinics, male and female medical wards where POCGMDs are frequently used whilst laboratory analysis of venous plasma glucose using reference (Hexokinase) method was carried out at the Central Laboratory of Aminu Kano Teaching Hospital Kano, Nigeria.

**Ethical Approval**

Ethical approval was also obtained from the Research Ethics Committee of Aminu Kano Teaching Hospital with the reference numbers NHREC/21/08/2008/AKTH/EC/2559 and AKTH/MAC/SUB/12A/P-3/VI/2659. Also, participants were enrolled in the study after they gave informed consent

**Sampling Technique**

A structured questionnaire was administered to the various POCGMD users in the Hospital to obtain information about the usage. Consented participants were recruited at accident and emergency, general outpatient Departments, specialty clinics, female and male medical wards.

**Blood Sample Collection and Analysis**

All consent participants' hands were washed with warm soapy water and then dried thoroughly prior to sample collection. Alcohol was used to wipe clean the puncture area. A sterile lancet or hypodermic needle and syringe were to collect whole blood from the consented participants following the ISO 15187: 2003 standard protocols for blood sample collection.

**Analytical Procedure**

**Quantitative Estimation of Glucose Concentrations**

The measurement techniques use glucose oxidase (GOX) as a catalyst for the oxidation of glucose to gluconic acid and hydrogen peroxide by POCGMDs and Hexokinase by Reference method described by Bergel *et al*. (1989). The glucose test strip was removed from the vial and inserted into the port of the POCGMDs with the arrow facing up into the test port of the POCGMDs firmly. About 10 to 20µL of whole blood was spotted on the top edge of the strip until an I-shape outline popped up. The POCGMDs automatically displayed the result within 5 to 9 seconds for Accu-Chek and Fine Test respectively.

**Quality Control**

**Precision assessment**

All measurements were taken following the ISO 15197 (2013) guideline. The quality control of the evaluated POCGMDs and strip storage followed the recommendations of the manufacturer.

**Repeatability precision**

Measurement of repeatability (Within-Run) was used to evaluate the closeness of agreement between a series of measurements with a POCGMD on a blood

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sample over a short period of time. The $HBA_1$ C blood sample with defined glucose concentrations in the range of low, intermediate, and high glucose (i.e. levels 1, 2, and 3 respectively) was used. Following the protocol described for POCGMDs, the measurements from each meter were determined in duplicate of the high, normal, and low glucose concentrations on the same day and the results were documented in ISO 15197 (2013).

**Reproducibility Precision**

For reproducibility evaluation (Run-to-Run). Three Randox® control sera levels 1, 2, and 3 were assayed as documented in ISO 15197 (2013) guideline.

**System accuracy**

According to ISO 15197 (2013), the evaluation of SMBG system accuracy was performed with at least 100 capillary/venous blood samples from different subjects. The glucose levels in the samples were distributed into defined glucose concentration intervals between ≤50 mg/dl and >400 mg/dl (Table 1). The samples from each target range were divided into two, one was analyzed using each glucometer and the second was sent to the laboratory for analysis with the reference method.

**Table 1: Glucose Concentration Distribution in the Venous Blood**

| S/NO. | Number of samples n=100 | Glucose Concentrations mg/dL |
|---|---|---|
| 1 | 5% | ≤50 |
| 2 | 15% | >50-80 |
| 3 | 20% | >80-120 |
| 4 | 30% | >120-200 |
| 5 | 15% | >200-300 |
| 6 | 10% | >300-400 |
| 7 | 5% | >400 |

**Data Analysis**

The precision was determined by calculating the Mean, Standard deviation, and Coefficients of Variation (CV). The CV was computed as the standard deviation divided by the mean and expressed as a percentage. A CV of less than 5% was considered as being precise. P-value < 0.05 was considered significant.

**Results**

**Repeatability Precision (within day):**

For Accu-Chek CV% of 1.85% at 79 mg/dL, 1.92% at 110 mg/dL and 3.17% at 324 mg/dL, while for Fine test was CV of 5.17% at 85 mg/dL, 2.76% at 115 mg/dL and 1.39% at 385 mg/dL both for level 1,2,3 respectively. A CV of less than 5% was considered as being precise, the lower the imprecision, the better of the device.

**Reproducibility Precision (day-to-day)**

For Accu-chek CV% of 12.2% at 14 mg/dL,17.5% at 67mg/dL and 2.39% at 106 mg/dL. While that of Fine Test was CV% of 7.38% at 29 mg/dL, 2.91% at 83 mg/dL and CV% of 1.84% at 184 mg/dL for both level 1,2, and 3 respectively. A CV of less than 5% was considered as being precise, the lower the imprecision, the better the reproducibility of the device.

**Table 2: Repeatability Precision (within day)**

| POCGMDs | Parameters | Repeatability | | |
|---|---|---|---|---|
| | | Level 1 | Level 2 | Level 3 |
| Accu Chek Active | Mean (mg/dL) | 79 | 110 | 324 |
| | SD | 1.5 | 2.1 | 10.3 |
| | CV (%) | 1.85 | 1.92 | 3.17 |
| Fine Test Auto-Coding | Mean (mg/dL) | 85 | 115 | 385 |
| | SD | 4.3 | 3.1 | 5.4 |
| | CV (%) | 5.17 | 2.76 | 1.39 |

**SD = Standard deviation, CV = Coefficient of variation**

**System Accuracy**

From all the POCGMDs and the reference hexokinase tested, the minimum glucose concentration measurements were observed by Fine test auto-coding (16.2 mg/dL), followed by Accu-Chek active (23.4 mg/dL) then reference method (25.2 mg/dL) while the

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maximum measurements were observed by Fine test auto-coding (865.8 mg/dL), followed by reference hexokinase (603.0 mg/dL) then Accu-chek active (455.4 mg/dL) respectively. The fine test auto-coding device had high mean glucose values of 201.0 mg/dL (that is >175.7 mg/dL which was the mean value of the reference method) showing that glucose value increased statistically at $P < 0.005$. All calculated Pearson correlation coefficients for the two POCGMDs were greater or equal to 0.8 (≥ 80%), which indicated that the POCGMDs showed a strong positive relationship with the reference to the hexokinase method for glucose measurement (Table 3).

**Table 3: Glucose Measurements in POCGMDs and the Reference Method**

| Glucose Measuring Device | N | Mean | Min | Max | Reference | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Mean difference (bias) | 95% CI | *P-value* | Correlation coefficient |
| Reference Method | 100 | 175.7 | 25.2 | 603.0 | - | | | |
| Accu-Check (Active) | 100 | 170.3 | 23.4 | 455.4 | - 5.41 | (-14.39, 2.91) | 0.235 | .935 |
| Fine Test (Auto-Coding) | 100 | 210.0 | 16.2 | 865.8 | 28.8 | (16.03, 52.46) | 0.00 | 0.790 |

**CI = confidence interval, n = sample size, min = minimum, max = maximum**

The accuracy assessment of the POCGMDs was assessed according to ISO 15197 standards and none has a measurement of ≥ 95% (±20, ±15, ±10, and ±5 mg/dl) compared to the reference results (<75 and <100 mg/dl).

**Table 4: Accuracy of POCGMDs for Glucose Measurement**

| Within accuracy limit (±15mg/dl and ±20%) | | BG (<75mg/dl) | | | BG (≥75mg/dl) | | | |
|---|---|---|---|---|---|---|---|---|
| N | % | ±5 | ±10 | ±15 | ±5 | ±10 | ±15 | ±20 |
| 6/400 | 1.5 | 1.5 | 1.5 | 1.5 | 98.5 | 98.5 | 98.5 | 98.5 |
| | | BG (<100mg/dl) | | | BG (≥100mg/dl) | | | |
| 8/400 | 2.0 | 2.0 | 2.0 | 2.0 | 98.0 | 98.0 | 98.0 | 98.0 |

**n=sample size, BG=Blood glucose**

**Bland Altman Analysis Plot**

The Bland Altman analysis showed that the two POCGMDs measured are more low-level and high-level range results compared to the reference method (Figure 1). However, the Fine test auto-coding POCGMD results at a lower level are lower than the reference (Figure 2).

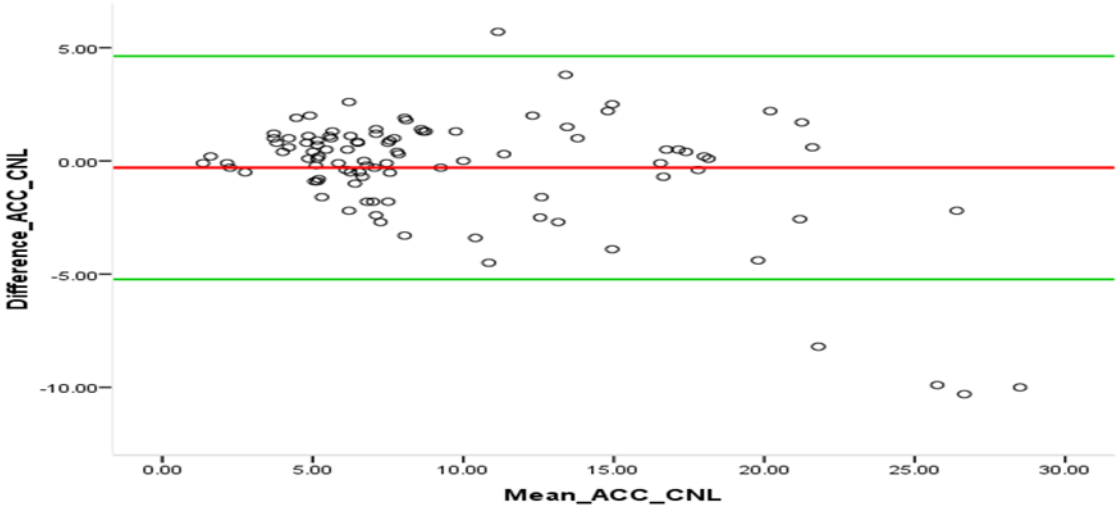


**Figure 1: Bland–Altman Plots comparing Accu-Chek and Reference Method glucose measurement**

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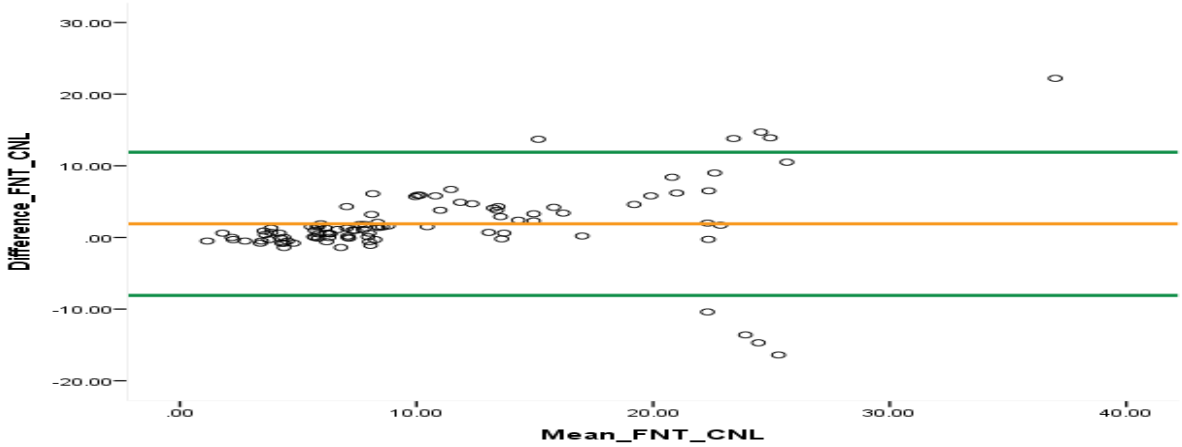


**Figure 2: Bland–Altman Plots comparing Fine-Test Auto Coding and Reference Method glucose measurement**

**Relationship between the POCGMDs and Reference Method**

The linear regression analysis showed positive intercepts of 0.75Xmg/dl and 1.25Xmg/dl for Accu-Chek and Fine-Test auto coding respectively with the reference method (figures 3 and 4).

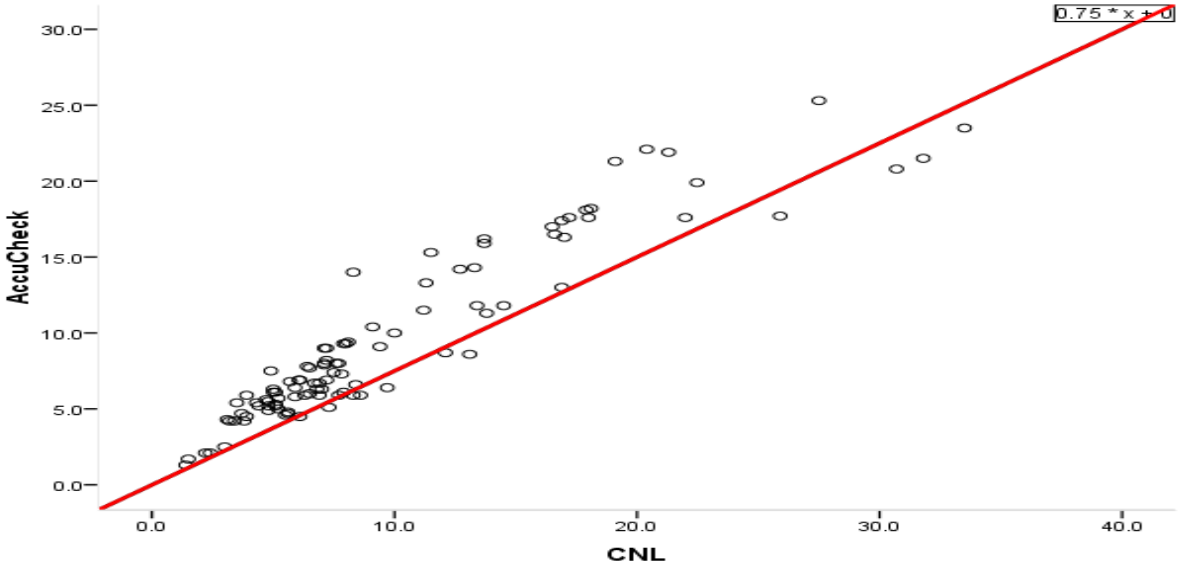


**Figure 3: Relationship between Accu-Check and Reference Method**

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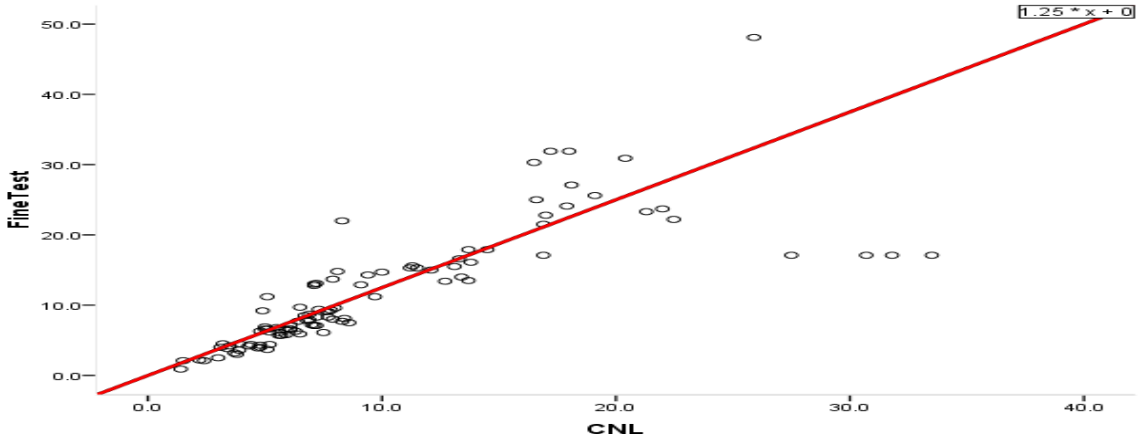


**Figure 4: Relationship between Fine Test Auto-coding and reference Method**

**Clarke Error Grid Analyses of POCGMDs**

This is an internationally recognized way of evaluating the compatibility of POCGMD with a laboratory reference method. This analysis partitions the blood glucose measurement ranges into zones, based on diabetic management.

**Table 5: Clarke Error Grid Analysis of POCGMDs**

| POCGMDs | Consensus Error Grid | | | | |
|---|---|---|---|---|---|
| | Zone A | Zone B | Zone C | Zone D | Zone E |
| Accu-chek active | 53/100(53%) | 34/100(34%) | 6/100(6%) | 7/100(7%) | 0/100(0%) |
| Fine-test auto-coding | 78/100(78%) | 15/100(15%) | 5/100(5%) | 2/100(2%) | 0/100(0%) |

**Zone A: Results to clinically correct treatment decisions either in hypoglycemia or hyperglycemia range, Zone B: >20% deviation from the reference; represents values that would lead to benign or no treatment error, Zone C: Represents values would lead to treatment decisions opposite to that called for by the blood glucose levels. Zone D: Represent a failure to detect and treat errors, Zone E: Is a clinically more serious error zone, POCGMDs generated values that failed to detect hypoglycemia or hyperglycemia. Values are opposite to the reference values resulting in corresponding treatment decisions opposite to those needed. All the POCGMDs readings were in Zone A, B or C and Zone D none in E. Though, there are higher reading in zone B, C and, D as compared to Fine test auto-coding in the same zones**.

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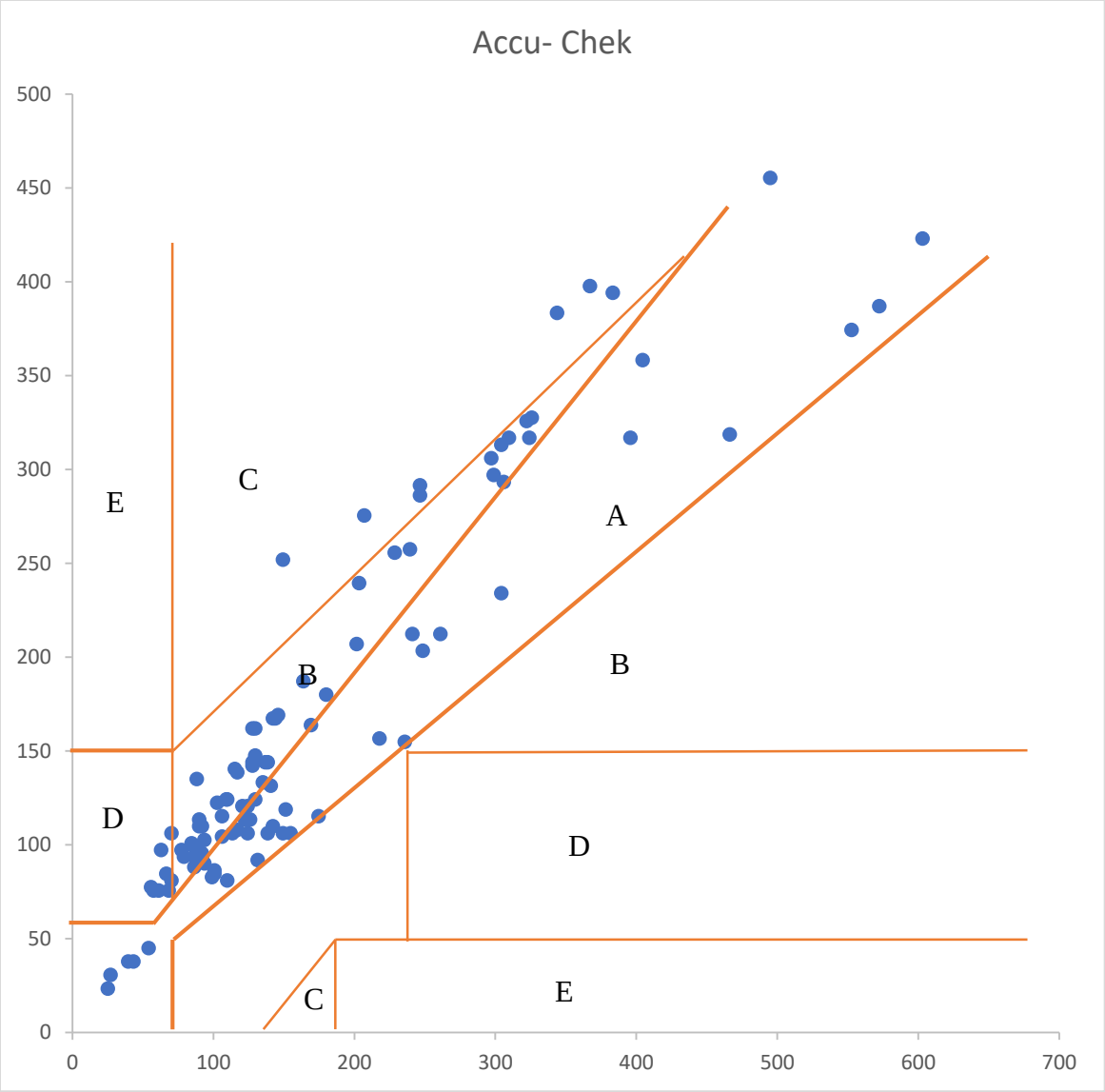


**Figure 5: Clarke Error Grid for Accu-Chek POCGMD**

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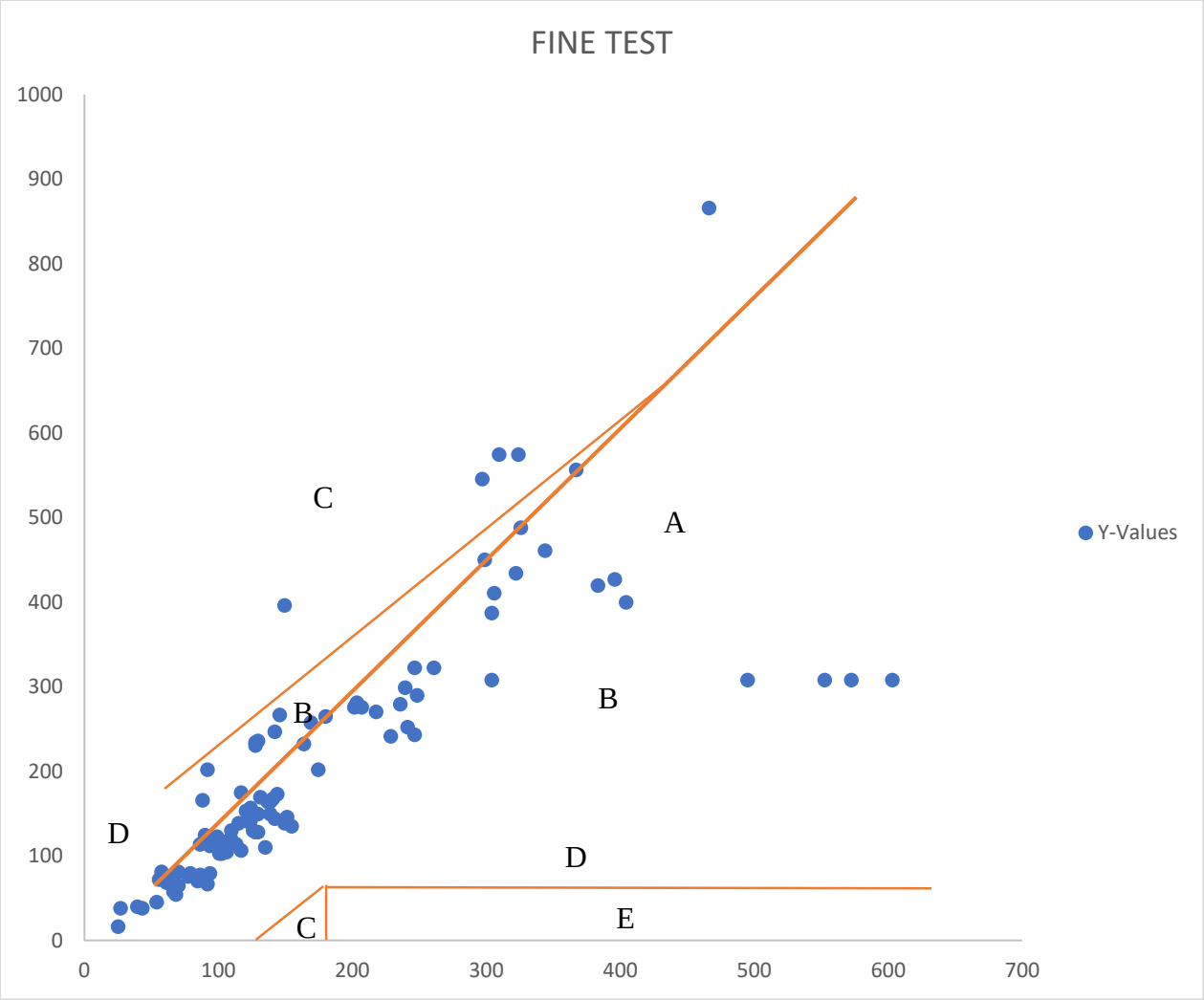


**Figure 6: Clarke Error Grid for Fine Test Auto-coding POCGMD**

**Discussion**

In Nigeria, where Medical Laboratory services encounter frequent challenges due to shortage of skilled manpower, electricity, and other hurdles, monitoring the control of blood glucose in an acceptable range remains a target for diabetes patients in both the hospital and outpatient environments. Glycemic control using an insulin infusion in critically ill patients requires frequent blood glucose monitoring with accurate POCGMDs available for bedside glucose measurement that forms the basis of the treatment decision aiming at glycemic control (Rebel *et al*., 2012).

The precision of POCGMDs evaluated in this study was expressed as the mean value, standard deviation, and percentage coefficient of variation (CV). CV <5% was considered as being precise according to ISO 15187: 2003 and 2013 criteria. The CV observed at level 1 repeatability was > 5% for Fine test auto-coding providing an acceptable repeatability precision at intermediate and high concentrations but failing at low concentrations. For the reproducibility precision (day to day) the CV of the Accu-Chek active at levels 1, 2, and 3 indicated poor reproducibility at low and intermediate levels with the exception of high concentration which is in agreement with Simeon-Pierre *et al.* (2019), whereas Fine test auto-coding reproducibility precision at three levels also displayed poor precision for the device, especially at low concentration of the standard. The precision of the two devices shows that Accu-Chek active demonstrate good repeatability while reproducible only at high concentration, while Fine care auto-coding exhibit poor precision for both repeatability and reproducibility at a low concentration which means the device cannot be relied on at normo or hypoglycemic state or overestimate the glucose hypoglycaemia. Our finding agrees with Simeon-Pierre *et al.* (2019) who

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blindly evaluated four glucometers to prevent any potential bias created by commercial pressure. Just to find that only two out of four devices' performance had an acceptable accuracy according to ISO standards and none achieved the ADA (1996) recommendations for self-blood glucose monitoring accuracy. All four POCGMDs showed less reliability with lower glucose values compared to normal or higher values. The high glucose values recorded by the POCGMDs were further strengthened in the linear regression analysis, where POCGMDs results clearly demonstrated an overestimation of the glucose concentrations which is in conflict with the study carried out in Ethiopia by Molla *et al.* (2014) where POCGMDs glucose values are less than those of the standard clinical chemistry reference method reported Essack *et al.* (2009).

This observed difference might be due to the type of POCGMDs assessed and the standard reference clinical method used in their studies (such as glucose oxidase by Humastar 80 machine), which is different from our reference hexokinase method performed on the Abbott C4000 chemistry analyzer. Also, there could be the effect of some interfering substances capable of increasing glucose measurement and this can cause a common problem of deceptive recording of glucose results. The study of Perwien *et al.* (2000) at a diabetes camp found that children ages 7–14 years made crucial errors in their glucose monitoring technique resulting from failure to wash their hands before measuring their glucose, leaving interfering substances (usually traces of food) on their fingers that often led to falsely high results, often by > 30%.

The POCGMDs assessed in our study overestimated the blood glucose concentration. Hence, the clinical implication of using any of these glucometers in the screening and diagnosis of diabetes is that they correctly identify patients with diabetes, but misdiagnose individuals with borderline normal or impaired fasting glucose as having impaired fasting glucose or diabetes, respectively which is in line with ISO 15197 (2003) guidelines that POCGMDs are nonetheless used for screening and diagnosis of diabetes.

Pearson correlation coefficients for the two POCGMDs showed ≥ 0.80 which is an indication of a strong positive relationship with the reference hexokinase method. On the other hand, none of the two POCGMDs fulfill the minimum accuracy of ISO 15197: 2003 and ISO 15197:2013 for glucose measurements which are ≥75 mg/dL and ≥100mg/dL respectively. Our findings is consistent with the findings of other studies (Freckmann, *et al*., 2012; Molla *et al*., 2014; Larsson *et al*., 2015) where the tested POCGMDs did not fulfill the ISO 15197 standards.

One specific concern with POCGMDs is errors in the hypoglycemic range and the potential impact on clinical decision-making which when errors occur in the lower glucose ranges, can results into reporting a higher than actual blood glucose value leading to a misdiagnosing of euglycemia for hypoglycemia and consequentially placing the patient at risk for neurological sequelae. Also, inaccurate glucose values in the hypoglycemic range might create a loss of confidence in POCGMDs users including diabetes patients, Physicians, Medical Laboratory professionals.

**Conclusion**

This study demonstrated that both Accu-Check and Fine Test auto coding commonly use POCGMDs in Nigeria did not fulfill the ISO 15197: 2003 and ISO 15197: 2013 minimum accuracy requirements for glucose measurement. Thus, this study suggested that Health institutions should evaluate POCGMDs with ISO standards and ADA requirements for self-blood glucose monitoring prior to their use. Also, regulatory authorities should ensure that POCGMDs satisfy the ISO and ADA quality requirements before they reach the end users.

**Recommendations**

Based on the findings from this study, the following recommendations are made;

i. All POCT devices must undergo quality checks routinely and weekly using quality control materials.
ii. Comparison of the analytical performance of POCGMDs with the Laboratory method using venous plasma should be done twice a year.
iii. Further multi-center studies should be carried out to corroborate the findings revealed in this study.

**Conflict of Interest**

None

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