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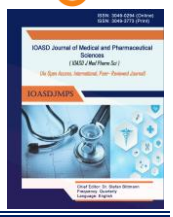

Validation of Precision and Accuracy of Point-of-Care Testing Glucose Analyzers with a Standard Laboratory Method (Glucose Oxidase Method)

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ABSTRACT

Accurate blood glucose measurement is essential for the diagnosis and management of diabetes mellitus. This study evaluated the precision and accuracy of three point-of-care testing (POCT) glucose analyzers—Accu-Chek, Accu-ANSWER, and VivaChek—against the standard laboratory glucose oxidase method. A total of 97 participants were recruited, and venous blood samples were analyzed using both POCT devices and the reference method. Results demonstrated that all three POCT devices consistently overestimated blood glucose levels, exhibiting a systematic positive bias ranging from +18.56 mg/dL to +19.99 mg/dL. Bland–Altman analysis revealed wide limits of agreement and evidence of proportional bias, with inaccuracies increasing at higher glucose concentrations. Only 39.18% of measurements met the ISO 15197:2013 accuracy criteria (±15%), while over 40% deviated by more than 25%. Among the devices, VivaChek showed relatively better precision, whereas Accu-Chek demonstrated the widest variability and lowest agreement with the reference method. Despite their convenience and rapid turnaround time, the findings indicate that these POCT devices have limited reliability for critical clinical decision-making. The study concludes that POCT glucose meters should be used cautiously and primarily for monitoring trends rather than definitive diagnosis or therapeutic decisions.

Keywords: Point-of-care testing, glucose oxidase, accuracy, precision, Bland–Altman analysis, diabetes mellitus.

Original Research Article

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INTRODUCTION

Determination of blood glucose is an essential part of clinical diagnosis, disease monitoring and therapeutic management in patients with diabetes mellitus and other metabolic disorders. Accurate measurement of blood glucose concentration is crucial in the determination of glycaemic state, monitoring of treatment response, detection of hypoglycaemia and hyperglycaemia, and guiding suitable therapeutic interventions [1]. The global incidence of diabetes mellitus is increasing, which has prompted increased demand for glucose testing methods that are accurate, precise, quick, accessible, economical and usable at various healthcare settings. The incidence of diabetes is a growing problem worldwide, according to the International Diabetes Federation, which stresses the need for accurate glucose monitoring at the institutional and community levels and the immense burden on healthcare systems [2].

Blood glucose measurement has traditionally been performed in centralised clinical laboratories using standardised biochemical procedures. Among these, the glucose oxidase-peroxidase (GOD-POD) method has been widely used because to its well-known analytical performance, specificity, reproducibility and precision [3]. In this method, glucose in the biological sample is enzymatically oxidised to produce hydrogen peroxide which combines with a chromogenic material to provide a quantifiable colour intensity proportionate to the glucose concentration. Laboratory approaches are usually performed under controlled settings utilising calibrated equipment and well-established quality-control procedures. Thus, they are frequently used as reference or comparative methods in the evaluation of different glucose measuring technologies [4].

However, the standard laboratory procedure might be linked with significantly long turn-around times and demands qualified individuals, specific equipment,

appropriate infrastructure and access to laboratory facilities. These restrictions may be especially relevant in emergency departments, primary care settings, rural settings, resource-limited settings and in home-based patient care. Therefore, the advent and rising use of point-of-care testing (POCT) devices have revolutionised the approach to glucose monitoring by facilitating instantaneous blood glucose assessment at or near the site of patient care [5].

POCT glucose meters are usually portable, relatively inexpensive, easy to use, and can generate readings in a few seconds or minutes. These properties have made them useful in emergency rooms, outpatient clinics, hospital wards, diabetic clinics, pharmacies, community health programs and home based diabetes treatment. The availability of data in the same setting could allow timely clinical action and can increase the efficiency of healthcare delivery by minimising the time between sample collection, analysis and clinical decision making [6]. Furthermore, portable glucometers can be used for self-monitoring of blood glucose in people with diabetes and may improve adherence to suggested therapy and lifestyle adjustments.

However, the analytical reliability of POCT glucose meters remains a topic of substantial clinical interest despite these important advantages. Several investigations found differences between the glucose readings acquired with the handheld glucometers and the glucose values achieved with the usual laboratory procedures [7]. These variances may be attributable to differences in instrument design, calibration processes, analytical technology, reagent or test-strip characteristics, and the reference technique utilised. The performance of POCT can also be affected by pre-analytical and environmental variables. For instance, the stability and performance of reagent strips may be affected by temperature and humidity, and improper storage or extended exposure to poor environmental conditions can further reduce analytical accuracy.

Variability of POCT glucose values could potentially be due to patient-specific factors. The importance of haematocrit measurement cannot be overemphasised as changes in the volume of red cells can interfere with the electrochemical or enzymatic reaction used by some glucose meters. Very high or low haematocrit readings may cause spuriously high or low glucose results. Other possible reasons of inaccuracy are poor peripheral circulation, aberrant oxygenation, interfering chemicals, inadequate hand washing, contamination of the sampling site, insufficient blood volume, and inappropriate application of blood to the test strip [8]. Therefore, operator training and adherence to the manufacturer's instructions are vital for attaining dependable results.

Inaccurate glucose measurement can have serious clinical repercussions. Falsely high glucose results can lead to incorrect treatment with insulin or other glucose lowering therapy which can increase the risk of hypoglycaemia. Alternatively, an erroneously low result may lead to needless supply of carbohydrates or failure to give adequate treatment for hyperglycaemia. Misclassification of individuals as normoglycaemic, prediabetic or diabetic can also occur due to measurement mistakes, especially when glucose readings are near recognised diagnostic limits. Such errors affect not only the management of individual patients but also the quality and safety of healthcare delivery [9].

The analytical performance of POCT glucose meters is of increasing importance with the growing use of these meters in clinical and non-clinical practice. Manufacturers publish performance requirements for their equipment, but real-world situations can vary significantly from controlled validation environments. Comparison to accepted laboratory procedures might thus provide useful data as to the extent to which individual glucometers generate readings that are sufficiently accurate and precise for clinical use [10].

The aim of the present study is therefore to evaluate the analytical performance of selected POCT glucose meters, Accu-Chek, Accu-ANSWER and VivaChek compared to the glucose oxidase reference technique. Special care is taken on accuracy, precision, systematic bias and agreement between the POCT devices and the laboratory reference method. The study intends to establish the degree of agreement and potential discrepant results amongst the devices assessed to give evidence that would aid healthcare professionals in the selection and appropriate use of POCT glucose meters. The findings may also lead to better quality assurance, safer clinical decisions and better patient care, especially in situations where point-of-care glucose testing is a key part of everyday clinical practice.

MATERIALS AND METHODS

Study Area

The was conducted at Enugu state university Teaching Hospital, Parklane, Enugu.

Study Design

The study is a cross-sectional study.

Study Population

Sample size determination

The primary endpoint is the proportion of POCT readings that meet the predefined accuracy criterion relative to the reference method. Sample size per device was calculated using Fisher's formula for a single proportion

$$n = (Z^2 \times p \times (1 - p)) / d^2$$

Assuming an expected pass-rate p = 0.90, 95% confidence (Z = 1.96), and precision d = 0.06, the minimum sample size per meter is:
$n = (1.96^2 \times 0.90 \times 0.10) / (0.06^2)$
$n = (3.8416 \times 0.09) / 0.0036$
$n = 0.345744 / 0.0036$
$n = 96.0 \approx 97$ per meter.

Because each participant will be tested on all three POCT meters, approximately 97 participants will yield ≥97 paired observations per meter (≈291 total paired comparisons). To accommodate potential data loss, we recruited 100 participants.

SUBJECT SELECTION CRITERIA

This was done by Inclusion and Exclusion Criteria.

INCLUSION CRITERIA

- Subjects were legal adults (≥18 years).
- Subjects were individuals who consent to participate.

EXCLUSION CRITERIA

- Subjects with hemolyzed or lipemic blood samples.
- Subjects unwilling to participate.
-

Ethical Approval

Ethical approval for this study was obtained from Enugu State University Teaching Hospital Ethics Committee. All participants provided written informed consent prior to sample collection.

Sample Collection

Samples were collected aseptically through Venipuncture at the antecubital vein of each subject.

Sample Analytical Procedures

Laboratory Glucose Oxidase Method

Principle

The glucose oxidase-peroxidase (GOD-POD) method oxidizes glucose to gluconic acid and H2O2 via glucose oxidase. Peroxidase decomposes H_2O_2, oxidizing a chromogen to a colored product measured spectrophotometrically

Procedures

Collect blood in fluoride tube, centrifuge for plasma. Mix 10µL plasma with 1 mL reagent, incubate at 37°C for 10-15 min, measure absorbance at 505 nm against standard

Validity

Linear 10-500 mg/dL, CV <5%, minimal interferences

Working Principles and Procedures of POCT Glucose Devices

Accu-Chek:

Principle

Uses glucose dehydrogenase biosensor; blood drop on strip generates current proportional to glucose

Procedure

Insert strip, apply 1 drop of lithium heparin anticoagulated blood and read the result in 5 seconds.

Accu-ANSWER

Principle

Glucose oxidase reacts with blood, producing current which is equivalent to the level of glucose in the blood

Procedure

Insert strip, apply 1 drop of lithium heparin anticoagulated blood and read the result after countdown

VivaChek

principle

Electrochemical with hematocrit correction; enzyme oxidizes glucose

Procedure

Insert strip, apply one drop of lithium heparin anticoagulated blood on the edge of the strip and wait for the blood to flow into the strip. Read the result after countdown.

Statistical Analysis

Data will be analyzed using Python (version 3.13) within Jupyter Notebook. Descriptive statistics (mean and standard deviation) will be computed using the pandas and numpy libraries. Agreement between the POCT devices and the reference laboratory method will be assessed using Bland–Altman analysis, which evaluates the bias (mean difference) and the 95% limits of agreement between paired measurements.

RESULTS

Comparative Data Analysis

Table 1 displays the individual glucose readings (mg/dL) for each method across 97 samples, including the calculated means and standard deviations (S.D.) for each device.

S/N	GLUCOSE OXIDASE	ACCU CHECK	MEAN OF ACCU	S.D OF ACCU	ACCU ANSWER	MEAN OF ANSWER	S.D OF ANSWER	VIVA CHECK	MEAN OF VIVA	S.D OF VIVA
1	230.00	298.00	264.00	48.08	262.00	246.00	22.63	253.00	241.50	16.26
2	69.00	88.00	78.50	13.44	89.00	79.00	14.14	77.00	73.00	5.66
3	73.00	95.00	84.00	15.56	89.00	81.00	11.31	81.00	77.00	5.66
4	63.00	81.00	72.00	12.73	73.00	68.00	7.07	77.00	70.00	9.90

S/N	GLUCOSE OXIDASE	ACCU CHECK	MEAN OF ACCU	S.D OF ACCU	ACCU ANSWER	MEAN OF ANSWER	S.D OF ANSWER	VIVA CHECK	MEAN OF VIVA	S.D OF VIVA
5	81.00	96.00	88.50	10.61	105.00	93.00	16.97	104.00	92.50	16.26
6	74.00	83.00	78.50	6.36	83.00	78.50	6.36	83.00	78.50	6.36
7	49.00	54.00	51.50	3.54	58.00	53.50	6.36	59.00	54.00	7.07
8	70.00	83.00	76.50	9.19	80.00	75.00	7.07	90.00	80.00	14.14
9	101.00	130.00	115.50	20.51	112.00	106.50	7.78	112.00	106.50	7.78
10	283.00	328.00	305.50	31.82	312.00	297.50	20.51	336.00	309.50	37.48
11	66.00	74.00	70.00	5.66	86.00	76.00	14.14	75.00	70.50	6.36
12	92.00	119.00	105.50	19.09	110.00	101.00	12.73	119.00	105.50	19.09
13	69.00	78.00	73.50	6.36	82.00	75.50	9.19	79.00	74.00	7.07
14	76.00	86.00	81.00	7.07	85.00	80.50	6.36	99.00	87.50	16.26
15	54.00	70.00	62.00	11.31	69.00	61.50	10.61	69.00	61.50	10.61
16	101.00	131.00	116.00	21.21	111.00	106.00	7.07	131.00	116.00	21.21
17	70.00	90.00	80.00	14.14	81.00	75.50	7.78	88.00	79.00	12.73
18	71.00	90.00	80.50	13.44	92.00	81.50	14.85	78.00	74.50	4.95
19	74.00	95.00	84.50	14.85	90.00	82.00	11.31	96.00	85.00	15.56
20	76.00	98.00	87.00	15.56	88.00	82.00	8.49	92.00	84.00	11.31
21	85.00	103.00	94.00	12.73	109.00	97.00	16.97	109.00	97.00	16.97
22	62.00	71.00	66.50	6.36	71.00	66.50	6.36	80.00	71.00	12.73
23	95.00	123.00	109.00	19.80	111.00	103.00	11.31	122.00	108.50	19.09
24	140.00	162.00	151.00	15.56	181.00	160.50	28.99	155.00	147.50	10.61
25	78.00	89.00	83.50	7.78	101.00	89.50	16.26	98.00	88.00	14.14
26	55.00	62.00	58.50	4.95	71.00	63.00	11.31	71.00	63.00	11.31
27	110.00	123.00	116.50	9.19	126.00	118.00	11.31	126.00	118.00	11.31
28	68.00	87.00	77.50	13.44	87.00	77.50	13.44	79.00	73.50	7.78
29	72.00	80.00	76.00	5.66	82.00	77.00	7.07	93.00	82.50	14.85
30	210.00	232.00	221.00	15.56	232.00	221.00	15.56	262.00	236.00	36.77
31	83.00	107.00	95.00	16.97	94.00	88.50	7.78	93.00	88.00	7.07
32	65.00	84.00	74.50	13.44	82.00	73.50	12.02	72.00	68.50	4.95
33	98.00	126.00	112.00	19.80	117.00	107.50	13.44	110.00	104.00	8.49
34	74.00	84.00	79.00	7.07	96.00	85.00	15.56	96.00	85.00	15.56
35	59.00	71.00	65.00	8.49	65.00	62.00	4.24	77.00	68.00	12.73
36	125.00	160.00	142.50	24.75	154.00	139.50	20.51	142.00	133.50	12.02
37	80.00	90.00	85.00	7.07	89.00	84.50	6.36	103.00	91.50	16.26
38	71.00	92.00	81.50	14.85	78.00	74.50	4.95	92.00	81.50	14.85
39	90.00	116.00	103.00	18.38	103.00	96.50	9.19	116.00	103.00	18.38
40	305.00	394.00	349.50	62.93	366.00	335.50	43.13	386.00	345.50	57.28
41	64.00	79.00	71.50	10.61	73.00	68.50	6.36	82.00	73.00	12.73
42	77.00	85.00	81.00	5.66	92.00	84.50	10.61	88.00	82.50	7.78
43	102.00	114.00	108.00	8.49	130.00	116.00	19.80	120.00	111.00	12.73
44	52.00	67.00	59.50	10.61	58.00	55.00	4.24	60.00	56.00	5.66
45	88.00	98.00	93.00	7.07	100.00	94.00	8.49	97.00	92.50	6.36
46	73.00	82.00	77.50	6.36	94.00	83.50	14.85	94.00	83.50	14.85
47	69.00	89.00	79.00	14.14	89.00	79.00	14.14	79.00	74.00	7.07
48	115.00	146.00	130.50	21.92	128.00	121.50	9.19	137.00	126.00	15.56
49	81.00	99.00	90.00	12.73	105.00	93.00	16.97	95.00	88.00	9.90
50	75.00	83.00	79.00	5.66	96.00	85.50	14.85	96.00	85.50	14.85
51	58.00	69.00	63.50	7.78	72.00	65.00	9.90	75.00	66.50	12.02
52	92.00	116.00	104.00	16.97	105.00	98.50	9.19	118.00	105.00	18.38
53	155.00	201.00	178.00	32.53	199.00	177.00	31.11	199.00	177.00	31.11
54	70.00	90.00	80.00	14.14	87.00	78.50	12.02	90.00	80.00	14.14
55	66.00	74.00	70.00	5.66	85.00	75.50	13.44	75.00	70.50	6.36
56	105.00	135.00	120.00	21.21	120.00	112.50	10.61	122.00	113.50	12.02
57	79.00	96.00	87.50	12.02	90.00	84.50	7.78	99.00	89.00	14.14
58	84.00	98.00	91.00	9.90	96.00	90.00	8.49	98.00	91.00	9.90
59	51.00	63.00	57.00	8.49	69.00	60.00	12.73	66.00	58.50	10.61
60	250.00	305.00	277.50	38.89	286.00	268.00	25.46	285.00	267.50	24.75
61	96.00	110.00	103.00	9.90	124.00	110.00	19.80	119.00	107.50	16.26
62	72.00	91.00	81.50	13.44	84.00	78.00	8.49	80.00	76.00	5.66
63	68.00	79.00	73.50	7.78	88.00	78.00	14.14	77.00	72.50	6.36
64	112.00	125.00	118.50	9.19	137.00	124.50	17.68	127.00	119.50	10.61
65	86.00	112.00	99.00	18.38	104.00	95.00	12.73	97.00	91.50	7.78
66	61.00	70.00	65.50	6.36	69.00	65.00	5.66	68.00	64.50	4.95
67	76.00	96.00	86.00	14.14	87.00	81.50	7.78	98.00	87.00	15.56
68	94.00	121.00	107.50	19.09	109.00	101.50	10.61	108.00	101.00	9.90

S/N	GLUCOSE OXIDASE	ACCU CHECK	MEAN OF ACCU	S.D OF ACCU	ACCU ANSWER	MEAN OF ANSWER	S.D OF ANSWER	VIVA CHECK	MEAN OF VIVA	S.D OF VIVA
69	130.00	149.00	139.50	13.44	150.00	140.00	14.14	147.00	138.50	12.02
70	67.00	80.00	73.50	9.19	74.00	70.50	4.95	74.00	70.50	4.95
71	82.00	91.00	86.50	6.36	105.00	93.50	16.26	91.00	86.50	6.36
72	56.00	67.00	61.50	7.78	64.00	60.00	5.66	69.00	62.50	9.19
73	100.00	122.00	111.00	15.56	129.00	114.50	20.51	114.00	107.00	9.90
74	78.00	96.00	87.00	12.73	101.00	89.50	16.26	101.00	89.50	16.26
75	71.00	91.00	81.00	14.14	81.00	76.00	7.07	91.00	81.00	14.14
76	275.00	309.00	292.00	24.04	357.00	316.00	57.98	313.00	294.00	26.87
77	63.00	78.00	70.50	10.61	81.00	72.00	12.73	82.00	72.50	13.44
78	89.00	116.00	102.50	19.09	115.00	102.00	18.38	103.00	96.00	9.90
79	108.00	124.00	116.00	11.31	130.00	119.00	15.56	139.00	123.50	21.92
80	54.00	65.00	59.50	7.78	62.00	58.00	5.66	63.00	58.50	6.36
81	74.00	96.00	85.00	15.56	89.00	81.50	10.61	94.00	84.00	14.14
82	97.00	125.00	111.00	19.80	124.00	110.50	19.09	109.00	103.00	8.49
83	65.00	73.00	69.00	5.66	75.00	70.00	7.07	74.00	69.50	6.36
84	120.00	155.00	137.50	24.75	146.00	133.00	18.38	152.00	136.00	22.63
85	83.00	95.00	89.00	8.49	93.00	88.00	7.07	107.00	95.00	16.97
86	70.00	77.00	73.50	4.95	77.00	73.50	4.95	80.00	75.00	7.07
87	57.00	74.00	65.50	12.02	73.00	65.00	11.31	64.00	60.50	4.95
88	91.00	106.00	98.50	10.61	118.00	104.50	19.09	104.00	97.50	9.19
89	180.00	227.00	203.50	33.23	231.00	205.50	36.06	230.00	205.00	35.36
90	79.00	101.00	90.00	15.56	90.00	84.50	7.78	89.00	84.00	7.07
91	64.00	73.00	68.50	6.36	83.00	73.50	13.44	71.00	67.50	4.95
92	104.00	124.00	114.00	14.14	130.00	117.00	18.38	126.00	115.00	15.56
93	75.00	97.00	86.00	15.56	97.00	86.00	15.56	88.00	81.50	9.19
94	68.00	87.00	77.50	13.44	76.00	72.00	5.66	81.00	74.50	9.19
95	118.00	153.00	135.50	24.75	135.00	126.50	12.02	134.00	126.00	11.31
96	87.00	105.00	96.00	12.73	109.00	98.00	15.56	112.00	99.50	17.68
97	53.00	63.00	58.00	7.07	68.00	60.50	10.61	65.00	59.00	8.49

Bland-Altman Method Comparison

The agreement between the point-of-care devices and the reference standard was evaluated using Bland-Altman plots to identify systematic bias and limits of agreement.

Accu-Chek vs. Glucose Oxidase

The analysis reveals a positive bias of 19.99 mg/dL, indicating that the Accu-Chek method consistently provides higher glucose readings than the reference.

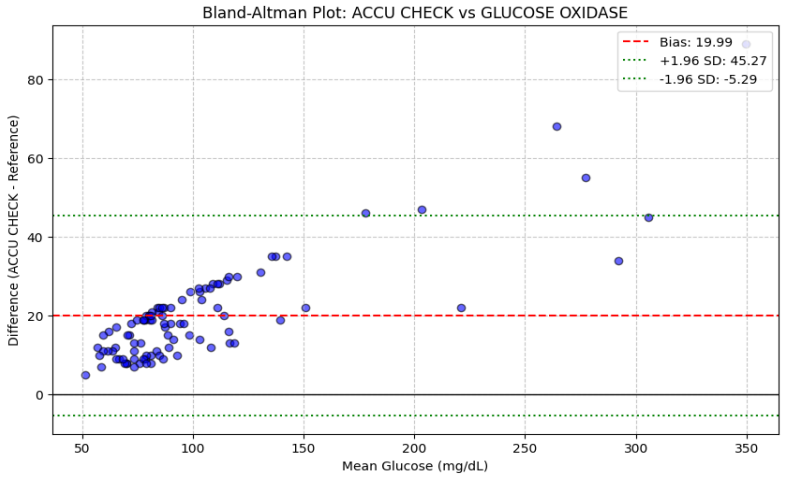

Figure 1: Bland-Altman plot comparing Accu-Chek and Glucose Oxidase reference method (n=97). The solid horizontal line represents the mean bias (19.99 mg/dL), while the dashed lines represent the 95% limits of agreement (-5.29 to 45.27 mg/dL).

Accu-ANSWER vs. Glucose Oxidase

The Accu-ANSWER device demonstrates a significant positive bias of 18.71 mg/dL, consistently overestimating glucose levels compared to the standard.

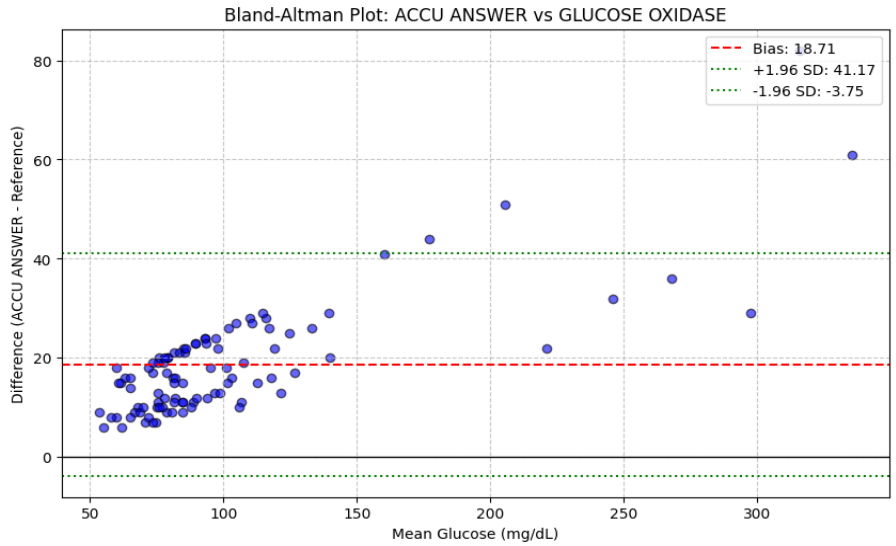

Figure 2: Bland-Altman plot comparing Accu-ANSWER and Glucose Oxidase reference method (n=97). The mean bias is indicated at 18.71 mg/dL with 95% limits of agreement ranging from -3.75 to 41.17 mg/dL.

VivaChek vs. Glucose Oxidase

The VivaChek device demonstrates a systematic positive bias of 18.56 mg/dL. The wide limits signify notable variability in individual measurements.

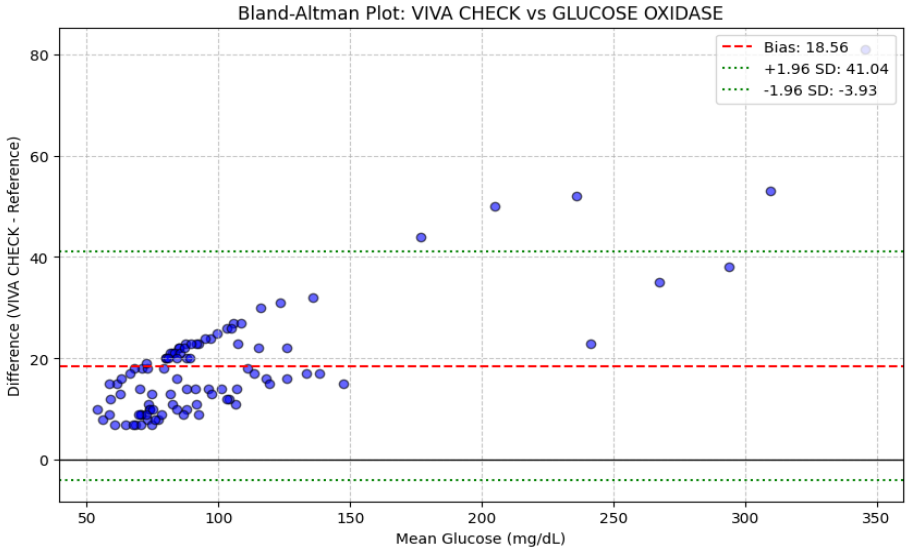

Figure 3: Bland-Altman plot comparing VivaChek and Glucose Oxidase reference method (n=97). The plot illustrates a mean bias of 18.56 mg/dL and 95% limits of agreement of -3.93 to 41.04 mg/dL.

DISCUSSION

The diagnostic performance and agreement of three point-of-care testing (POCT) glucometers, Accu-Chek, Accu-ANSWER and VivaChek, against a laboratory reference glucose oxidase method were evaluated. Results showed a consistent positive bias for all 3 devices with mean differences of +18.56 mg/dL to +19.99 mg/dL vs the reference technique. Therefore, the glucometers gave somewhat higher blood glucose results on average than the laboratory reference method. POCT glucometers have several important advantages, such as speed, portability, convenience and use in locations where conventional laboratory facilities are limited. Nevertheless, analytical accuracy is still important, since glucose measurements are often used to guide diagnosis and therapeutic decisions [11].

The positive bias found in this study is in agreement with earlier publications that show that handheld glucose meters may give results that are different from laboratory measurements. Most current glucose meters are calibrated to give plasma-equivalent glucose readings [12], and changes in calibration techniques, sample matrices, enzymatic methods and instrument technology may contribute to the disparities between POCT and laboratory values. The extent of disparity revealed in this investigation, however, is clinically meaningful. 39.18% of the measurements were

within the globally acceptable accuracy margin of ±15% and >40% of the measurements differed by >25% of the reference method. The significant percentage of measurements outside the permitted range raises concerns regarding the dependability of these devices for clinical decision making.

The results are particularly relevant in light of the precision criteria placed on blood glucose monitoring systems. The performance was found to be much worse than the predicted analytical standards, with just 2.06% of the measurements achieving the more stringent ±10% accuracy criteria. This finding reinforces the concerns raised by [13] that commercially accessible glucometers may not always show appropriate analytical performance, especially when used under normal or real-world situations. The devices may be used by patients and healthcare workers under variable conditions including differences in sample collection, hand hygiene, storage of test strips, environmental temperature, humidity, and operator technique that may differ from controlled laboratory evaluations.

Contrary to the present results, however, [14] found an increased performance with newer Accu-Chek systems. Discrepancies between that study and this one may be attributed to the production of the device, manufacturing lot, test-strip properties, calibration techniques or environmental factors. Test strips are quite sensitive to storage conditions and too much temperature or humidity may change its analytical performance. Environmental factors including temperature and humidity have been documented to have considerable effect on glucometer accuracy and lead to systematic measurement mistakes [15]. These findings underline the need of following strictly the manufacturers' guidelines for storage and handling of the glucometers and corresponding test strips.

The Bland-Altman analysis confirmed extra variability between the POCT devices and the reference technique. The wide limits of agreement observed, particularly for Accu-Chek, which reached as high as +45.27 mg/dL, demonstrate that individual measurements could deviate significantly from the laboratory reference value, even when the average bias appeared to be rather stable. This difference between mean bias and individual agreement is of clinical importance. A gadget could show a seemingly little average difference, yet nevertheless produce clinically significant errors in individual patients. Extreme variations in glucose measurement may have substantial clinical effects, especially when glucose readings are used to estimate insulin dosage or other therapeutic measures, it was stressed. Therefore, the wide limits of agreement in the present investigation suggest a potential risk of misclassification of the glycaemic status of patients [16]. The limits of agreement among the three glucometers tested were considerably narrower for VivaChek, indicating relatively superior precision. This may be attributed to improvements in biosensor technology and interference-correction methods implemented in newer versions of glucose meters [17]. However, the somewhat improved performances of VivaChek should not be regarded as indicative of appropriate clinical accuracy. Approximately 51.55% of the VivaChek readings went beyond the ±20% accuracy limit, suggesting that there were still significant measurement mistakes. Therefore, although VivaChek may have performed better than the other devices tested in terms of agreement and precision, the performance is not sufficient to justify unreserved reliance for essential diagnostic or treatment decisions.

A modest positive bias in glucose meters has sometimes been believed to be potentially useful, as it could lessen the possibility of undetected hypoglycaemia [18]. The amount of the positive bias that we detected in this investigation, however, of around 18 to 20 mg/dL appears to be too great to represent simply a protective safety margin. Chronic overestimation may lead to inaccurate clinical interpretation of glucose status and may contribute to overtreatment, particularly among patients on insulin or other glucose-lowering drugs. Misclassification of an individual as normoglycaemic, prediabetic or diabetic can also occur when measurements are close to diagnostic thresholds.

Haematocrit may be another factor contributing to the observed variability. Changes in the amount of red blood cells can interfere with electrochemical measurements of glucose and can cause either positive or negative variations depending on the technology utilised by a particular glucometer [19]. In the present investigation, haematocrit was neither controlled nor measured and so constitutes a potential confounding factor. Other patient-related factors such as oxygenation state, peripheral perfusion and the presence of interfering drugs may also affect POCT glucose findings. Similarly, operator-related issues, such as inadequate hand cleaning, insufficient blood volume, wrong application of blood to the test strip, or improper storage of the strips, may also cause differences in measurements [20].

The results therefore emphasise the need of quality assurance in the use of POCT glucose meters. To enhance dependability, routine validation of glucometer performance against established laboratory methodologies, adequate staff training, correct storage of test strips, frequent equipment maintenance and compliance with manufacturer instructions are necessary. Confirmation by a validated laboratory method should be sought where a glucose result is discordant with the patient's clinical condition or is likely to impact a key treatment choice. This is particularly important in hospital, emergency care, diabetic clinics and other situations where accurate glucose measurement is critical.

The present findings do show that the three glucometers tested are quick and convenient methods for measuring glucose, however their analytical performance differed widely and showed a constant propensity to overestimate. The findings support the premise that convenience and fast turnaround time should not compensate for analytical accuracy. POCT devices remain useful tools for immediate monitoring of glucose but their results should be evaluated in the light of their analytical limitations and the clinical conditions of the patient.

CONCLUSION

This investigation showed that Accu-Chek, Accu-ANSWER and VivaChek glucometers had a constant positive bias compared with the laboratory glucose oxidase reference method with mean differences of approximately 18-20 mg/dL. Only 39.18% of the measurements met the ±15% accuracy threshold; over 40% of the measurements deviated more than 25% from the reference technique. The relatively low number of data that met the tighter ±10% threshold is another indication of weak analytical agreement.

VivaChek showed the narrowest ranges of agreement and hence the best precision of the other devices, but overall performance was still poor with 51.55% of the readings outside ±20% accuracy range. These data show that none of the glucometers tested could be considered a complete replacement for a validated laboratory glucose assay when accurate measurements are needed.

Accu-Chek, Accu-ANSWER and VivaChek glucometers should be used with caution as POCT devices, particularly when readings are close to diagnostic or therapeutic cut-offs. Useful for fast monitoring of glycaemic trends but should not be used in isolation for final diagnosis or for important treatment choices where laboratory confirmation is possible. Regular quality-control assessment, correct storage and handling of test strips, adequate user training and periodic comparison with laboratory reference methods are indicated to increase the reliability and clinical usefulness of POCT glucose testing.

REFERENCES

1. Bender, C., Vestergaard: and Cichosz, S.L. (2025) 'The History, Evolution and Future of Continuous Glucose Monitoring (CGM)', *Diabetology*, 6(3):17.
2. Freckmann, G., Schmid, C., Baumstark, A., Rutschmann, S., Haug, C. and Heinemann, L. (2012) 'System accuracy evaluation of 43 blood glucose monitoring systems for self-monitoring of blood glucose according to DIN EN ISO 15197', *Journal of Diabetes Science and Technology*, 6(5): 1060–1075
3. Kovatchev, B.P., Gonder-Frederick, L.A., Cox, D.J. and Clarke, W.L. (2015) 'Evaluating the accuracy of continuous glucose monitoring', *Diabetes Care*, 38(6): 1104–1110.
4. Gautier-Stein, A, Mithieux, G. (2023) Intestinal gluconeogenesis: metabolic benefits make sense in the light of evolution. *Nature Reviews Gastroenterology & Hepatology*, 20(3): 183-194.
5. Li, M., Chi, X., Wang, Y., Setrerrahmane, S., Xie, W. and Xu, H. (2022) 'Trends in insulin resistance: insights into mechanisms and therapeutic strategy', *Signal Transduction and Targeted Therapy*, 7(1): 216.
6. Umpierrez, G.E., Davis, G.M., ElSayed, N.A., Fadini, G.P., Galindo, R.J., Hirsch, I.B., Klonoff, D.C., McCoy, R.G., Misra, S., Gabbay, R.A., Bannuru, R.R. and Dhatariya, K.K. (2024) 'Hyperglycaemic crises in adults with diabetes: a consensus report', *Diabetologia*, 67: 1455–1479.
7. Sacks, D.B. (2011) 'Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus', *Diabetes Care*, 34(6):61–99.
8. Ramljak, S., Lock, J.P., Schipper, C., Pankalla, N., Haug, C., Gilmer, R. and Freckmann, G. (2013) 'Hematocrit interference on blood glucose self-monitoring systems: a combined laboratory and field study', *Diabetes Technology & Therapeutics*, 15(4): 308–316.
9. Tappy, Luc. (2021) Metabolism of sugars: A window to the regulation of glucose and lipid homeostasis by splanchnic organs. *Clinical Nutrition*, 40(4): 1691-1698.
10. Akoumianakis, I., Polimeni, A., Herdman, L., Sayers, S., Pople, J., Krasopoulos, G., Sayeed, R., Petrou, M., Antoniades, C. and Channon, K.M. (2024) 'Amylin, another important neuroendocrine hormone for the treatment of obesity?', *International Journal of Molecular Sciences*, 25(3): 1517.
11. Bauer, M., Schlippenbach, C., Lange, S. and Bechmann, N. (2022) 'Comparison of POCT glucose meters and analysis of the internal and external quality control', *Journal of Laboratory Medicine*, 46(4): 207-214.
12. Attitalla, I. H., Sulaiman, G. M., & Alnafea, M. A. (2026). Molecular Detection and Characterization of Antimicrobial Resistance Genes among Multidrug-Resistant Gram-Negative Bacteria Isolated from Clinical Specimens. *International Journal of Applied Medical and Health Sciences, 1*(1), 49-57.
13. Ginsberg, B.H. (2009) 'Factors affecting blood glucose monitoring: sources of errors in measurement', *Journal of Diabetes Science and Technology*, 3(4): 903–913.
14. Katz, Abram. (2022) A century of exercise physiology: key concepts in regulation of glycogen metabolism in skeletal muscle. *European Journal of Applied Physiology*, 122(8): 1751-1772.
15. Lu, X., Xie, Q., Pan, X., Zhang, R., Zhang, X., Han, M., Li, Y., Li, L., Tong, L., Wang, Y., Liu, Y., Zhu, Z. and Zhang, Y. (2024) 'Type 2 diabetes mellitus in

adults: pathogenesis, prevention and therapy', *Signal Transduction and Targeted Therapy*, 9(1): 262.
16. Movahednasab, M., Dianat-Moghadam, H., Khodadad, S., Nedaeinia, R., Safabakhsh, S., Ferns, G. and Salehi, R. (2025) 'GLP-1-based therapies for type 2 diabetes: from single, dual and triple agonists to endogenous GLP-1 production and L-cell differentiation', *Diabetology & Metabolic Syndrome*, 17(1): 60.
17. Rebello, Candida J., Greenway, Frank. (2025) From starvation to time-restricted eating: a review of fasting physiology. *International Journal of Obesity*, 49(1): 43-48.
18. Khan, A.I., Vasquez, Y., Gray, J., Wians, F.H. and Kroll, M.H. (2010) 'The impact of temperature and humidity on the performance of bedside glucometers', *Archives of Pathology & Laboratory Medicine*, 134(10):1542–1547.
19. Klonoff, D.C. (2021) Measuring glucose with point-of-care meters: Be careful!, *Anesthesia Patient Safety Foundation Newsletter*.
20. Kushner: R., Fonseca, V., Nichols, J.H., Shubrook, J.H., Miller, E., Wright, E., DeFilippi, C. and Vassalotti, J.A. (2025) 'Clinical Need for Point-of-Care Testing for Diabetes in Clinical and Laboratory Improvement Amendments–Waived Settings', *Clinical Diabetes*, 43(2): 227–239.