Annals of Medical Laboratory Science (2021) **1**(2): 1 - 8
https://www.annalsmls.org
https://doi.org/10.51374/annalsmls.2021.1.2.0037

A comparative study of glycaemic variability using four different Point-of-Care Testing (POCT) devices

Peter Paul Mwinsanga Dapare[1*], Yussif Adams[1], Simon Bannison Bani[1], Moses Banyeh[1], Eric Mishio Bawa[1], Endorah Fotwe Blankson[1]

[1]Department of Biomedical Laboratory Science, School of Allied Health Sciences, University for Development Studies, Tamale, Ghana
**Corresponding Author: E-mail: peterpauldapare@yahoo.com*

How to cite this paper: Dapare, P.P.M., Adams, Y., Bannison, S.B., Banyeh, M., Bawa, E.M. and Blankson, E.F. (2021) A comparative study of glycaemic variability using four different Point-of-Care Testing (POCT) devices. *Annals of Medical Laboratory Science* **1**(2): 1 - 8

Received: September 20, 2020
Accepted: March 18, 2021
Published: June 20, 2021

ABSTRACT

Background: Blood glucose measurement is a way of monitoring changes in glycaemia. Different point-of-care testing (POCT) glucose meters are on the market and hence there is an increase in variability of the results given by these meters. This study sought to measure the glycaemic variability using four different point-of-care glucose meters

Methods: Four point of care glucometers namely; Accu-chek performer nano, OneTouch select plus flex, OneTouch Ultra 2 and Easy Check were used test blood samples from a total of 100 patients visiting the collection point of the Tamale Teaching Hospital Laboratory. A chemistry analyzer (Mindray BS 240 fully automated) was used as the reference method.

Results: The median (interquartile range), Bland Altman Plot and Regression Equation were used to assess the agreement between the various meters and the reference method. The OneTouch Select plus had the least bias (-0.85) and the the OneTouch Ultra 2 had the highest bias (1.49). The OneTouch select had the best limits of agreement (-2.51 – 0.82) and the OneTouch Ultra 2 had the widest limits of agreement (-1.91 – 4.89) when compared to the reference method.

Conclusion: OneTouch Select plus had the best agreement with the reference method and the OneTouch Ultra 2 had the least agreement with the reference method. Blood glucose meters should be used for the monitoring of blood glucose however, it should not be used as a diagnostic tool.

Annals of Medical Laboratory Science (2021) 1(2), 1 - 8

Keywords: glucometer, point-of-care, blood glucose, glycaemia

INTRODUCTION

Glucose is an obligate carbohydrate fuel for some tissues (e.g. erythrocytes) and preferred fuel for the body in general (Marshall, 2012). Blood glucose measurement is a method of testing the concentration of glucose in the blood and it used as a way of monitoring changes in glycaemia, particularly vital in the management of diabetes (Kiechle and Main, 2000).

Blood glucose monitoring reduces the occurrence of short term, potentially life-threatening complications of hypoglycemia and the long-term effects of hyperglycemia American Diabetes Association, 2017). Monitoring is usually done at home using glucose meters and in the laboratories by professionals (Kiechle and Main, 2000).

Diabetes and hyperglycaemia are common challenges of hospitalized patients and it is therefore essential to monitor blood glucose levels in such patients so that appropriate medications and food can be given them (Klonoff, 2014). Self-monitoring of blood glucose levels plays an important role in the efficacy of current therapy for diabetes mellitus so it is necessary for such individuals to regularly monitor their blood glucose levels so that they can make suitable lifestyle decisions and take appropriate medications. Hypoglycaemia and hyperglycaemia in individuals can be very dangerous and could even be fatal if

https://doi.org/10.51374/annalsmls.2021.1.2.0037

not diagosed and managed properly. It has therefore become expedient to have and include point-of-care testing methods in the monitoring of diabetes and blood glucose levels in hospitalized patients to facilitate rapid treatment decisions in response to changes in blood glucose levels.

Point-of-care testing reduces the turn-around time as it takes <5 minutes. It also reduces pre-analytical and post-analytical errors because the manufacturers have built into their newer point-of-care blood glucose meters, a number of control processes to minimize the occurrences of post-analytical and pre-analytical errors and to detect them in case they occur. It uses less blood and reduces the risk of anaemia in hospitalized patients due to frequent venessection (Rajendran and Rayman, 2014). Factors considered when choosing a glucose meter include; the accuracy of its results, the ease of technique, maintenance and the price of both the meter and strips (Ekhlaspour et al., 2017).

Different POC glucose meters are on the market and hence there is an increase in variability of the results given by these meters. Manufacturers' adherence to standards of ISO 15197 has over the years been seen to be compromised (Hellman, 2012). Test strips used for these POC glucose meters has also seen to be compromised by some manufacturers. This has warranted the need to determine the degree of variability amongst the different types of POC glucose meters used and its agreement with results from the standard laboratory. Commonly used POC glucose meters used in Ghana include; OneTouch Select, ACCU Chek, Selectra, OneTouch Ultra, Easy Chek, Life Check, Q-Check, Sannuo GA-3, OK and many more glucose meters.

The increase in the global prevalence of diabetes, need for accuracy in self-monitoring glucose systems and price pressures have caused the medical device manufacturers to develop and manufacture more types and brands of glucose meters (Hughes, 2009). POC glucose meters are a very vital part in diabetes management, but inaccurate results from these meters can cause harm to patients.

Blood glucose testing by POC meters has revolutionized the monitoring of diabetes in recent times by giving relatively accurate measurements of the actual blood glucose of patients in real time (Hellman, 2012). For instance, the difference in glucose levels given by different meters may be as great as 50-70 mg/dl (Dungan et al., 2007). A study done by Freckmann *et al.* (2010) reviewed 27 meters that had been approved for use in Europe from 18 companies. Though manufacturers claimed they adhered to ISO 15197 standard, the study revealed that, 41% of the meters were not equally accurate or precise especially during the hypoglycaemic range when accuracy is very important. Another study done by (Kristensen et al., 2006) where they tested the accuracy of the strips of nine meters within specified hematocrit ranges revealed that, contrary to claims of five manufacturing companies, their strips showed relatively wide variations within those given ranges.

In our health setting, different POC glucose meters are sometimes used for the same patient at different times. These POC meters have different reference ranges and therefore should be interpreted differently however, on a regular routine, the values read by the devices are just recorded and treatment continues from there. The different POC glucose meters vary in the results they give but usually, it is not taken into consideration by the healthcare providers. Despite great improvement in almost 50years of self-monitoring of glycaemia, significant concerns remain. This study therefore seeks to compare the results produced by four different POC glucose meters and to estimate the degree of variability amongst these meters and a reference method. It also seeks to offer guidance on the proper use and interpretation of results given by these devices.

MATERIALS AND METHODS

Study Design

This was a cross-sectional study carried out at the medical laboratory of the Tamale Teaching Hospital from January to June, 2019.

https://doi.org/10.51374/annalsmls.2021.1.2.0037

Ethical Considerations
Ethical clearance for this research work was gotten from the Tamale Teaching Hospital. Informed consent was sought from each participant before the study was carried out. Confidentiality of records was assured.

Study Population
Consenting patients visiting the laboratory's sample collection point at the Tamale Teaching Hospital were included the study.

Selection of Study Participants
Verbal informed consent was obtained from the hospital's laboratory management for the study giving vivid explanations of the need to carry out the study. Patients were fully informed of the processes and benefits involved. The participants were informed of the type of test to be carried out and at a free cost. Also, participants were selected randomly for the study.

Data collection
Sociodemographic and Medical History
A self-designed semi-structured questionnaire was administered to each consented participant for socio -demographic characteristics such as age, gender, diabetic status, fasting status and knowledge on glucometers.

Blood samples were collected from 100 random patients who came to the collection point and dispensed into sodium fluoride tubes. Samples were taken from the antecubital fossa veins and a few of them from the hand veins. During venipuncture from the antecubital fossa veins, the torniquette was tied for less than a minute and same was done for samples taken from the hand veins. Also, participants were given questionnaires to answer to be able to categorize results under age, gender, fasting and random blood glucose and knowledge of point-of-care glucose meters.

Test Procedure
A sodium fluoride tube was used this test. Patients' venous samples were taken and dispensed into the tube. Whole blood was used to check the blood glucose value using the 4 different POC glucose meters first. Then, samples were span and plasma was separated, the glucose levels were then checked again using the chemistry analyser. Blood glucose estimation using the different glucose meters was done within the shortest possible time (under 2 minutes). This was to ensure that the variability will not be as a result of too much time spacing between the usage of the different glucose meters on the same sample. This was a precaution taken during testing.

Reading of Results
Results given by the different POC glucose meters were written down and compared with the reference ranges to tell whether or not a patient has hyperglycaemia, normoglycaemia or hypoglycaemia. Results given by the chemistry analyser was also compared with standards and references to show the degree of agreement between the results given by the individual POC glucose meters.

Data Analysis
Data collected was entered into Microsoft excel spreadsheet. The relationship between the different POC glucose meters and their agreement with the results from the analyzer, was determined using the Regression equation, Bland Altman plot analysis and the one-way ANOVA. The analysis was performed using GraphPad Prism version 9.2.0 for windows.

Table 1: General Characteristics

Variable	Summary
Age	36(2-93)
Gender	
Male	41(41%)
Female	59(59%)
Diabetic Status	
Yes	17(17%)
Fasting Status	
Yes	39(39%)
Knowledge of Glucose Meters	
Yes	28(28%)

Data presented as frequency (percent); Age in median (interquartile range)

https://doi.org/10.51374/annalsmls.2021.1.2.0037

RESULTS

General Characteristics of Studied Population

Table 1 shows the demographics of the study indicating gender, age, diabetic status fasting state and knowledge of glucose meters. A total of 100 people visiting the collection point of the hospital's laboratory were included in the study. Out of the 100 people, 59 of them were females and 41 of them were males. A total of 17 people out of the 100 people were known diabetics. 39 out of the hundred people were fasting when sample was taken and only 28% of the study subjects knew about glucose meters.

Comparison of Plasma Glucose Concentrations as Measured by Glucometers and Reference Method.

Table 2 shows the median of the different glucose meters as compared with the reference method. The reference had a median value of 5.79mmol/l with range of [5.36-6.34(mmol/l)] of all the samples measured. OneTouch select plus had the closest median value to the reference, having a median of 5.10mmol/l and a range from [4.70-5.78 (mmol/l)]. The Easy-Check had a median of 5.05 mmol/l and a range of [4.48-6.18 (mmol/l)]. Accu-check had a median of 4.60 mmol/l ranging from [4.20-5.20 (mmol/l)]. The OneTouch Ultra had the highest median of 7.0 mmol/l with a range of [6.13-9.18 (mmol/l)]. Most of the glucose meters showed a negative bias with mean difference being -1.4 mmol/l for ACCU check performer nano, -1.35 mmol/l for the Easy Check and -0.85 mmol/l for the OneTouch select plus flex. However, the OneTouch Ultra 2 showed a positive bias with a mean difference of 1.49 mmol/l (Table 2)

Table 2: Comparison of Blood Glucose Concentration obtained by Glucose Meters and Reference Method

Device	Plasma Glu concentration (mmol/l) [Median (IQR)]	Bias (mmol/l)
Reference	5.79 (5.36-6.43)	-
Accu-Check	4.60 (4.20-5.20)	-1.4
Easy-Check	5.05 (4.48-6.18)	-1.35
Select Plus	5.10 (4.70-5.78)	-0.85
Ultra	7.00 (6.13-9.18)	1.49

Glu: Glucose, IQR: Interquartile range

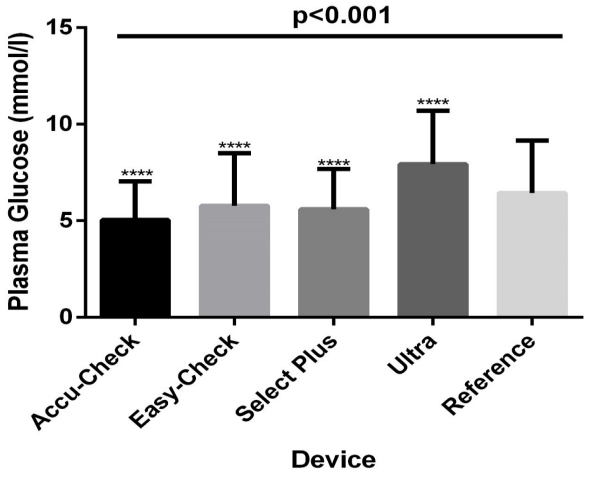

Figure 1: One Way ANOVA Comparing all Devices to the Reference Value

One Way ANOVA of Concentrations Obtained by Glucometers and Reference Method

Figure 1 shows the relationship between the different devices used. It also shows the agreement between the different meters and the reference. The p value as calculated using the paired one-way ANOVA being <0.001 shows that, the measurements from the various meters are statistically different and their individual relationship with the reference is also statistically different. It shows that the Easy-check agrees the most with the reference, followed by OneTouch select plus, Accu-check and then by the OneTouch Ultra.

Association between Plasma Glucose Concentrations Obtained by Glucometers and Reference Method

Table 3 shows the association between the plasma glucose concentrations obtained by the glucose

Table 3: Association Between Concentrations Obtained by Reference and Other Devices

Device	Regression Equation	R^2	P-value
Reference	-	-	-
Accu-Check	$y = 0.71x + 0.5$	0.92	$p < 0.001$
Easy-Check	$y = 0.72x + 0.6$	0.91	$p < 0.001$
Select Plus	$y = 0.75x + 0.8$	0.95	$p < 0.001$
Ultra	$y = 0.82x + 2.7$	0.64	$p < 0.001$

https://doi.org/10.51374/annalsmls.2021.1.2.0037

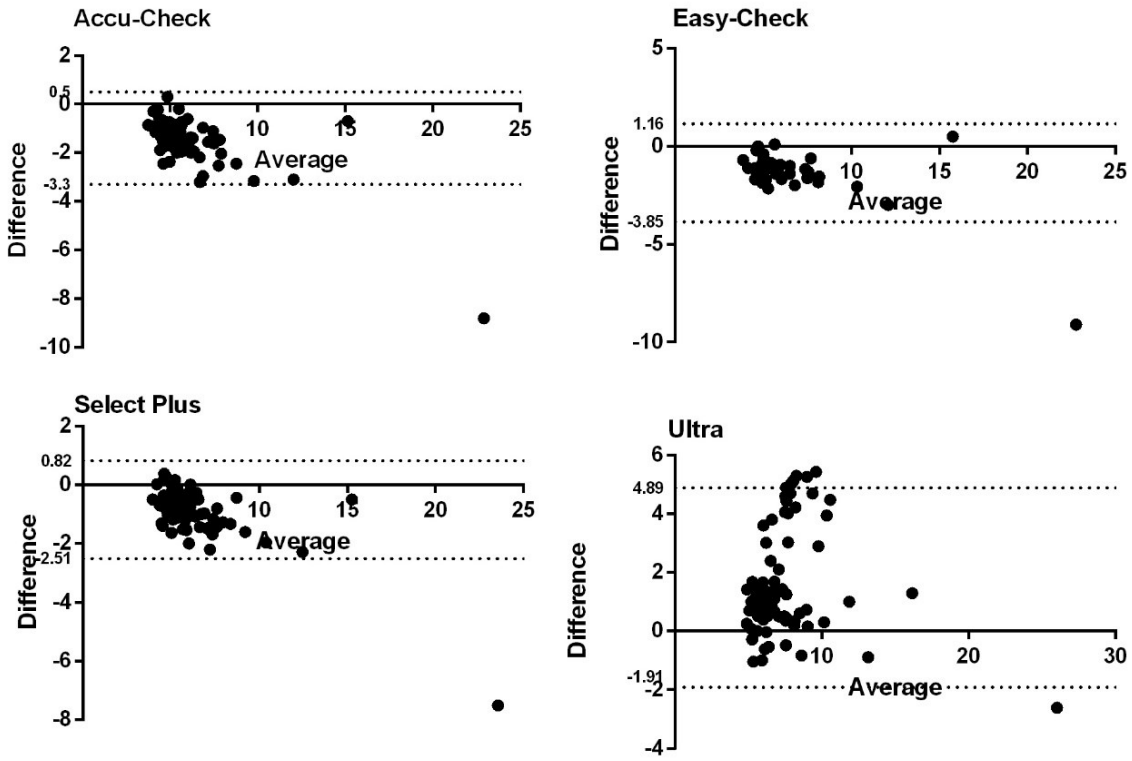

Figure 2: Bland Altman analysis: Dotted lines represent 95% limits of agreement

meters and the reference method. In the equation, OneTouch Ultra has the closest value to the reference method. However, association was stronger between the Select Plus and the reference method ($R^2 = 0.95$, $p < 0.001$), followed by Accu-check and OneTouch Ultra had the least strength of association ($R^2 = 0.64$, $p < 0.001$).

Bland Altman Plot analysis comparing results obtained by Glucometers to the Reference Method

Figure 2 is the Bland Altman plot analysis comparing the glucometer readings to the reference. The dotted lines represent the 95% limits of agreement. The plot shows that the OneTouch select plus has the narrowest limits of agreement (-2.51 – 0.82), the Easy-Check comes next then the Accu-check. The OneTouch Ultra showed the widest limits of agreement (-1.91 – 4.89), indicating the lowest agreement with the reference method.

DISCUSSION

Self-monitoring with blood glucose is very essential in the management of diabetes and for determination of glycaemia in hospitalized patients (Klonoff, 2014). Their results influence decisions like insulin therapy and other medications and hence results given by these meters should be as accurate as possible (Klonoff, 2014). Though the precision and accuracy of most meters have improved over the past fifty years, there are still significant concerns regarding the standardization of the meters (Dungan *et al.*, 2007). In this study, different glucose meters were investigated. The meters used have been calibrated using whole blood/plasma. Results from the study shows that devices were not satisfactory, since there were substantial discordance when results from the glucose meters were compared to the reference method.

According to a study done in South Africa

https://doi.org/10.51374/annalsmls.2021.1.2.0037

comparing five glucometers, the OneTouch ultra showed a negative bias of -3.4, and it was the second glucose meter used in the study with the least bias (Essack *et al.*, 2009). Three Accu-Chek meters were used as well in this study (Accu-Chek Horizon, Accu-Chek Active and Accu-Chek Advantage), the Horizon showed a negative bias -6.0 and the Active showed a negative bias of -5.2, the Advantage showed had a bias of +6.0 (Essack *et al.*, 2009). However in this study, the OneTouch Ultra showed a positive bias and was the glucose meter with the widest limits of agreement. This could be attributed to the fact that, the OneTouch ultra is an older device from the OneTouch company and could probably be the reason for the dissatisfactory results given by this meter in the research.

The Accu-Chek used in this study (Accu-Chek performer nano), a newer device from Accu-Chek showed a negative bias of -1.35. This indicates that, the devices manufactured by this company has been improved over the years even though there are still significant concerns especially regarding the their standardization and their agreement with the reference method.

The OneTouch select plus flex showed the best agreement with the reference method, showing the least bias and and the best limits of agreements in the Bland Altman plot analysis. This could be associated with the fact that, it is a newer product from the OneTouch company and so have improved in general. It is believed that as the years go by, newer devices manufactured are better as compared to older devices (Dungan *et al.*, 2007).

The Easy-Check was the second glucometer with the best agreement to the reference method showing the least bias after the OneTouch Select Plus. The Easy-Check which is a new device from the Christland Ghana has given satisfactory results for being the second glucose meter with the narrowest limits of agreement after the OneTouch Select plus but it still has a long way for its agreement with the reference. The Accu-Check performer nano, recorded most of the values lower than the reference and the rest of the devices. It is a newer device from the Accu-Chek company and so has seen improvement. Having a lesser bias as compared to the other devices from the company used in other studies.

The OneTouch Ultra however, was reading most of its results higher than the reference and so showed a positive bias. It had the least agreement with the reference method as compared to the rest of the devices. It showed the highest variability with the reference method at low glucose levels. This could be because it is an earlier device from the OneTouch and it seems like the performance of this device has reduced as compared to other studies done previously.

Hypoglycaemia is very critical and needs to be detected by glucose meters. Therefore, failure of this OneTouch Ultra glucose meter to detect severe hypoglycaemia may pose dangers in managing patients with hypoglycaemia. With the exception of the OneTouch ultra 2, the rest of the meters recorded values lower than the reference method. As stated above, results from these glucose meters influence treatment decisions such as insulin therapy and so failure of these devices to recognize hyperglycaemia can lead to critical medical errors ultimately affecting the quality of care given to patients.

Other studies comparing glucose meters to themselves also revealed that most devices used in the clinical setting and by the patients at their homes, had general issues with respect to standardization and their agreement with the reference method (Poirier *et al.*, 1998; Cohen *et al.*, 2006; Essack *et al.*, 2009). These studies agreed with each other regarding standardization of the various glucose meters they used in their study having significant p-values. In our study, findings agree with the results from the other studies as there was a significant difference between glucose meters and the reference method.

Self monitoring of blood glucose is very essential in managing diabetes and the study reveals that only 28 people out of the 100 knew about glucose

https://doi.org/10.51374/annalsmls.2021.1.2.0037

meters. Out of the 17 diabetic patients who partook in the study, only 6 of them knew of glucose meters. This infers that, their blood glucose is most likely only monitored when they go to the diabetic clinic for their periodic checkups which is bad for proper management of diabetes. The limitation of the study were as follows; due to response from participants, workload in the laboratory and the stress involved, estimation of glycaemia with the glucose meters could not be done in the conventional way and so venous blood was used in the study. Also, glucose levels were estimated only once with each of the glucose meters (repeated analysis was not done on the meters) and so precision of glucose meters was not evaluated.

CONCLUSION

The results from the analysis shows that, the OneTouch select plus has the best agreement to the reference followed by the Easy-check and Accu-chek. The OneTouch Ultra 2 had the least agreement with the reference method. Among the glucose meters used, the Onetouch select plus is highly recommended for use at the hospitals and also by the patients themselves at home. The Easy check is also recommended for use. Glucose meters should be used for monitoring purposes solely and not for diagnostic purposes. In addition to monitoring blood glucose of diabetics at diabetic clinics and in-patients at the health facility, blood glucose levels should also be monitored with a laboratory method since values from glucose meters and laboratory vary significantly.

COMPETING INTEREST

Authors declare that they have no competing interests

ACKNOWLEDGEMENTS

We are grateful to the Upper East Regional Hospital (Bolgatanga-Ghana) and all subjects for their kind collaboration.

AUTHORS' CONTRIBUTIONS

Authors PPMD, YA and MB designed the study. Authors PPMD, EMB and EFB performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript. Author SBB and EMB managed the analyses of the study. Authors EFB and YA managed the literature searches. All authors read and approved the final manuscript.

REFERENCES

American Diabetes Association (2017). Classification and diagnosis of diabetes. *Diabetes care* 40 (Supplement 1), S11-S24.

Cohen M., Boyle E., Delaney C. and Shaw J. (2006) A comparison of blood glucose meters in Australia. *Diabetes research and clinical practice* 71(2), 113-118.

Dungan K., Chapman J., Braithwaite S.S. and Buse J. (2007) Glucose measurement: confounding issues in setting targets for inpatient management. *Diabetes care* 30(2), 403-409.

Ekhlaspour L., Mondesir D., Lautsch N., Balliro C., Hillard M., Magyar K., Radocchia L.G., Esmaeili A., Sinha M. and Russell S.J. (2017) Comparative accuracy of 17 point-of-care glucose meters. *Journal of diabetes science and technology* 11(3), 558-566.

Essack Y., Hoffman M., Rensburg M., Van Wyk J., Meyer C. and Erasmus R. (2009) A comparison of five glucometers in South Africa. *Journal of Endocrinology, Metabolism and Diabetes of South Africa* 14(2), 102-105.

Freckmann G., Baumstark A., Jendrike N., Zschornack E., Kocher S., Tshiananga J., Heister F. and Haug C. (2010) System accuracy evaluation of 27 blood glucose monitoring systems according to DIN EN ISO 15197. *Diabetes technology & therapeutics* 12(3), 221-231.

Hellman R. (2012) Glycemic variability in the use of point-of-care glucose meters. *Diabetes Spectrum* 25(3), 135-140.

Hughes M.D. (2009) The business of self-monitoring of blood glucose: a market profile. *Journal of diabetes science and technology* 3(5), 1219-1223.

https://doi.org/10.51374/annalsmls.2021.1.2.0037

Kiechle F.L. and Main R.I. (2000) Blood glucose: measurement in the point-of-care setting. *Laboratory Medicine* 31(5), 276-282.

Klonoff D.C. (2014) Point-of-care blood glucose meter accuracy in the hospital setting. *Diabetes Spectrum* 27(3), 174-179.

Kristensen G.B., Nerhus K., Thue G. and Sandberg S. (2006) Results and feasibility of an external quality assessment scheme for self-monitoring of blood glucose. *Clinical chemistry* 52(7), 1311-1317.

Marshall W. (2012) Glucose (blood, Serum, Plasma). In *Clinical Biochemistry*.

Poirier J.-Y., Le Prieur N., Campion L., Guilhem I., Allannic H. and Maugendre D. (1998) Clinical and statistical evaluation of self-monitoring blood glucose meters. *Diabetes Care* 21(11), 1919-1924.

Rajendran R. and Rayman G. (2014) Point-of-care blood glucose testing for diabetes care in hospitalized patients: an evidence-based review. *Journal of diabetes science and technology* 8(6), 1081-1090.

ISSN 2773-8353