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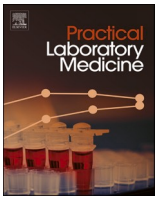

Validation of the efficacy of pooled serum for serum glucose inhouse quality control material in comparison with commercial internal quality control in clinical chemistry laboratory

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ABSTRACT

Background: This study aimed to create an in-house glucose quality control material for humans, addressing the challenge of obtaining high-cost commercially prepared quality control materials in developing countries.
Methods: An in-house quality control material for glucose was prepared using a pooled serum sample and analyzed using a fully automated chemistry analyzer following the ISO 80 guidelines. The mean, standard deviation (SD), and coefficient of variance were calculated from the first 30 days of measurement, and the variability was checked over eight months using SPSS software. The study used Pearson's correlation with a 95% confidence interval and a P-value less than 0.05, which was statistically significant.
Results: The average mean ± SD of human serum glucose was 185.2 ± 8.4 mg/dL, indicating that the precision between each measurement was better. The prepared in-house quality control material was stable for approximately five months without any significant change in the serum glucose concentration (mg/dl) (p-value<0.05).
Conclusions: The study suggests that room-temperature, 2–8 °C, and −20 °C to −30 °C storage of human serum samples for glucose analysis is a viable option, with stable glucose concentrations for up to 30 days. Pooled serum is a cost-effective method for in-house quality control, especially in resource-limited laboratories.

1. Introduction

Quality control is the process of detecting analytical errors during patient sample analysis to ensure the reliability and accuracy of test results, thereby enhancing patient care. Quality control in medical laboratories is crucial for monitoring and evaluating the analytical process that produces patient results [1,2]. To achieve quality in a medical laboratory, various tools are utilized, including machine performance checks, error control during patient sample analysis, and careful sample collection procedures [3–7]. Medical

Abbreviations: CM, Control Material; EQC, External Quality Assurance; HM-QC, Home-Made Quality Control; HM-QCM, Home-Made Quality Control Material; IN-QC, In-House Quality Control; IQC, Internal Quality Control; ISO, International Standard Organization; PC, Pathological Control; SOP, Standard Operating Procedures; SST, Serum Separated Tube.

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laboratory tests rely on the correct performance of machines using quality control materials with known results to ensure quality [3,8].

Quality control materials are patient-like reference materials used in clinical laboratory analysis to verify the accuracy of analytical procedures and are typically derived from human serum, urine, or spinal fluid [3–5,8,9]. Quality control materials can detect and correct deficiencies in a laboratory's internal analytical process before patient results are released, either as liquid or freeze-dried materials. Control products should be tested similarly to patient samples before releasing patient results, as they typically contain various analytes based on their nature [1,3,10–12].

Internal quality control (IQC) involves incorporating control materials, which represent the test materials in terms of matrix composition, physical preparation, and analyte concentration range, into the analytical sequence [3,4,13–16]. IQC is a vital component in medical laboratory science, ensuring accurate and reliable test results that directly impact patient care [17,18]. Accurate and reliable laboratory results are crucial for informing clinical decisions, providing appropriate treatment for patients, building confidence in the laboratory's accuracy and reliability, and leading to better patient outcomes and provider satisfaction [17].

The performance of each laboratory machine can be significantly influenced by various factors, such as environmental, human, reagent change, and operator-related factors [3,12,19–21]. Therefore, each laboratory should regularly assess the performance and stability of each machine used for patient sample analysis using quality control materials. Regular laboratory use of control materials is crucial for quality control, but developing countries face challenges in the cost and availability of commercial quality control materials. Therefore, the current study aimed to prepare an in-house quality control for serum glucose.

2. Methods and materials

2.1. Study setting

A cohort study was conducted to prepare in-house quality control sera from pooled human serum, which was prepared by mixing different human serum samples collected from six diabetic patients in the Debre Markos University laboratory from August 1, 2022, to April 30, 2023.

2.2. Sampling and data collection procedure

A pooled serum was prepared by combining serum samples obtained from six voluntary diabetic patients. A total of 15 ml of serum was collected from the participants, with each contributing 3 ml. The collected samples were then pooled into three separate vials, each containing an equal amount of serum. These vials were stored at different temperature conditions: room temperature, 2–8 °C, and −20 °C to −30 °C. The pooled serum in each vial was then subjected to lyophilization for 8 h. Once the pooled sera were obtained, the material underwent a processing stage involving mixing and blending to ensure adequate homogeneity and stability for its intended use.

2.3. Guideline for preparation of in-house quality control material

The in-house liquid human quality control serum was prepared based on the ISO-80 guidelines for quality control preparation, ISO-33 guidelines for quality control material calibration, method validation and verification, and control chart preparation; ISO-35 guidelines for characterization and certification of quality control materials; and ISO-15189 standard guidelines for quality control preparation protocol for medical laboratory science [1,3,22–26].

2.4. Laboratory sample collection and analysis

The whole blood sample was stored at room temperature for 10–20 min until it was coagulated and centrifuged at 3000 rpm for 5 min to separate the serum from the red cells. After centrifugation, the serum samples were immediately separated from the red blood cells and transferred into labeled-capped tubes (Nunc tubes). Each aliquot was then divided into three equal volumes and stored at room temperature, in a refrigerator at 2–8 °C, and in a deep freezer (−20 to −30 °C).

The prepared liquid quality control human serum and the commercially lyophilized control sera were analyzed on a fully automated Cobas clinical chemistry machine (Cobas 6000 c501) for comparison of the serum glucose results (mg/dl). All the aliquots were stored at room temperature in a deep freezer (−20 to −30 °C), and 2–8 °C was analyzed for consecutive 30 days and then once every month for consecutive 8 months. The mean, standard deviation, and variance were calculated using the measurement results from the first 30 days, while monthly results for eight months were used to check for variability between findings. For the first 30 days, three quality control serum samples were analyzed for serum glucose (one aliquot from room temperature, one aliquot from 2 to 8 °C, and one aliquot from −20 to −30 °C), and for those analyzed every month, two quality control serum samples (one aliquot from 2 to 8 °C and one aliquot from −20 to −30 °C) were analyzed. The initial 90 results were obtained over 30 days and the mean, SD, and coefficients of variation were calculated. The analysis was done by using one new run per day (not returned to the store after a run) and one in-out run per day (returned to the store after a run), with consideration of the three storage conditions (room temperature, 2–8 °C, and -20–30 °C).

2.5. Operational definition

- **Diabetic participants:** have a serum glucose level ≥140 mg/dL.
- **Fasting blood sample:** a blood sample collected after 8 h of fasting
- **In-out run/day:** The aliquot was prepared and stored for multiple runs, and the remaining aliquot was returned to the refrigerator the next day after being brought to room temperature.
- **New run/day:** An aliquot was prepared and stored for a single run, and the remaining aliquot was not returned to the refrigerator once it was brought to room temp for analysis.
- **Pooled serum:** refers to a serum sample created by combining serum samples collected from six diabetic individuals.

2.6. Stability and Homogeneity Assessment

Stability Assessment: The ability of the pooled serum to maintain its properties, specifically the glucose concentration, was evaluated by subjecting it to three storage conditions (room temperature, 2–8 °C, and −20 °C to −30 °C) and measuring the glucose concentration at regular intervals. Acceptable stability was determined when the mean glucose concentration remained within a specified range over the defined stability period (within the 95% confidence interval, as shown in charts 1-3, following CLSI recommendations).

Homogeneity Assessment: The uniform distribution of glucose within the pooled serum, ensuring consistent glucose concentration throughout the material, was assessed by analyzing multiple aliquots of the pooled serum and measuring their glucose concentrations. Consistency across the measured glucose concentrations indicates good homogeneity.

2.7. Data quality assurance

Data and sample collection procedures were conducted using standardized guidelines and operating procedures, with equipment calibrated monthly using a type-auto-calibrator before the test analysis. In addition, two levels (normal and pathological) of commercial IQC samples were run along with the aliquot and interpreted using the Westgard multirule algorithm.

2.8. Data analysis and interpretation

Data were cleared, edited, manually checked for completeness, entered into Epi data, and then analyzed using SPSS (version 20.0, USA). After organizing and cleaning the data**, the** mean, SD, and coefficient of variation were calculated.

2.9. Ethical considerations

The study received ethical approval based on the Helsinki Declaration from Debre Markos University College of Health Science (Reference No. HSC/R/C/Ser/co/316/11/21), obtained written informed consent, and ensured confidentiality using codes for data collection. Participants were informed of the risks and benefits of the study, their right to withdraw at any time, how confidentiality was maintained using codes, and their right to obtain their results for free. Written informed consent was obtained from the patient for publication of this case report. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

3. Result

The study aimed to develop an internal quality control system for measuring human serum glucose levels. It compared two different

Table 1
Mean, standard deviation (SD), and coefficient of variation (coefficient of variation) of routinely analyzed runs for the first 30 consecutive days at the three storage conditions (room temperature, 2–8 °C, and −20–(-30) °C) to prepare in-house quality control.

Routinely analyzed run-finding statistics	Statistics	Run type	In-house control results at the three storage conditions			P-value
			at 2–8°C	at -20 to -30°C	at room temp	
	Mean	PC-01 (in-out run/day)	170.2	160.6	175.8	0.002
		PC-02 (new run/day)	172.7	168.8	176.9	
	SD	PC-01 (in-out run/day)	9.6	8.2	15.4	
		PC-02 (new run/day)	7.9	6.8	14.6	
	% coefficient of variation	PC-01 (in-out run/day)	5.6	5.1	8.8	
		PC-02 (new run/day)	4.6	4.0	8.3	

NB: **%coefficient of variation**-percent of coefficient of variance, **SD**−standard deviation, **New run/day**-control sample discarded after one run or not returned to a storage site, **PC**- Pathological control, **In-out run/day**-control sample not discarded after one run or returned to a storage site, **01, 02**- random test order for each run.

methods: using the control once per day (referred to as the "new run per day") versus using it multiple times throughout the day (referred to as the "in-out run per day").

The results showed that when the control was used once per day, it had a significantly lower coefficient of variation compared to using it multiple times throughout the day. The coefficient of variation is a measure of the variability in the measurements. For the control stored at room temperature, the coefficient of variation was 8.3% for the new run per day and 8.88% for the in-out run per day. For the control stored at 2 °C–8 °C, the coefficients of variation were 4.6% and 5.6% for the new run per day and in-out run per day, respectively. Similarly, for the control stored at −20 °C to −30 °C, the coefficients of variation were 4.0% and 5.1% for the new run per day and in-out run per day, respectively. These differences in variation were found to be statistically significant ($p < 0.05$), indicating that the new run-per-day method resulted in more consistent and reliable measurements.

Overall, the study concluded that the internal quality control stored at −20 °C to −30 °C exhibited significantly good stability. This was supported by the lower variability observed among the measurements. Storing the control at colder temperatures helped maintain its stability and accuracy, making it an effective method for quality control in measuring human serum glucose levels (Table 1).

Both in-house QC materials (refrigerator and frozen) displayed similar overall ranges of glucose concentration throughout the eight months. Over eight months, in-house QC material stored at both refrigerator (2–8 °C) and frozen (−20 °C to −30 °C) temperatures maintained relatively stable glucose concentrations, exhibiting ranges similar to commercially available control serum. While slight variations existed, no consistent trends indicated major degradation, suggesting both storage options as viable for in-house QC with comparable performance. The in-house glucose quality control material stored at 2–8 °C showed significantly higher variability compared to frozen storage (−20 to −30 °C). The refrigerator-stored aliquot's glucose concentration fluctuated between 159 and 177 mg/dL (range 28 mg/dL), while the frozen aliquot only varied between 160 and 170 mg/dL (range 10 mg/dL). This suggests frozen storage offers greater stability and consistency for in-house glucose QC material (Table 2).

Overall, storing in-house QC material for human serum glucose at −20 °C to −30 °C resulted in significantly lower variability and higher stability compared to 2–8 °C storage, regardless of the analysis method (in-out run or new run). Both "in-out run" and "new run" methods displayed lower average mean glucose levels with frozen storage (−20 °C to −30 °C) compared to refrigerator storage (2–8 °C).

Frozen storage led to substantially lower standard deviations (SD) and, consequently, lower coefficients of variation (CV) for both run types, indicating significantly reduced variability in glucose measurements. The improvement in CV was more pronounced for "new run" aliquots, suggesting frozen storage is particularly beneficial for mitigating degradation associated with repeated freeze-thaw cycles ($p > 0.05$) (Table 3).

A control chart, specifically a Levey-Jennings (LJ) chart, was utilized to assess the stability of a test over time by plotting the findings of each run. This chart compares the results of a control sample to predefined control limits, which are set at a certain number of standard deviations from the mean. In this study, the LJ chart was employed to monitor the stability of glucose concentration in a pooled serum sample stored at room temperature for 30 days. The LJ chart plotted the concentration of glucose in a pooled serum sample stored at room temperature for 30 days, showing the stability of the glucose concentration within the control limits over time, indicating that room-temperature storage is a viable option for the quality control material. The data points consistently fell within the control limits, indicating that the concentration of glucose in the prepared pooled serum sample quality control material remained consistent and did not exhibit significant fluctuations (Chart 1).

Chart 2 shows the changes in glucose levels analyzed for 30 consecutive days from a pooled serum sample stored at 2–8 degrees C to prepare an internal quality control for serum glucose. The glucose concentration remained stable at 2–8 degrees C for 30 days, with no significant fluctuations outside the control limits. The mean concentration was 172.7 mg/dL (172.7± 7 mg/dL), indicating suitable storage conditions for glucose stability (Chart 2).

Chart 3 shows the results of a study that measured the concentration of glucose in a pooled serum sample stored at −20 °C to −30 °C for 30 days. In this case, the concentration of glucose in the sample remained within the control limits for the entire 30-day study. This

Table 2
The concentration of glucose analyzed from in-house control material aliquot for the consecutive eight months.

Month	Commercial control sera which is storage at 2–8 °C (mg/dl)	Glucose concentration findings were analyzed from inhouse control sera stored at two different storage condition					
		Storage conditions		Max (mg/dl)	Min (mg/dl)	Range	Mode
		2–8 °C	−20 –(-30)°C (mg/dl)				
Aug	175	166	167	177 for R and 170 for F	159 for R and 160 for F	28 for R and 10 for F	160 for R and 165 for F
Sep	174	167	165				
Oct	170	160	160				
Nov	171	173	170				
Dec	176	159	165				
Jan	173	177	166				
Feb	175	173	165				
Mar	175	160	164				

NB: **F**-freezing (aliquot stored at −20 –(-30)°C), **R**-refrigerator (aliquot stored at 2–8 °C), All the months mentioned in this table are the consecutive months in which a glucose test was done. The glucose level in the stored aliquot was taken on the fourth day of the month for eight consecutive months.

Table 3
The average mean, SD, and coefficient of variation of runs were analyzed for consecutively eight months at the two storage conditions (2–8 °C and −20 – (−30)°C) to prepare in-house quality control for human serum glucose.

Average statistics for consecutive eight-month runs for each storage condition of the glucose level findings				
Average Monthly statistics or finding	**Statistics**	**Each run**	**Storage conditions**	
			Inhouse control results at 2–8°C (mg/dl)	**Inhouse control results at -20 to -30°C (mg/dl)**
	Mean	PC-01 (in-out run/ day)	170.2	166.9
		PC-02 (new run/ day)	168.1	165.4
	SD	PC-01 (in-out run/ day)	8.0	4.2
		PC-02 (new run/ day)	6.9	3
	% coefficient of variation	PC-01 (in-out run/ day)	4.7	2.5
		PC-02 (new run/ day)	4.1	1.8

The mean, standard deviation, and percent of coefficient of variance given in this table are calculated for all eight-month run findings.

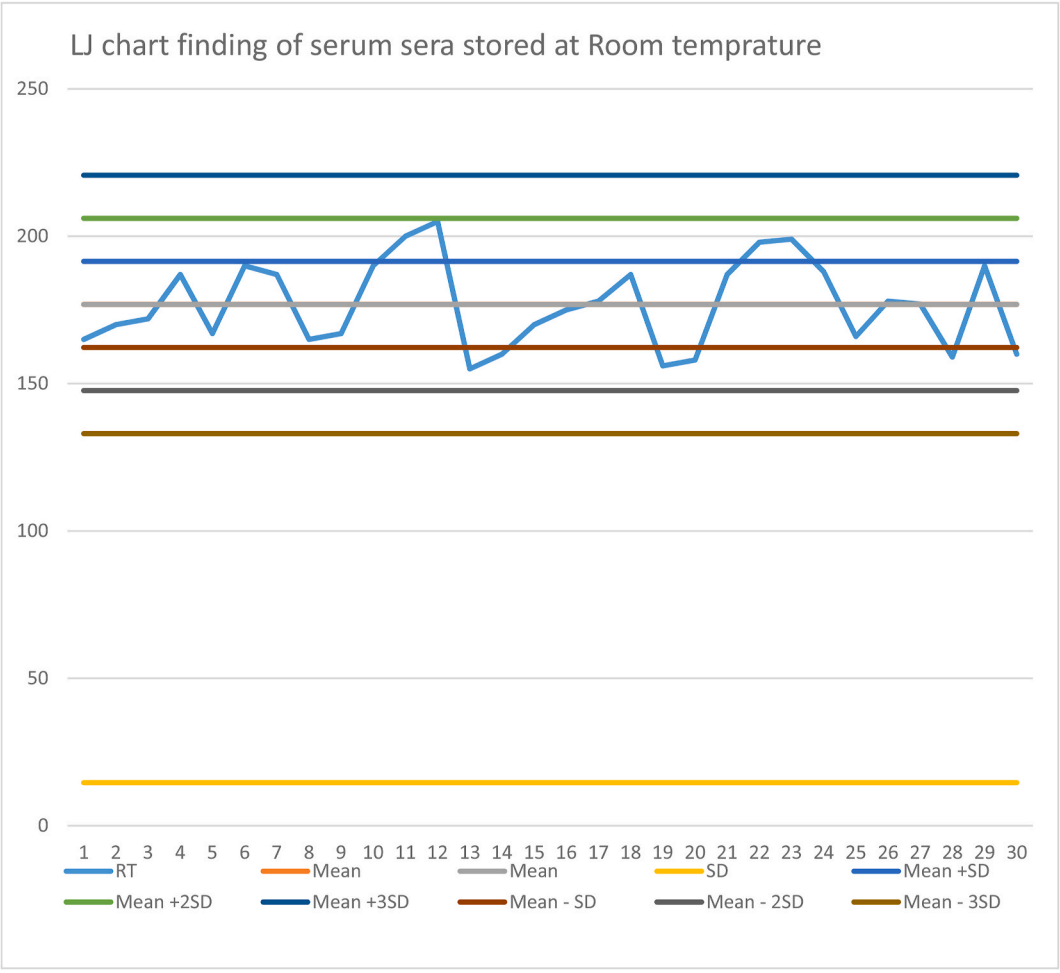

Chart 1. Levey-Jennings (LJ) chart finding for glucose analyzed for 30 consecutive days from a human serum sample stored at room temperature to prepare quality control for serum glucose.

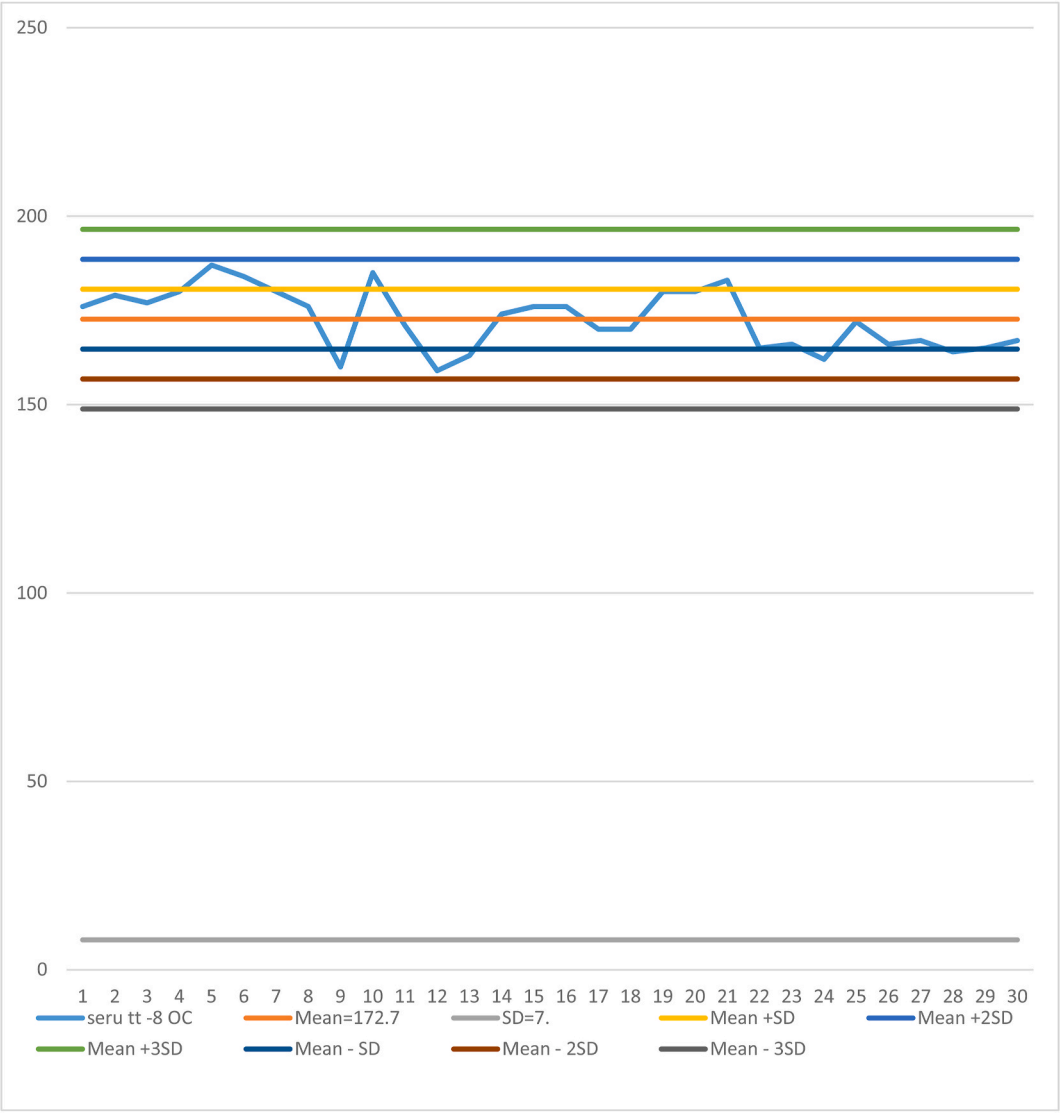

Chart 2. Levey-Jennings (LJ) chart findings for glucose were analyzed for 30 consecutive days from a human serum sample stored at 2^{O}C to 8^{O}C to prepare quality control for serum glucose.

suggests that the sample was stable at −20 °C to −30 °C for at least 30 days (Chart 3).

4. Discussion

Hospital laboratories in developing countries, despite facing challenges like equipment breakdown and standard reagent shortages, receive daily samples and strive to ensure daily accuracy and reliability. Quality control sera, available in various formats and either assayed or unassayed versions, are used to monitor the precision of chemistry assays and instruments at two or three concentrations [4].

The study examined how different storage conditions affected the linearity of daily new (not returned to the store after a run) and in-out runs (returned to the store after a run). The results showed that the coefficient of variation for the new run per day and the in-out run per day varied depending on the storage conditions. For sera stored at room temperature, the coefficient of variation for the new run per day was 8.3, and for the in-out run per day, it was 8.88. For sera stored at 2–8 °C, the coefficient of variation for the new run per day was 4.6, and for the in-out run per day, it was 5.6. Finally, for sera stored at −20 to −30 °C, the coefficient of variation for the new run per day was 4.0, and for the in-out run per day, it was 5.1. These differences in coefficient of variation were found to be statistically significant ($p < 0.05$).

The findings suggest that the in-out run, which involves multiple testing cycles within a day, exhibited more variability compared to the daily new run, which involves testing a fresh sample each day. This implies that performing daily new runs is more effective in

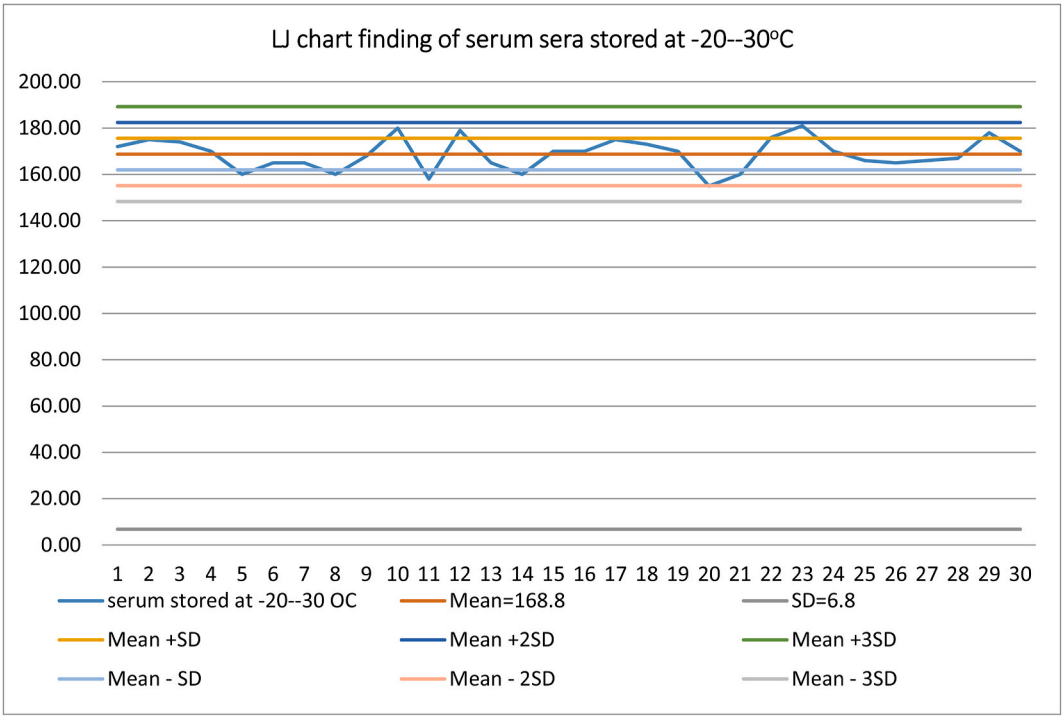

Chart 3. Levey-Jennings (LJ) chart finding for glucose analyzed for 30 consecutive days from a human serum sample stored at -20^{O}C to -30^{O}C to prepare quality control for serum glucose.

controlling the performance of the testing machine, ensuring consistent and reliable results. Overall, the study found that the storage conditions of sera influenced the linearity of daily new runs and in-out runs, with the in-out run showing more variability. Performing daily new runs was identified as a more effective approach for monitoring and maintaining the performance of the testing machine.

This study demonstrated significant stability in in-house quality control material stored at −20 °C to −30 °C over eight months, evidenced by consistently lower variability in glucose measurements compared to other storage temperatures. These findings align with previously published data by Sweta et al. [27], Eliezer et al. [28], Andrea et al. [29], and Berhanu et al. [30], solidifying the potential of frozen storage for maintaining QC material integrity. The use of in-house pooled serum, prepared separately, has been identified as a viable alternative to conventional control materials in developing countries. By utilizing in-house quality control materials, laboratory services in developing countries can maintain the quality and accuracy of their testing processes.

Furthermore, daily analysis of the samples revealed a higher rate of variability among sera stored at room temperature and 2–8 °C compared to those stored at −20 to −30 °C. This suggests that utilizing in-house quality control materials is preferable for effectively monitoring and controlling the performance of testing machines. By implementing in-house control materials, laboratories can mitigate the variations introduced by different storage conditions and ensure the accuracy and reliability of their testing procedures.

The study analyzed valves and found that all valves were within the 95% confidence interval, indicating no significant variation between individual measurements. The Levey-Jennings (LJ) chart indicated that sara stored at both 2–8 °C and −20 to −30 °C exhibited a narrower coefficient of variation. So can be used as glucose control material for up to 8 months without significant changes in glucose concentration. This narrower variation enhances the detection of errors, particularly within pathological ranges. These findings suggest that storing pooled serum samples for glucose analysis at room temperature for up to 30 days is a viable option. The evidence of stability over this time frame supports the use of room-temperature storage as a convenient and reliable method for maintaining the quality of pooled serum samples designated for glucose analysis. Consequently, in-house quality control using human serum can be considered a suitable substitute for commercially prepared serum in laboratory settings. The use of in-house quality control sera can enhance error detection and serve as a suitable substitute for commercially prepared serum in laboratory settings.

These findings demonstrate the potential of in-house human serum as a cost-effective and reliable alternative to commercially prepared control sera for glucose measurements. Its stability at room temperature and superior error detection capabilities suggest its potential application in various laboratory settings. Further research investigating cost-effectiveness and implementation strategies in diverse settings could solidify its role as a valuable tool for improving laboratory efficiency and accuracy in resource-limited environments.

4.1. Limitations of the study

The study's findings offer a promising solution for resource-limited settings, but there are several important limitations to consider.

These include the limited generalizability to other healthcare settings, the need for longer-term stability assessment, the necessity for detailed cost analysis, the exploration of implementation challenges, and the evaluation of the in-house quality control material's effectiveness across different glucose ranges. Addressing these limitations in future research will strengthen the foundation for implementing cost-effective, in-house quality control in resource-limited settings for hyperglycemic glucose monitoring.

5. Conclusion

The findings of this study support the use of cost-effective in-house human serum as a viable option for hyperglycemic glucose quality control in resource-limited settings. We have successfully demonstrated the feasibility and potential benefits of this approach, drawing the following key conclusions.

- **Financial Sustainability:** Our method utilizes readily available resources like human serum, significantly reducing dependence on expensive commercially prepared QC materials. This can translate to substantial cost savings, particularly in regions with limited financial resources for healthcare.
- **Performance and Reliability:** The in-house QC material exhibited comparable performance to commercially available options, demonstrating stability and accuracy in hyperglycemic glucose measurements. This ensures reliable monitoring of instrument and assay performance, even in challenging environments.
- **Enhanced Error Detection:** Compared to commercially available controls, our in-house QC material yielded a narrower coefficient of variation, indicating its superior sensitivity for detecting errors within clinically relevant ranges. This can contribute to improved patient care by ensuring the accuracy of hyperglycemia diagnoses and treatment decisions.
- **Practical Implementation:** The straightforward preparation and storage procedures associated with our method are well-suited for resource-limited settings. Additionally, the use of locally sourced human serum reduces reliance on complex import and supply chains, enhancing accessibility and sustainability.

The study demonstrates the potential of in-house human serum as a cost-effective, reliable, and sustainable alternative for glucose QC in resource-limited settings.

5.1. Recommendation

Based on the findings of this study, the implementation of cost-effective in-house human serum for glucose quality control in resource-limited settings is recommended. This recommendation is supported by several factors.

- Firstly, in-house human serum offers a cost-effective alternative to commercially prepared control materials. By utilizing locally available resources and simple production methods, laboratories can significantly reduce expenses associated with quality control practices. This cost-effectiveness is particularly beneficial for resource-limited settings where financial constraints may limit access to commercial control materials.
- Secondly, the study found that in-house human serum provides consistent and accurate glucose measurements, ensuring accurate diagnosis and monitoring of hyperglycemia, compared to commercially prepared control materials.
- Additionally, the narrower coefficient of variation observed in the in-house human serum enhances error detection. This increased sensitivity enables laboratories to identify and correct potential errors, leading to improved accuracy and precision in glucose measurements. By using in-house human serum, laboratories can improve the reliability of their testing procedures.
- Furthermore, implementing in-house quality control promotes local production and self-sustainability in resource-limited settings. By utilizing locally available resources and expertise, laboratories can reduce dependence on external suppliers and ensure a continuous supply of control materials. This not only enhances the laboratory's autonomy but also contributes to the development of local scientific capacity and expertise.
- Despite these recommendations, the study highlights the need for further research, external validation, and long-term stability assessments to ensure the effectiveness and reliability of in-house quality control human serum.

Ethics approval and consent to participate

The study was conducted after obtaining ethical approval from the Research and Ethics Institutional Review Board of Debre Markos University College of Health Science (*Reference No. HSC/R/C/Ser/co/316/11/21) on* August 18, 2022. Written informed consent was obtained from all participants before data collection. Participants were also informed that all data obtained from them would be kept confidential using codes rather than any personal identifiers.

Consent for publication

Written informed consent was obtained from the patient for publication of this case report. A copy of the written consent is available for review by the editor-in-chief of this journal on request.

Availability of data and materials

The datasets are accessible to the corresponding author upon request.

Authors' disclosures or potential conflicts of interest

No authors declared any potential conflicts of interest.

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CRediT authorship contribution statement

Haymanot Tewabe: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Asaye Mitiku:** Writing – original draft, Visualization, Validation, Software, Project administration, Investigation, Formal analysis, Data curation, Conceptualization. **Abebe Yenesew:** Writing – review & editing, Visualization, Validation, Software, Methodology, Investigation, Formal analysis, Data curation.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

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We would like to express our gratitude to all study participants for their willingness to participate.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.plabm.2024.e00377.

References

[1] G. Anido, Quality Control: Preparation of Quality Control Materials in Clinical Chemistry and Haematology, SAGE Publications, 1975.
[2] G.J. Proksch, D.P. Bonderman, Preparation of optically clear lyophilized human serum for use in preparing control material 22 (4) (1976) 456–460.
[3] S. Wood, A.J.A. Botha, Q. Assurance, The new ISO Guide 80: guidance for the in-house preparation of quality control materials (qcms) 19 (6) (2014) 477–480.
[4] M.N. Zafar, S. Syed, Economy and quality assessment of home made clinical chemistry reagents 42 (4) (1992) 95–97.
[5] M. Aydos, et al., Laboratory data quality control: a new cost-effective approach 51 (5–6) (2018) 160–171.
[6] P. Hyltoft Petersen, et al., Proposed Guidelines for the Internal Quality Control of Analytical Results in the Medical Laboratory, 1996.
[7] G.S. Cembrowski, R.N. Carey, Laboratory Quality Management: QC [and] QA, Amer Society of Clinical, 1989.
[8] M.N. Zafar, S. Syed, Economy and quality assessment of home made clinical chemistry reagents, JPMA. The Journal of the Pakistan Medical Association 42 (4) (1992) 95–97.
[9] S. Wood, A. Botha, The new ISO Guide 80: guidance for the in-house preparation of quality control materials (qcms), Accred Qual. Assur. 19 (2014) 477–480.
[10] I.M. Weisbrot, Statistics for the Clinical Laboratory, Lippincott Williams & Wilkins, 1985.
[11] J.O. Westgard, Quality Planning and Control Strategies, 2001.
[12] P.J. Howanitz, J.H. Howanitz, Laboratory Quality Assurance, mcgraw-Hill Professional Publishing, 1987.
[13] K.F. Lauer, Reference materials and methods in clinical chemistry 12 (1974) 558–574.
[14] H.H. Ku, Final measurement results: reprints, in: Advanced Mass Measurements Workshop, 1992.
[15] J.O. Westgard, et al., A multi-rule Shewhart chart for quality control in clinical chemistry 27 (3) (1981) 493–501.
[16] J. Westgard, et al., Combined Shewhart-cusum control chart for improved quality control in clinical chemistry 23 (10) (1977) 1881–1887.
[17] R. Agarwal, Quality-improvement measures as effective ways of preventing laboratory errors, Lab. Med. 45 (2) (2014) E80–e88.
[18] H. Holt, D.B. Freedman, Internal quality control in point-of-care testing: where's the evidence? Ann. Clin. Biochem. 53 (2) (2016) 233–239.
[19] T. Aronsson, C.-H. De Verdier, T.J.C.C. Groth, Factors influencing the quality of analytical methods—a systems analysis, with use of computer simulation 20 (7) (1974) 738–748.
[20] W.H. Organization, Laboratory Design and Maintenance, 2020.
[21] W.H. Organization, Laboratory Biosafety Manual, World Health Organization, 2020.
[22] Guide, R.I., Guidance for the In-House Preparation of Quality Control Materials (Qcms).
[23] P.H. Petersen, et al., Proposed guidelines for the internal quality control of analytical results in the medical laboratory 34 (12) (1996) 983–1000.

[24] J.-C. Libeer, Good medical laboratory services—guidelines, in: Laboratory Techniques in Thrombosis—A Manual, Springer, 1999, pp. 9–19.
[25] D. Mok, E. Ang, ISO 15189: 2012 implementation: an update of related international standards and guidance documents for medical laboratory quality management, N. Z. J. Med. Lab. Sci. 70 (2) (2016) 42–66.
[26] M.H. Thelen, et al., Flexible Scope for ISO 15189 Accreditation: a Guidance Prepared by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group Accreditation and ISO/CEN Standards (WG-A/ISO), vol. 53, 2015, pp. 1173–1180, 8.
[27] S. Kulkarni, S.A. Pierre, R. Kaliaperumal, Efficacy of pooled serum internal quality control in comparison with commercial internal quality control in clinical biochemistry laboratory, J. Lab. Phys. 12 (3) (2020) 191–195.
[28] Togbe, E., Assessment of Bovine Serum as an Internal Quality Control Material in a Clinical Chemistry Laboratory Set-Up at the Komfo Anokye Teaching Hospital in Ghana.
[29] A. Padoan, et al., An approach for estimating measurement uncertainty in medical laboratories using data from long-term quality control and external quality assessment schemes, Clin. Chem. Lab. Med. 55 (11) (2017) 1696–1701.
[30] B. Haile, et al., Preparation of in-house quality control human serum for urea and its use in clinical chemistry, Clin. Lab. 66 (3) (2020).