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(RESEARCH ARTICLE)

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Verification of the analytical performance of the serum glucose assay on the Abbott Alinity ci®

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Abstract

The precision and reliability of the serum glucose assay on the Abbott Alinity ci® analyzer were systematically evaluated. The study was conducted over 30 days in the biochemistry laboratory of Mohammed VI University Hospital. Two phases were carried out: reproducibility assessment involving daily measurements across low, medium, and high glucose levels, and repeatability testing involving 30 replicates per sample. The hexokinase enzymatic approach was employed for glucose quantification. Data analysis utilized the BYG middleware and complied with FSCB and RICOS standards. For reproducibility, the coefficient of variation (CV) values were low, ranging from 1.49% to 1.84%. Repeatability CV values were even lower, varying from 0.34% to 0.94%. Results aligned well with quality control limits, confirming the assay's consistency and precision. This study underscores the robustness and reliability of the hexokinase method on the Alinity ci® platform for serum glucose analysis, with implications for accurate patient care. By adhering to strict analytical performance verification, laboratories ensure dependable clinical outcomes. This research contributes to the foundation of knowledge supporting serum glucose measurement reliability.

Keywords: Serum glucose assay; Abbott Alinity ci analyzer; Precision; Reliability; Biochemistry laboratory; Mohammed VI University Hospital; Reproducibility assessment; Repeatability testing; Hexokinase enzymatic method

1. Introduction

The field of clinical diagnostics stands at the crossroads of precision and innovation, where advancements in analytical methodologies converge with the critical need for accurate patient assessments. Amidst the multitude of clinical parameters, glucose assumes a paramount role, reflecting not only metabolic status but also acting as a sentinel for various medical conditions. As diagnostic platforms evolve to meet escalating demands, it becomes imperative to rigorously scrutinize the analytical capabilities of assays, particularly with regard to vital analytes like glucose, employing methods of proven accuracy such as the hexokinase enzymatic approach.

Glucose, a central carbohydrate metabolite, orchestrates a wide array of physiological processes, from energy provision to signaling cascades that underpin cellular function. Its quantification not only illuminates the intricacies of metabolic pathways but also aids in the identification and monitoring of diabetes mellitus and other metabolic disorders. In this context, the hexokinase method stands as a venerable approach [1], capitalizing on enzymatic specificity to deliver results of high precision and reliability.

The Abbott Alinity ci® Analyzer represents an exemplar of technological advancement in clinical chemistry instrumentation, offering the promise of improved throughput, efficiency, and accuracy. In the pursuit of data-driven diagnostics, it is imperative to rigorously verify the analytical performance of assays within such platforms.

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Analytical method verification is a systematic procedure encompassing the assessment of analytical process capabilities. This involves quantification via a standardized operational protocol [2], followed by a comparative analysis against criteria established by esteemed societies (such as RICOS and FSCB). This methodological evaluation equips laboratories with comprehensive insights into their analysis techniques, performance metrics, and constraints. Of paramount importance is the assurance that these metrics guarantee the dependability of analytical outcomes and foster clinically relevant interpretations for both patients and healthcare providers.

1.1. Principle of the assay method

Glucose is phosphorylated by hexokinase (HK) in the presence of adenosine triphosphate (ATP) and magnesium ions, resulting in the production of glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). Glucose-6-phosphate dehydrogenase (G-6-PDH) specifically oxidizes G-6-P into 6-phosphogluconate, with concurrent reduction of nicotinamide adenine dinucleotide (NAD) to reduced nicotinamide adenine dinucleotide (NADH) [3]. One micromole of NADH is generated for each micromole of consumed glucose. The produced NADH absorbs light at 340 nm, and this increase in absorbance can be detected through spectrophotometry.

2. Material and methods

This prospective study was conducted within the biochemistry laboratory of Mohammed VI University Hospital, spanning a duration of 30 days.

Our study encompassed two distinct phases. The initial phase entailed evaluating reproducibility through daily control measurements across three levels—low, medium, and high—over a span of 30 days to gauge the consistency. In the subsequent phase, we acquired a collection of serum samples characterized by evenly distributed glucose values across the measurement spectrum. These samples were then categorized into three groups based on their glucose levels—low, medium, and high. For each sample, a total of 30 replicates were executed to ascertain repeatability. The analytical procedure was executed employing the Glucose reagent kit on the chemistry module. The data manipulation was facilitated by the BYG middleware, which serves as a bridge between the Alinity platform and the iLab result validation software. The coefficient of variation (CV) values generated through our investigation were subsequently compared to the standards stipulated by respected professional bodies (FSCB and RICOS).Results

3. Results

3.1. Reproducibility results

In the reproducibility test, the same sample is analyzed under varying conditions to assess how factors like operators, time, reagent batches, and calibrations affect the results. The goal is to establish acceptance criteria for priors, especially in decision support systems. The Coefficient of Variation (CV) is used to measure the variability of the results.

-For the low, medium, and high levels, the CV values are provided (CV1 = 1.49%, CV2 = 1.63%, CV3 = 1.84%) These results are illustrated on the Levey-Jennings graphs (Fig. 1, fig. 2, fig. 3).

The argument of the conclusion for each level is that the CV of Reproducibility is correct and falls below the tolerated limit. Additionally, FSBC (a quality control system) and RICOS (a global quality control network) limits with expansion factors are mentioned, and the CV values are compared to these limits (Table. 1).

Table 1 Reproducibility results of blood assay by level with comparison to FSBC and RICOS data (with expansion coefficient k = 1.211)

Level of IQC	Number of values	Mean (g/l)	Standard Deviation	Coefficient of Variation CV (%)	Reference CV: FSBC 1999 (%)	Reference CV: RICOS (%)
Low	30	0.51	0.008	1.49	3.88	3.39
Medium	30	1.31	0.021	1.63	2.91	3.39
High	30	2.99	0.055	1.84	1.94	3.39

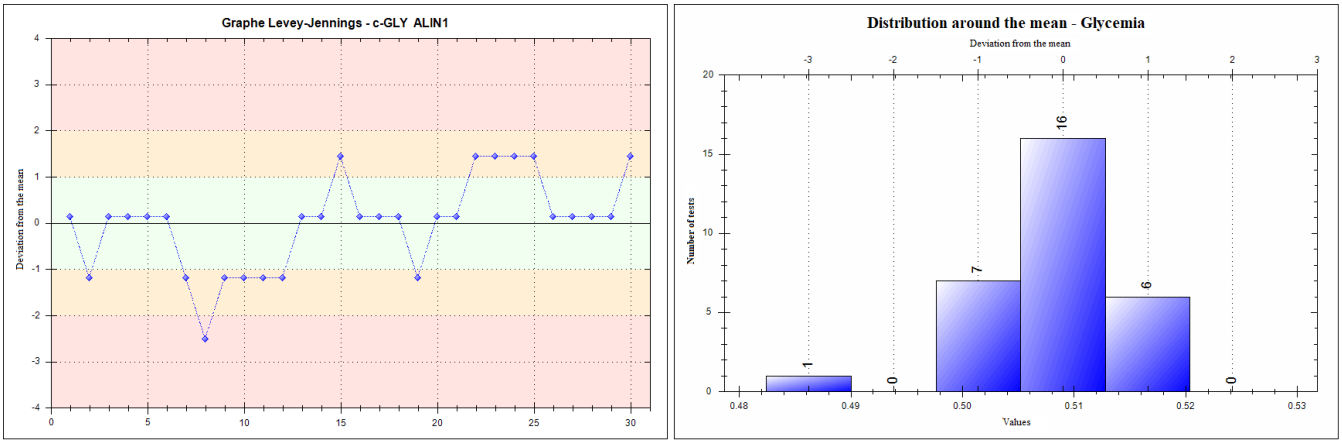

Figure 1 Low Level of Reproducibility: Levey Jennings graph and the distribution around the mean – Glucose

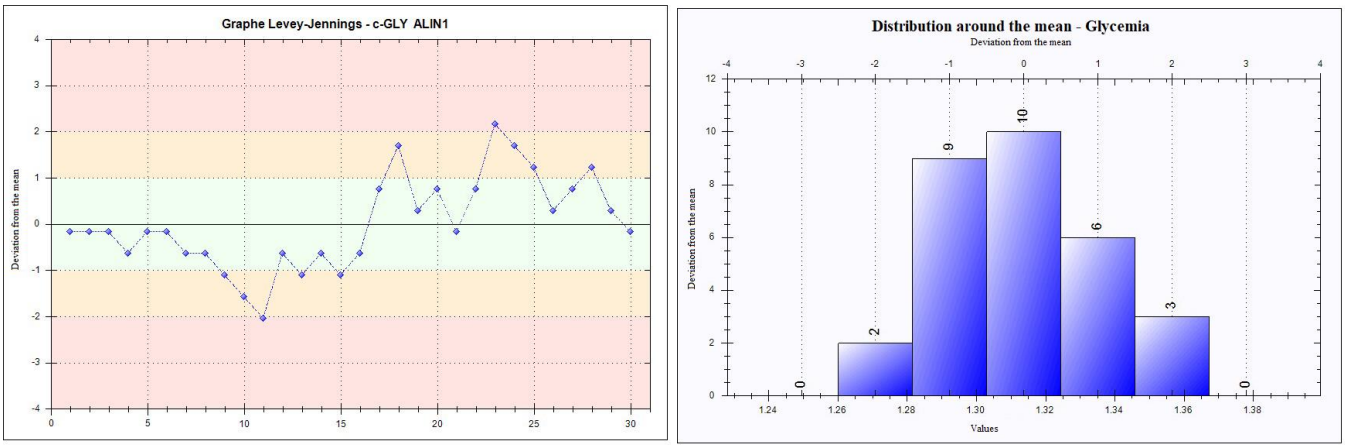

Figure 2 Medium Level of Reproducibility: Levey Jennings graph and the distribution around the mean – Glucose

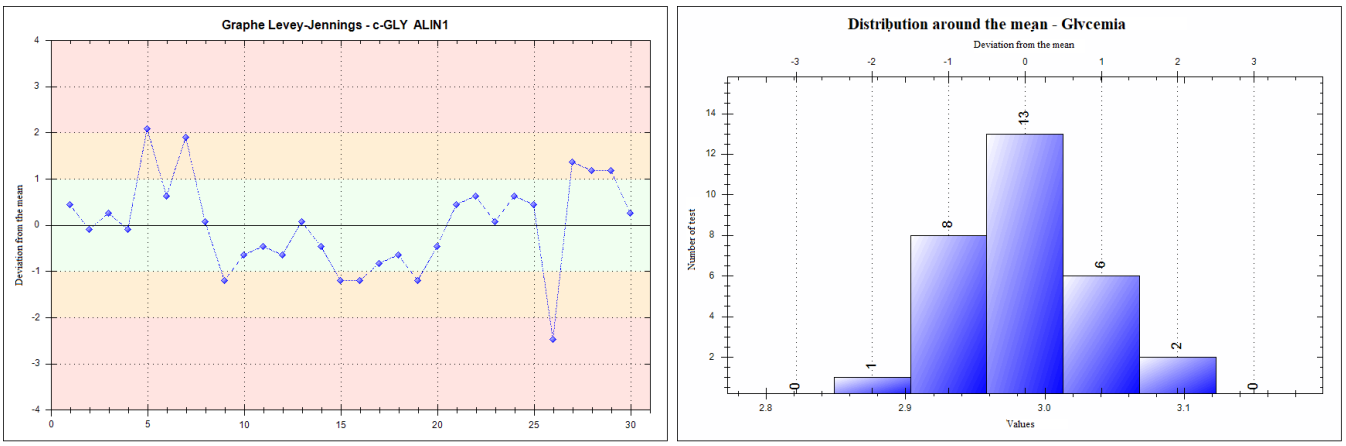

Figure 3 High Level of Reproducibility: Levey Jennings graph and the distribution around the mean – Glucose

3.2. Repeatability Results

The repeatability test involves analyzing the same sample under optimal conditions to assess the system's performance and functionality. CV values are again used to measure variability.

For the low, medium, and high levels, the CV values are provided (CV1 = 0.94%, CV2 = 0.41%, CV3 = 0.34%) These results are illustrated on the Levey-Jennings graphs (Fig. 4, fig. 5, fig. 6)

The argument of the conclusion for each level is that the CV of Repeatability is correct and falls below the tolerated limit.

Similar to the intermediate fidelity results, FSBC and RICOS limits with expansion factors are mentioned, and the CV values are compared to these limits (Table. 2).

Table 2 Repeatability results of blood assay by level with comparison to FSBC and RICOS data (with expansion coefficient k = 1.211)

Level of IQC	Number of values	Mean (g/l)	Standard Deviation	Coefficient of Variation CV (%)	Reference CV: FSBC 1999 (%)	Reference CV: RICOS (%)
Low	30	0.40	0.004	0.94	2.40	2.54
Medium	30	1.06	0.004	0.41	2.18	2.54
High	30	2.87	0.010	0.34	1.45	2.54

In both cases, the conclusion is based on the comparison of CV values to specific tolerance limits. The provided CV values represent the variability observed in the measurements. The fact that the calculated CV values are below the specified limits suggests that the system's reproducibility and repeatability are within an acceptable range.

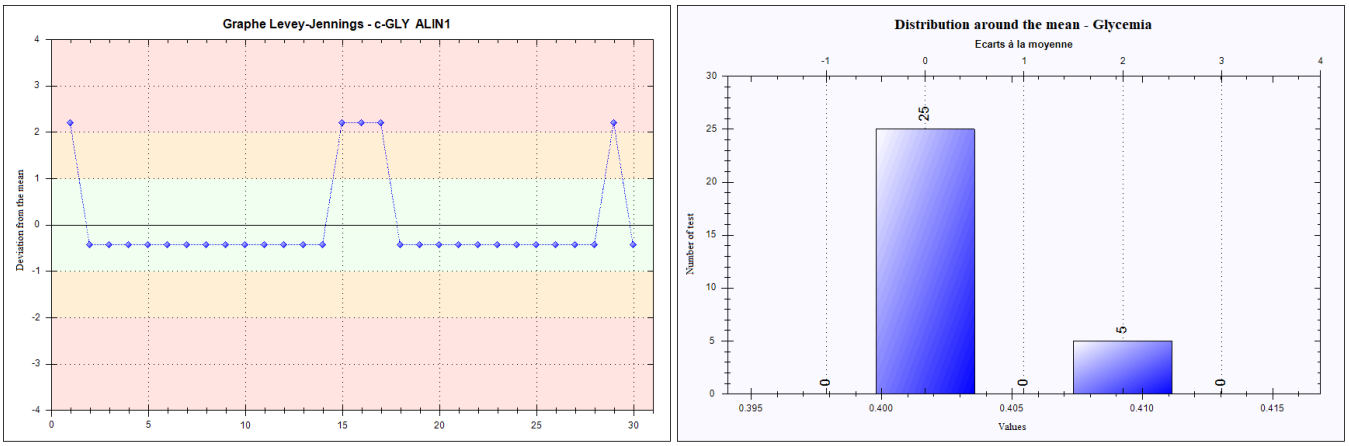

Figure 4 Low Level of Repeatability: Levey Jennings graph and the distribution around the mean – Glucose

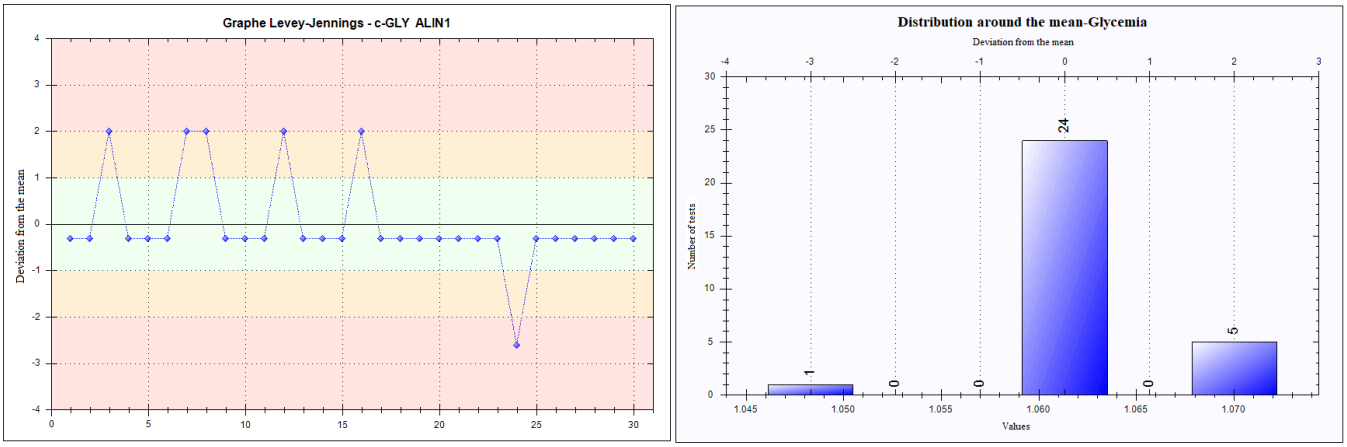

Figure 5 Medium Level of Repeatability: Levey Jennings graph and the distribution around the mean – Glucose

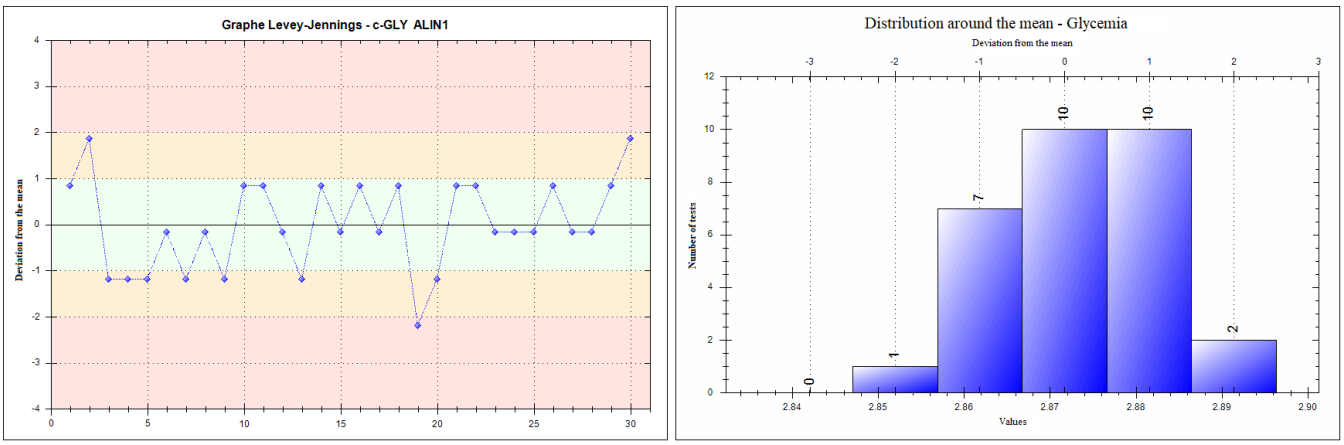

Figure 6 High Level of Repeatability: Levey Jennings graph and the distribution around the mean – Glucose

4. Discussion

In 1995, around 135 million individuals were affected by diabetes, and it was projected that the number of cases would rise by 300 million by the year 2025. By the conclusion of 2012, an estimated 347 million people were living with diabetes, and predictions indicated a potential increase to 552 million cases by 2030. This would constitute approximately 9.9% of the global adult population[4]. Effectively managing this medical condition necessitates a rapid, selective, and accurate measurement of blood glucose levels, whether for diagnosis or monitoring purposes. Numerous techniques for glucose measurement are available, with one of the most widely adopted methods being the enzymatic approach. This method is preferred due to its specificity, reliability, and simplicity in comparison to other methodologies[5]. Several enzymatic methods can be employed, such as glucose oxidase/peroxidase or hexokinase/G6PD.

Mastering the method employed by the biologist in the laboratory is a continuous concern, and its verification/validation is both a regulatory requirement (Moroccan Guide for the Good Performance of Medical Laboratory Analyses) and a normative one (ISO 15189:2012 standard) [6]. By establishing predetermined analytical objectives, this mastery allows for the generation of accurate and dependable results.

The reproducibility test serves as a critical assessment of how consistent the assay's results are when different variables are introduced. This includes variations in operators, time, reagent batches, and calibrations – all factors that can impact the reliability of the results. To quantify this variability, the Coefficient of Variation (CV) is used. The CV provides a percentage measure of how much the results deviate from the mean, indicating the level of dispersion or scatter in the data.

For each of the low, medium, and high levels, the CV values are 1.49%, 1.63%, and 1.84%, respectively. These values are relatively low, which implies that the assay is producing consistent results across different conditions.

The reproducibility results suggest that the enzyme hexokinase method is robust and stable across various conditions. The low CV values indicate that even when different factors are altered, such as the operator or reagent batch, the assay consistently produces results that are close to the mean value. This reliability is crucial in medical testing, where consistency ensures that the test results can be trusted for clinical decisions. The fact that the CV values align with established quality control limits indicates that the assay meets industry standards for reproducibility, reinforcing its suitability for accurate diagnostic use.

The repeatability test focuses on the precision of the assay under controlled and optimal conditions. This is important because it assesses the ability of the method to yield similar results when the same sample is analyzed multiple times.

The CV values for repeatability are remarkably low: CV1 = 0.94%, CV2 = 0.41%, and CV3 = 0.34%. These values indicate an extremely small amount of variability, reaffirming the high precision of the assay.

The repeatability results suggest that the enzyme hexokinase method provides consistent and highly precise measurements when analyzing the same sample multiple times. The exceptionally low CV values emphasize that the assay's outcomes are extremely stable and predictable under controlled conditions. This level of precision is essential in clinical testing, where small variations can have significant implications for patient care. The alignment of the CV values with quality control standards underscores the assay's reliability and suitability for generating repeatable results.

Both the reproducibility and repeatability results collectively reinforce the robustness and reliability of the serum glucose assay using the enzyme hexokinase method. The assay demonstrates low variability and high precision across varying conditions and repeated analyses of the same sample. These qualities are paramount in clinical diagnostics, where accurate and dependable results are crucial for patient care. The comparison to quality control standards provides an objective validation of the assay's performance, reassuring researchers and healthcare professionals that the method produces consistent and trustworthy results. The meticulous evaluation of variability ensures that the assay meets industry standards and can be confidently employed in clinical decision-making processes.

5. Conclusion

In summation, the meticulous evaluation of the analytical performance of the serum glucose assay on Abott Alinity ci using the enzyme hexokinase method unveils its robustness, reliability, and accuracy. The alignment of CV values with quality control standards reinforces the confidence in the assay's consistency. Such dependable performance has substantial implications for healthcare, where the accuracy of diagnostic results directly impacts patient outcomes. This study serves as a testament to the meticulous quality assurance processes implemented in laboratory settings and reaffirms the importance of verifying the analytical performance of clinical assays. Ultimately, this research contributes to the foundation of knowledge that underpins the reliability of serum glucose measurements, supporting clinical practices and patient well-being.

Compliance with ethical standards

Acknowledgments

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Disclosure of conflict of interest

The authors declare no conflict of interest.

Statement of ethical approval

The present research work does not contain any studies performed on animals/humans subjects by any of the authors.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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