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

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Abstract

Background: Accurate determination of serum glucose is essential for the diagnosis and monitoring of diabetes mellitus. In accordance with ISO 15189 requirements, clinical laboratories must verify the analytical performance of measurement procedures prior to routine use.

Objective: To verify the repeatability and reproducibility of the serum glucose assay performed on the Abbott Alinity c® analyzer using an enzymatic hexokinase method.

Methods: A precision verification study was conducted over a 30-day period in the biochemistry laboratory of the Military Hospital of Marrakech. Three levels of commercial quality control materials (low, medium, and high) were analyzed. Repeatability was evaluated by 30 consecutive measurements for each level on the same day, while reproducibility was assessed by daily measurements over 30 days. Mean values, standard deviation (SD), and coefficient of variation (CV) were calculated and compared with recommended acceptance criteria [3–5].

Results: Repeatability CVs were 0.50%, 0.34%, and 0.40% for low, medium, and high control levels, respectively. Reproducibility CVs ranged from 0.96% to 1.27%. All CVs were below the recommended limits.

Conclusion: The serum glucose assay on the Abbott Alinity c® analyzer demonstrates excellent analytical precision and is suitable for routine clinical use.

Keywords: Glucose; Analytical performance; Precision; Verification; Abbott Alinity c®; Clinical chemistry

1. Introduction

Serum glucose measurement plays a central role in the diagnosis, monitoring, and management of diabetes mellitus and other disorders of carbohydrate metabolism. Due to the significant clinical impact of glucose results, analytical reliability is essential to ensure appropriate patient care [3,5].

International standards, including ISO 15189 [2] and guidelines from the Clinical and Laboratory Standards Institute (CLSI) [1], require medical laboratories to verify the analytical performance of measurement procedures prior to routine implementation, even when using manufacturer-validated assays [3].

Among analytical performance characteristics, precision—expressed as repeatability and reproducibility—is a key indicator of the reliability and stability of an analytical system. The Abbott Alinity c® analyzer is a fully automated

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clinical chemistry platform widely used in routine laboratories and employs an enzymatic hexokinase method for glucose determination.

The objective of this study was to verify the repeatability and reproducibility of the serum glucose assay on the Abbott Alinity c® analyzer under routine laboratory conditions [2,5].

2. Materials and Methods

2.1. Study design and setting

This analytical verification study was carried out in the biochemistry laboratory of the Military Hospital of Marrakech over a period of 30 days.

2.2. Analytical system

Serum glucose measurements were performed using the Abbott Alinity c® analyzer (Abbott Diagnostics, USA). The assay is based on an enzymatic hexokinase method, which is considered the reference method for glucose determination.

2.3. Principle of the method

The glucose assay is based on a two-step enzymatic reaction. In the first step, glucose is phosphorylated to glucose-6-phosphate (G-6-P) by hexokinase in the presence of adenosine triphosphate (ATP) and magnesium ions (Mg^{2+}), ensuring high specificity for glucose. In the second step, glucose-6-phosphate dehydrogenase catalyzes the oxidation of G-6-P to 6-phosphogluconate with the concomitant reduction of nicotinamide adenine dinucleotide (NAD^{+}) to NADH. The increase in absorbance due to NADH formation is measured spectrophotometrically at a wavelength of 340 nm and is directly proportional to the glucose concentration in the sample.

2.4. Quality control materials

Three levels of commercial quality control materials specific to glucose were used:

- Low level
- Medium level
- High level

2.5. Precision study protocol

The method verification was conducted in accordance with ISO 15189 [2] requirements and the COFRAC technical guide GTA 04.

- **Repeatability (within-run precision):** Each control level was analyzed 30 consecutive times under identical analytical conditions on the same day.
- **Reproducibility (between-run precision):** Each control level was analyzed once daily over a 30-day period.

2.6. Statistical analysis

For each control level, mean, standard deviation (SD), and coefficient of variation (CV) were calculated using EVM statistical software (BYG Informatics). The obtained CVs were compared with acceptable performance criteria recommended by the French Society of Clinical Biology (SFBC) and the Ricos biological variation database. [3]

3. Results

3.1. Repeatability

Repeatability results for the serum glucose assay performed on the Abbott Alinity c® analyzer are presented in **Table 1**. The coefficient of variation (CV) values ranged from **0.34% to 0.50%** across the three control levels. All repeatability CVs were well below the acceptable limits recommended by the French Society of Clinical Biology (SFBC) [5].

Table 1 Repeatability of serum glucose assay on Abbott Alinity c®

Control level	Number of values	Mean (mmol/L)	Standard Deviation (mmol/L)	Coefficient of Variation (CV) (%)	CV(%) (SFBC)	CV(%) (RICOS)
Low	30	2.97	0.015	0.50	2.4	2.54
Medium	30	6.23	0.021	0.34	1.8	2.54
High	30	19.47	0.077	0.40	1.2	2.54

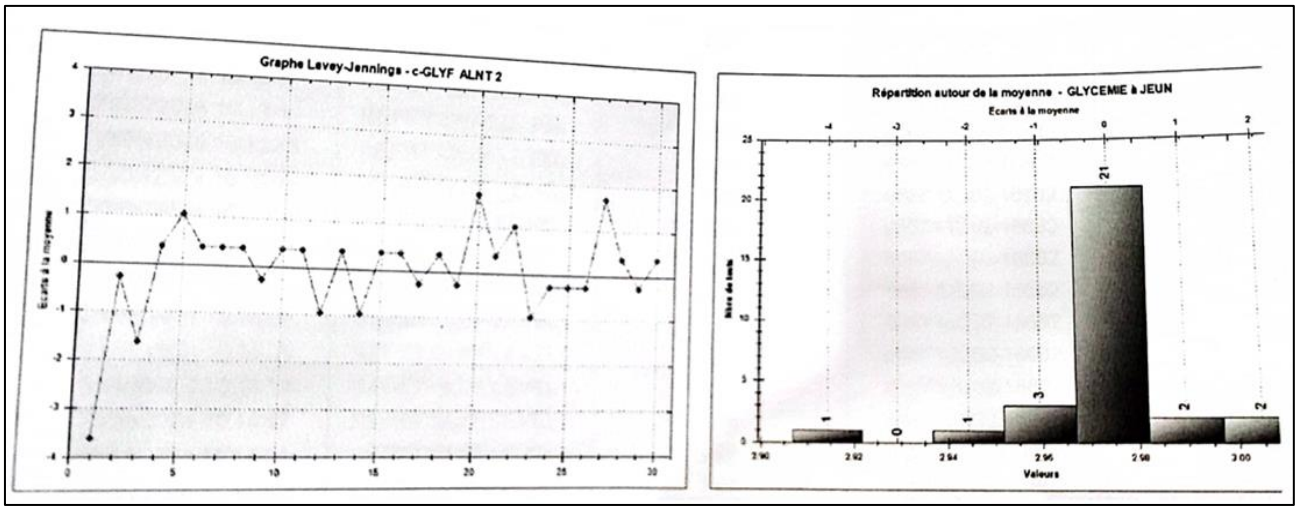

Figure 1 Low level of repeatability: Levey-Jenning graph and the distribution around the mean

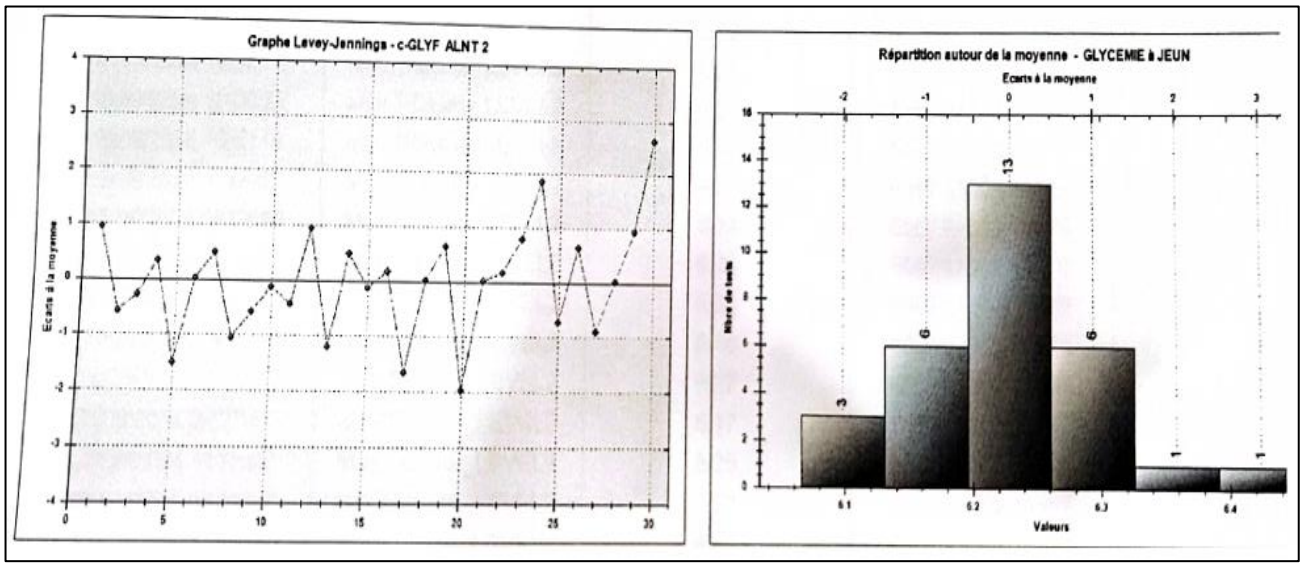

Figure 2 Medium level of repeatability: Levey-Jenning graph and the distribution around the mean

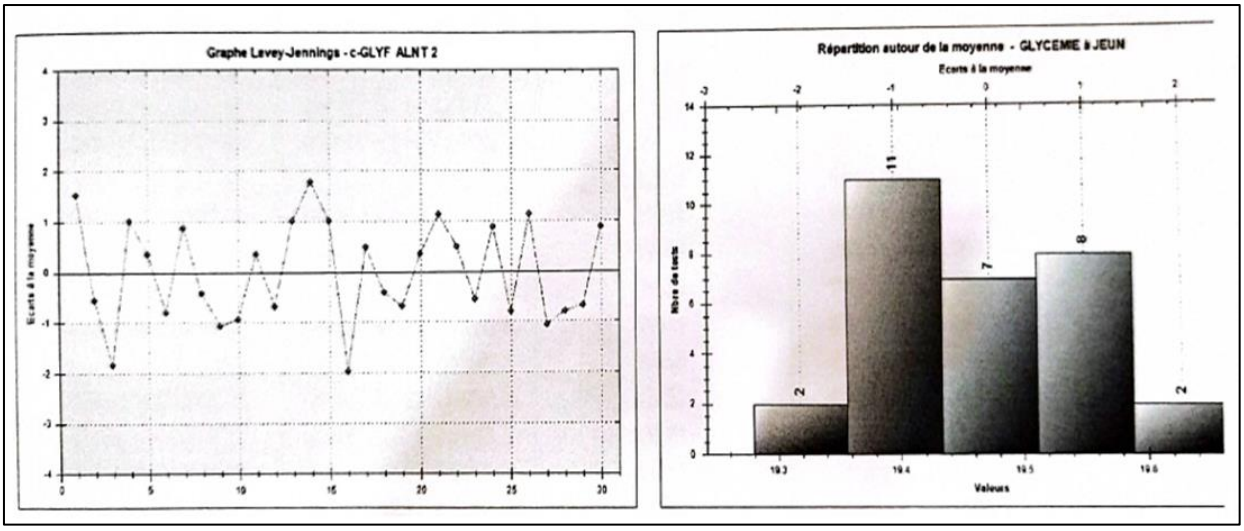

Figure 3 High level of repeatability : Levey-Jenning graph and the distribution around the mean

3.2. Reproducibility

Reproducibility results are summarized in Table 2. CV values ranged from 0.96% to 1.27%, remaining below the recommended acceptance criteria.

Table 2 Reproducibility of serum glucose assay on Abbott Alinity c®

Control level	Number of values	Mean (mmol/L)	Standard Deviation (mmol/L)	CV (%)	CV(%) (SFBC)	CV(%) (RICOS)
Low	30	2.97	0.038	1.27	3.2	3.39
Medium	30	6.23	0.065	1.05	2.4	3.39
High	22	19.34	0.186	0.96	1.6	3.39

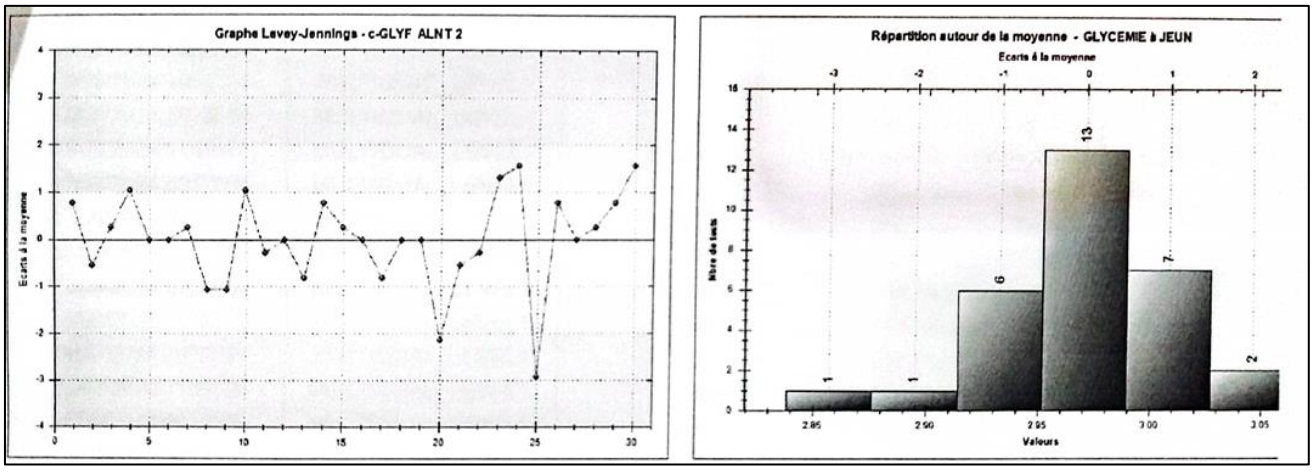

Figure 4 Low level of reproducibility: Levey-Jenning graph and the distribution around the mean

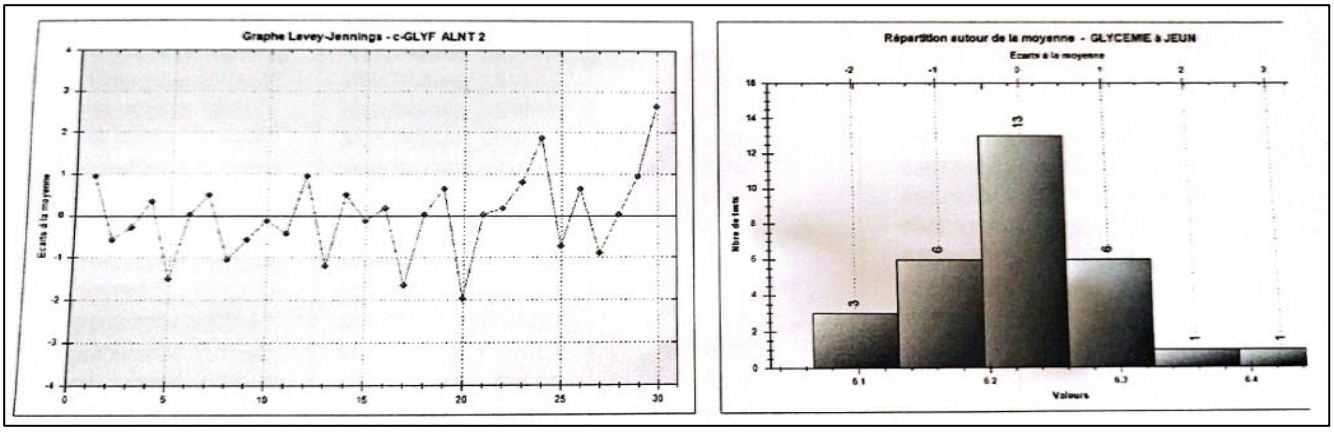

Figure 5 Medium level of reproducibility: Levey-Jenning graph and the distribution around the mean

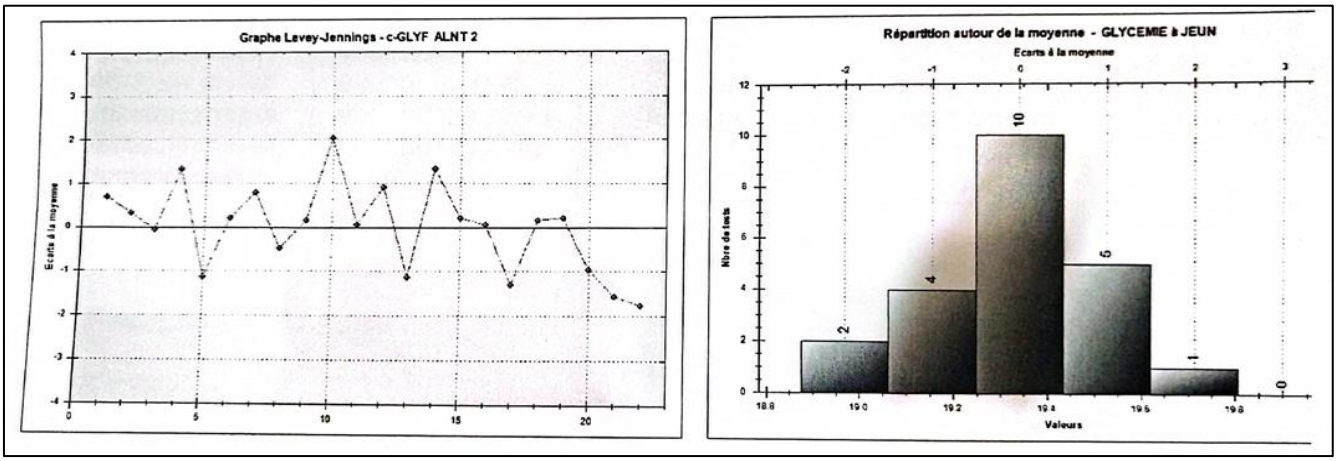

Figure 6 High level of reproducibility: Levey-Jenning graph and the distribution around the mean

4. Discussion

The verification of analytical precision is a fundamental requirement to ensure the reliability of laboratory results. In this study, both repeatability and reproducibility of the serum glucose assay on the Abbott Alinity c® analyzer demonstrated excellent analytical performance.

Repeatability CVs were markedly lower than the acceptance limits recommended by scientific societies, reflecting high within-run stability of the analytical system [1,5]. Reproducibility CVs obtained over a 30-day period confirmed the robustness and consistency of the assay under routine laboratory conditions [1,2,4].

These findings are consistent with previously published data on hexokinase-based glucose assays, which are known for their high specificity and low analytical imprecision [3,4].The evaluation of three clinically relevant concentration levels further supports the applicability of this assay across the analytical measurement range encountered in routine practice.

A limitation of this study is that only precision parameters were evaluated. Additional studies assessing accuracy, linearity, and method comparison would provide a more comprehensive analytical validation [2,3].

5. Conclusion

The serum glucose assay performed on the Abbott Alinity c® analyzer using an enzymatic hexokinase method demonstrates excellent repeatability and reproducibility. All precision parameters met the recommended acceptance criteria, confirming that the assay is suitable for routine clinical use in compliance with ISO 15189 requirements [2].

Compliance with ethical standards

Acknowledgments

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Disclosure of conflict of interest

The authors declare that they have no conflict of interest.

Statement of ethical approval

This study does not involve any experiments on human participants or animals. Therefore, approval from an ethics committee was not required.

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