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(RESEARCH ARTICLE)

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Verification of analytical performance of glycosuria assay on the Abbott Architect® analyzer: Experience of the Biochemistry Laboratory, Mohammed VI University Hospital of Oujda

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Abstract

The aim of our study was to evaluate the analytical performance of the glycosuria assay method using the ARCHITECT c Systems automated analyzer in the biochemistry laboratory of the Mohammed VI University Hospital in Oujda.

Glycosuria, defined as the presence of glucose in urine, is a key biomarker in the diagnosis and monitoring of diabetes mellitus, reflecting disturbances in glucose metabolism.

We conducted a performance study of the ARCHITECT c Systems analyzer, focusing on repeatability and reproducibility, in accordance with the COFRAC GTA 04 accreditation technical guide, which aligns with the quality requirements of ISO 15189 standards.

The results of our study demonstrate satisfactory repeatability for two levels of glycosuria (Low, High), with CV1 = 1.70%, CV2 = 1.68%, Similarly, reproducibility was satisfactory with coefficients of variation (CV) for the same levels, showing CV1 = 3.66%, CV2 = 1.55%.

The reliability of our glycosuria assay results is confirmed by the satisfactory analytical performance obtained, which meets the quality standards required for clinical laboratory diagnostics. These findings underline the robustness of the ARCHITECT c Systems analyzer and its compliance with ISO 15189 accreditation criteria.

Keywords: Glycosuria; Verification; Repeatability; Reproducibility; ARCHITECT c Systems; ISO 15189

1. Introduction

Glycosuria, defined as the presence of glucose in urine, is a pivotal parameter for both the screening and monitoring of diabetes mellitus. In healthy individuals, urinary glucose levels typically remain below 0.8 mmol/L, highlighting the significance of sensitive and accurate measurement techniques for timely detection and effective disease management. With the continuous advances in clinical laboratory methodologies, verifying the analytical performance of glycosuria assays has become indispensable for ensuring reliable patient results and guiding therapeutic decisions.

Our study focuses on the method verification of the glycosuria assay performed on the Abbott ARCHITECT® analyzer. This endeavor forms part of a broader quality assurance initiative within the central laboratory of Mohammed VI University Hospital of Oujda, aligning with the stringent requirements outlined by NF EN ISO 15189. Through a systematic evaluation—encompassing analytical performance criteria, standardized operational procedures, and

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alignment with recognized standards—this verification underscores the laboratory's commitment to delivering accurate, reproducible results. Ultimately, such rigorous assessment not only fortifies the accreditation dossier but also enhances the overall quality of care provided to patients.

1.1. Interest of glycosuria determination

Glycosuria refers to the presence of glucose in urine, predominantly influenced by the interplay between blood glucose concentration and the renal threshold for glucose reabsorption. Under normal physiological conditions, the renal tubules efficiently reabsorb nearly all filtered glucose, keeping urinary glucose levels at negligible concentrations (usually below 0.8 mmol/L). Elevated glycosuria may arise from hyperglycemia—as seen in diabetes mellitus—or from a reduced renal threshold, which can occur in certain hereditary or acquired conditions. The hallmark of its clinical relevance lies in its role as a non-invasive indicator of altered glucose homeostasis, often prompting further investigations into possible disturbances in carbohydrate metabolism (1).

Historically, clinicians recognized the diagnostic importance of urine "sweetness" centuries ago, with early methods relying on taste or rudimentary chemical tests. Over time, the advent of more refined analytical techniques—including enzymatic assays and automated platforms—has allowed for heightened sensitivity and specificity in detecting urinary glucose (2). Consequently, glycosuria measurement is routinely incorporated into screening programs for diabetes mellitus, gestational diabetes, and other metabolic disorders. Its clinical significance extends beyond mere diagnosis, as monitoring glycosuria can offer insights into therapeutic efficacy and patient adherence to treatment regimens. With the current emphasis on comprehensive diabetes management, glycosuria assessment remains a foundational tool, reinforcing its enduring relevance in both primary care and specialized settings (3).

1.2. Principle of the glycosuria assay method

This assay typically relies on an enzymatic colorimetric principle to quantify glucose in urine. First, the urine sample is combined with a reagent containing hexokinase and glucose-6-phosphate dehydrogenase (G6PDH). Hexokinase catalyzes the phosphorylation of glucose in the presence of ATP and magnesium ions, producing glucose-6-phosphate (G6P). G6P is then oxidized by G6PDH, resulting in the simultaneous reduction of NAD to NADH. The production of NADH generates a measurable increase in absorbance, which is directly proportional to the urinary glucose concentration. (4)

2. Materials and Methods

This prospective study was carried out in the Biochemistry Laboratory of Mohammed VI University Hospital over a 30-day period, following the guidelines of the French Accreditation Committee's (COFRAC) technical guide GTA 04 (5). The work was divided into two main phases:

- **Phase 1: Reproducibility Assessment**

Control samples at two different glycosuria concentrations (low, high) were analyzed daily over 30 days to evaluate the consistency of the assay.

- **Phase 2: Repeatability Assessment**

A broad collection of urine samples covering a wide spectrum of glycosuria values was assembled and categorized into low and high groups. Each sample was then tested 30 times to determine the assay's repeatability.

All glycosuria measurements were performed using a dedicated reagent kit on the Abbott ARCHITECT® analyzer. Data generated were processed via the BYG middleware, which serves as an interface between the analyzer and the iLab result validation software. The resulting coefficient of variation (CV) values were subsequently compared against performance specifications recommended by established professional bodies, specifically the Federation of Clinical Chemistry and Laboratory Medicine (FSCB).

3. Results

3.1. Repeatability

Repeatability is defined as the analysis of an identical sample under identical conditions, such as the same operator, the same batch of reagents, the same instrument and the same calibration in the shortest possible time [6]. The repeatability results shown in Table 1 show satisfactory repeatability for all two levels (Low; High), as follows: CV1 = 1.70 %, CV2 = 1.68 %.

The coefficients of variation for each level remain lower than the reference values (SFBC).

Table 1 Glucosurie repeatability results on the Abbott ARCHITECT® in comparison with reference values (SFBC)

Level of IQC	Numbers of value	Mean(g/l)	Standard deviation	Coefficient of variation CV (%)	References CV: SFBC (%)
Low	30	0.30	0.005	1.70%	4.50%
High	30	3.56	0.06	1.68%	3.75%

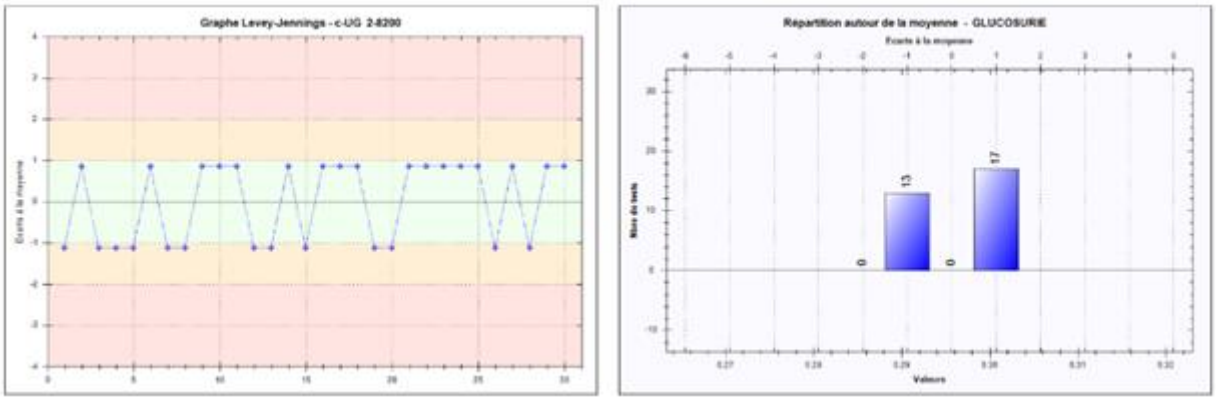

Figure 1 Low level of repeatability: Levey Jennings graph and distribution around the mean

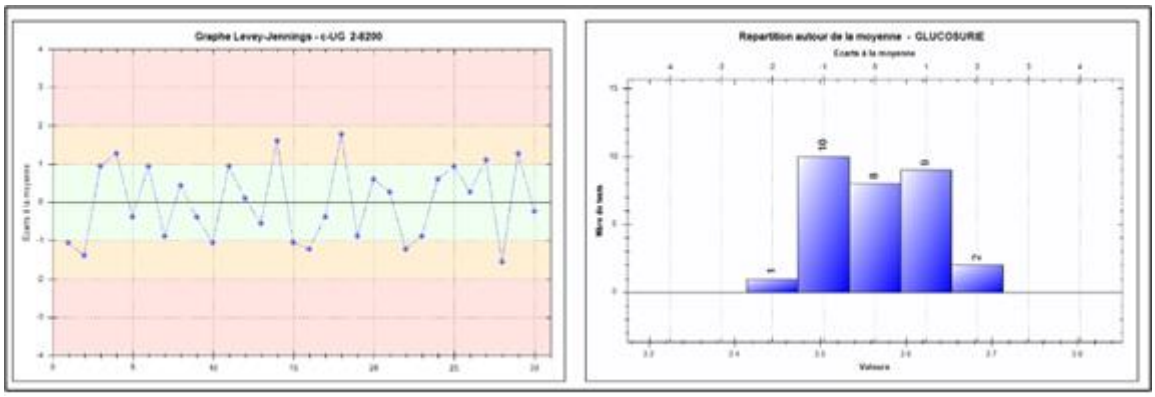

Figure 2 High Level of Repeatability: Levey Jennings graph and the distribution around the mean

3.2. Reproducibility

Reproducibility is also known as the intermediate precision of a method, and is measured to assess the impact of changing factors (operator, time, reagent lots or calibrations) on the results of the assay method [6]. Table 2 shows the

results of satisfactory insulin reproducibility, in relation to the coefficient of variation (CV) in the two levels (Low, High), respectively CV1 = 3.66%, CV2 = 1.55%.

Compared with the reference values set by SFBC, the coefficients of variation for each level remain lower

Table 2 Glucosurie reproducibility results on the Abbott ARCHITECT® in comparison with reference values (SFBC)

Level of IQC	Numbers of value	Mean(g/l)	Standard deviation	Coefficient of variation CV (%)	References CV: SFBC (%)
Low	30	0.30	0.011	3.66%	6.00%
High	30	3.56	0.06	1.55%	5.00%

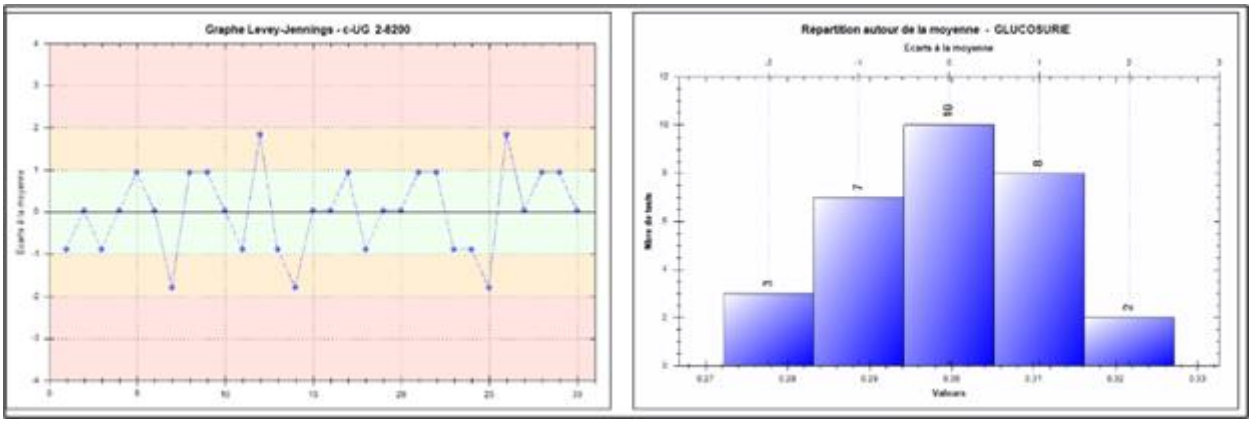

Figure 3 Low level of repeatability: Levey Jennings graph and distribution around the mean

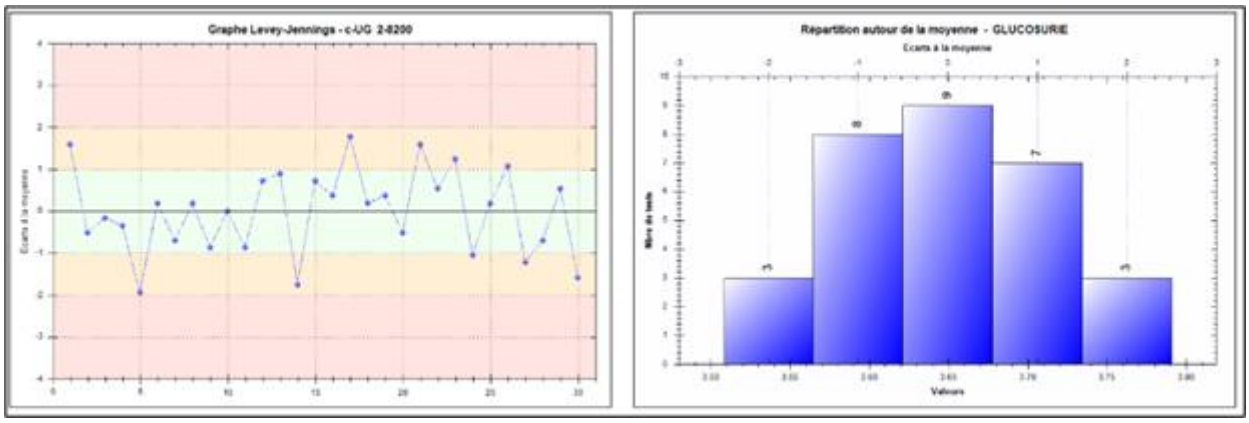

Figure 4 High level of repeatability: Levey Jennings graph and distribution around the mean

The levey-jennings graph of reproducibility and repeatability highlights the precision of the analytical performance of the insulin parameter by showing the dispersion of the set of independent measurements around its central values (figure 2-4).

4. Discussion

Glycosuria, the presence of glucose in urine, is a critical parameter for diagnosing and monitoring metabolic disorders such as diabetes mellitus. Accurate glycosuria assessment is essential for effective clinical decision-making and patient management. In this study, the glycosuria assay was conducted using the enzymatic hexokinase method on the

ARCHITECT c Systems analyzer, as specified by the manufacturer. This method is widely recognized for its precision and reliability in clinical applications.

The enzymatic hexokinase method operates by phosphorylating glucose in the presence of adenosine triphosphate (ATP) and magnesium ions to form glucose-6-phosphate (G6P). G6P is subsequently oxidized to 6-phosphogluconate via glucose-6-phosphate dehydrogenase (G6PDH), resulting in the simultaneous reduction of nicotinamide adenine dinucleotide (NAD) to NADH. The production of NADH is directly proportional to the glucose concentration and is measured photometrically at 340 nm. This reaction ensures high specificity and sensitivity for urinary glucose measurement.

In our analysis, method verification focused on two key performance metrics: repeatability and reproducibility. Repeatability assesses the assay's precision under consistent conditions, while reproducibility evaluates its reliability under variable circumstances, including different operators and reagent batches. The results demonstrated low coefficients of variation (CV), indicating excellent precision and compliance with the analyzer's specifications.

The successful implementation of this method not only confirms its robustness but also aligns with the central laboratory of Mohammed VI University Hospital of Oujda's commitment to quality assurance and patient safety. By adhering to rigorous verification protocols as stipulated by ISO 15189, we ensure that the analytical results are accurate and reliable, supporting clinicians in making informed decisions for patient care. Moreover, this methodology contributes to establishing a solid foundation for accreditation and continuous quality improvement in laboratory practices.

5. Conclusion

In summary, our study thoroughly verifies the analytical performance of the glycosuria assay using the enzymatic hexokinase method on the ARCHITECT c Systems analyzer. The results obtained from this verification demonstrate exceptional precision, consistency, and stability, meeting both the supplier's requirements and ISO 15189 quality standards. This confirms that the method employed by our laboratory is reliable and suitable for clinical diagnostics and decision-making.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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