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(RESEARCH ARTICLE)

Verification of the analytical performance of the urinary creatinine assay on Abbott Architect ci8200

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Abstract

The urinary creatinine assay is a pivotal diagnostic tool for assessing kidney function, hydration status, and muscle metabolism. This study evaluated the analytical performance of the urinary creatinine assay method using an Abbott kit on the Architect ci8200® automated system in the biochemistry laboratory of CHU Mohammed VI, Oujda. Method verification was conducted in two phases: intermediate fidelity testing using internal quality controls and repeatability testing on patient urine samples across low and high creatinine concentration levels.

The results demonstrated excellent analytical performance, with coefficients of variation (CV) for intermediate fidelity (CV1 = 1,95% and CV2 = 1.46%) and repeatability (CV1 = 0.78% and CV2 = 0.87%) well within the limits established by the French Society of Clinical Biology (SFBC). Levey-Jennings charts illustrated consistent and robust performance.

This method also underwent a comparative analysis using the Bland-Altman diagram, which confirmed its accuracy and precision relative to established standards. These findings underscore the reliability of the urinary creatinine assay method, ensuring high-quality diagnostic outcomes.

Keywords: Creatinine urinary; Reproductibility; Repeatability; Quality

1. Introduction

The urinary creatinine assay test is a diagnostic procedure used to measure the concentration of creatinine in a urine sample. Creatinine is a waste product of muscle metabolism, and its excretion is relatively stable under normal physiological conditions. This test plays a crucial role in assessing kidney function, hydration status, and muscle mass [1].

As an analytical process, laboratory method verification involves assessing the performance of a specific method using a standardized protocol. This evaluation is typically guided by criteria established by reputable organizations such as the Reference Institute for Clinical and Healthcare Standards (RICOS) and the Swiss Society of Clinical Chemistry (SFBC) [2][3]. These criteria ensure that the method meets stringent quality and reliability standards for clinical application.

In our work, we wanted to evaluate the analytical performance of the urinary creatinine assay method using an Abbott kit onthe Architect ci8200® automated system in the biochemistry laboratory of the CHU Mohammed VI d'Oujda.

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2. Materials and methods

The study was designed in two distinct phases. Initially, we proceeded with an evaluation of intermediate fidelity test, also known as intra-laboratory reproducibility test by conducting daily internal quality controls with varying concentrations ow and high—over a periodof 30 days. In the second phase, two samples were chosen randomly from the daily patient samples. Each of these samples was then classified into two groups representing low, and high levels of creatinine. To assess repeatability, each urine sample underwent 30 individual assays.

Otherwise, a method comparison was performed between the two automated systems, Architect ci8200®, using the Bland-Altman diagram to illustrate and assess the differences between the results generated by these systems in relation to their respective means.

Urine samples were collected in dry tubes and centrifuged at 4000 rpm for 10 minutes at room temperature.

To ensure the reliability of the findings, the results were compared against the standards established by the French Society of Clinical Biology (SFBC).

3. Results

The intermediate fidelity outcomes were acceptable for the two levels with CV1= 1,95 % and CV2=1,46 % respectively on 30 samples. Comparing these results with the CVs (6.06) adopted by the SFBC, we note that the results are in line with and below the tolerated limits. The graphics presented in the figure 1 and 2 illustrate these results. Levey-Jennings charts were created, providing a clear visualization of the analytical process's consistent and robust performance.

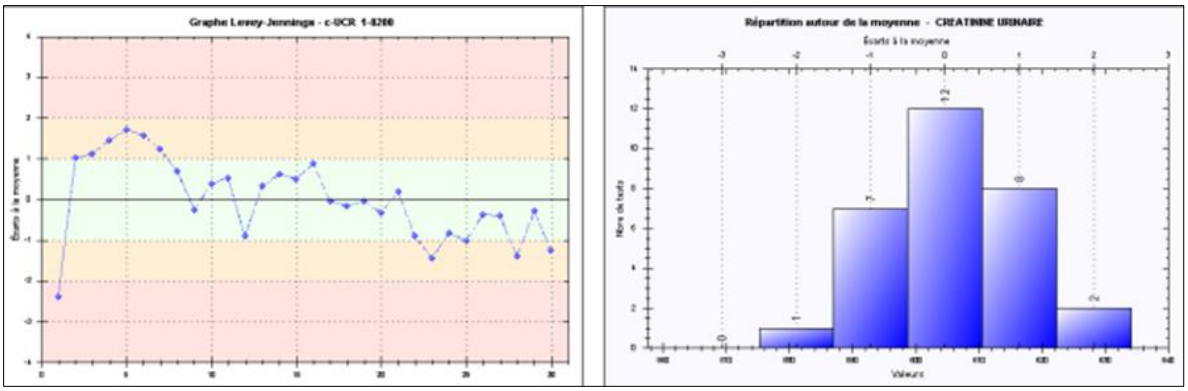

Figure 1 Low Level of Reproducibility: Levey Jennings graph and the distribution around the mean – Urinary Creatinine

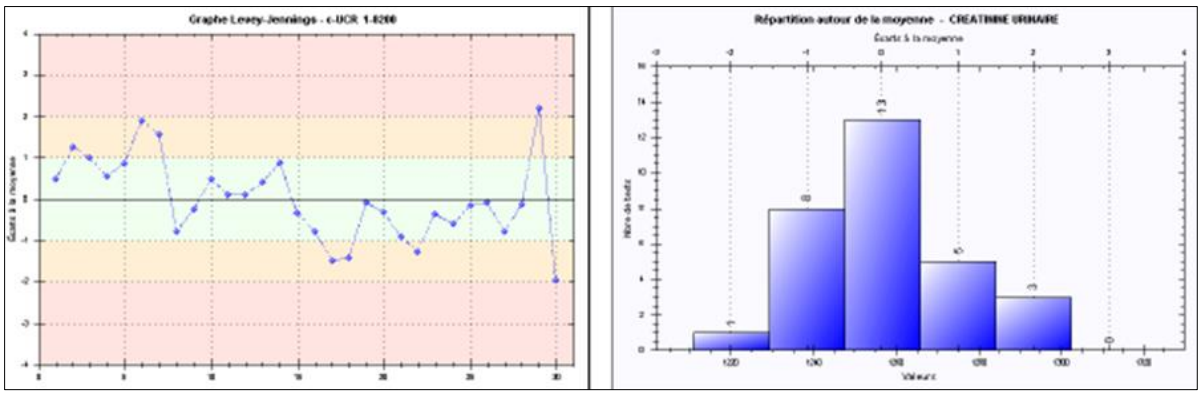

Figure 2 High Level of Reproducibility: Levey Jennings graph and the distribution around the mean – Urinary Creatinine

The repeatability testing results demonstrated excellent performance across the two concentration levels low and high. The coefficient of variation (CV) values obtained were CV1 = 0.78% and CV2 = 0.87 %, respectively, highlighting a high level of precision and reliability of the method across varying concentrations.

To further illustrate these results, Levey-Jennings charts were created, providing a clear visualization of the analytical process's consistent and robust performance. These graphs, presented in Figures 3 and 4, effectively showcase the method's precision and accuracy across the tested concentration ranges.

The repeatability testing also involved a thorough evaluation of the coefficient of variation (CV) at each concentration level. These values were benchmarked against the limits set by the French Society of Clinical Biology (SFBC) and RICOS, (CV = 4.5% for low and high concentrations). This meticulous comparison reaffirms the method's adherence to established standards.

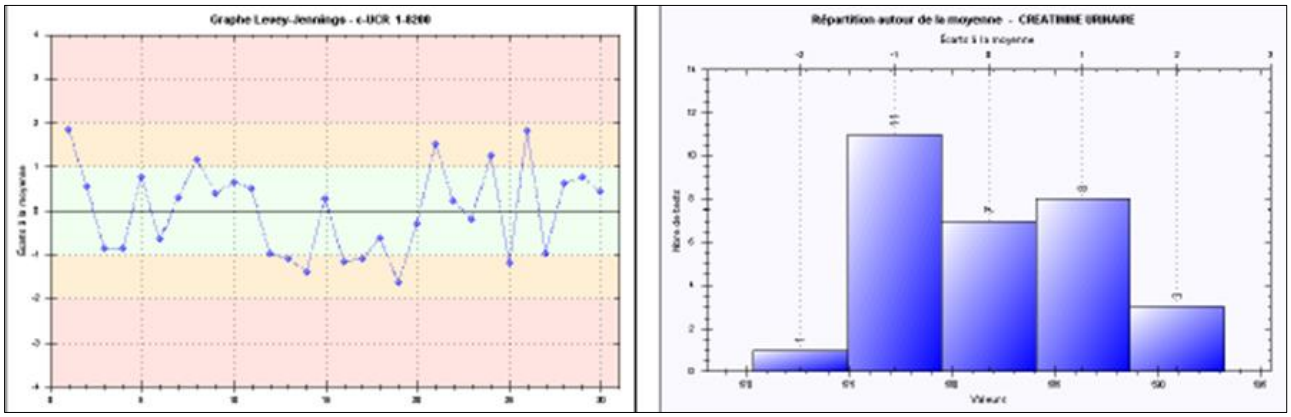

Figure 3 Low Level of Repetability: Levey Jennings graph and the distribution around the mean – Urinary Creatinine

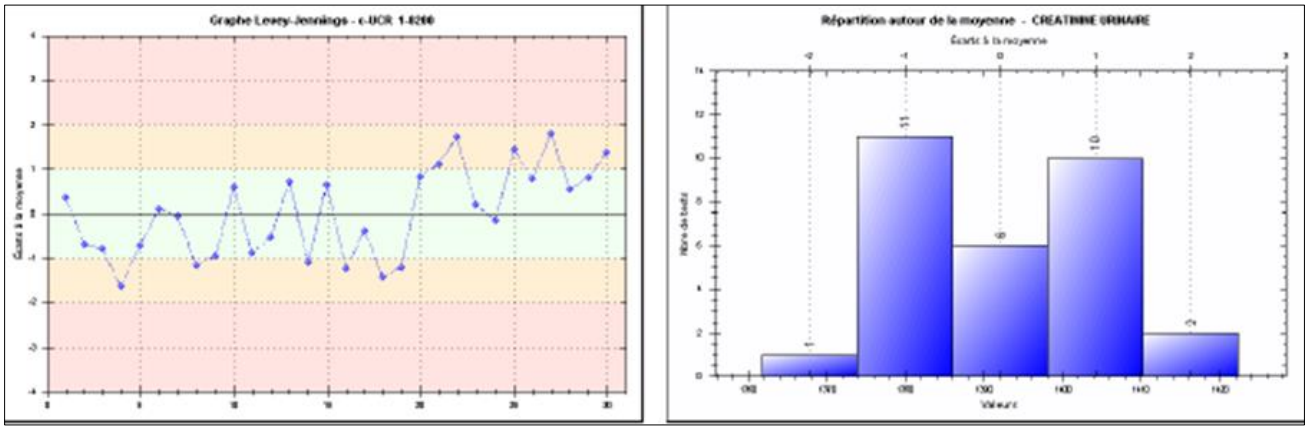

Figure 4 High Level of Repetability: Levey Jennings graph and the distribution around the mean – Urinary Creatinine

4. Discussion

The urinary creatinine test is a fundamental diagnostic tool in clinical laboratories, widely used for evaluating kidney function, hydration status, and muscle metabolism. Creatinine, a byproduct of muscle metabolism, is excreted in urine at a relatively stable rate under normal physiological conditions, making it a reliable marker for assessing renal health [4].

It acts as a reliable indicator of kidney filtration efficiency, aiding in the diagnosis and monitoring of renal disorders such as chronic kidney disease and acute renal failure. Additionally, urinary creatinine levels are crucial for normalizing other urinary analytes, such as in the urine albumin-to-creatinine ratio (ACR), a critical test for detecting kidney damage

and assessing disease progression. Its measurement also plays a role in hydration status evaluation and is integral to toxicology studies, reflecting its broad clinical significance [5].

In clinical practice, urinary creatinine levels are also used to standardize other urinary analytes, ensuring consistency despite variations in urine concentration. This normalization is vital in toxicology, hydration assessment, and other diagnostic applications. Method verification for the urinary creatinine test is essential to ensure accurate, reliable, and reproducible results, as inaccuracies can lead to diagnostic errors and inappropriate treatment decisions [6].

The verification process involves evaluating key analytical performance characteristics, including repeatability, reproducibility, linearity, sensitivity, and specificity. For instance, repeatability ensures that results are consistent under identical testing conditions, while reproducibility assesses reliability across different conditions, such as variations in reagent batches, operators, or equipment settings. These evaluations help maintain compliance with quality standards, such as those outlined in ISO 15189, which is now a requirement for laboratory accreditation [7][8].

At the CHU Mohammed VI in Oujda, the central laboratory has incorporated method verification protocols to uphold high standards of patient care and laboratory service. This quality-driven approach ensures the accuracy of urinary creatinine results, contributing to better diagnostic and therapeutic outcomes for patients [9-14].

5. Conclusion

The urinary creatinine assay method evaluated on the Architect ci8200® system demonstrated excellent precision and reliability, with all coefficients of variation well within accepted standards. These results confirm the method's suitability for clinical use, ensuring accurate and consistent diagnostic outcomes in assessing kidney function and other related parameters. This study highlights the importance of method verification in maintaining high laboratory quality standards and improving patient care.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

Statement of ethical approval

Ethical committee approval was unnecessary due to the nature of the article.

Statement of informed consent

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

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