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(RESEARCH ARTICLE)

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Verification of the analytical performance of the serum phosphorus assay on Abbott Architect ci8200

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Abstract

This study aimed to evaluate the analytical performance of the serum phosphorus assay using the Abbott Architect ci8200® automated system in the biochemistry laboratory of CHU Mohammed VI, Oujda. Method verification was conducted following NF ISO 15189 standards and COFRAC guidelines, assessing key performance parameters such as repeatability, reproducibility, and measurement uncertainty. The colorimetric method for phosphorus determination demonstrated excellent precision, with coefficients of variation (CV) for repeatability ranging from 0.93% to 1.06% across low, medium, and high concentrations. Reproducibility assessments yielded CVs between 2.07% and 2.53%, indicating robust intra-laboratory performance. A comparative analysis between systems using the Bland-Altman method showed strong agreement, with a correlation coefficient of 0.997. Measurement uncertainties at all levels were within acceptable limits. These findings confirm the reliability and accuracy of the assay, highlighting its suitability for clinical diagnostics and its alignment with international accreditation standards.

Keywords: Iso 15189; Method verification; Phosphorus; Architect ci8200; Quality

1. Introduction

As an analytical process, laboratory method verification implies evaluation of performance of that particular process accompanied with the application of a standardized protocol. This evaluation is in practice guided with criteria which are set by reputable bodies like RICOS and SFBC [1][2]. As a result, the laboratories are able to clearly know their analytical methods, the advantages, and the weaknesses. The main objective is to ascertain that the methods employed provide satisfactory levels of performance with respect to obtaining and interpreting clinical and other analytical results and that patients and care providers are most importantly benefited.

Phosphorus is an important mineral in the body, making up around 1-1.4%Trusted Source of fat-free mass. It's a crucial building block of bones, teeth, deoxyribonucleic acid (DNA), ribonucleic acid (RNATrusted Source), as well as certain fats, proteins, and sugars. Additionally, phosphorus is involved in making adenosine triphosphate (ATP)Trusted Source, which is a source of energy for our cells, as well as activating enzymes, maintaining pH balance, and storing energy.[3] [4]

The majority of the body's phosphorus (80 to 85%) is found in the bones in the form of hydroxyapatite. The remaining phosphate is present as inorganic phosphorus and phosphate esters. Serum calcium and phosphorus concentrations are generally interrelated. An increase in serum phosphorus levels can be observed in cases of hypervitaminosis D,

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hypoparathyroidism, and renal failure. Conversely, a decrease in serum phosphorus levels is noted in cases of rickets (vitamin D deficiency), hyperparathyroidism, and Fanconi syndrome [5] [6]

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

2. Material and methods

2.1. C Principe of methods

Inorganic phosphate reacts with ammonium molybdate to form a heteropolyacid complex. The use of a surfactant eliminates the need for preparing a protein-free filtrate. Absorbance at 340 nm is directly proportional to the concentration of inorganic phosphorus in the sample. Any nonspecific absorbance in the sample must be corrected by analyzing sample blanks.

2.2. Verification process

This process evaluates performance parameters such as repeatability and reproducibility, utilizing patient samples from the hospital and internal quality controls.

Subjects were selected randomly as part of the routine workflow. Blood samples were collected in dry tubes and centrifuged at 4000 rpm for 10 minutes at room temperature.

For repeatability, samples were categorized into three groups: low, medium, and high levels. Each sample was analyzed 30 times under identical conditions: the same operator, reagent batch, instrument, and calibration, all on the same day.

Reproducibility was evaluated by analyzing three control levels (low, medium, and high) daily over a 30-day period. Statistical data processing was performed using the EVM intermediate module from BYG Informatics.

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

Additionally, 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.

3. Results

The repeatability testing results demonstrated excellent performance across all three concentration levels—low, medium, and high. The coefficient of variation (CV) values obtained were CV1 = 1.06%, CV2 = 0.93%, and CV3 = 1.03%, 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 1, 2, and 3, 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, incorporating expansion factors (k = 1.211 for low, medium and high concentrations). This meticulous comparison reaffirms the method's adherence to established standards.

Low level:

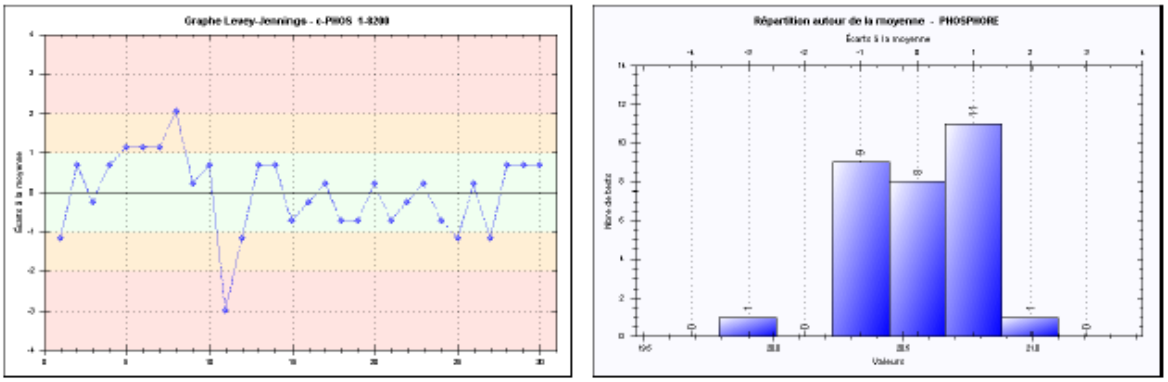

Figure 1 Low level of repeatability: Levey Jennings graph and the distribution around the mean – Phosphorus

Medium level:

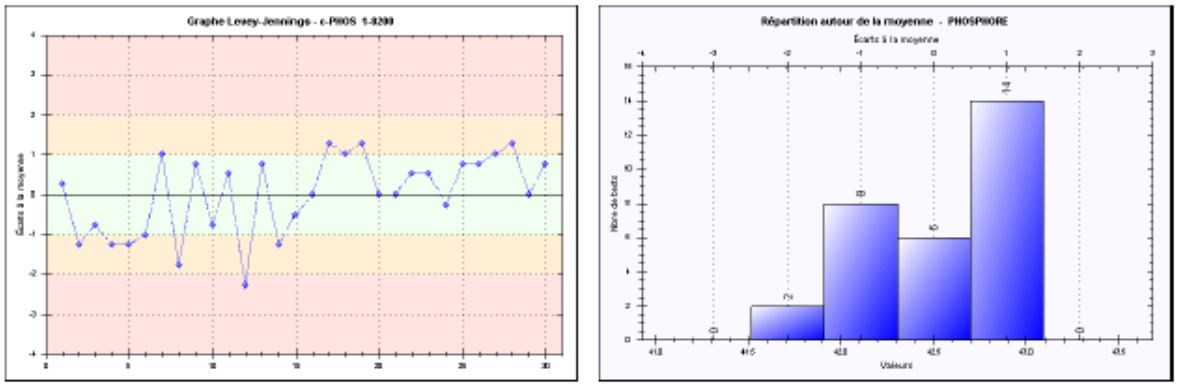

Figure 2 Medium level of repeatability: Levey Jennings graph and the distribution around the mean – Phosphorus

High level:

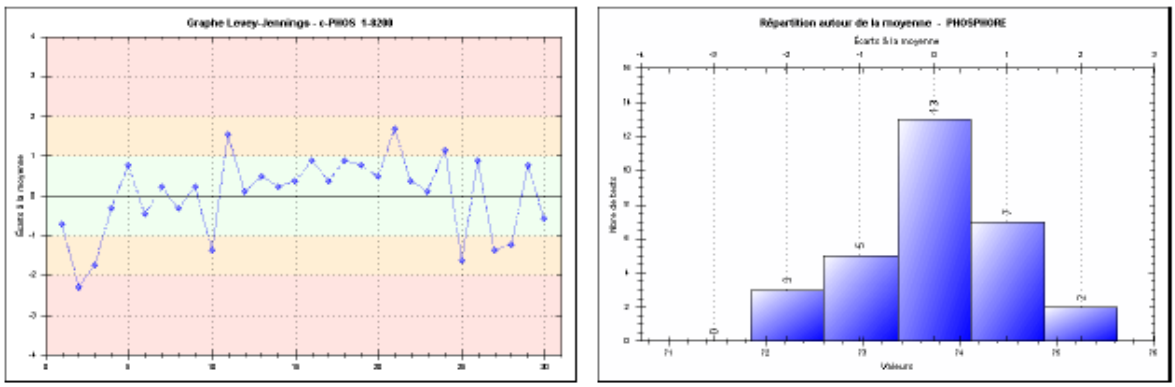

Figure 3 High level of repeatability: Levey Jennings graph and the distribution around the mean – Phosphorus

The intermediate fidelity test, also referred to as intra-laboratory reproducibility, assesses the performance of a test by analyzing the same sample under varying conditions, such as changes in the operator, timing, reagent batches, or calibrations. This method establishes acceptance criteria based on existing knowledge, incorporating biological variability, particularly in decision-support contexts.

The intermediate fidelity test results indicated a high degree of consistency across all concentration levels: low, medium, and high, with coefficients of variation (CV) recorded at 2.53 %, 2.07 %, and 2.47%, respectively. These findings are visually represented in Levey-Jennings charts (Figures 4, 5, and 6), illustrating the method's strong reproducibility.

The analysis also included a detailed evaluation of the CV of reproducibility for each concentration level, expressed as percentages. These values were compared against the limits established by FSBC and RICOS, which account for expansion factors (k = 1.211 for low,medium and high levels standards, ensuring reliability and accuracy in its analytical performance.

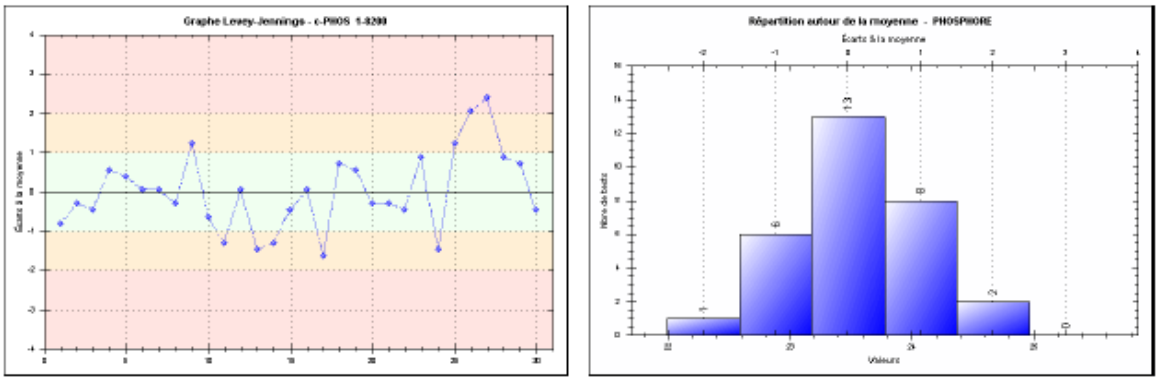

Figure 4 Low level of Reproductibility : Levey Jennings graph and the distribution around the mean – Phosphorus

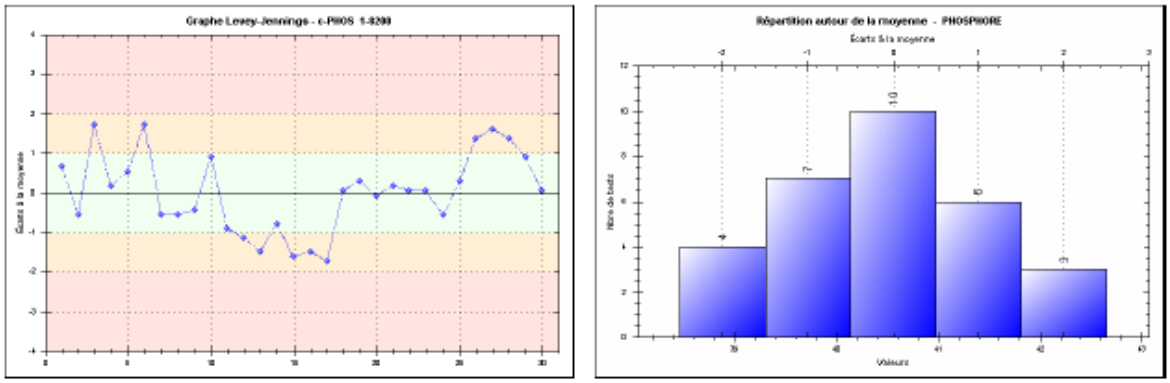

Figure 5 Medium level of Reproductibility: Levey Jennings graph and the distribution around the mean – Phosphorus

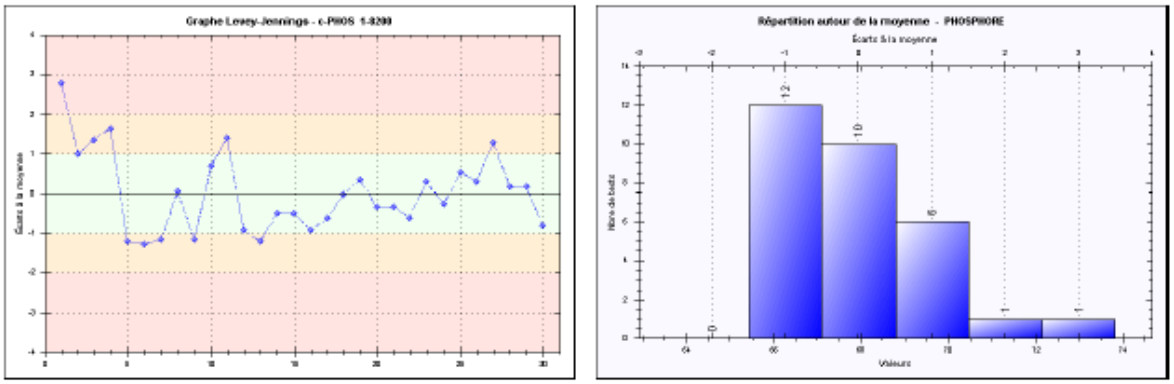

Figure 6 High level of Reproductibility: Levey Jennings graph and the distribution around the mean – Phosphorus

Method comparative : The methods were compared on 30 samples. The Bland-Altman diagram shows that the mean bias between the twoautomata is approximately 11.61% (Figure1) with a linear regression equation Y = 0.901 X + 2.757. The correlation coefficient (r) was 0.997 (Figure7) , with a mean difference of 1.61 mg/L and a standard deviation of 2.914 mg/L.

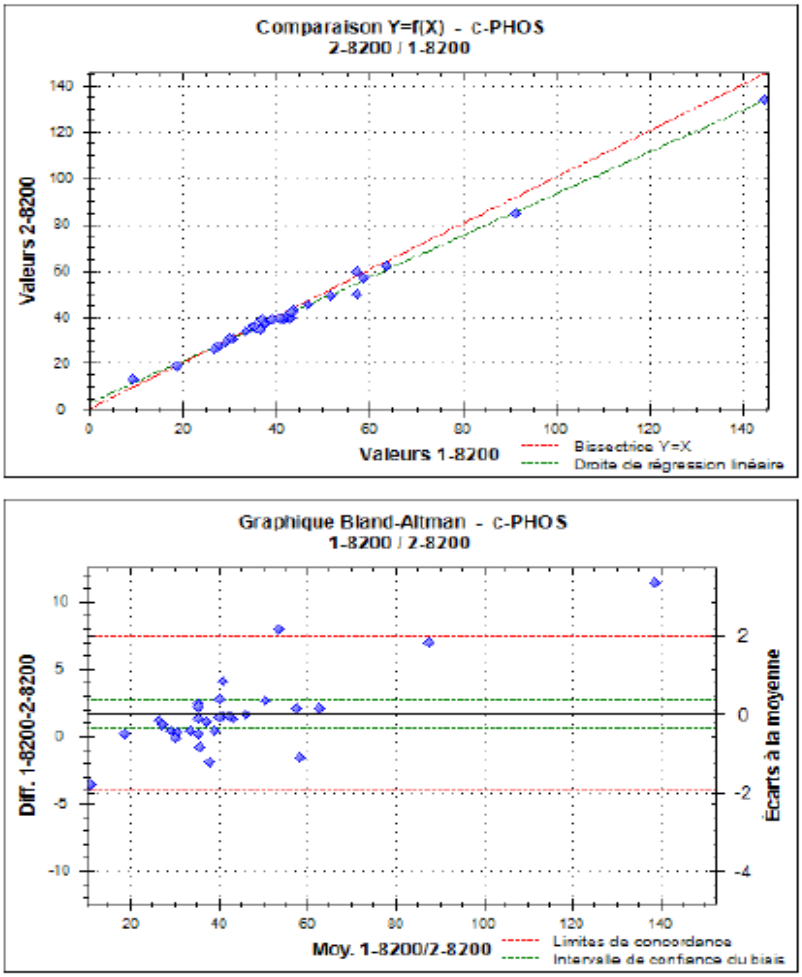

Figure 7a Serum phosphorus method comparison result between two Architect ci8200®; **Figure 7b** The Bland-Altman diagram for serum phosphorus

We also assessed the measurement uncertainty at different levels of the Abbott Architect ci8200® instrument, with results falling within acceptable limits. The calculated measurement uncertainties were 2.52% for level 1, 2.07% for level 2, and 2.47% for level 3.

4. Discussion

The central laboratory of Mohammed VI University Hospital in Oujda is dedicated to maintaining the highest standards of analytical performance, adhering to NF ISO 15189 and COFRAC guidelines for method validation and verification. These processes are essential to ensure the reliability, accuracy, and reproducibility of results, which are critical for clinical diagnostics and patient care [7-10]

As part of its quality assurance strategy, the laboratory undertakes method verification and validation to assess analytical performance parameters, including precision, reproducibility, and repeatability. These evaluations are conducted in line with international accreditation standards and aim to confirm that the methods used meet stringent quality control requirements [11].

Intermediate fidelity testing evaluates the robustness of an assay under varying conditions, such as different operators, reagent batches, and calibration protocols. Results are assessed using statistical measures like coefficients of variation (CV), which must align with established quality limits to demonstrate reliability across diverse scenarios |12]

Repeatability assessments focus on evaluating the consistency of results when the same sample is analyzed under identical conditions. This process ensures minimal variability and confirms the precision of the method, which is crucial for maintaining trust in clinical outcomes [13]

By verifying and validating analytical methods according to strict standards, the laboratory ensures the delivery of accurate and consistent results. These efforts strengthen the laboratory's role as a reference center, enhance its accreditation readiness, and contribute to advancements in medical diagnostics and patient care. Such rigorous quality assurance processes reflect the laboratory's commitment to excellence and its pivotal role in supporting healthcare providers and improving patient outcomes [14]

5. Conclusion

The analytical performance of the automated Architect ci8200 system demonstrated satisfactory results, ensuring reliable determination of phosphorus. Verifying analytical methods in medical laboratories is a critical process to guarantee the accuracy, precision, and reliability of test results. This verification confirms that the chosen method is fit for its intended purpose, delivers consistent and reproducible results, aligns with claimed performance characteristics, and meets stringent quality control and quality assurance standards. This version maintains the focus on general analytical performance and method verification while ensuring adaptability to various parameters or assays.

Compliance with ethical standards

Acknowledgments

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Disclosure of conflict of interest

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

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