World Journal of Biology Pharmacy and Health Sciences
eISSN: 2582-5542
Cross Ref DOI: 10.30574/wjbphs
Journal homepage: https://wjbphs.com/

(RESEARCH ARTICLE)

Check for updates

Verification of the analytical performance of the serum phosphorus assay on the Abbott Alinity ci®: Experience of the central laboratory Mohammed VI University Hospital of Oujda

Sabah Mokhtari [1, 2, *], Loubna Yacoubi [1, 2], Imane Naji [1, 2], Marouane Kaabouchi [1, 2], NismaDouzi [1, 2], Issam Mokhtari [1, 2], El-houcine Sebbar [1, 2] and Mohammed Choukri [1, 2]

[1] *Central Laboratory, Mohammed VI University Hospital of Oujda, Morocco.*
[2] *Faculty of Medicine and Pharmacy of Oujda, Mohammed First University, Morocco.*

World Journal of Biology Pharmacy and Health Sciences, 2023, 16(01), 233–238

Publication history: Received on 11 August 2023; revised on 26 September 2023; accepted on 28 September 2023

Article DOI: https://doi.org/10.30574/wjbphs.2023.16.1.0401

Abstract

Introduction: In our study, we aimed to evaluate the analytical performance of the serum phosphorus determination method using an Abbott kit on the Alinity c automaton at the biochemistry laboratory of Mohammed VI University Hospital of Oujda.

Materials and methods: We evaluated the performance of the kit using flexible scope A and conducted a thorough performance study on the Alinity c automaton. This study encompassed assessments of repeatability, reproducibility and comparisons of results obtained from two Alinity c automatons.

Results: The obtained results met the acceptability criteria recommended by the supplier and the French Society of Clinical Biology(Société Française de Biologie Clinique SFBC) Valtec protocol, indicating overall satisfaction with the study. The Alinity c automaton exhibited the necessary analytical performance to ensure accurate and dependable determination of phosphorus levels.

Discussion: Ensuring accurate and reliable results, the verification of the serum phosphorus determination method in the medical laboratory is crucial. This process entails implementing quality control measures, calibration, and comparing with established reference methods. It guarantees that the laboratory's phosphorus testing method is precise, accurate, and compliant with industry standards, thereby upholding the quality of patient care.

Conclusion: The verification study of the serum phosphorus determination method yielded satisfactory results, providing high reliability to the test results from the central laboratory at Mohammed VI University Hospital of Oujda. This verification study serves as a strong foundation in the accreditation process, ensuring the accuracy and quality of laboratory testing, and enhancing the overall reliability of patient care

Keywords: verification; Phosphorus; Quality; Alinity c; ISO 15189

1. Introduction

Phosphorus is an essential mineral in the physiology of the human body, mainly found in bones and teeth in the form of hyddroxyapatite in association with calcium. It is also a major component of nucleic acids such as DNA and RNA, and is involved in vital cellular processes such as energy production and acid-base balance, the functioning of enzymes, cell membranes and the body's signalling pathways. Phosphoremia or phosphatemia can be used as an indicator of various

*Corresponding author: Sabah Mokhtari

diseases and conditions [1-5]. Abnormal levels of phosphorus in the blood can be observed in a variety of situations, such as kidney disease, hormonal imbalances and bone disorders. High levels of phosphorus, known as hyperphosphatemia, can cause symptoms such as muscle weakness, bone pain and calcium deposits in soft tissues. Phosphorus determination is crucial and requires the availability of accurate and reliable tests for diagnostic and therapeutic monitoring purposes. The method for determining phosphorus levels must be verified in accordance with established standards, such as ISO 15189 for medical laboratories, to guarantee the accuracy and reliability of the results [3-5]. The phosphorus method verification process includes quality control measures, calibration and comparison with established reference methods. This process identifies and addresses potential sources of error, validates method performance and ensures consistent and accurate results. Compliance with the ISO 15189 method verification standard guarantees the precision and accuracy of the laboratory's phosphorus determination method, and compliance with pre-established standards. Reliable phosphorus assay results are essential for accurate diagnosis, appropriate treatment decisions and monitoring of disease progression. Inaccurate or unreliable results can lead to misdiagnosis and inappropriate treatment. The verification process, in accordance with ISO 15189, is a guarantor of the reliability of the laboratory's phosphorus determination method, and enables trust between healthcare providers, patients and stakeholders [1-7]. Successful verification of the phosphorus determination method, in accordance with ISO 15189, enhances the laboratory's credibility, reputation and competitiveness in the healthcare industry [6-9]. In our study, we aimed to evaluate the analytical performance of the serum phosphorus determination method using an Abbott kit on the Alinity c automated system at the biochemistry laboratory of the CHU Mohammed VI of Oujda.

1.1. Reminder about phosphorus

Phosphorus is an essential mineral in the human body, and the most abundant after calcium. Together with calcium, it forms hydroxyapatite crystals stored in bones and teeth, contributing to bone hardness and stability. It plays a vital role in a variety of physiological processes, including energy production through ATP (adenosine triphosphate), the main source of energy for cellular processes such as muscle contraction, nerve function and metabolism [1-5], DNA synthesis and cell signalling. It is an essential component of DNA and RNA molecules, responsible for the transfer of genetic information and protein synthesis, and for acid-base balance. Phosphorus exists as phosphate in the body, and is absorbed from the small intestine in the form of inorganic or organic phosphate compounds. It is regulated by factors such as dietary intake, hormonal control and renal excretion. Blood phosphorus levels (phosphoremia or phosphatemia) are closely regulated by hormonal control, mainly by parathyroid hormone (PTH) and vitamin D. PTH promotes the release of phosphate from the bones into the blood, increases phosphate reabsorption in the kidneys and stimulates the production of active vitamin D, which improves intestinal phosphate absorption. Vitamin D also helps maintain appropriate levels of calcium and phosphate in the blood. Medical conditions such as kidney disease, hormonal imbalances and metabolic disorders can disrupt the body's normal phosphorus physiology. Abnormal levels of phosphorus in the blood can lead to a variety of health problems, including bone disorders, muscle weakness, nerve dysfunction and altered cellular processes [1-5].

2. Material and methods

2.1. Principle of the phosphorus determination method on Alinity c

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

2.2. Verification procedure

The Biochemistry Laboratory of the CHU Mohammed VI of Oujda carries out rigorous verification of the analytical performance of phosphorus assay kits using the "Chemistry" module of the Abbott Alinity c. automated system.

The verification process meticulously follows the flexible A scope, which implies a complete verification of all elements to guarantee the accuracy and reliability of results. An in-depth performance study has been carried out on each controller, evaluating key parameters such as repeatability, reproducibility and accuracy.

Results were then compared with another Abbott Architect 8200c system to ensure consistency and reliability. These techniques are classified in category A of the flexible range for method verification, as indicated in COFRAC guide SH-GTA-04. Standard deviations (SD) and coefficients of variation (CV) were carefully assessed and analyzed during the performance evaluation process. A comparison of results was made according to the standards set by the SociétéFrançaise de Biologie Clinique (SFBC), to ensure that the Abbott Alinity c used in the biochemistry laboratory at CHU Mohammed VI of Oujda was in line with industry references and guidelines.

3. Results

The results reveal satisfactory repeatability for Abbott Alinity c® at low, medium and high levels, as shown by coefficients of variation (CV) of 0.61%, 0.53% and 0.64% respectively, as presented in Table 1.

Table 1 Repeatability results for phosphoruson Alinity c automaton

Sample	N	Mean	SD	CV%	CV SFBC	Conclusion
Level 1	30	21.14 mg/l	0.129 mg/l	0,61	3.0	Validated
Level 2	30	34.96 mg/l	0.186 mg/l	0,53	2.48	Validated
Level 3	30	56.63 mg/l	0.361 mg/l	0,64	1.8	Validated

The intra-laboratory reproducibility of Alinity c® was found to be acceptable for levels 1, 2 and 3, with corresponding coefficients of variation (CV) of 2.68%, 1.96% and 2.58% respectively, as shown in Table 2.

Table 2 Reproducibility results for phosphorus on Alinitycautomaton

Sample	N	Mean	SD	CV%	CV% SFBC	Conclusion
Level 1	30	22.38 mg/l	0.60 mg/l	2.68	4.84	Validated
Level 2	30	42.65 mg/l	0.84 mg/l	1.96	4.0	Validated
Level 3	30	65.82 mg/l	1.7 mg/l	2.58	2.91	Validated

Comparative analysis between Alinity c and Architect 8200 c using the Bland-Altman diagram (figure 1) showed that the mean bias between the two Abbott Alinity c automata was approximately 7.08. The correlation coefficient (r) was 0.96, with a mean difference of 3.29 mg/l and a standard deviation of 11.715 mg/l. The linear regression equation was calculated as follows: Y= 1.01 X + 1.11 (figure 2).

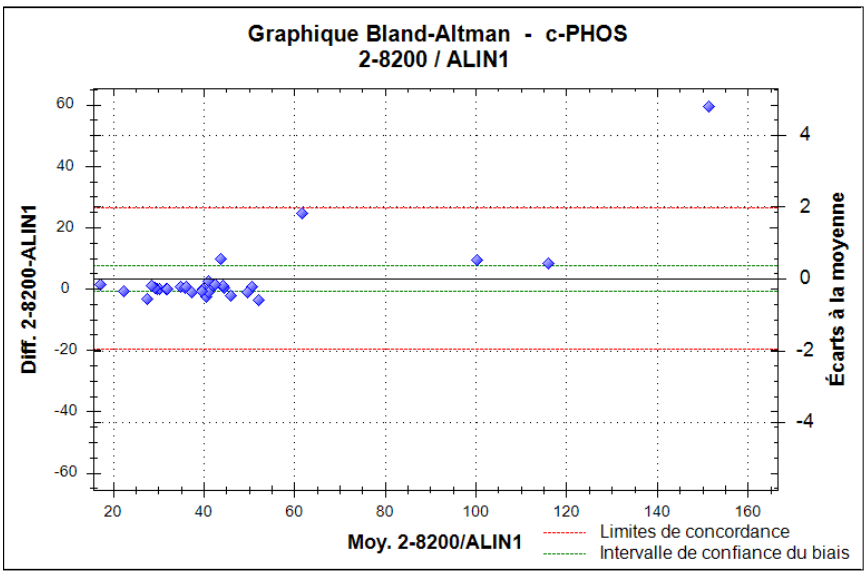

Figure 1 The Bland-Altman diagram for phosphorus

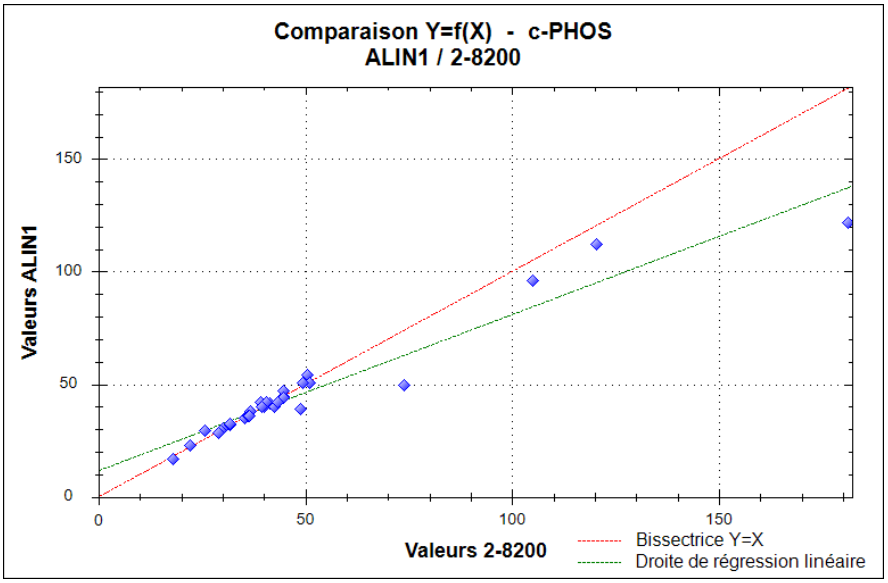

Figure 2 Correlation study for phosphorus

4. Discussion

Repeatability and reproducibility are statistical methods used in process control to measure the precision and variation present in our PLCs.

- Repeatability evaluation determines optimum performance conditions and verifies the correct operation of the system, including instruments and reagents, for the parameter under evaluation.
- Reproducibility evaluates the precision of the method by varying factors such as operators, time, reagent batches and calibrations.

We have chosen serum phosphorus as a control parameter in view of its value in the diagnosis and management of pathologies and special situations such as :

- Hypophosphatemia: including alcoholism, burns, fasting and diuretics, also during total parenteral nutrition, refeeding after prolonged undernutrition and severe respiratory alkalosis, and in renal failure patients on dialysis with antacids as phosphate binders, or hyperphosphatemia usually caused by advanced renal failure;
- Pseudo-hyperparathyroidism (multiple myeloma, macroglobulinemia, dyslipidemia, hemolysis and hyperlipidemia) and hypoparathyroidism are less frequent causes. Diabetic acidocetosis, rhabdomyolysis, severe infection, tumor lysis syndrome and iatrogenic causes such as the excretion of phosphate-containing enemas are also causes of hyperphosphoremia, [1-5].

Phosphorus levels can also be used to guide treatment strategies and optimize patient outcomes.

The Biochemistry Laboratory of the CHU Mohammed VI of Oujda represents a leading healthcare facility in the eastern region of Morocco that is committed to maintaining the highest standards of analytical performance in order to provide reliable and accurate laboratory results for patients, following pre-established guidelines and references [13-18]. As part of its commitment to quality, the central laboratory has implemented a method verification procedure in accordance with Scope A, as well as an accreditation process.

We have followed a "Scope A" verification process, which is specifically designed for methods that have already been validated in their respective fields.

Abbott's biochemistry techniques are CE marked and essential for clinical diagnosis in medical laboratories. These techniques are classified in the flexible category of scope A for method verification, as specified in COFRAC guide SH-GTA-04. [6-10].

The CE marking of Abbott's biochemical techniques guarantees their compliance with regulatory standards applicable to clinical diagnosis in medical laboratories. The flexible category A for method verification, as specified in COFRAC guide SH-GTA-04, provides a recognized and accepted approach for verifying the performance of these techniques in the laboratory [7-11].

The results of the repeatability and reproducibility study for phosphorus show satisfactory performance in relation to supplier data and CSFB criteria.The study indicates that the two automated systems provide similar results for phosphorus when using the same samples for comparison [6-12].

Verification of the analytical performance of serum phosphorus determination is of paramount importance in clinical laboratories, due to its critical role as a key parameter in medical practice.

Serum phosphorus levels are widely used in the diagnosis and monitoring of various diseases, such as bone disorders, kidney disease and metabolic disorders.

Accurate and reliable measurement of serum phosphorus is necessary for satisfactory management, treatment planning and monitoring of patient response [6-10]. The verification process involves a comprehensive assessment of the assay's performance characteristics, including repeatability, reproducibility, sensitivity, specificity and linearity. This rigorous process establishes the reliability and credibility of the assay, ensuring that results are accurate, precise and consistent, and therefore valid and meaningful for patient care [8-12].

Any inaccurate measurement of serum phosphorus levels can lead to misdiagnosis of bone disorders, resulting in incorrect treatment plans, unnecessary interventions or delayed diagnosis of underlying conditions. [7-9].

In addition, verification of serum phosphorus determination is essential to comply with regulatory requirements and accreditation standards.

Compliance with these standards is essential to maintain the integrity of laboratory tests and guarantee the validity and reliability of patient results.

In addition, verification of serum phosphorus assays is vital to maintaining a laboratory's reputation and credibility. Clinical laboratories must meet the highest standards of quality and accuracy in their testing processes. Assay verification highlights the laboratory's competence and ability to deliver accurate and reliable results to clinicians and patients, preserving healthcare providers' confidence in the laboratory's testing capabilities [4-7].

5. Conclusion

Our study showed satisfactory results, meeting the criteria set by the supplier and the SFBC Valtec protocol. The Alinity c demonstrated reliable analytical performance for the accurate determination of phosphorus. Phosphorus is an essential mineral in the human body, playing a vital role in various physiological processes. It is also a valuable marker for disease diagnosis and monitoring. The reliability of phosphorus analysis results is essential to patient care. Compliance with the ISO 15189 method verification standard ensures the accuracy and reliability of laboratory results, promotes patient safety and reinforces the credibility of the laboratory. The verification process serves as the basis for accreditation, improves the quality of patient care and builds trust between healthcare providers and patients.

Compliance with ethical standards

Acknowledgments

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Disclosure of conflict of interest

The authors declare no conflict of interest in preparing this article.

Statement of informed consent

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

References

[1] BERNDT, Theresa et KUMAR, Rajiv. Novel mechanisms in the regulation of phosphorus homeostasis. Physiology, 2009, vol. 24, no 1, p. 17-25.

[2] TARTIBIAN, Bakhtyar, AFSAR GAREBAG, Rogayee, MALANDISH, Abbas, et al. Correlation between blood pressure and vitamin D, parathyroid hormone, calcium, and phosphorus in sedentary postmenopausal women. Tehran University Medical Journal TUMS Publications, 2016, vol. 74, no 8, p. 554-561.

[3] BERGWITZ, Clemens et JÜPPNER, Harald. Regulation of phosphate homeostasis by PTH, vitamin D, and FGF23. Annual review of medicine, 2010, vol. 61, p. 91-104.

[4] RENKEMA, Kirsten Y., ALEXANDER, R. Todd, BINDELS, René J., et al. Calcium and phosphate homeostasis: concerted interplay of new regulators. Annals of medicine, 2008, vol. 40, no 2, p. 82-91.

[5] CHANG, Alex R. et ANDERSON, Cheryl. Dietary phosphorus intake and the kidney. Annual review of nutrition, 2017, vol. 37, p. 321-346.

[6] Pascal, P, Beyerle F. Quality standards applicable in medical biology analysis laboratories. PathologyBiology, 2006, vol. 54, no. 6, p. 317-324.

[7] PIERRE, Daniel. Cofrac accreditation of medical biology laboratories within the framework of the HPST law. Revue Francophone des Laboratoires, 2010, vol. 2010, no. 419, p. 27-28.

[8] REIFENBERG, Jean-Marc, RIOUT, Erwann, and LEROY, Alain. Metrology in a medical biology laboratory: issues and difficulties. Revue Francophone des laboratories, 2014, vol. 2014, no. 461, p. 69-76.

[9] Vassault A, Arnaud J, Szymanovicz, A, et al. Analytical validation of the results. In: Annals of Clinical Biology. 2010. p. 223-226.

[10] GUZEL, Omer et GUNER, Ebru Ilhan. ISO 15189 accreditation: Requirements for quality and competence of medical laboratories, experience of a laboratory I. Clinical biochemistry, 2009, vol. 42, no 4-5, p. 274-278.

[11] ABDELWARETH, Laila O., PALLINALAKAM, Fasila, IBRAHIM, Faisal, et al. Fast track to accreditation: an implementation review of College of American Pathologists and International Organization for Standardization 15189 Accreditation. Archives of pathology & laboratory medicine, 2018, vol. 142, no 9, p. 1047-1053.

[12] Kalra K. Method development and validation of analytical procedures. Quality Control of Herbal Medicines and Related Areas, 2011, vol. 4, p. 3-16.

[13] Sebbar E-H, Sam H, Sidqi Z, et al. Calcium Intakes in the Diet of Eastern Morocco's Population. Journal of Pharmacy and Nutrition Sciences, 2018, vol. 8, no 3, p. 91-96.

[14] Sebbar E-H, Saalaoui E, Choukri M. Evaluation of nutritional intakes of vitamin D in a population of eastern Morocco. Nutrition Practices Review, 2018, Vol 14 - No. 55, p. 44-45.

[15] Sebbar E-H, Elmazgaldi I, Lahmar M, et al. Modalités de l'enquêtealimentaire. L'Aide-Soignante, 2022

[16] Sebbar E-H, Choukri M. Comparison between two automated immunoassay methods for total 25-hydroxyvitamin D: Alinity c ® versus Cobas e411®, Materials Today: Proceedings, 2022.

[17] Sebbar E-H, Choukri M. Vitamin D status in the population of Eastern Morocco: Study of vitamin D2 and vitamin D3 by high performance liquid chromatography, Materials Today: Proceedings, 2022.

[18] Rahmani N, Sebbar E-H, Azghar A, et al. Benefit of vitamin B12 supplements in elderly. Pratiques en Nutrition, 2019, 15(57), pp. 44–45.