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(RESEARCH ARTICLE)

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

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Abstract

Magnesium is recognized as the fourth most important cation in the body and the second most abundant intracellular cation, following potassium. Its physiological significance lies in its capacity to form complexes with crucial intracellular anionic ligands, notably ATP, and its ability to compete with calcium for specific binding sites on proteins and cell membranes. Over 300 enzyme reactions rely on magnesium. The concentration of free magnesium within cells determines the magnesium content of these enzymes. Magnesium influences myocardial contraction and the electrical activity of myocardial cells, as well as the specialized conduction systems of the fetus, by modulating the transmembrane movements of ions like sodium, potassium, and calcium. Furthermore, magnesium can affect the contractility of vascular smooth muscle, and alterations in intracellular magnesium levels may impact cell proliferation or contraction. Magnesium is involved in nucleic acid and protein metabolism, intermediary metabolism, energy production, and consumption reactions, and it plays specific roles in various physiological systems such as the neuromuscular and cardiovascular systems.

Our research aims to assess the analytical accuracy of the serum magnesium assay method utilizing an Abbott kit on the Architect ci8200 automated system in the biochemistry laboratory of Mohammed VI University Hospital of Oujda. The evaluation of the kit's analytical accuracy was conducted within the flexible scope A by conducting a performance analysis on the Architect ci8200. We examined repeatability, reproducibility, measurement imprecision, and compared results between two Architect ci8200 instruments. All findings align with the acceptability criteria recommended by the supplier and the Valtec protocol of the Société Française de Biologie Clinique (SFBC), indicating overall satisfactory outcomes for the study.

The Architect ci8200 automated system demonstrated satisfactory analytical performance for reliably determining serum magnesium levels. Method verification in medical laboratories is essential to guarantee the accuracy, precision, and reliability of test results. Verification entails confirming that the test method used is suitable for its intended purpose, yields result consistent with the claimed performance characteristics, and meets the laboratory's quality control and quality assurance standards.

Keywords: Magnesium; Verification; Quality; Architect ci 8200; Repeatability; Reproducibility

1. Introduction

Verification of methods in laboratory analysis entails assessing the effectiveness of an analytical procedure using a standardized protocol [1]. This assessment adheres to predefined criteria established by reputable organizations like

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RICOS and SFBC [2], [3]. Through this process, laboratories gain a thorough comprehension of their analysis techniques, performance capacities, and constraints. The aim is to ascertain that these performances meet standards that ensure the precision and dependability of analytical findings and their clinical implications, thereby benefiting patients and healthcare providers alike.

Our research aims to assess the analytical accuracy of the serum magnesium assay method utilizing an Abbott kit on the Architect ci8200 automated system in the biochemistry laboratory of Mohammed VI University Hospital of Oujda. The evaluation of the kit's analytical accuracy was conducted within the flexible scope A by conducting a performance analysis on the Architect ci8200. We examined repeatability, reproducibility, measurement imprecision, and compared results between two Architect ci8200 instruments. All findings align with the acceptability criteria recommended by the supplier and the Valtec protocol of the Société Française de Biologie Clinique (SFBC), indicating overall satisfactory outcomes for the study.

1.1. Interest of serum magnesium determination

Magnesium is recognized as the fourth most important cation in the body and the second most abundant intracellular cation, following potassium. Its physiological significance lies in its capacity to form complexes with crucial intracellular anionic ligands, notably ATP, and its ability to compete with calcium for specific binding sites on proteins and cell membranes. Over 300 enzyme reactions rely on magnesium. The concentration of free magnesium within cells determines the magnesium content of these enzymes. Magnesium influences myocardial contraction and the electrical activity of myocardial cells, as well as the specialized conduction systems of the fetus, by modulating the transmembrane movements of ions like sodium, potassium, and calcium. Furthermore, magnesium can affect the contractility of vascular smooth muscle, and alterations in intracellular magnesium levels may impact cell proliferation or contraction. Magnesium is involved in nucleic acid and protein metabolism, intermediary metabolism, energy production, and consumption reactions, and it plays specific roles in various physiological systems such as the neuromuscular and cardiovascular systems [4].

1.2. Princip of the assay method

The magnesium present in the sample acts as a cofactor in an enzymatic reaction with isocitrate dehydrogenase. The increase in optical density at 340 nm caused by the formation of NADPH is directly proportional to the magnesium concentration.

2. Material and methods

This is a prospective study that was conducted in the biochemistry laboratory of the Mohammed VI University Hospital, over a period of 30 days. Our study was divided into two parts. The first step concerned the assessment of reproducibility through the daily passing of control of the three levels—low, medium, and high—over a period of 30 days. The serum samples were gathered in the second stage, and the magnesium readings were uniformly spread across the measurement range. Three groups of samples were created: low, medium, and high levels. The magnesium kit ran the test on the Chemistry module. The BYG middleware, a gateway program between the Architect ci8200 and the iLab result validation software, processed data. The CV values obtained by our study were compared with those set by the learned societies (SFBC and RICOS). Furthermore, we conducted a method comparison between the two automated systems Architect ci8200®, employing the Bland-Altman diagram to visualize and analyze the differences in results obtained from these techniques in relation to their respective means.

3. Results

3.1. Intermediate fidelity results

The intermediate fidelity test, also known as intra-laboratory reproducibility, involves analyzing the same sample under diverse conditions, where at least one variable is altered, such as the operator, time, reagent batches, or calibrations.[5]

This approach facilitates the establishment of acceptance criteria based on prior knowledge, taking into account biological variations, especially in the context of decision support systems. By subjecting the sample to various conditions and meticulously observing the resultant outcomes, researchers can discern the influence of different factors on the test's accuracy and reliability. This process contributes to a comprehensive understanding of the test's robustness and performance, aiding in the development and optimization of diagnostic methodologies and enhancing the overall quality of laboratory analyses in the field of clinical diagnostics[6].The intermediate fidelity results

demonstrated a high level of satisfaction across all three levels: low, medium, and high, with a coefficient of variations (CV) of 2.69%, 2.41%, and 2.07%, respectively.

The conclusion drawn from the intermediate fidelity results for the low, medium, and high levels of analysis reveals a meticulous evaluation of the coefficient of variation (CV) of Reproducibility, expressed as percentages. These CV values are compared against the appropriate FSBC and RICOS limits.

3.1.1. Low Level

The FSBC limit with the expansion factor (k = 1.211) is determined to be 4.84%, while the RICOS limit with the same expansion factor is 2.18%. The CV of Reproducibility (2.69) at the low level is observed to be correct and well below the tolerated limit, ensuring a high level of precision and reliability in the measurements at this level.

3.1.2. Medium Level

For the medium level, the FSBC limit with the expansion factor (k = 1.211) is found to be 3.88%, and the RICOS limit with the expansion factor is 2.18%. In this case, the CV of Reproducibility (2.41) is deemed correct, as it falls below the tolerated limit, further validating the precision and reproducibility of the assay at this level.

3.1.3. High Level

At the high level of analysis, the FSBC limit with the expansion factor (k = 1.211) is calculated to be 3.88%, whereas the RICOS limit with the expansion factor stands at 2.18%. Once again, the CV of Reproducibility (2.07) is considered correct, as it remains below the tolerated limit, attesting to the assay's accuracy and reliability even at this demanding level of analysis.

3.2. Repeatability results

Repeatability testing involves subjecting the same sample to a series of analyses under specific conditions, namely the same operator, the same batch of reagents, the same instrument, and the same calibration, all performed in the shortest feasible timeframe. The overarching objective is to meticulously assess the analyte's performance under optimal conditions and to verify the proper functioning of the system, encompassing the instrument and reagents. This assessment serves as a crucial step in ensuring the accuracy and reliability of the analytical process for the specific analyte of interest.[5], [7] For each analyte/matrix combination to be measured on a particular analyzer, the repeatability calculation must be carried out, considering multiple concentration levels. These chosen levels are strategically aligned with distinct medical decision areas. The calculated coefficient of variation (CV) is then meticulously compared against a pre-established acceptable limit CV, previously determined based on specific quality and accuracy criteria.

The outcomes derived from the repeatability testing exhibited commendable performance across all three concentration levels: low, medium, and high. The CV values obtained were as follows: CV1 = 1.55%, CV2 = 1.13%, and CV3 = 1.03% respectively. These results affirm a satisfactory level of repeatability, indicative of the method's precision and reliability, even under varying concentration levels. The conclusion drawn from the repeatability testing showcases a meticulous assessment of the coefficient of variation (CV) of Repeatability for the low, medium, and high concentration levels. The CV values are compared against the established SFBC and RICOS limits.

3.2.1. Low Level

For the low concentration level, the SFBC limit with the expansion factor (k = 1.211) is determined to be 3.63%, while the RICOS limit with the same expansion factor stands at 1.63%. The CV of Repeatability (1.55) obtained at this level is found to be correct, as it remains below the tolerated limit. This exemplary precision demonstrates the method's ability to consistently deliver reliable results, even at lower analyte concentrations, thereby instilling confidence in the assay's clinical utility.

3.2.2. Medium Level

At the medium concentration level, the SFBC limit with the expansion factor (k = 1.211) is calculated to be 2.91%, while the RICOS limit with the same expansion factor is 1.63%. In this case, the CV of Repeatability (1.13) is confirmed to be correct, as it falls below the accepted limit, underscoring the assay's robust performance and reproducibility at intermediate analyte concentrations

3.2.3. High Level

The high concentration level yields similar results, with the SFBC limit and RICOS limit both determined to be 2.91% and 1.63%, respectively. The CV of Repeatability (1.03) at this level is deemed correct, further emphasizing the method's precise and reliable performance even under challenging conditions.

We conducted a method comparison study using 30 samples to assess the agreement between two automats. The BlandAltman diagram (Figure 1) revealed an average bias of approximately -0.40 %, and a linear regression equation **Y = 1.063 X - 1.28** was derived from the analysis. The mean of the differences between the two automata was -0.086 g/l.

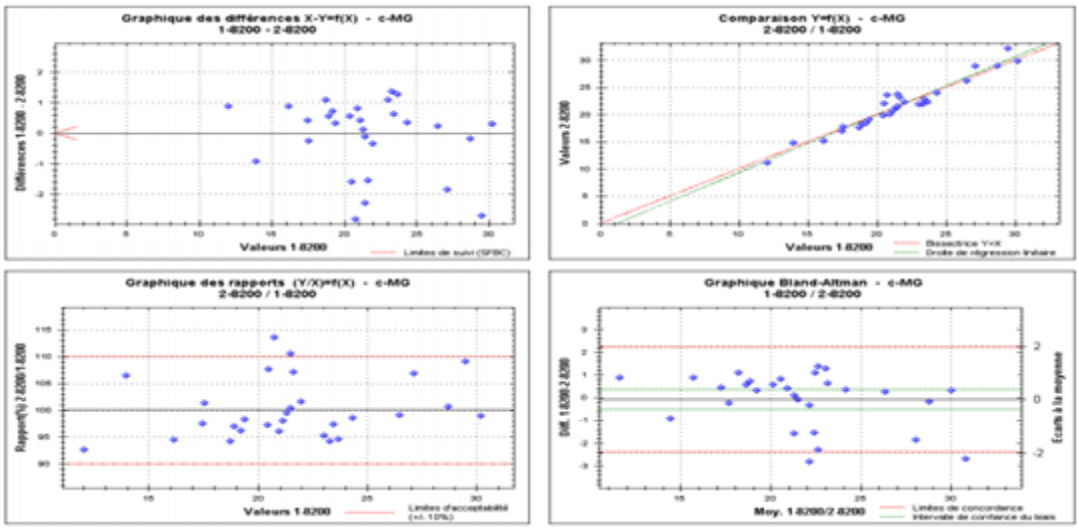

Figure 1 Serum magnesium method comparison result between two Architect ci8200®

4. Discussion

We have conducted the validation and verification of our method in accordance with the quality requirements outlined in scope A of the NF ISO 15189 standard, following the guidelines specified in the COFRAC guide SH-GTA-04. Our main objective is to guarantee the reliability and accuracy of our test results. Method validation and verification are pivotal stages in the accreditation process, to which our laboratory is fully dedicated [8–9]. The results of our study strongly indicate the reliability of the magnesium assay results, particularly in assessing reproducibility across three concentration levels, all of which produced satisfactory outcomes.

The careful examination of the coefficient of variation (CV) values in comparison with the established limits highlights the strength and accuracy of the analytical method across the entire range of analysis. These findings confirm the method's ability to consistently produce precise and reliable results, meeting the rigorous standards of clinical diagnostics. This thorough assessment of intermediate precision establishes a solid foundation for integrating the method into clinical decision support systems, indicating its suitability for critical diagnostic scenarios. Furthermore, it underscores the laboratory's dedication to quality assurance and expertise, strengthening the credibility and reliability of the analytical data generated in clinical settings. Additionally, the evaluation of repeatability also yielded convincing results.

The remarkably low coefficients of variation obtained in both reproducibility and repeatability analyses unequivocally meet the stringent standards established by esteemed learned societies such as RICOS and SFBC. These minimal CV values highlight the assay's exceptional precision and reliability across all three concentration levels, even when confronted with challenging analyte concentrations.

The comparison of CV values against the established limits reaffirms the analytical method's excellent repeatability, showcasing its capability to consistently deliver accurate and reproducible results across a wide range of analyte concentrations. The assay's precision, as evidenced through these comprehensive repeatability evaluations, underscores its suitability for integration into medical decision support systems, clinical diagnostic algorithms, and high-stakes diagnostic applications. By consistently achieving CV values below the tolerated limits, the method

demonstrates its adherence to rigorous quality control measures, thereby instilling trust in the reliability of clinical data generated and contributing to advancements in medical knowledge and patient care.

The impressive performance of the magnesium assay, as demonstrated through thorough assessments of reproducibility and repeatability, stands as a testament to the laboratory's steadfast dedication to upholding stringent quality control measures. These results validate the laboratory's adherence to international standards and guidelines, establishing it as a leader in clinical diagnostics and research. By consistently achieving CV values well below acceptable limits, the laboratory instills confidence among healthcare providers and patients in the accuracy and reliability of the analytical data produced, thereby enhancing patient care and advancing the field of clinical diagnostics. These exemplary findings contribute to the ongoing evolution of medical knowledge and promote a culture of continuous improvement in laboratory practices, ultimately benefiting the health and well-being of the population served by Mohammed VI University Hospital.

The central laboratory of Mohammed VI University Hospital in Oujda has implemented a comprehensive quality strategy, which includes a meticulous method verification process. Conducting such studies is crucial for establishing a robust and reliable accreditation process for the laboratory's analyses. As a reference center in the Eastern region of Morocco, the laboratory plays a crucial role in delivering diagnostic services not only to referred or hospitalized patients but also in assessing the overall health of the general population in the region through various scientific studies [10-11].

5. Conclusion

The Architect ci8200 automated system demonstrated satisfactory analytical performance for reliably determining serum magnesium levels. Method verification in medical laboratories is essential to guarantee the accuracy, precision, and reliability of test results. Verification entails confirming that the test method used is suitable for its intended purpose, yields result consistent with the claimed performance characteristics, and meets the laboratory's quality control and quality assurance standards.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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