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(RESEARCH ARTICLE)

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VERIFICATION OF THE ANALYTICAL PERFORMANCE OF THE IGE ASSAY ON ABBOTT ARCHITECT CI8200

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ABSTRACT

Measurements of IgE are useful to carry out on a routine basis for diagnosis, postoperative monitoring and assessment of treatment of the atopy-associated diseases such as atopic asthma, rhinitis and dermatitis etc., as well as of the infectious diseases, caused by parasites and of the IgE-myeloma.

The objective of this study was to independently evaluate the analytical performance of the IgE assay on the Abbott Architect ci8200 automated system and to ensure the best reliability of the results according to the recommendations of the NF ISO 15,189 standard. Our study was performed according to the Scope A criteria detailed in the Medical Biology Method Verification/Validation Guide. We evaluated the repeatability and the intermediate precision of the IgE assay. The coefficients of variation obtained by our study were compared with those set by SFBC.

The results obtained showed a satisfactory repeatability for the 2 levels; low and high with respectively CV1 = 3.85 % and CV2 = 1.56 %, a satisfactory intra-laboratory reproducibility for the 2 levels; low and high with CV1 = 7.48 % and CV2 = 5.19 % % respectively. The results obtained allowed us to verify the performance of the method and compare them to the analytical objectives set in order to meet regulatory and normative requirements. The central laboratory of the University Hospital Mohammed VI of Oujda is committed to a quality policy that includes an approach of mastery of the different analytical systems used.

Keywords: Ige; Verification; Quality; Architect Ci 8200; Repeatability; Reproducibility

1 INTRODUCTION

The verification of an analytical method is a process which consists in evaluating the performances of the analytical process, in quantifying them by following a standardized operating protocol then in judging them, compared to criteria defined by the learned societies (RICOS, FSCB), which consequently allows the laboratory to have a good knowledge of its methods of analyses, of its performances and its limits. It must ensure that these performances are sufficient to ensure the reliability of the analytical results and the clinical interpretations useful to the patient and the prescriber.[1, 2]

IgE is one of the parameters measured in our laboratory on the Abbott Architect ci8200 automated system. In order to ensure the quality of our IgE results, it was of paramount importance to commit to the procedure of the verification of its determination method. [3]

The objective of our work is the evaluation of the analytical performance of IgE determination by the Quantia IgE reagent according to the criteria of scope A detailed in the guide of verification/validation of methods in medical biology.

1.1 Interest of IgE determination:

IgE assay, also known as Immunoglobulin E assay, is a diagnostic laboratory test crucial for evaluating allergic conditions. Immunoglobulin E (IgE) is an antibody associated with allergic reactions and is integral in triggering responses to allergens. The IgE assay quantifies the levels of IgE antibodies in a person's blood, aiding in the identification of specific allergens causing allergic reactions [4]. This test provides essential information for diagnosing and managing allergic diseases, such as allergic asthma, atopic dermatitis, allergic rhinitis, and food allergies [5]. Accurate measurement of IgE levels helps in tailoring appropriate treatments and interventions to alleviate allergic symptoms and improve patients' quality of life [6]. Utilizing advanced immunoassay technologies, including enzyme-linked immunosorbent assays (ELISA) and radioallergosorbent tests (RAST), the IgE assay has become a valuable tool in allergy diagnosis and research [7].

1.2 Principle of the assay method

The Quantia IgE reagent is a suspension of polystyrene latex particles of uniform size coated with anti-human IgE monoclonal antibody. When a sample containing IgE is mixed with the reagent, a clear agglutination occurs, which can be measured by turbidimetry. Results are expressed in IU/mL of IgE based on 2nd WHO International Reference Preparation. [8, 9]

Table 1: Quantia IgE reagent kit contents [10]

Reactive Ingredients	Preservative	Volume
Glycine buffer 170 mM pH containing bovine serum albumin.	Sodium azide (<0,1%)	16 mL
Suspension of polystyrene latex particles coated with anti-human IgE monoclonal antibody in a glycine buffer containing bovine serum albumin.	Sodium azide (<0,1%)	5 mL

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 two levels—low and high—over a period of 30 days. The serum samples were gathered in the second stage, and the IgE readings were spread across the measurement range. Two groups of samples were created: low and high levels. The IgE 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).

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. 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[11].

The intermediate fidelity results demonstrated a high level of satisfaction for the two levels: low and high, with a coefficient of variations (CV) of 7.48% and 5.19%, respectively. These outcomes have been visually represented through Levey-Jennings graphs, as shown in **Error! Reference source not found.** and **Error! Reference source not found.**.

The conclusion drawn from the intermediate fidelity results for the low 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 limits, which include expansion factors (k = 1.211 for low and k = 1.211 for high).

3.1.1 Low Level

The FSBC limit with the expansion factor (k = 1.211) is determined to be 14.54%. The CV of Reproducibility (7.48) 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.

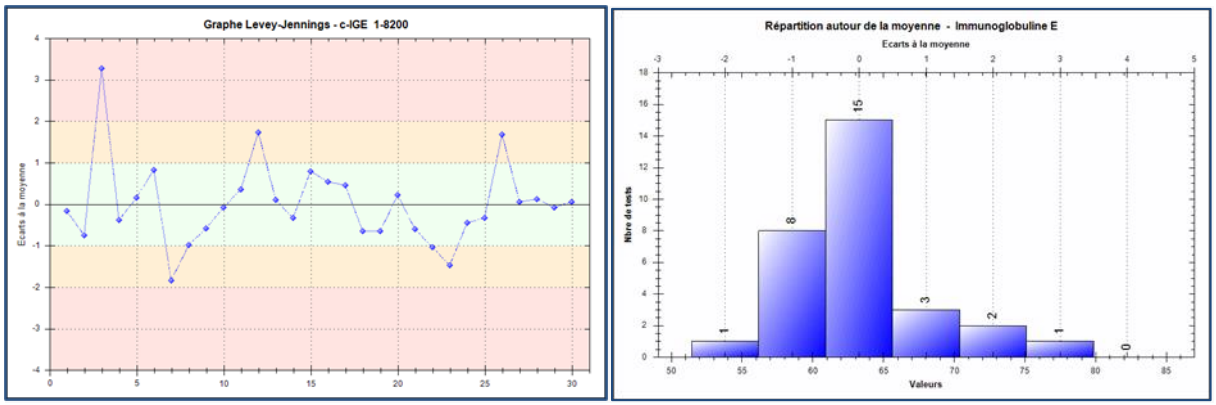


Figure 1: Low Level of Reproducibility: Levey Jennings graph and the distribution around the mean – IgE assay.

3.1.1.1 High Level

At the high level of analysis, the FSBC limit with the expansion factor (k = 1.211) is calculated to be 9.69%. Once again, the CV of Reproducibility (5.19) 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.

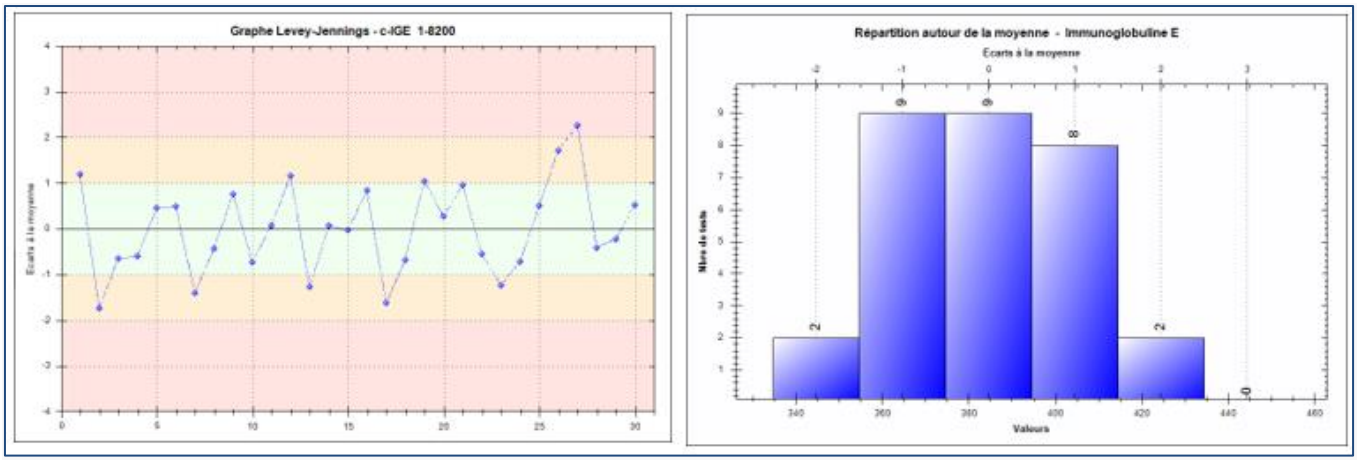


Figure 2: High Level of Reproducibility: Levey Jennings graph and the distribution around the mean – IgE assay.

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.[12, 13]

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 for the two concentration levels: low and high. The CV values obtained were as follows: CV1 = 3.85% and CV2 = 1.56% respectively. These results affirm a satisfactory level of repeatability, indicative of the method's precision and reliability, even under varying concentration levels.

To visually represent these exemplary findings, Levey Jennings graphs were constructed, effectively demonstrating the consistent and robust performance of the analytical process. These graphical representations, as shown in Figure 3 and Figure 4 provide a comprehensive visualization of the method's accuracy and precision across the range of analyzed concentrations.

The conclusion drawn from the repeatability testing showcases a meticulous assessment of the coefficient of variation (CV) of Repeatability for low and high concentration levels. The CV values are compared against the established SFBC limits, which include expansion factors (k = 1.211 for both low and high).

3.2.1 Low Level

For the low concentration level, the SFBC limit with the expansion factor (k = 1.211) is determined to be 10.9%. The CV of Repeatability (3.85) 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.

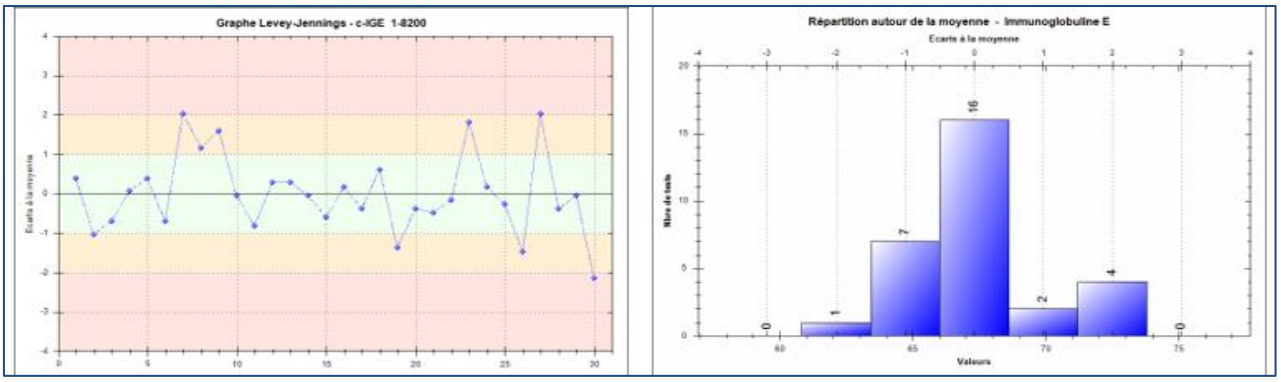


Figure *3*: Low level of repeatability: Levey Jennings graph and the distribution around the mean – IgE assay.

3.2.1.1 High Level

The high concentration level yields similar results, with the SFBC limit determined to be 7.27%. The CV of Repeatability (1.56) at this level is deemed correct, further emphasizing the method's precise and reliable performance even under challenging conditions.

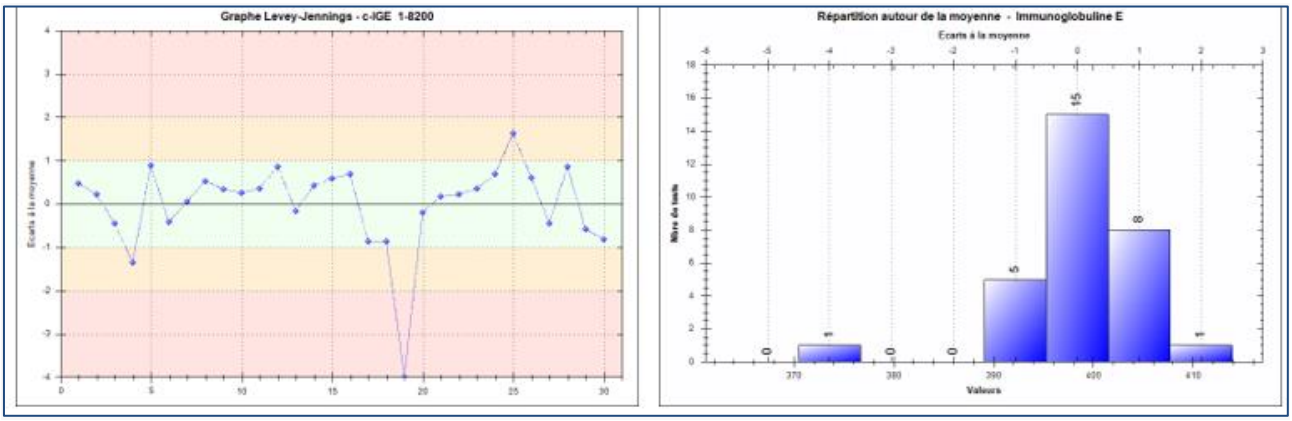


Figure *4*: High level of Repeatability: Levey Jennings graph and the distribution around the mean – IgE.

4 DISCUSSION

We undertook the process of validating and verifying our method according to the quality requirements outlined in scope A of the NF ISO 15,189 standard, adhering to the guidelines specified in the COFRAC guide SH-GTA-04. Our primary goal is to ensure the reliability and accuracy of our test results. Method validation and verification are crucial steps in the accreditation process, to which our laboratory is fully committed. [14, 15]

The outcomes of our study robustly demonstrated the reliability of the IgE assay results when evaluating reproducibility for two concentration levels, both of which yielded satisfactory results (***Table 2***). For the low concentration level, 30 values were meticulously analyzed, with a mean of 63.28 IU/mL and a coefficient of variation (CV) of 7.48% (**Error! Reference source not found.**). Similarly, at the high concentration level, 30 values were analyzed, showing an average of 384.57 IU/mL with a CV of 5.19% (**Error! Reference source not found.**).

The meticulous comparison of the CV values against the established limits underscores the robustness and precision of the analytical method across the entire range of analysis. The findings affirm the method's capability to consistently deliver accurate and reproducible results, fulfilling the stringent requirements of clinical diagnostics. This comprehensive evaluation of intermediate fidelity provides a robust basis for integrating the method into clinical decision support systems and underscores its suitability for use in high-stakes diagnostic scenarios. Moreover, it demonstrates the laboratory's commitment to quality assurance and proficiency, reinforcing the credibility and trustworthiness of the analytical data generated in clinical practice.

Table 2: Reproducibility results obtained on the 2 levels: low and high.

Operators evaluated	Number of values	Variability results
Low level	30	Mean: 63.28 IU/mL SD: 4.735 IU/mL CV: 7.48 %
High level	30	Mean: 384.57 IU/mL SD: 19.943 IU/mL CV: 5.19 %

The evaluation of repeatability also yielded compelling results. At the low concentration level, 30 values were subjected to analysis, resulting in a mean of m1 = 67.31 IU/mL and an acceptable low CV of 3.85%. The high concentration level was also satisfactory, with 30 values analyzed, leading to an average of m2 = 398.39 IU/mL and a CV of 1.56%.

Table 3: Repeatability results obtained on the 2 levels: low and high.

Samples	Number of values	Mean	SD	CV
Low level	30	67.31 IU/mL	2.593 IU/mL	3.85 %
High level	30	398.39 IU/mL	6.200 IU/mL	1.56 %

The exceptionally low coefficients of variation achieved in both reproducibility and repeatability analyses unequivocally meet the rigorous requirements set forth by esteemed learned societies such as SFBC. These low CV values underscore the assay's outstanding precision and reliability for both concentration levels, even when dealing 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 IgE assay, as evidenced by the meticulous evaluation of reproducibility and repeatability, serves as a testament to the laboratory's unwavering commitment to adhering to stringent quality control measures. The results substantiate the laboratory's adherence to international standards and guidelines, positioning it as a center of excellence in clinical diagnostics and research. By consistently achieving CV values well below the acceptable limits, the laboratory enhances the trust of healthcare providers and patients in the accuracy and reliability of the analytical data generated, ultimately benefiting patient care and advancing the field of clinical diagnostics. These exemplary findings contribute to the ever-evolving landscape of medical knowledge and foster a culture of continuous improvement in laboratory practices, ultimately benefitting the health and well-being of the population served by the Mohammed VI University Hospital.

The central laboratory of the Mohammed VI University Hospital in Oujda has established a comprehensive quality strategy, encompassing a meticulous method verification procedure. Undertaking such a study is pivotal in establishing a robust and reliable accreditation process for the laboratory's analyses. As a center of reference in the Eastern region of Morocco, the laboratory plays a pivotal role in providing diagnostic services not only to referred or hospitalized patients but also in evaluating the overall health of the general population in the region through various scientific studies.[16, 17]

5 CONCLUSION

The analytical performance of the Architect ci8200 automated system was satisfactory for a reliable determination of IgE. Verification of methods of dosage in the medical laboratory is crucial to ensure the accuracy, precision, and reliability of laboratory test results. Verification involves confirming that the test method employed is appropriate for the intended use, produces results that are consistent with the claimed performance characteristics, and meets the laboratory's quality control and quality assurance requirements.

STATEMENTS ON COMPLIANCE WITH ETHICAL STANDARDS

Acknowledgments

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Disclosure of Conflict of Interest

The authors declare no conflict of interest in the preparation and publication of this article.

Statement of Ethical Approval

Ethical approval was not required for this study, as it involved the verification of the analytical performance of a laboratory assay using routine laboratory data and/or quality-control materials, without direct intervention involving human participants.

Statement of Informed Consent

Informed consent was not required for this study because it involved analytical performance verification and did not involve direct participation or intervention with human subjects.

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