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(RESEARCH ARTICLE)

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Verification of the analytical performance of the serum C-reactive Protein (CRP) assay on the Abbott® ARCHITECT ci8200 in the Biochemistry Laboratory of the Mohammed VI University Hospital, Oujda

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Abstract

The validation of analytical methods is mandated by the NF EN ISO 15189 standard. It consists of assessing an analytical method's performance based on a structured protocol and comparing the results to predefined analytical targets. In this context, this study evaluates the analytical performance of -reactive Protein (CRP) immunoassay using immunoturbidimetry on the Abbott ARCHITECT® ci8200 analyzer. Conducted over 30 days in the biochemistry laboratory of Mohammed VI University Hospital, the research assesses reproducibility and repeatability based on ISO 15189 accreditation guidelines. Results show low coefficients of variation (CV), with reproducibility ranging from 1.83% to 3.42% and repeatability from 1.96% to 7.67%, meeting established quality standards. These findings confirm the robustness and reliability of the method, ensuring accurate CRP measurement for clinical diagnostics.

Keywords: C-reactive protein; Immunoturbidimetry; Abbott ARCHITECT®; Biochemistry laboratory; Reproducibility; Repeatability

1. Introduction

In compliance with ISO 15189 standards, verifying analytical methods to confirm meeting intended clinical and analytical requirements is mandatory. It is a process that involves evaluating the performance of an analytical method, quantifying it by following a standardized operating protocol, and then verifying it compared to standards determined by learned societies (RICOS, FSCB) (1). Among the clinical parameters, C-reactive protein (CRP) plays a crucial role as a biomarker of inflammation and infection. Thus, reliable CRP measurement is essential for guiding clinical decisions and improving patient outcomes.

C-reactive protein (CRP) is an acute-phase protein primarily synthesized by the liver in response to inflammatory stimuli, particularly interleukin-6 (IL-6). It is a key biomarker of systemic inflammation and is widely used in clinical practice for diagnosing and monitoring various pathological conditions, including infections, autoimmune diseases, and cardiovascular disorders (2). Clinically, CRP measurement is valuable due to its rapid rise in response to inflammation, with levels increasing within hours and peaking around 48 hours before gradually declining as the inflammatory process resolves. Given its broad clinical applications, CRP remains a cornerstone biomarker in laboratory medicine, aiding in disease diagnosis, prognosis, and treatment monitoring. (3)

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The Architect ci8200® by Abbott is an integrated clinical chemistry and immunoassay analyzer designed for high-throughput laboratory diagnostics, providing a comprehensive testing platform. In order to ensure precision and reliability of analytical method on these platforms, it is mandatory to rigorously verify the analytical performance of assays.

Analytical method verification is a structured process that evaluates the capabilities of an analytical procedure. It involves quantification through a standardized operational protocol, followed by comparison with established criteria established by esteemed societies such as RICOS and FSCB. This assessment provides laboratories with valuable insights into their analytical techniques, performance parameters, and limitations. Most importantly, it ensures that these performance metrics uphold the reliability of analytical results, enabling clinically meaningful interpretations for both patients and healthcare professionals.

1.1. Principle of the assay method

The CRP serum assay on the Architect ci8200® (Abbott) is based on a turbidimetric immunoassay using latex-enhanced immunoturbidimetry. This method quantifies C-reactive protein (CRP) levels in serum or plasma by measuring the change in turbidity caused by antigen-antibody reactions. The patient's serum or plasma sample is mixed with polystyrene latex particles coated with specific anti-CRP antibodies. The CRP present in the sample, binds to the coated antibodies, forming immune complexes that cause an increase in turbidity. The increase in turbidity is proportional to the CRP concentration in the sample. The Architect ci8200® measures this turbidity using a photometric detection system at a specific wavelength.

2. Material and methods

In compliance with ISO 15189 standards, verifying analytical methods to confirm meeting intended clinical and analytical requirements is mandatory. It is a process that involves evaluating the performance of an analytical method, quantifying it by following a standardized operating protocol, and then verifying it compared to standards determined by learned societies (RICOS, FSCB) (1). Among the clinical parameters, C-reactive protein (CRP) plays a crucial role as a biomarker of inflammation and infection. Thus, reliable CRP measurement is essential for guiding clinical decisions and improving patient outcomes.

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3. Results

3.1. Reproducibility results

Reproducibility tests evaluate result consistency when the method is performed under varying conditions like operators, instruments, laboratories, calibrations or time points. The objective of reproducibility tests is to assess acceptance criteria especially in decision support systems. The variability of results is measured with the Coefficient of Variation (CV). This method improves insight into the test's reliability and effectiveness, contributing to the refinement

and advancement of diagnostic techniques while enhancing the overall quality of laboratory analyses in clinical diagnostics.

For the low, medium, and high levels, the CV values provided were CV1= 3.42%, CV2 =1.83%, CV3 = 3.28%. These results are illustrated on the Levey-Jennings graphs (Fig. 1, fig. 2, fig. 3).

The reproducibility test results were acceptable across each single level with coefficient of variation falling below the tolerated limits set by the manufacturer's specifications. No CV reference values were established by RICOS. These results are visually represented on the table 1 to improve the clarity of the results.

Table 1 Reproducibility results of blood assay by level with comparison to FSBC and Manufacturer's specifications

Level of Internal quality control (IQC)	Number of values	Mean (g/l)	Standard Deviation (g/l)	Coefficient of Variation CV (%)	Reference CV SFBC 1999 (%)	Reference CV: Manufacturer's specifications
Low level	30	3.10	0.106	3.42	14.42	6
Medium level	30	9.12	0.167	1.83	7.27	6
High level	30	30.71	1.008	3.28	6.08	6

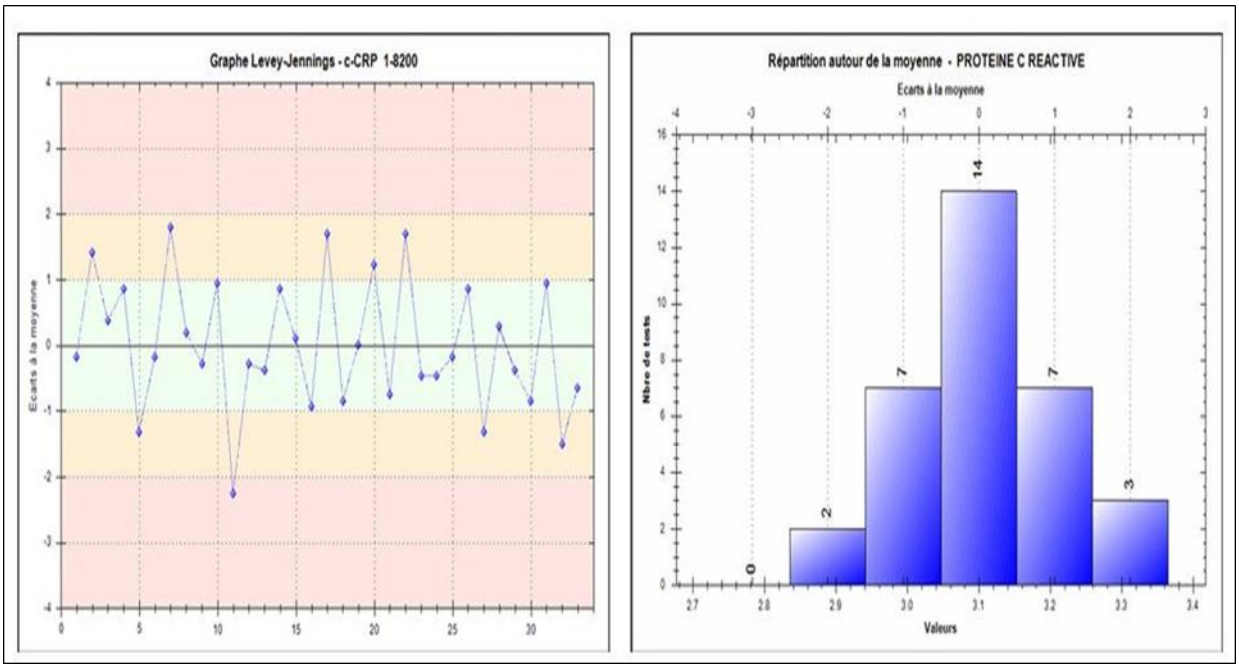

Figure 1 Low Level of Reproducibility: Levey Jennings graph and the distribution around the mean – CRP

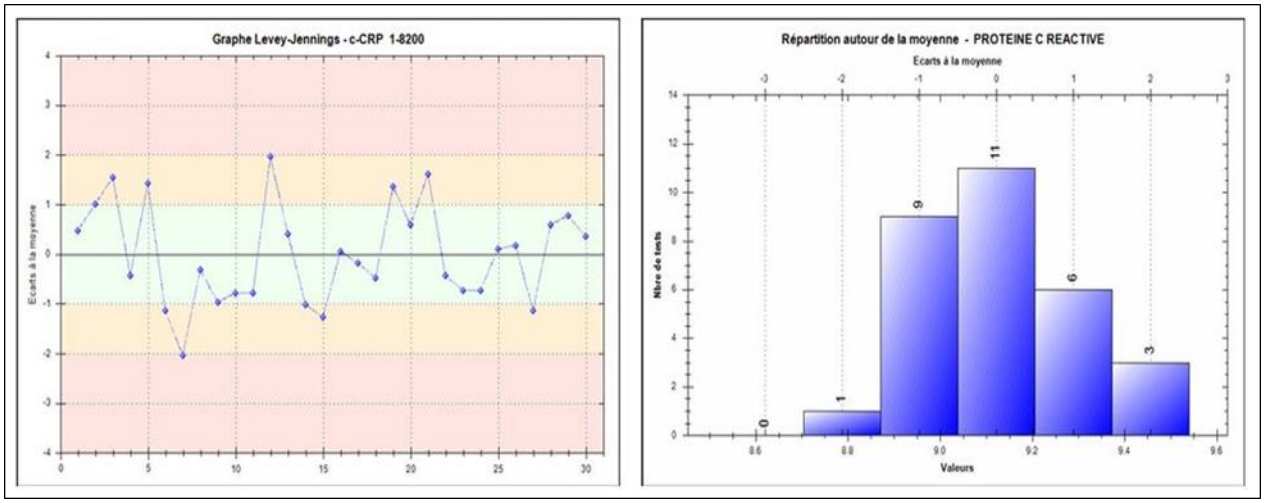

Figure 2 Medium Level of Reproducibility: Levey Jennings graph and the distribution around the mean – CRP

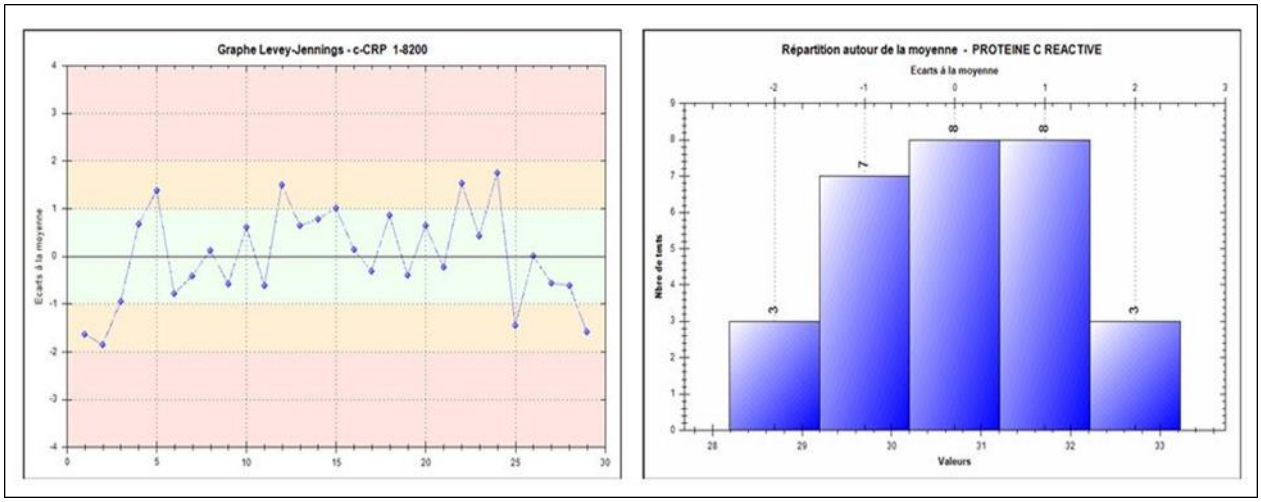

Figure 3 High Level of Reproducibility: Levey Jennings graph and the distribution around the mean – CRP

3.2. Repeatability Results

Repeatability refers to the ability of an analytical method to produce consistent results when the same sample is tested multiple times under identical conditions (same instrument, same operator, same reagents, and within a short time frame). It reflects the method's intra-assay precision. It is also expressed as a coefficient of variation (CV%).

For the low, medium, and high levels, the CV values are provided (CV1 = 7.67 %, CV2 = 4.77 %, CV3 = 1.96 %). These results are illustrated on the Levey-Jennings graphs (Fig. 4, fig. 5, fig. 6).

The conclusion for each level asserts that the repeatability CV is accurate and remains within the acceptable limits. Additionally, FSBC limits (with expansion coefficient k = 1.211) are mentioned, and the CV values are compared to these limits (Table 2).

Table 2 Repeatability results of blood assay by level with comparison to FSBC

Level of Internal quality control (IQC)	Number of values	Mean (g/l)	Standard Deviation (g/l)	Coefficient of Variation CV (%)	Reference CV SFBC 1999 (%)
Low level	30	3.42	0.262	7.67	9.00
Medium level	30	9.36	0.447	4.77	5.45
High level	30	31.75	0.623	1.96	4.54

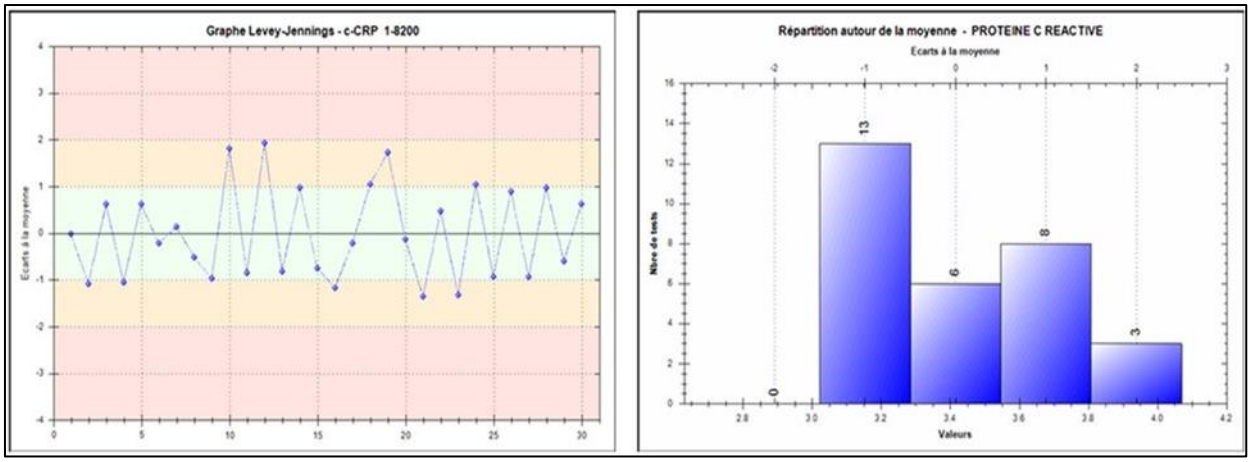

Figure 4 Low Level of Repeatability: Levey Jennings graph and the distribution around the mean – CRP

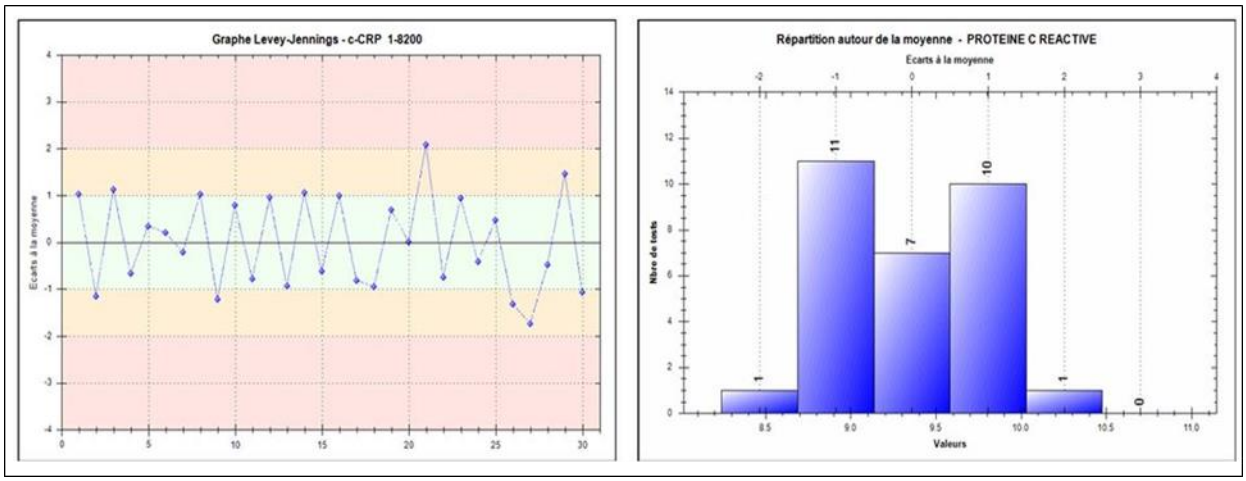

Figure 5 Medium Level of Repeatability: Levey Jennings graph and the distribution around the mean – CRP

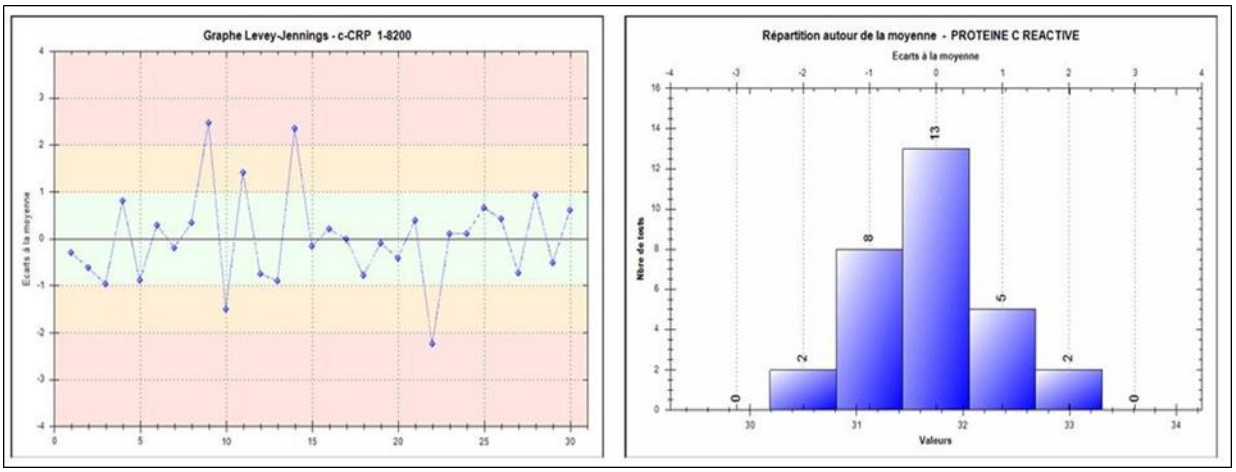

Figure 6 High Level of Repeatability: Levey Jennings graph and the distribution around the mean – CRP

Whether in reproducibility or repeatability, the conclusion relies on comparing CV values to predefined tolerance limits. The reported CV values reflect the measurement variability. Since the calculated CV values fall below the established limits, this indicates that the system maintains acceptable reproducibility and repeatability.

4. Discussion

C-reactive protein (CRP) is an acute-phase protein synthesized by the liver in response to inflammation. Discovered in 1930 by Tillet and Francis, it was initially identified as a substance in the serum of patients with acute inflammation that reacted with the "c" carbohydrate antigen of the pneumococcal capsule (4). Today, CRP measurement is a crucial tool in clinical medicine for diagnosis, therapeutic monitoring, and cardiovascular risk assessment.

Since its discovery, CRP has been extensively studied as an inflammatory biomarker. Its synthesis is induced by pro-inflammatory cytokines during inflammatory or infectious processes. CRP exists in conformationally distinct forms, such as native pentameric CRP and monomeric CRP, each exhibiting different functional properties (5). As an acute-phase protein, its plasma concentration can increase exponentially within hours following an inflammatory stimulus.

CRP measurement is utilized in various clinical contexts, including: diagnosis and monitoring of bacterial and viral infections, evaluation of chronic inflammatory diseases and cardiovascular risk stratification.

The accuracy and reliability of CRP measurements are critical for ensuring proper result interpretation. These parameters are assessed based on two criteria. Repeatability is the ability of an analytical method to provide consistent results under identical conditions (same operator, same instrument, same day), while reproducibility refers to the ability of a method to provide consistent results under varied conditions (different operators, equipment, or laboratories). Coefficients of variation (CV) are commonly used to assess these parameters. The CV provides a percentage measure of how much the results deviate from the mean, indicating the level of dispersion or scatter in the data. Excessive variability may be attributed to technical errors, differences in calibrators, or suboptimal analytical conditions. High precision and reproducibility are essential for reliable CRP quantification. In this context, the laboratory evaluates the effectiveness of its method by comparing obtained results with expected reference data from sources like manufacturers or scientific organizations. This comparison determines the compliance of the method with the required criteria for the specific tests performed. To ensure a valid and relevant assessment, the characteristics of the samples used in this process are precisely defined (6).

This study aimed to verify the analytical performance of C-reactive protein assays on the Architect c® system within the Biochemistry Laboratory of Mohammed VI University Hospital in Oujda. Concerning reproducibility, for each of the low, medium, and high levels, the CV values are 3.42%, 1.83%, 3.28% respectively. These values are relatively low, which implies that the assay is producing consistent results across different conditions. The reproducibility results suggest that the turbidimetric immunoassay using latex-enhanced immunoturbidimetry method is robust and stable across various conditions. The alignment of CV values with established quality control limits confirms that the assay meets industry standards for reproducibility, validating its reliability for precise diagnostic applications.

On the other hand, the repeatability assessment has shown that the turbidimetric immunoassay assay used in our laboratory exhibits satisfactory precision. Yet the coefficients of variation for repeatability were not remarkably low for the low and medium levels (7.67 %, 4.77 % respectively), but they remain lower compared to the coefficient of variation provided by the SFBC, emphasizing minimal variability in repeated measurements under the same conditions. This level of precision is essential in clinical testing, where small variations can have significant implications for patient care.

The coefficients of variation derived from the analysis of repeatability and reproducibility were well within acceptable limits, meeting the supplier's specified criteria. The results reinforce the robustness and reliability of the serum CRP assay using the turbidimetric immunoassay using latex-enhanced immunoturbidimetry method. The assay determines low variability and high precision across varying conditions and repeated analyses of the same sample, marking the assay method convenient for precise and reliable measurements in critical clinical diagnostics.

5. Conclusion

C-reactive protein measurement is a fundamental tool in clinical medicine, enabling the detection, monitoring, and risk stratification of various pathological conditions. However, the reliability of results depends on rigorous evaluation of the repeatability and reproducibility of the analytical methods used. Strict standardization and adherence to analytical performance criteria are essential to ensure interpretable and comparable results across laboratories.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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