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Verification of the analytical performance of the serum Beta-2 microglobulin (β2M) assay on the Abbott Alinity ci®: Experience of the Biochemistry Laboratory of the Mohammed VI University Hospital, Oujda

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Abstract

The verification of analytical performance is a critical step in ensuring the reliability and accuracy of laboratory assays. This study aims to evaluate the analytical performance of the beta-2 microglobulin (β2M) immunoassay on the Abbott Alinity ci® platform in the central laboratory of Mohammed VI University Hospital of Oujda over a 30-day duration. The study assesses key analytical parameters, including precision, reproducibility, and repeatability against established standards, based on ISO 15189 accreditation guidelines. Results show low coefficients of variation (CV), with reproducibility ranging from 2.36% to 2.94% and repeatability from 1.00%to 2.55%, meeting the stringent criteria set by recognized professional societies. These findings confirm the robustness and reliability of the method and validate the analytical performance of the β2M assay, underscoring its suitability for clinical use.

Keywords: Biochemistry Laboratory; Reproducibility; Repeatability; Beta-2 Microglobulin; Abbott Alinity ci®

1. Introduction

Beta-2 microglobulin (β2M) continues to be a focal point in recent scientific research due to its multifaceted roles in health and disease. It is a low-molecular-weight protein used as a biomarker for renal function, hematological malignancies, and autoimmune disorders. In fact, studies have reinforced the utility of β2M as a prognostic indicator in various blood cancers. Elevated serum β2M levels have been associated with poorer outcomes in multiple myeloma and lymphoma. Specifically, in acute lymphoblastic leukemia (ALL), higher β2M levels at diagnosis correlate with lower complete response rates and reduced survival, underscoring its significance in pretreatment evaluations(1). Moreover, β2M serves as a sensitive marker for renal health. Elevated levels in serum or plasma can indicate kidney dysfunction, particularly affecting the renal tubules. Monitoring β2M levels is valuable in assessing renal function in kidney transplant recipients and patients with suspected tubulointerstitial diseases.(2) These advancements underscore the importance of β2M in clinical diagnostics, therapeutic interventions, and understanding of disease mechanisms.

Accurate quantification of β2M is essential for clinical decision-making. The Abbott Alinity ci® is a widely used automated system for immunoassays, and verifying its performance for β2M measurement is crucial for ensuring quality results in patient care. This study follows ISO 15189 accreditation guidelines and manufacturer specifications to validate the reliability of the β2M assay.

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1.1. Principle of the assay method

The β2-Microglobulin (β2M) assay on the Abbott Alinity c system is based on a turbidimetric immunoassay principle. The Alinity c β2-Microglobulin reagent consists of a suspension of uniformly sized polystyrene latex particles coated with the IgG fraction from a specific anti-human β2M serum. When a sample containing β2M is mixed with the reagent, a distinct agglutination occurs, which can be measured by turbidimetry. The degree of agglutination is directly proportional to the concentration of β2M in the sample. This turbidity change is measured photometrically by the Alinity c system at a specific wavelength. The instrument compares the turbidity with a standard calibration curve. The β2M concentration is calculated based on the absorbance of the agglutination reaction.

2. Materials and Methods

This prospective study was conducted in the biochemistry laboratory of Mohammed VI University Hospital over a 30-day duration. The investigation focused on the reproducibility and repeatability of β2M dosage. The study was conducted in two phases: first, daily control measurements at three levels (low, medium, high) over 30 days assessed reproducibility and consistency. In the second phase, serum samples with varying β2M concentrations were grouped into three levels, and 30 replicates per sample were performed to evaluate repeatability. The analysis was performed using a β2M reagent kit on the chemistry module, and data statistical analysis was facilitated by the EVM intermediate module from BYG Informatics. The coefficient of variation (CV) values obtained were compared with manufacturer's specifications, no CV reference values were established by Ricos.

3. Results

3.1. Reproducibility results

Reproducibility tests assess the consistency of results when a method is applied under different conditions, such as varying operators, instruments, laboratories, calibrations, or time points. Their primary goal is to evaluate acceptance criteria, particularly in decision support systems. The variability in results is quantified using the Coefficient of Variation (CV). By providing deeper insights into a test's reliability and performance, this approach helps refine diagnostic techniques and enhance the overall quality of laboratory analyses in clinical diagnostics.

For the low, medium, and high levels, the CV values provided were CV1= 2.36%, CV2 =2.94%, CV3 = 2.44%. These results are illustrated on the Levey-Jennings graphs (Fig. 1, fig. 2, fig. 3).

The reproducibility test demonstrated acceptable results at each individual level, with the Coefficient of Variation (CV) remaining within the allowable limits defined by the manufacturer's specifications. No CV reference values were established by RICOS. To enhance clarity, these findings are visually summarized in Table 1.

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 (mg/l)	Standard Deviation (mg/l)	Coefficient of Variation CV (%)	Reference CV SFBC 1999 (%)	Reference CV : Manufacturer's specifications
Low level	30	1.11	0.026	2.36	9.75	4.4
Medium level	30	1.51	0.045	2.94	8.48	4.4
High level	30	2.14	0.052	2.44	8.48	4.4

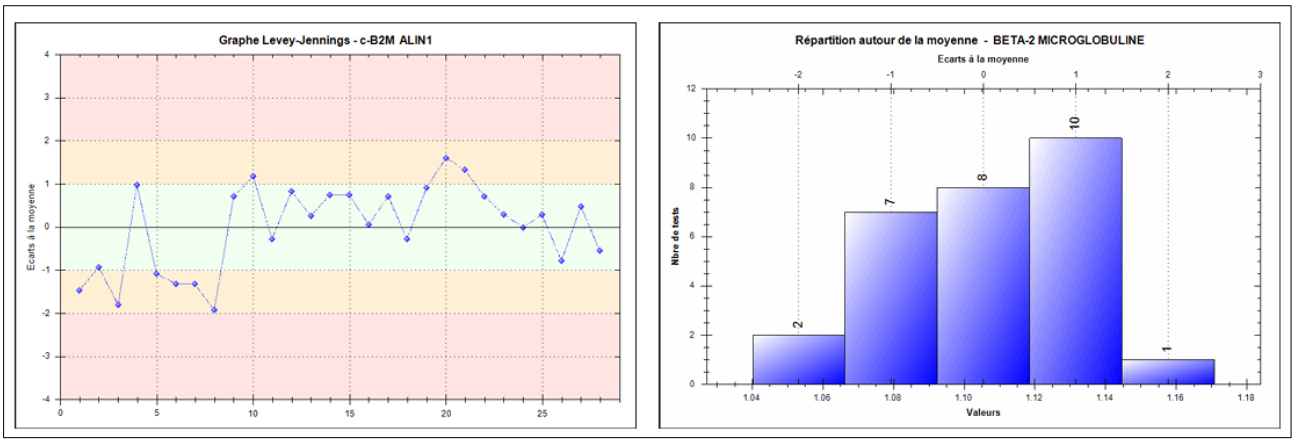

Figure 1 Low Level of Reproducibility: Levey Jennings graph and the distribution around the mean – β2M

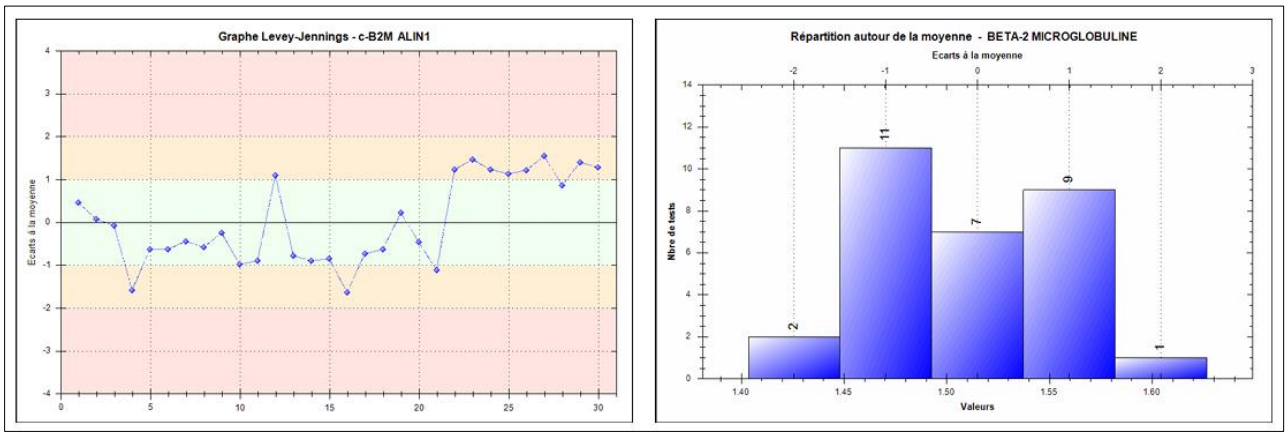

Figure 2 Medium Level of Reproducibility: Levey Jennings graph and the distribution around the mean – β2M

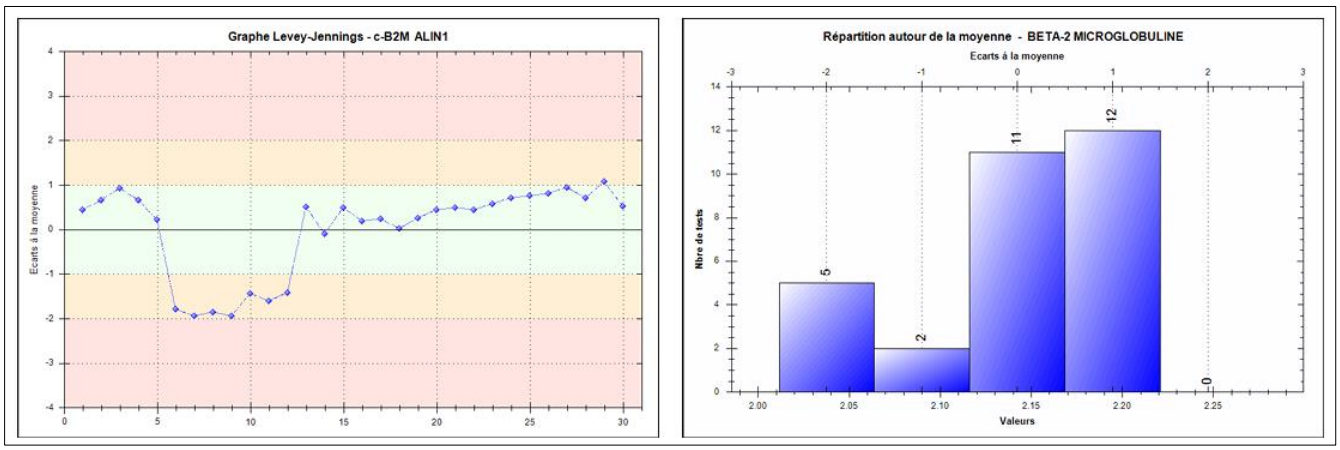

Figure 3 High Level of Reproducibility: Levey Jennings graph and the distribution around the mean – β2M

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%).

Similarly, for the low, medium, and high levels, the CV values are provided (CV1 = 2.55 %, CV2 = 1.68%, CV3 = 1.00%). These results are illustrated on the Levey-Jennings graphs (Fig. 4, fig. 5, fig. 6).

The conclusion for each level confirms that the repeatability Coefficient of Variation (CV) is precise and falls within the permissible range. Furthermore, the FSBC limits (with an expansion coefficient k = 1.211) and manufacturer's specifications are considered, and the CV values are evaluated in relation to these limits, as shown in Table 2.

Table 2 repeatability results of blood assay by level with comparison to FSBC and Manufacturer's specifications;

Level of Internal quality control (IQC)	Number of values	Mean (mg/l)	Standard Deviation (mg/l)	Coefficient of Variation CV (%)	Reference CV SFBC 1999 (%)	Reference CV : Manufacturer's specifications
Low level	30	0.97	0.025	2.55	7.27	4.1
Medium level	30	1.33	0.022	1.68	6.36	4.1
High level	30	1.72	0.017	1.00	6.36	4.1

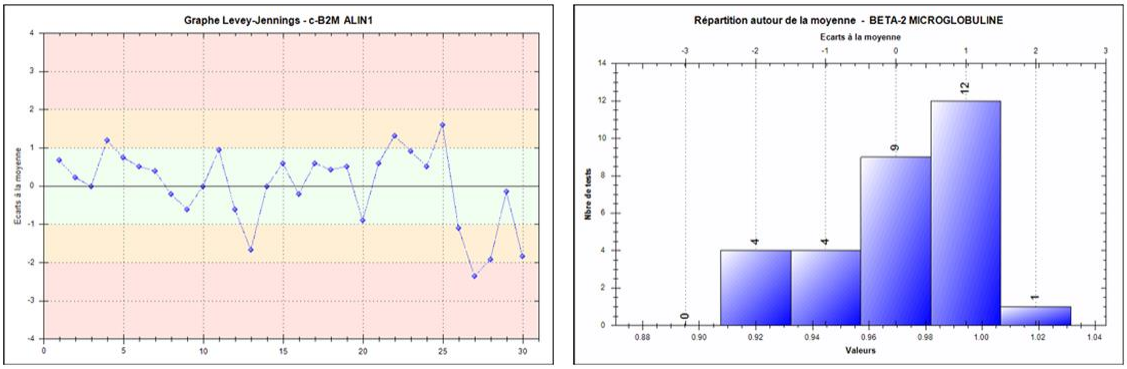

Figure 4 Low Level of Repeatability: Levey Jennings graph and the distribution around the mean – β2M

Regardless of whether assessing reproducibility or repeatability, the conclusion is drawn by comparing Coefficient of Variation (CV) values to predefined tolerance limits. The reported CV values represent measurement variability. Since the calculated CV values fall below the established limits, this indicates that the system maintains acceptable reproducibility and repeatability.

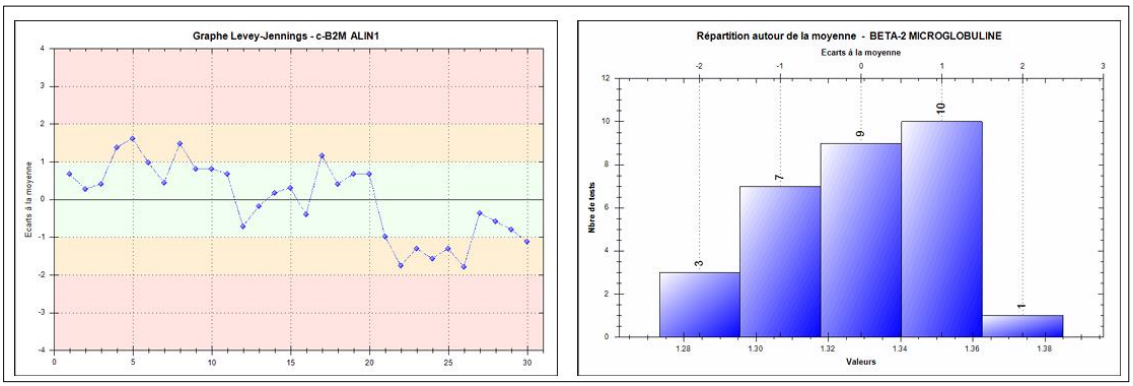

Figure 5 Medium Level of Repeatability: Levey Jennings graph and the distribution around the mean – β2M

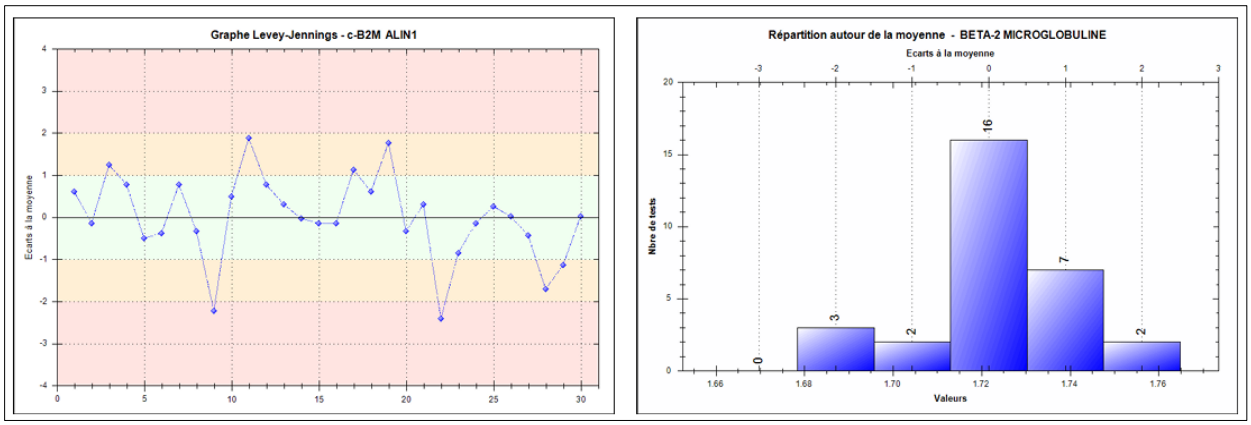

Figure 6 High Level of Repeatability: Levey Jennings graph and the distribution around the mean – β2M

4. Discussion

Beta-2 microglobulin (β2M) is a small protein that plays a crucial role in the immune system as a component of Major Histocompatibility Complex (MHC) class I molecules, which are present on the surface of all nucleated cells and are essential for antigen presentation to cytotoxic T cells. The β2M gene, encoding this protein, has been extensively studied, and its complete amino acid sequence was determined in 1973, providing key insights into its function(3). Clinically, β2M serves as a valuable biomarker in various diseases. Elevated serum levels are associated with renal disorders, particularly in patients undergoing long-term hemodialysis, where β2M accumulates and contributes to dialysis-related amyloidosis, leading to joint pain and dysfunction(2). In hematologic malignancies, such as multiple myeloma and lymphomas, β2M acts as a prognostic marker, correlating with disease severity(4) (5). Additionally, its levels are relevant in infectious diseases, with studies indicating that low β2M concentrations can be linked to non-progression in HIV infection. These findings highlight the broad clinical significance of β2M in both diagnostics and prognosis, reinforcing its importance in laboratory medicine and disease monitoring.

The precision and reliability of β2M measurements are essential for accurate result interpretation. These aspects are evaluated using two key criteria. Repeatability refers to an analytical method's capacity to generate consistent results under identical conditions (same operator, instrument, and day), whereas reproducibility assesses the method's consistency when conditions vary (different operators, instruments, or laboratories). These parameters are typically quantified using coefficients of variation (CV), which express the percentage deviation of results from the mean, reflecting data dispersion. Excessive variation can stem from technical inconsistencies, differences in calibration, or suboptimal analytical conditions. Ensuring high precision and reproducibility is crucial for the reliability of β2M quantification. To this end, laboratories assess method performance by comparing obtained results with reference values from manufacturers or scientific organizations. This comparison determines whether the method meets the required standards for the specific assays conducted. To maintain a valid and relevant evaluation, the sample specifications used in this verification process are rigorously defined. (6)

This study aimed to verify the analytical performance of the serum Beta-2 microglobulin (β2M) assay on the Abbott Alinity ci®. Concerning reproducibility, for each of the low, medium and high levels the CV values were 2.36%, 2.94%, 2.44% respectively, which are relatively low, suggesting that the assay produces consistent results across varying conditions. On the other hand, the CV values for repeatability are low: CV1 = 2.55 %, CV2 = 1.68%, CV3 = 1.00%. These values indicate that the variability is minimal, confirming the high precision of the assay.

In summary, the CV values are relatively low, which implies that the assay is producing consistent results across different conditions. The coefficients of variation derived from the analysis of repeatability and intermediate fidelity were well within acceptable limits, meeting the supplier's specified criteria. These outcomes confirm the efficacy of assay method based on immunoturbidimetry, demonstrating its consistency and stability. Unreliable results could lead to misdiagnosis, inappropriate treatment decisions, or failure to detect disease progression. Therefore, verifying the assay on Alinity ci® ensures clinically actionable and reproducible β2M quantification. In addition, evaluating the assay against quality control standards offers an objective confirmation of its performance, ensuring healthcare professionals and researchers that the method produces reliable and consistent results.

5. Conclusion

The verification study confirms the reliability and accuracy of the β2M assay on the Abbott Alinity ci® platform. These findings support its implementation in routine clinical diagnostics, ensuring high analytical performance and compliance with international quality standards. Continuous monitoring and quality control are essential to maintaining optimal assay performance in real-world laboratory settings.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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