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Verification of the analytical performance of BNP (Brain Natriuretic Peptide) Assay on the Abbott Alinity ci®: Experience of the Biochemistry laboratory of Mohammed VI University Hospital in Oujda/Morocco

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Abstract

Brain Natriuretic Peptide (BNP) is a good cardiac biomarker used for diagnostic, prognostic, and therapeutic monitoring in heart failure, but also in other affections like pulmonary arterial hypertension (PAH). The purpose of our work is to evaluate the analytical performance of the BNP assay on the Abbott Alinity ci® Analyzer at the Biochemistry laboratory of the Mohammed VI University Hospital in Oujda. The methodology of this work is based on the evaluation of reproducibility and repeatability, based on the technical accreditation guide (SH GTA 04) of the French Accreditation Committee (COFRAC). The results obtained for the different BNP dosage verification criteria show satisfactory repeatability for all levels (1: low / 2: medium, and 3: high), Intra-laboratory reproducibility was also satisfactory for all levels. By comparing these results with the CV used by the CLSI, we see that the results are consistent with and below the tolerated limits. This study shows that the Biochemistry laboratory of the Mohammed VI University Hospital in Oujda can provide accurate and precise results which regards with the requirements of learned societies for the determination of BNP.

Keywords: Analytical performance; BNP; Repeatability; Reproducibility; Abbott Alinity ci® analyzer

1. Introduction

Brain Natriuretic Peptide (BNP) is a peptide made up of 32 amino acids, it was discovered for the first time in the pig brain, hence its name. The BNP is produced following the proteolysis of a precursor (ProBNP) which also gives an inactive product (NT-ProBNP), and these two products can be measured in serum (1). These two peptides are produced by cardiomyocytes following excessive stretching of the ventricles, which is encountered mainly in heart failure and other affections such as pulmonary arterial hypertension (PAH). BNP measurement can have diagnostic, prognostic, or therapeutic monitoring value, hence the importance of reliable measurement of this cardiac biomarker (2). The purpose of our study is the verification of the BNP Assay by Chemiluminescent Microparticle Immunoassay (CMIA) on the Abbott Alinity ci® Analyser. This assessment consists of studying the analytical performance of the operational processes used by our laboratory and comparing them to the standards developed by learned societies in the field of method verification (CLSI, RICOS, etc.). These global processes verification provide the laboratory with a real and up-to-date picture of the performance of its analysis methods, but also of their limitations, which must be minimized to produce accurate results that meet the requirements of analytical standards and allow the adequate and easy clinical interpretation that leads to optimal therapeutic decision-making, especially with this biomarker which is a major parameter in heart failure. This BNP process verification is part of a global quality management approach for our

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laboratory, which includes, among other things, verifications of all dosing methods used by the Central Laboratory of the Mohammed VI University Hospital in Oujda.

2. Material and methods

This is a prospective study carried out in the Biochemistry Laboratory of the Mohammed VI University Hospital in Oujda for 30 days. The methodology of this work is based on the assessment of reproducibility (intermediate fidelity) and repeatability, based on the recommendations of the technical guide for accreditation (SH GTA 04) of the French Accreditation Committee (COFRAC). Technically, this work was carried out in two phases, The first phase aimed to evaluate the reproducibility of the BNP results provided by the Analyser, and to do this, daily tests were carried out by different operators on control samples at three concentration levels (low, medium and high), according to the manufacturer's recommendations, and this for 30 days, the main objective of this phase was the evaluation of the consistency and reliability of the results in different conditions (spaced periods, different operators, etc.). The second phase consists of evaluating the repeatability of the same samples, without time spacing and without changing the operator. To do this, a collection of patient serum samples was carried out and classified into three groups of BNP concentrations (low, medium, and high) with a homogeneous distribution of BNP values over the entire measurement spectrum, then each serum sample was tested 30 times without delay (one test after the other). The BNP Assay was carried out using a reagent kit dedicated to this purpose on the Abbott Alinity ci® Analyzer. The BNP dosing method used by this module is a two-step immunoassay for the quantitative determination of human BNP in human plasma collected in EDTA using Chemiluminescent Microparticle Immunoassay (CMIA) technology with flexible assay protocols, called Chemiflex. First, the sample and the anti-BNP antibody-coated paramagnetic microparticles are brought together and the BNP contained in the sample binds to the anti-BNP antibody-coated microparticles. Second, after washing, the acridinium-labeled anti-BNP antibody conjugate is added to form a reaction mixture. After another wash cycle, the pre-activation and activation solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured in relative light units (RLU). There is a direct relationship between the amount of BNP present in the sample and the number of RLU detected by the Alinity optical system. The statistical processing of the data was performed using the EVM middleware from BYG Informatics, which is a software that links the data from the Analyser (Alinity ci® platform) to the validation software iLab. To ensure the reliability of the results obtained, we compared the coefficients of variation of these measurements to the standards established by the Clinical & Laboratory Standards Institute (CLSI Guidelines).

3. Results

3.1. Reproducibility (intermediate fidelity)

The results obtained for the different BNP Assay verification criteria show satisfactory intra-laboratory reproducibility for all levels with respective coefficients of variation of 1.99 % for low-level concentration (CV1), 3.45 % for medium-level concentration (CV2), and 1.18 % high-level concentration (CV3) (Table 1).

To further illustrate these results, the EVM middleware provided us with a graphical representation in the form of a Levey-Jennings curve, to better visualize the distribution of results around the mean (Figure 1, Figure 2, and Figure 3).

Table 1 Reproducibility results of each BNP blood Assay level and comparison to CLSI data

Level of IQC	Number of values	Mean (pg/mL)	Standard Deviation (pg/mL)	Coefficient of Variation CV (%)	References CV (%) (CLSI)
Low	30	95.04	1.890	1.99 %	4.2 %
Medium	30	472.29	16.293	3.45 %	4.5 %
High	30	3640.64	42.966	1.18 %	2.2 %

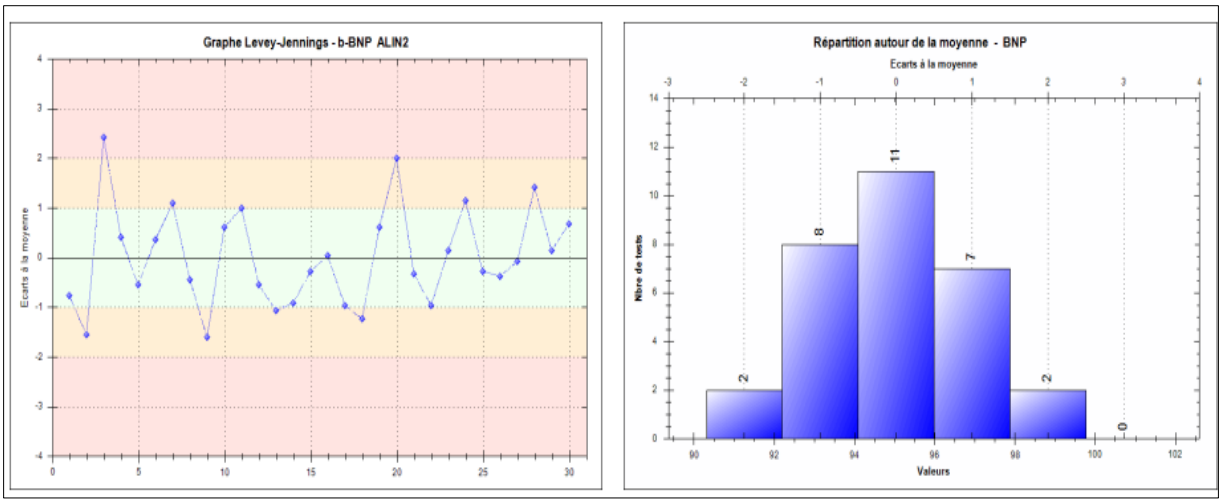

Figure 1 Low level of reproducibility: Levey Jennings curve and distribution around the mean

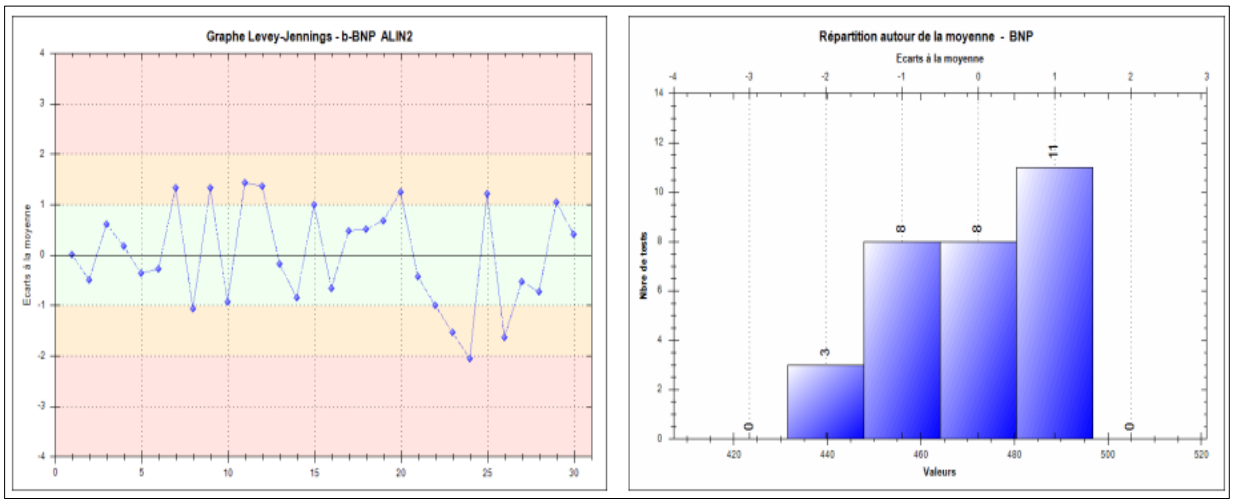

Figure 2 Medium level of reproducibility: Levey Jennings curve and distribution around the mean

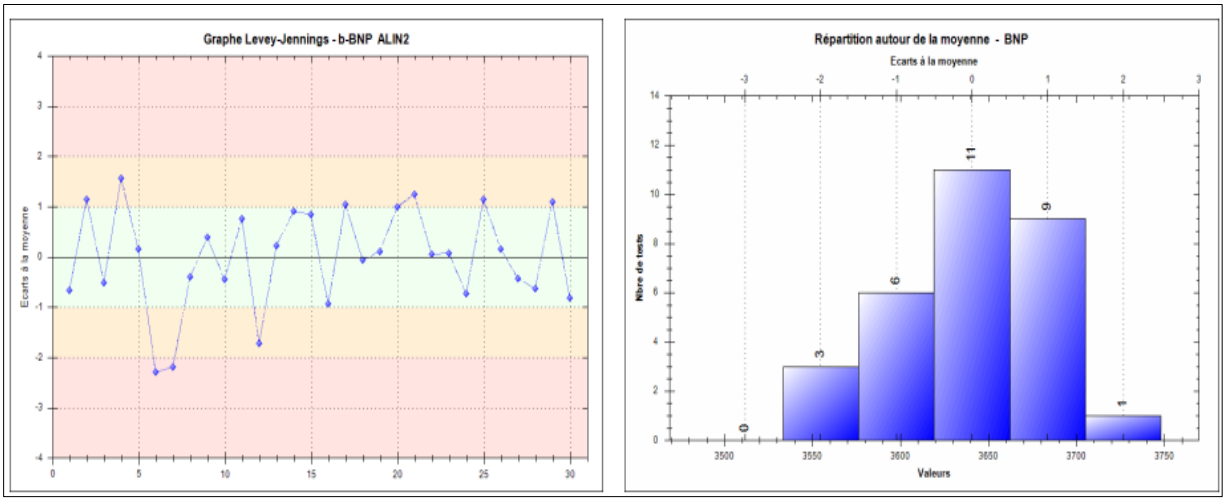

Figure 3 High level of reproducibility: Levey Jennings curve and distribution around the mean

3.2. Repeatability

Concerning this verification component, the results of the BNP Assay also show satisfactory repeatability for all levels (low, medium, and high) with the values of CV1 = 2.29 %, CV2 = 2.71 %, and CV3 = 1.25 % respectively (Table 2).

And also to illustrate the results, the EVM provided us a graphical representation in the form of a Levey-Jennings curve, to better visualize the distribution of the results around the mean (Figure 4, Figure 5, and Figure 6).

Table 2 Repeatability results of each BNP blood assay level and comparison to CLSI data

Level of IQC	Number of values	Mean (pg/mL)	Standard Deviation (pg/mL)	Coefficient of Variation CV (%)	References CV (%) (CLSI)
Low	30	81.92	1.873	2.29 %	3.4 %
Medium	30	441.80	11.972	2.71 %	3.5 %
High	30	3245.38	40.437	1.25 %	1.9 %

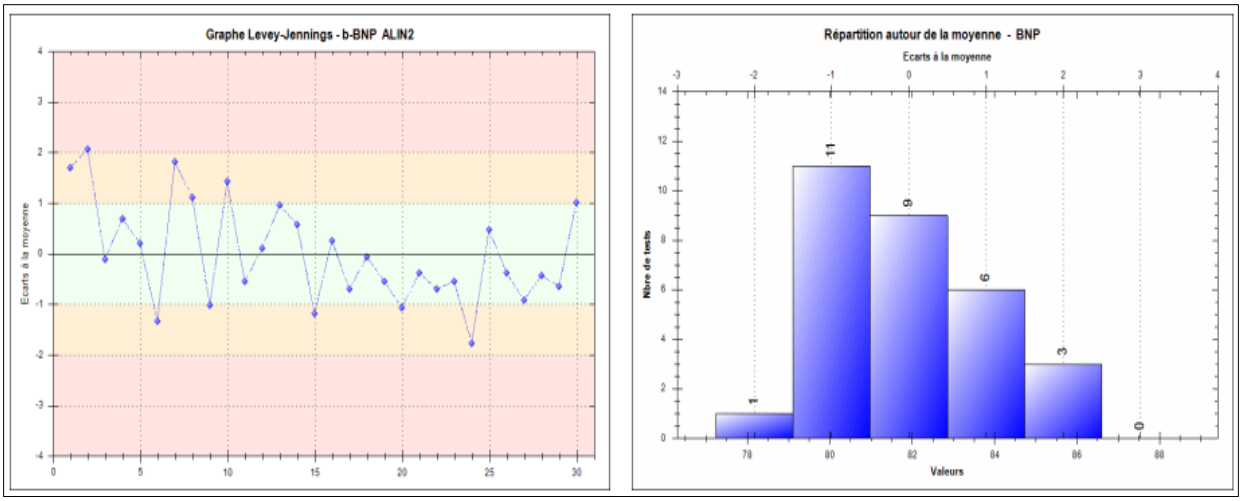

Figure 4 Low level of repeatability: Levey Jennings curve and distribution around the mean.

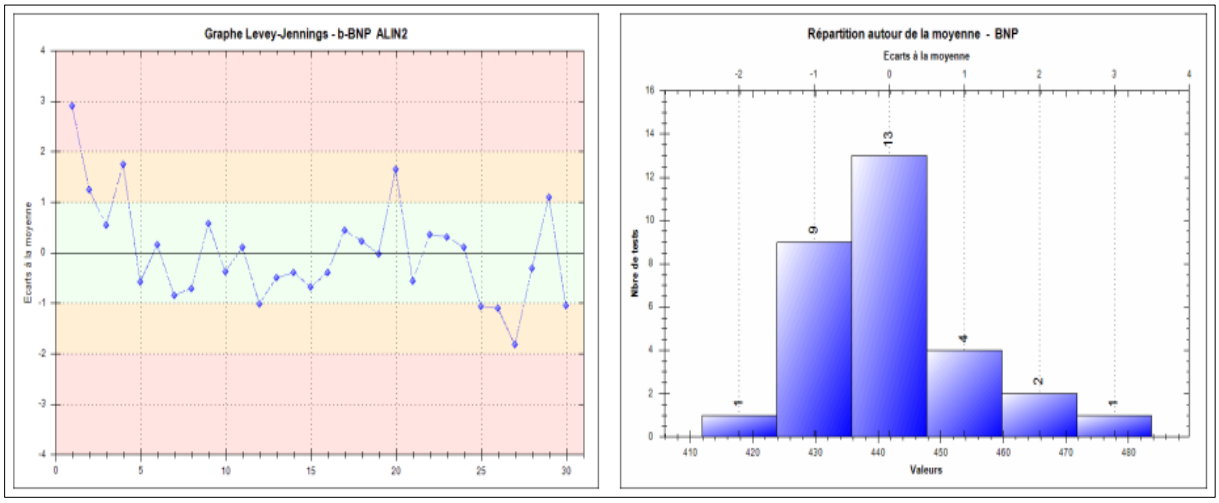

Figure 5 Medium level of repeatability: Levey Jennings curve and distribution around the mean

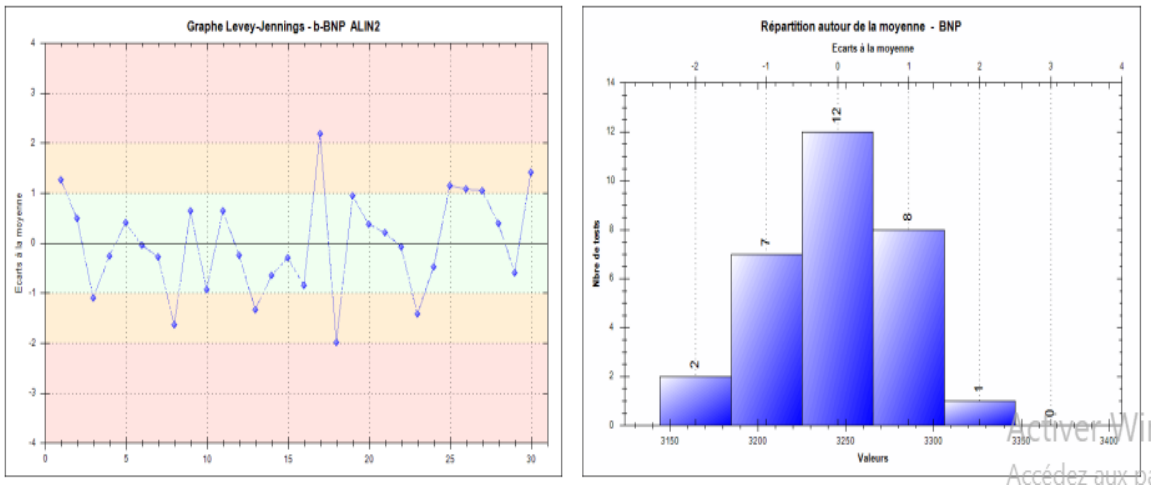

Figure 6 High level of repeatability: Levey Jennings curve and distribution around the mean

4. Discussion

Brain Natriuretic Peptide (BNP) is a good cardiac biomarker used for diagnostic, prognostic, and therapeutic monitoring in heart failure, but also in other affections like pulmonary arterial hypertension (PAH), hence the need to provide clinicians with accurate and reliable results. Verification of Assay methods (using the manufacturer's catalog) and validation of assay methods (verification of a new method or a method with some deviations from the manufacturer's method) are essential tools in a medical biology laboratory to ensure the accuracy, precision, and reliability of the results provided by this laboratory. These methods (verifications/validations) are also required by the regulatory standards described in the Moroccan Guide for the Good Execution of Medical Biology Analyses (GBEA) and in ISO 15189:2022 (3)(4)(5). The BNP Assay by Chemiluminescent Microparticle Immunoassay (CMIA) is a validated method that only requires verification of its analytical performance on the Abbott Alinity ci® Analyser based on the COFRAC SH-GTA-04 guide (6).

Repeatability and reproducibility (intermediate fidelity) are statistical tools that assess the precision, fidelity, and accuracy of measurements made by automated systems in each medical biology laboratory, hence the ethical and regulatory need to have assay methods that are verified and validated within each laboratory. The intermediate fidelity test (also called intra-laboratory reproducibility) consists of examining a single sample under various operating conditions by modifying at least one factor (operator, timing, reagent kits, calibration kits, etc.). This process makes it possible to establish acceptance criteria consistent with previous data, taking into account biological variations, this is particularly useful in decision support systems (7)(8). By comparing the results of the intermediate fidelity assessment with the coefficients of variation retained by the CLSI, we see that the results are consistent and below the tolerated limits. This suggests that this assay technique is robust and reliable and that it can be used for clinical diagnosis. Repeatability testing involves analyzing a single sample under specific conditions, with the same operator, the same instrument, the same reagent kits, and the same calibration kits, and this without delay whenever possible (9). This process aims to characterize the optimal analytical performance of the system (instrument/reagent) for the specific analyte, ensuring the verification of its proper operation under these controlled conditions. For a given analyzer, this calculation must be performed for each matrix/analyte pair to be measured at several concentration levels (minimum two). The concentration levels are chosen according to the medical decision domains (10)(11).

The repeatability assessment demonstrates that the BNP assay in our laboratory by Chemiluminescent Microparticle Immunoassay (CMIA) has a high precision because the coefficients of variation of the repeatability were constantly minimal, which leads us to conclude that there is low variability of repeated measurements under the same conditions. The coefficients of variation and standard deviations of the repeatability and intermediate fidelity tests were very acceptable. The results of these tests were following the supplier's requirements and the CLSI criteria. These results confirm that the Chemiluminescent Microparticle Immunoassay (CMIA) method used by the Biochemistry Laboratory of the Mohammed VI University Hospital in Oujda for the dosing of BNP on the Abbott Alinity ci® analyzer is robust and reliable at different concentration levels and this is confirmed by the comparison of these results with international standards, particularly CLSI. This study shows that the Biochemistry Laboratory of the Mohammed VI University Hospital in Oujda can provide accurate and precise results that can be used for clinical diagnosis and decision-making.

5. Conclusion

At the end of this work, we can conclude that the analytical performances of the Abbott Alinity ci® concerning the dosing of BNP by Chemiluminescent Microparticle Immunoassay (CMIA) are significant and meet the requirements set by learned societies for this dosing, in particular the CLSI. Therefore we can say that the method used by our Laboratory is reliable and the results obtained are accurate and usable for a good clinical diagnosis and better decision-making especially in heart failure.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors declare that they have no competing interests.

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References

[1] Alcidi G, Goffredo G, Correale M, Brunetti ND, Iacoviello M. Brain Natriuretic Peptide Biomarkers in Current Clinical and Therapeutic Scenarios of Heart Failure. J Clin Med. 2022;11(11).

[2] Hendriks PM, van de Groep LD, Veen KM, van Thor MCJ, Meertens S, Boersma E, et al. Prognostic value of brain natriuretic peptides in patients with pulmonary arterial hypertension: A systematic review and meta-analysis. Am Heart J. 2022;250:34–44.

[3] Jean-paul S, Herm I, Ich J marie, Lartigau J. Guide to the proper execution of medical biology analyses (GBEA): its application in the public hospital sector. 1999;27–37.

[4] FDU Laboratory, CI Structuration, DU Laboratory. GBEA: Guide to the proper execution of medical biology analyses.

[5] « ISO 15189:2022 », Medical laboratories Requirements for quality and competence. 2022.

[6] GTA SH. COFRC SH GTA 04, "Technical guide for accreditation of verification (scope A) / validation (scope B) of medical biology methods.

[7] Ismail F, Asmae R, El Moujtahide Dounia, Sebbar EH, Mohammed Choukri. Verification of the analytical performance of ASO (AntiStreptolysin O) Assay on the Abbott Alinity ci®: Experience of the Biochemistry laboratory of Mohammed VI University Hospital in Oujda/Morocco. World J Biol Pharm Heal Sci. 2024;29(2):042–6.

[8] Rhoubi A, Faiz I, Sebbar EH, Moujtahid D El. Reliability of PSA assays : A key asset for early prostate cancer detection. 2025;(3):1–6.

[9] Krimi K, Kidoun A, Elazzouzi MK, Sebbar E, Choukri M, Rchid SM, et al. Verification of methotrexate dosage method on Alinity c Abbott automated system in the biochemistry laboratory of CHU Mohammed VI d ' Oujda. 2024;0–6.

[10] Karim M, Azzouzi EL, Rchid SM, Bourchid K, Elmoujtahide D, Sebbar H, et al. Verification of analytical performance of the 25-OH vitamin D assay on the Abbott Alinity ci ® : Experience of the central laboratory of Mohammed VI University Hospital of Oujda. 2024;2–8.

[11] Kajeiou Z, Yacoubi L, Mokhtari I, Dahmani S, Sebbar E houcine, Choukri M. Verification of the analytical performance of the serum total cholesterol assay on Abbott Architect ci8200 Verification of the analytical performance of the serum total cholesterol assay on Abbott Architect ci8200. 2023;(August).