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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

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Abstract

ASO (AntiStreptolysin O) is an antibody directed against streptolysin O which is an exotoxin secreted by *Streptococcus pyogenes*. The assay is mainly used for the diagnosis of post-streptococcal complications (AAR, nephropathy, etc.), False positives may be observed in cases of hyperlipemic serum, or liver disease. The objective of our work is to evaluate the analytical performance of the ASO assay on the Abbott Alinity ci® 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 ASO dosage verification criteria show satisfactory repeatability for both levels (1: low / 2: medium), Intra-laboratory reproducibility was also satisfactory for both 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 is able to provide accurate and precise results which regards with the requirements of learned societies for the determination of ASO.

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

1. Introduction

ASO (AntiStreptolysin O) is an antibody directed against streptolysin O, which is an exotoxin secreted by *Streptococcus pyogenes* (Group A Streptococcus) living in the nasopharynx and by some strains of group C and G streptococcus (1). This assay can be used for the diagnosis of streptococcal infections, but it is mainly used for the diagnosis of post-streptococcal complications (AAR, nephropathies, endocarditis, etc.), especially in cases of high titer or seroconversion (2). False positives can be observed in cases of hyperlipidemic serum, or in cases of liver disease (3). The objective of our work is the verification of the ASO Assay by immuno-turbidimetry on the Abbott Alinity ci® Analyser. This assessment consists to study 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 in order to produce accurate results that meet the requirements of analytical standards and allow adequate and easy clinical interpretation that leads to optimal therapeutic decision-making. This ASO process verification is part of a global quality management approach for our laboratory, which includes, among other things, verifications of all dosing methods used by the Central Laboratory of the Mohammed VI University Hospital in Oujda.

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2. Material and methods

This is a prospective study carried out in the Biochemistry Laboratory of the Mohammed VI University Hospital in Oujda over a period of 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, a first phase which aimed to evaluate the reproducibility of the ASO results provided by the Analyser, and to do this, daily tests were carried out by different operators on control samples at two concentration levels (low and medium), according to the manufacturer's recommendations, and this for a period of 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 to evaluate the repeatability on the same samples, without time spacing and without changing the operator. And to do this, a collection of patient serum samples was carried out and classified into two groups of ASO concentrations (low and medium) with a homogeneous distribution of ASO values over the entire measurement spectrum, then each serum sample was tested 30 times without delay (one test after the other). The ASO Assay was carried out using a reagent kit dedicated to this purpose on the Abbott Alinity ci® Analyzer. The ASO dosing method used by this module is an immuno-turbidimetric method which consists in measuring the turbidity of the reaction medium after the addition of the serum sample containing the antistreptolysin O antibodies which will act with the reagent consisting of latex particles coated with streptolysin O and formation of a clear agglutination measurable by turbidimetry. 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 ASO Assay verification criteria show satisfactory intra-laboratory reproducibility for all levels with respective coefficients of variation of 2.10% for low level concentration (CV1) and 1.5% for medium level concentration (CV2) (Table 1).

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

Level of IQC	Number of values	Mean (UI/mL)	Standard Deviation (UI/mL)	Coefficient of Variation CV (%)	References CV (%) (CLSI)
Low	30	198,69	4,172	2,10 %	2,3 %
Medium	30	370,72	5,561	1,50 %	1,8 %

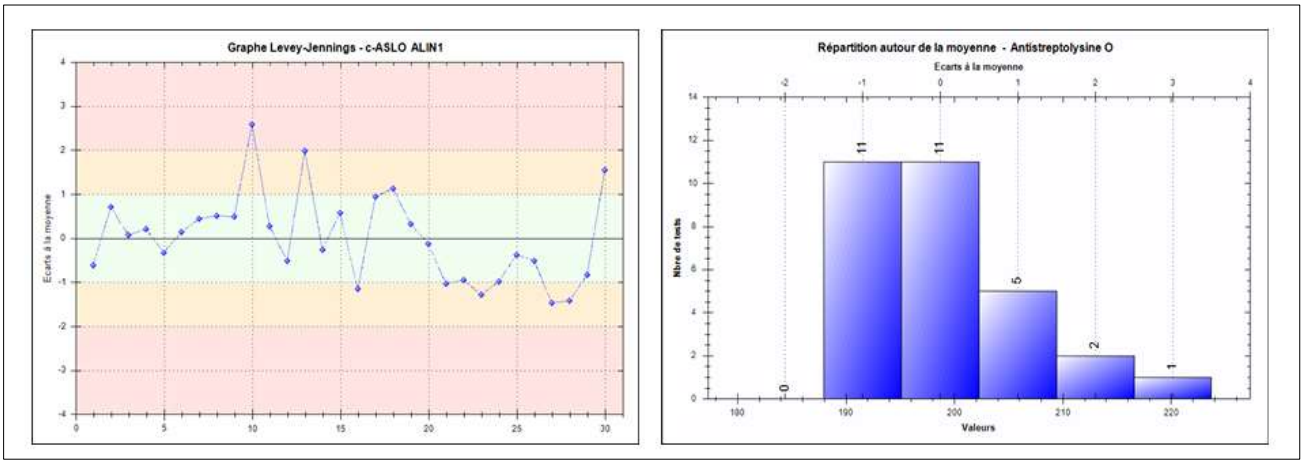

Figure 1 Low level of reproducibility: Levey Jennings curve and distribution around the mean

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

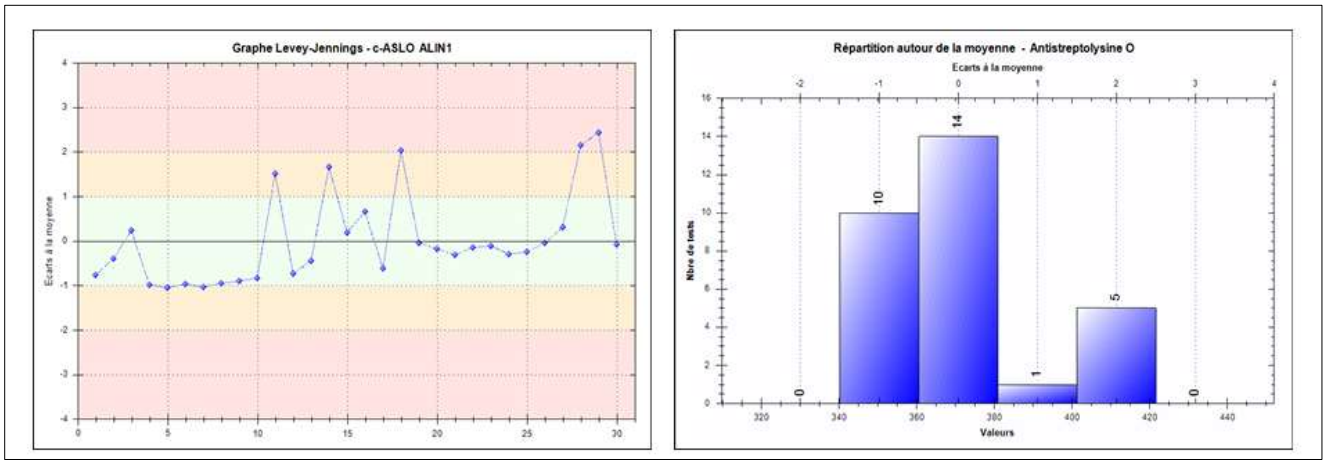

Figure 2 Medium level of reproducibility: Levey Jennings curve and distribution around the mean

3.2. Repeatability

Concerning this verification component, the results of the ASO Assay also show satisfactory repeatability for all levels (low and medium) with the values of CV1 = 0.46% and CV2 = 0.17% respectively (Table 2).

And also in order 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 3 and Figure 4).

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

Level of IQC	Number of values	Mean (UI/mL)	Standard Deviation (UI/mL)	Coefficient of Variation CV (%)	References CV (%) (CLSI)
Low	30	189,81	0,877	0,46 %	1,4 %
Medium	30	340,25	0,563	0,17 %	0,9 %

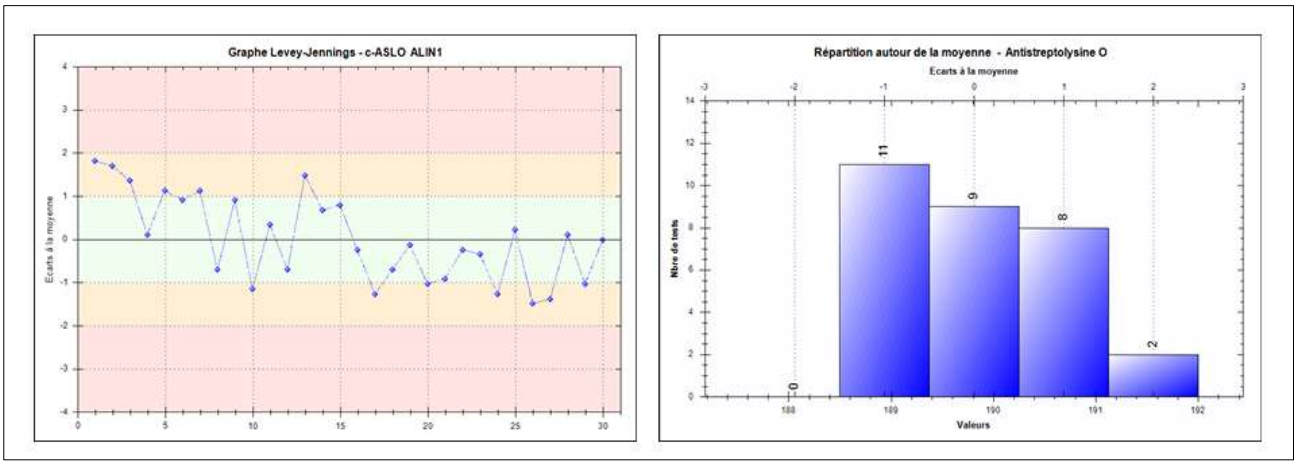

Figure 3 Low level of repeatability : Levey Jennings curve and distribution around the mean

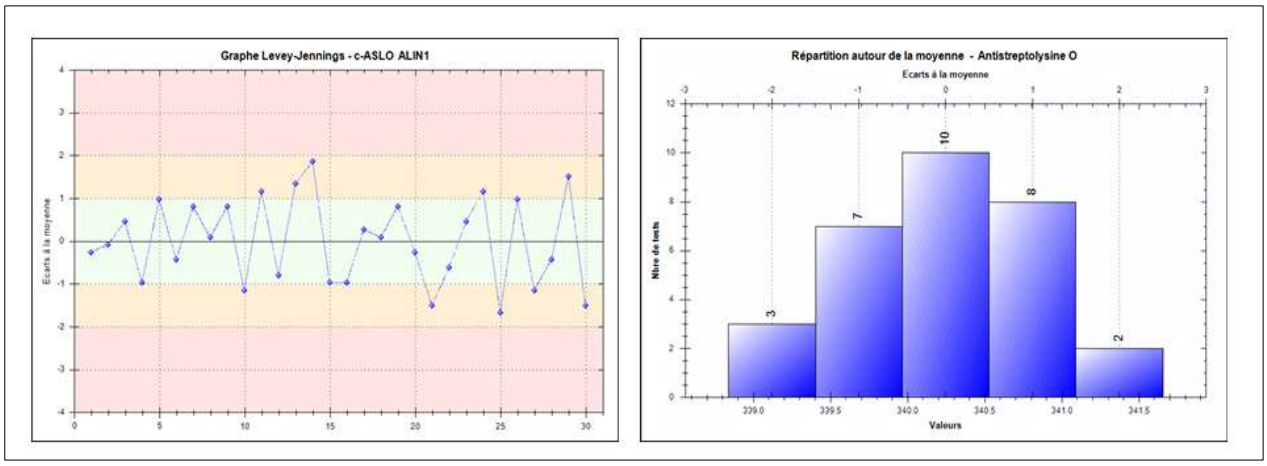

Figure 4 Medium level of repeatability : Levey Jennings curve and distribution around the mean

4. Discussion

ASO (AntiStreptolysin O) is a marker of *Streptococcus pyogenes* infection, but it is especially a good marker in the diagnosis of post-streptococcal complications (AAR, nephropathies, endocarditis, etc.) (4), 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 (5)(6)(7). The ASO Assay by immuno-turbidimetric technique is a validated method which only requires verification of its analytical performance on the Abbott Alinity ci® Analyser based on the COFRAC SH-GTA-04 guide (8).

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 (9)(10). 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 (11). 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 and at several concentration levels (minimum two). The concentration levels are chosen according to the medical decision domains (12)(13).

The repeatability assessment demonstrates that the ASO assay in our laboratory by immuno-turbidimetry has a high precision, because the coefficients of variation of the repeatability were constantly minimals, 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 acceptables. The results of these tests were in accordance with the supplier's requirements and the CLSI criteria. These results confirm that the immuno-turbidimetry method used by the Biochemistry Laboratory of the Mohammed VI University Hospital in Oujda for the dosing of ASO 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 is able to 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 ASO by immuno-turbidimetry 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.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors declare that they have no competing interest.

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