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(RESEARCH ARTICLE)

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Verification of analytical performance of the aspartate aminotransferase assay on the Abbott Alinity ci®: Experience of the central laboratory Mohammed VI Oujda

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Abstract

The standard NF EN ISO 15 189 mandates the verification of analytical methods. It involves evaluating an analytical method's effectiveness in accordance with a precisely laid out protocol before comparing it to previously established analytical objectives. Any biologist must be concerned with mastering this approach. In this work, we compare two automats: Alinity ci ® and Architect ci-8200® Abbott, to show the results of the protocol of verification of the method of determination of aspartate aminotransferase (AST). Aspartate aminotransferase is an enzyme found in many tissues, particularly liver and muscle, including heart muscle. Its measurement is particularly useful for diagnosing and monitoring liver disease.

Keywords: Aspartate aminotransferase; Verification; Repeatability; Reproducibility; Alinity ci®; Architect ci8200®

1. Introduction

Analytical method verification is a process that involves evaluating the performance of an analytical method, quantifying it by following a standardized operating protocol, and then evaluating it, relative to standards determined by learned societies (RICOS, FSCB), thus allowing the laboratory to have a good knowledge of its analytical methods, performance and limitations. In order to ensure the accuracy of the analytical results and the clinical interpretations that are beneficial to the patient and the prescriber, it must ensure that these performances are sufficient (1) (2). Through this work, we compare two automats: Alinity ci® Architect ci8200® Abbott to present the findings of the protocol of the verification of the AST assay method. This work forms an essential basis for the execution of an accreditation procedure and is a component of the quality process to which our laboratory is committed.

2. Reminder on aminotransferases

Aminotransferases are enzymes that catalyze the alpha-amino group transfer from an amino acid to an alpha-keto acid. With other pyridoxal-phosphate-dependent enzymes, they share some mechanisms. Aminotransferases are divided into several classes, including classes I, II, III, IV, and V, depending on the domain features. The class-I pyridoxal-phosphate-dependent aminotransferase, which includes 11 proteins in the human proteome, includes ALT and AST (3). For many years, the serum concentrations of the enzymes alanine (ALT) and aspartate aminotransferases (AST) have been used as indicators of liver damage from a variety of causes, such as viral hepatitis and fatty liver (4). It is important to note that the primary cause of the high serum AST activity seen in patients with acute heart failure and myocardial infarction is the accompanying acute central necrosis of the liver linked to circulatory changes (5) .Transaminases are good predictors of the individual elements of this very complex trait, according to the rising prevalence of cardiovascular

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disease (CVD) and metabolic syndrome around the world, including type 2 diabetes (6) and decreased hepatic insulin sensitivity (7), coronary heart disease (8) , atherothrombotic risk profile (9), and overall risk of cardiovascular (10) and metabolic disease (11). Heart, liver, muscle, and kidney tissues contain the highest levels of AST. Significant rises in serum AST concentrations may result from damage to these tissues. After a myocardial infarction, serum AST rises within 6–8 hours of the onset of pain, peaks in 18–24 hours, and then returns to normal levels by day 4–5. The increase in serum concentrations is nearly proportional to the severity of tissue injury and can reach 10 to 15 times the normal levels (12).

3. Material and methods

3.1. Principle of the assay method

The AST contained in the sample catalyzes the transfer of the amino group from L-aspartate to α-ketoglutarate, forming oxaloacetate and L-glutamate. In the presence of NADH and malate dehydrogenase (MDH), oxaloacetate is reduced to L-malate. At reaction, NADH is oxidized to NAD. The reaction is monitored by measuring the decrease in absorbance at 340 nm, caused by oxidation of NADH to NAD (13)

3.2. Verification procedure

This comparative descriptive study was carried out over the course of 38 days at the biochemistry laboratory of the Mohammed VI University Hospital of Oujda. Our study's working to approach was adapted based on the protocol of the COFRAC certification technical guide GTA 04. Aspartate aminotransferase was tested on the Alinity ci® automaton by Kinetic spectrophotometry as part of the method's verification in order to assess the analytical performance in terms of repeatability and reproducibility using samples from patients being treated at the Mohammed VI University Hospital in Oujda in addition to internal quality controls. Alinity ci® and Architect ci8200®, two automatons, were also compared in the matter of methods. The differences between the two techniques were plotted against the means of the two techniques using the Bland-Altman diagram, which was also used. The data was statistically processed using the EVM middleware module of BYG Informatics, a gateway application between the Alinity and the iLab result validation software. Our study's coefficients of variation (CV) values were contrasted with those established by the learned societies (FSCB and RICOS). Random subjects were chosen from the regular workflow. There were no exclusion criteria applied.

Two phases of our research were conducted. The first step concerned the assessment of reproducibility through the daily passage of control of the three levels: low, medium, and high over a period of 38 days. Aspartate aminotransferase values that were evenly distributed across the measurement range were obtained from a group of serum samples in the subsequent step. Three groups of samples were created: low, medium, and high levels. 30 runs of each sample were performed to evaluate repeatability. Increase to prove that the candidate method is sufficiently consistent with the reference method by comparing the two automatons.

4. Results

The results demonstrate that repeatability is satisfactory for Alinity ci® at low, medium, and high levels, as demonstrated by coefficients of variation (CV) of 0.96%, 0.77%, and 0.25% respectively, as presented in Table1.

Table 1 Repeatability results for AST on Alinity ci® automaton

Sample	N	Mean	SD	CV%	CV% FSCB	Conclusion
Level 1	30	36.13 UI/l	0.346 UI/l	0.96	4.50	Validated
Level 2	30	100.50 UI/l	0.777 UI/l	0.77	4.50	Validated
Level 3	30	231.13 UI/l	0.571 UI/l	0.25	3.75	Validated

The intra-laboratory reproducibility of Alinity ci® was found to be acceptable for levels 1, 2, and 3, with corresponding coefficients of variation (CV) of 3.239%, 3.148%, and 3.475% respectively, as shown in Table 2.

Table 2 Reproducibility results for AST on Alinity ci® automaton

Sample	N	Mean	SD	CV%	CV% FSCB	Conclusion
Level 1	32	37.91UI/l	1.228UI/l	3.239	6	Validated
Level 2	33	118.18UI/l	3.720UI/l	3.148	6	Validated
Level 3	34	209.59UI/l	7.283 UI/l	3.475	5	Validated

In the comparison analysis using the Bland-Altman diagram (Figure 1), it was observed that the average bias between the two automatons Alinity ci® and Architect ci8200®, is about -8.73 % UI/l .The correlation coefficient (r) was 1, with a mean difference of -5.10 UI/l and the standard deviation of the differences is 2.591 UI/l. The linear regression equation was Y = 1.05 X + 2.56 (Figure 2).

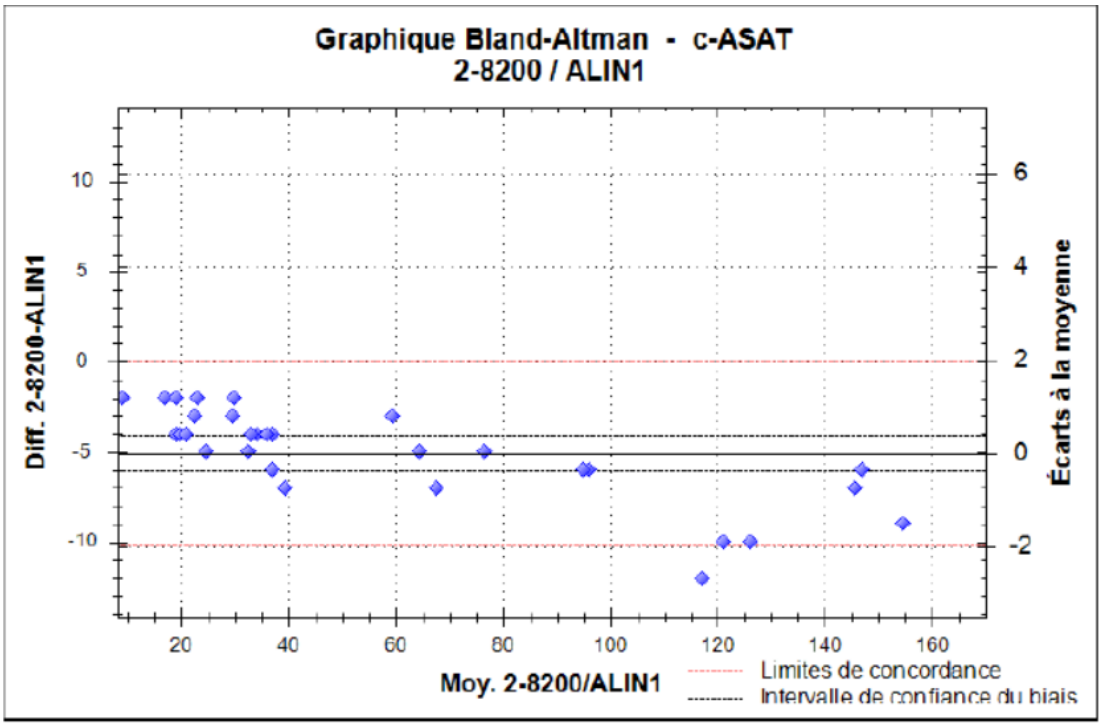

Figure 1 The Bland-Altman diagram for AST

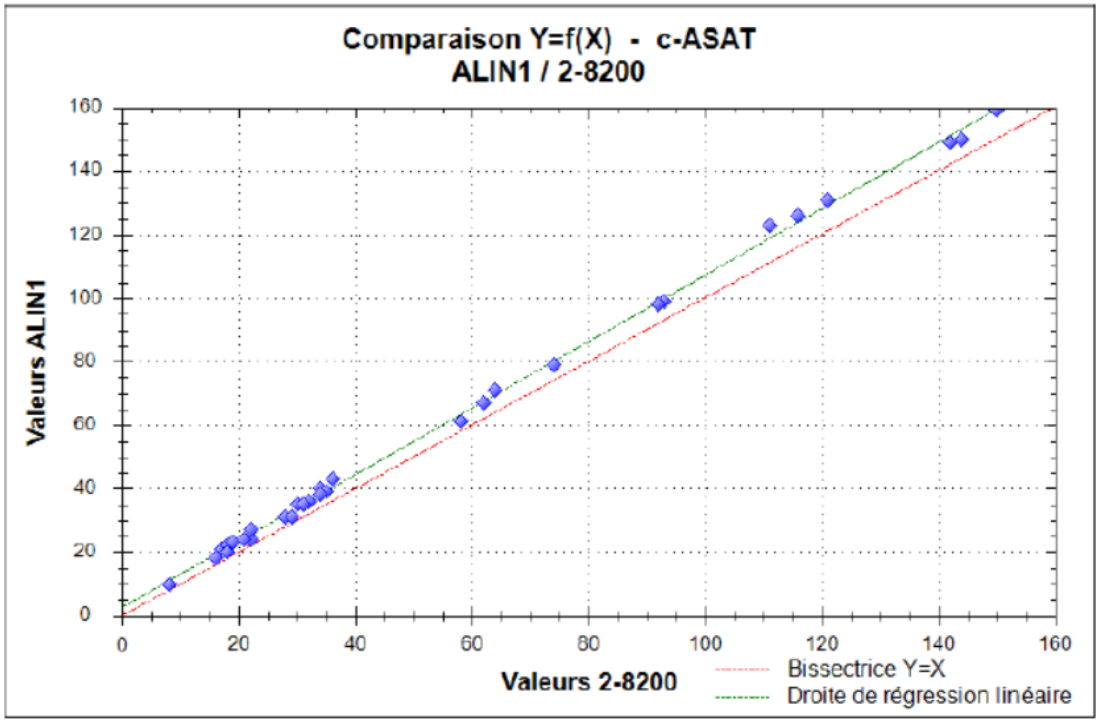

Figure 2 Correlation study for AST

5. Discussion

The recognized methods were a priori validated in their application domain as part of our "scope A verification/validation" process. The Abbott biochemistry methods are advertised with a CE mark, which is required for use in clinical diagnosis in medical biology. As a result, these techniques are categorized in flexible range A for the method verification, which can be carried out using the COFRAC guide SH-GTA-04. It will only be necessary to carry out a method verification in the laboratory procedures rather than a full method validation. As a result, there is no longer a need to confirm the technique's sensitivity and specificity, the reagents' stability, its robustness, or a comparison with a reference method (14) (15).

For the evaluated parameter, the assessment of repeatability establishes ideal performance conditions and confirms proper system operation, including the use of instruments and reagents. Reproducibility evaluates method faithfulness using a variety of variables, including operators, time, batches of reagents and calibrations (16). In order to correctly and pertinently interpret the results, it is crucial to have a critical reading of them. This interpretation focuses on the clinical significance of the result while also considering its representativeness and biological variations, which can vary in importance depending on the compound. The main objective of method verification/validation is to be aware of one's limitations and, consequently, to be aware of the relevance of one's method to its clinical application (12). Overall, the coefficients of variation obtained for the study of repeatability and intra-laboratory reproducibility are excellent and satisfy both the Valtec protocol's (FSCB) criteria as well as the supplier's requirements. A technical verification/validation file's completion is an essential component for any medical analysis laboratory seeking ISO15189 accreditation (17). The repeatability and reproducibility of the AST parameter were assessed, and they were found to be satisfactory. In conclusion, the automated system can be said to be suitable for medical laboratories due to its analytical performance in determining common biochemical parameters. In addition to laboratory personnel, equipment, and environmental factors, the accuracy and reliability of the results obtained during an examination are also influenced by the methods and any subsequent validation or verification (14) (15) (18) (19). The central laboratory of the Mohammed VI University Hospital in Oujda has implemented a quality strategy that includes a method verification process. The completion of this study will offer the opportunity to establish, in a trustworthy manner, a process of accreditation of the analyses performed in our laboratory, which serves as a center of reference in Morocco's Eastern region, not only for the care of referred or hospitalized patients but also for the assessment of the region's general population's health through various scientific studies (20) (21)

6. Conclusion

The findings of our study enabled us to evaluate the performance of the AST assay method and compare it to the analytical goals established in the accreditation procedure that our laboratory is taking part in. As a result, the two automatons Alinity ci® and Architect ci-8200® are comparable.

Compliance with ethical standards

Disclosure of conflict of interest

The authors declare no conflict of interest.

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