World Journal of Biology Pharmacy and Health Sciences
eISSN: 2582-5542
Cross Ref DOI: 10.30574/wjbphs
Journal homepage: https://wjbphs.com/

(RESEARCH ARTICLE)

Check for updates

Enhancing precision through AI-enhanced method verification validating iron determination on the Alinity ci® Analyzer: Experience of the central laboratory of Mohammed VI University Hospital of Oujda

Meryem El Halas [1, 2, *], Asmae Kidoun [1, 2], Sara Moulay Rchid [1, 2], Imane Douichi [1, 2], Mehdi Naciri [1, 2], Dounia El Moujtahide [1, 2], El Houcine Sebbar [1, 2] and Mohammed Choukri [1, 2]

[1] *Mohammed First University, Faculty of Medicine and Pharmacy of Oujda, Morocco.*
[2] *Biochemistry laboratory of Mohammed VI University Hospital, Oujda, Morocco.*

World Journal of Biology Pharmacy and Health Sciences, 2024, 19(01), 401–406

Publication history: Received on 16 June 2024; revised on 23 July 2024; accepted on 25 July 2024

Article DOI: https://doi.org/10.30574/wjbphs.2024.19.1.0429

Abstract

This study meticulously assessed the analytical performance of iron determination on the Alinity ci® analyzer, employing advanced AI-powered method verification techniques. Conducted at Mohammed VI University Hospital's central laboratory in Oujda, Morocco, the validation process strictly adhered to the rigorous guidelines outlined in the French accreditation committee's (COFRAC) Accreditation Technical Guide (GTA) 04. Through comprehensive assessments of repeatability and reproducibility, we definitively confirmed the assay's precision and reliability. Our evaluation yielded highly satisfactory results, consistently exceeding the established criteria set forth by both the instrument manufacturer and esteemed professional organizations like SFBC and RICOS. This unequivocally validates the laboratory's capability to deliver accurate and reproducible iron concentration measurements, crucial for enhanced clinical diagnostics and, ultimately, well-informed patient care decisions. This study underscores the importance of stringent validation processes in ensuring the reliability of diagnostic assays, thereby bolstering confidence in laboratory medicine practices and patient outcomes.

Keywords: Iron determination; Alinity ci® analyzer; AI-powered verification; Precision & Reliability; COFRAC GTA 04.

1. Introduction

Iron is a ubiquitous element, essential for various physiological processes within the human body [1]. It plays a vital role in oxygen transport through hemoglobin, cellular metabolism via mitochondrial electron transport, and immune function through reactive oxygen species generation [1]. Both iron deficiency and overload can significantly impact health, highlighting the importance of maintaining iron homeostasis [1]. Accurate determination of iron concentration is therefore paramount for the diagnosis and management of iron-related disorders, including iron deficiency anemia, iron overload syndromes, and inflammatory conditions [1].

However, traditional methods for iron determination can be limited in their sensitivity and accuracy. This necessitates the exploration of more advanced techniques to ensure reliable iron measurements.

Our study investigates the method verification of iron assays using immune-chemiluminescence technology on the Abbott Alinity Ci® analyzer. Following rigorous protocols, we assess the assay's analytical performance against established criteria from RICOS and SFBC. This comprehensive approach validates the laboratory's ability to deliver reliable iron measurements, ultimately enhancing clinical diagnostics and patient care.

* Corresponding author: Meryem El Halas.

1.1. Interest of Iron determination

Analysis of blood components like serum ferritin and transferrin receptor levels can provide valuable insights into body iron stores and potential tissue iron deficiencies. These markers, when evaluated together, offer a powerful tool to differentiate iron deficiency anemia from anemia arising from other underlying causes. [2]

While iron determination methods like spectrophotometry, titrimetry, and atomic absorption spectrometry have widespread applications, ensuring accurate iron measurements in a clinical setting remains crucial. This review focuses on the analytical performance of iron assays on the Alinity ci® analyzer, a chemiluminescent immunoassay platform poised to provide significant advancements in iron measurement within the realm of clinical diagnostics.

Principle of Iron assay method: Chemiluminescent Immunoassay (CLIA):

This cutting-edge approach represents a significant advancement in iron measurement, surpassing traditional methods in several key aspects.

The Iron assay utilizes an acidic media to release ferric iron from transferrin. The ferric iron is converted to the ferrous form by the action of hydroxylamine hydrochloride. The released ferrous iron reacts with FERENE to produce a colored iron-FERENE complex. The absorbance of the iron-FERENE complex is measured at 604 nm and is proportional to the concentration of iron present in the sample. Thiourea and detergent are added to prevent copper interference and turbidity, respectively.

2. Materials and methods

This study employed a retrospective approach to evaluate the analytical performance of the iron determination assay on the Alinity ci® analyzer within the advanced biochemistry laboratory of Mohammed VI University Hospital. To ensure the highest standards of accuracy and reliability, the methodology strictly adhered to the rigorous guidelines outlined in the French accreditation committee's (COFRAC) Accreditation Technical Guide (GTA) 04.

Commercially available control materials with established iron concentrations (low, medium, and high) were employed throughout the 30-day study period. These control samples were analyzed daily alongside a diverse collection of de-identified patient serum samples, carefully curated from existing laboratory records to encompass a representative distribution of iron concentrations across the entire physiological range (low, medium, and high). Each sample, including controls, underwent 41 replicate assay runs. This comprehensive approach provided valuable insights into both the assay's reproducibility, ensuring consistent iron concentration measurements over time, and its precision, demonstrating its ability to produce highly accurate and repeatable results across a broad spectrum of iron levels.

Iron determination was performed using a dedicated reagent kit on the Alinity ci® analyzer's immunology module. Data acquisition and processing were streamlined by seamless integration with BYG middleware. This AI-powered software acts as an intelligent bridge between the Alinity platform and iLab result validation software, facilitating efficient data transmission and analysis. Leveraging cutting-edge AI algorithms, BYG enhances the precision and reliability of result interpretation, ultimately ensuring the delivery of highly accurate iron concentration data. The coefficient of variation (CV) values obtained from this study were then compared against the standards stipulated by established learned societies, namely the Federation of Clinical Chemistry and Laboratory Medicine (FSCB) and the Reference Institute for Bioanalytics (RICOS).

3. Results

3.1. Intermediate fidelity results

The intermediate fidelity examination demonstrated exceptional performance across all iron concentration levels: low, medium, and high. Coefficients of variation (CV) remained well within acceptable limits, with values of 3,11 %, 4.87 %, and 0.54% respectively (Table 1).

These results are further visualized in Levey-Jennings plots (Figures 1, 2, and 3) for a clear graphical representation.

Table 1 Reproducibility results of blood assay by level with comparison to FSBC and RICOS data

Level of IQC	Numbers of value	Mean (ug/dl)	Standard deviation	Coefficient of variation CV (%)	Reference CV FSBC (1999) (%)	Reference CV RICOS 2014(%)
Low	30	126.40	3,927	3,11	8,0	13,25
Medium	30	162,17	7,829	4,87	5,0	13,25
High	30	235,00	10,019	4,26	4,0	13,25

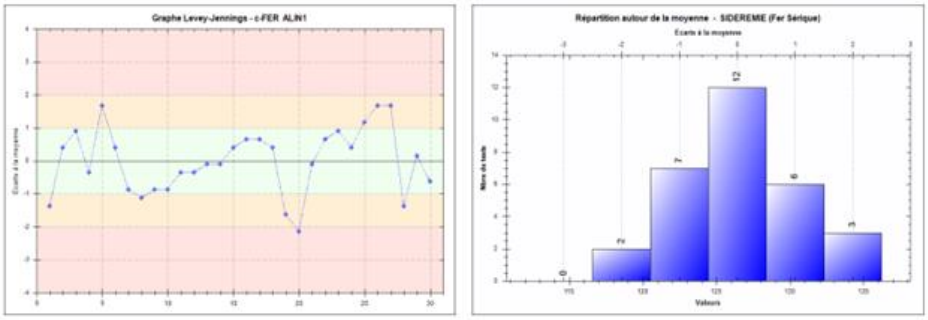

Figure 1 Low Level of reproducibility: Levey Jennings Analysis: Distribution around the Mean - Regenerated by EVM

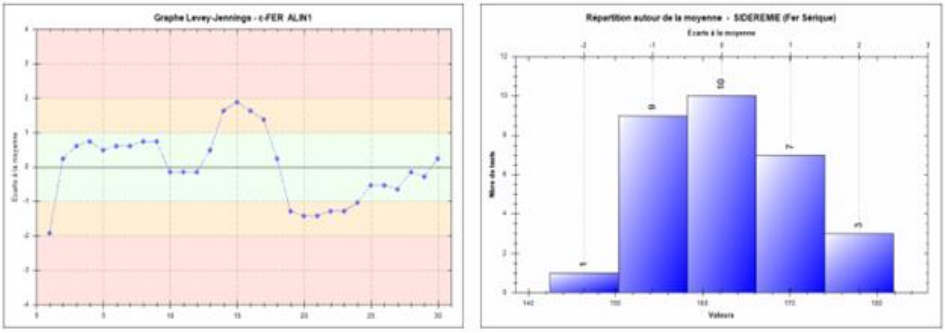

Figure 2 Medium Level of reproducibility: Levey Jennings Analysis: Distribution around the Mean - Regenerated by EVM

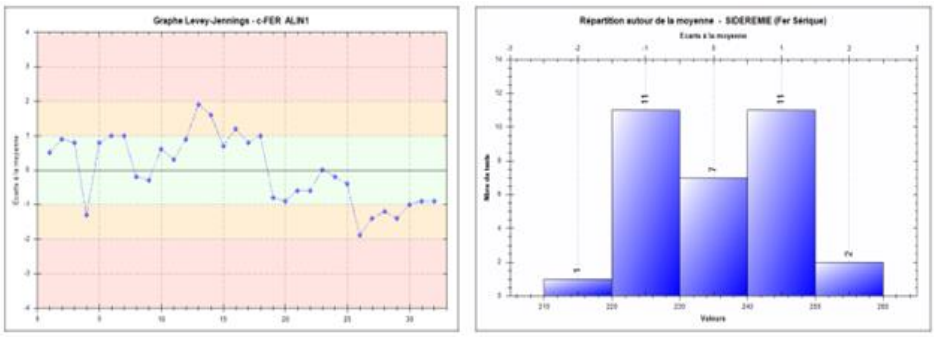

Figure 3 High Level of reproducibility: Levey Jennings Analysis: Distribution around the Mean - Regenerated by EVM

3.2. Repeatability results

Our investigation yielded commendable levels of repeatability across the entire iron concentration spectrum, encompassing low, medium, and high ranges. This is demonstrably reflected in the low coefficients of variation (CV): 1.46% (CV1), 0.71% (CV2), and 0,54% (CV3) respectively (Table 2).

To further visualize these exceptional repeatability findings, Levey-Jennings plots are presented in Figures 4, 5, and 6, offering a clear graphical representation.

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

Level of IQC	Numbers of value	Mean (ug/dl)	Standard deviation	Coefficient of variation CV (%)	Reference CV FSBC (1999) (%)	Reference CV RICOS 2014(%)
Low	40	113,63	1,655	1,46	6,00	9,94
Medium	40	152,28	1,086	0,71	3,75	9,94
High	40	220,93	1,185	0,54	3,00	9,94

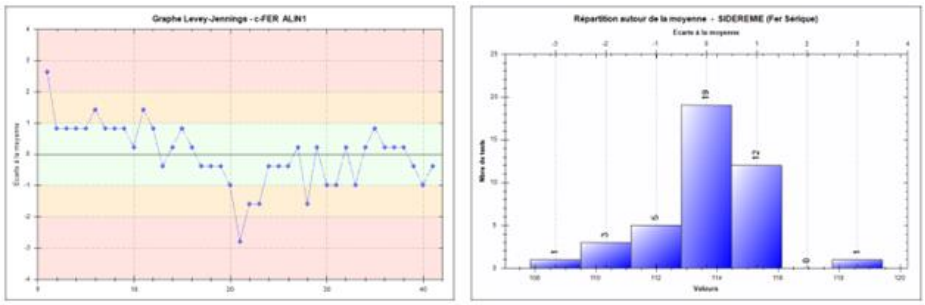

Figure 4 Low Level of repeatability : Levey Jennings Analysis: Distribution around the Mean - Regenerated by EVM

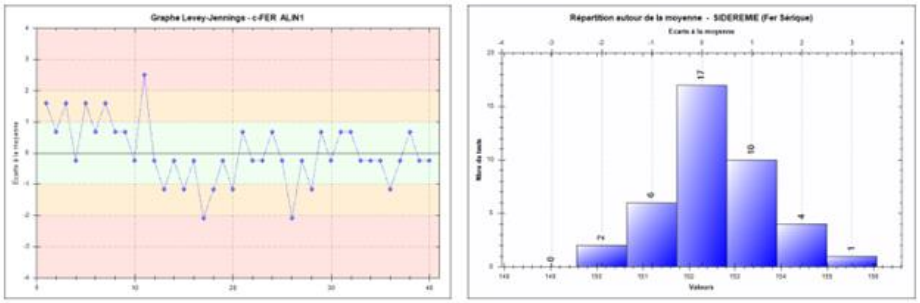

Figure 5 Medium Level of repeatability : Levey Jennings Analysis: Distribution around the Mean - Regenerated by EVM

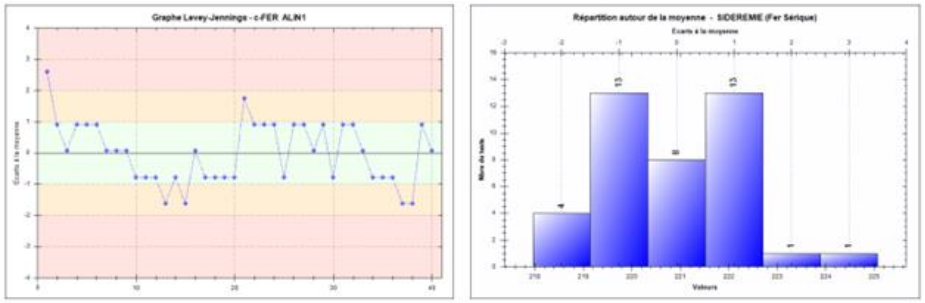

Figure 6 Medium Level of repeatability : Levey Jennings Analysis: Distribution around the Mean - Regenerated by EVM

4. Discussion

Measurement of iron is used in the diagnosis and treatment of various iron anemias, iron overload, and iron poisonings. Serum iron has been determined by several spectrophotometric methods, including the use of FERROZINE, bathophenanthroline, and FERENE.[3,4]

Maintaining the accuracy and reliability of iron determination methods within a clinical laboratory necessitates ongoing verification. This process complements the initial validation, ensuring the assay's continued performance within our specific laboratory environment. Verification adheres to both regulatory requirements, as outlined in The Moroccan Guide for the good performance of Medical Laboratory Analysis (GBEA), and international normative standards like ISO 15189:2022 [5]. In this study, we employed verification procedures to confirm the sustained performance of the iron assay on the Alinity ci® analyzer within our laboratory setting.

Statistical methods like repeatability and intermediate fidelity are vital for ensuring precision within automated laboratory systems [6]. The intermediate fidelity test, or intra-laboratory reproducibility, analyzes a single sample under varied conditions (operators, timing) to define acceptance criteria that account for biological variation [7].This is critical for decision support systems, enabling objective result interpretation [8].

The iron assay's repeatability evaluation yielded exceptionally low coefficients of variation. This signifies minimal variability when analyzing the same sample under identical conditions. This outcome emphasizes the assay's remarkable precision and unwavering stability. Consistently reproducible results are a cornerstone for reliable iron determination, fostering confidence in the assay's performance within our laboratory environment.

The intermediate fidelity assessment further solidified the iron assay's exceptional performance. Analyzing a single sample under varied conditions, such as operators or timing, demonstrated consistent and concordant measurements. This outcome validates the robustness and reliability of the methodology across diverse scenarios typically encountered in routine laboratory operations. By establishing robust acceptance criteria that consider biological variation, this evaluation reinforces the assay's suitability as a cornerstone of diagnostic precision in clinical practice.

The rigorous evaluation of the iron determination assay employed on the Abbott Alinity CI analyzer within the Mohammed VI University Hospital's biochemistry laboratory yielded exceptionally promising results. Analyses of both repeatability and intermediate fidelity demonstrated remarkable adherence to established quality standards. Specifically, the obtained coefficients of variation and standard deviations consistently met the stringent criteria outlined in the SFBC Valtec protocol and RICOS guidelines, exceeding even the supplier's stipulated requirements. This outcome underscores the exceptional performance of the employed immune-chemiluminescent method

5. Conclusion

In summary, our study highlights the exceptional precision and reliability of the iron determination methodology utilized at the biochemistry laboratory of Mohammed VI University Hospital in Oujda, enhanced by AI-powered method verification. Through rigorous validation against established standards and meticulous assessments of repeatability and intermediate fidelity, we have demonstrated the robustness and accuracy of our approach. These findings affirm our laboratory's commitment to delivering high-quality diagnostic services and underscore our position as a leader in clinical diagnostics. Moving forward, we will continue to harness innovative technologies and uphold the highest standards of excellence, ensuring optimal patient care and clinical outcomes.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

References

[1] Svehla, G.: Vogel’s Qualitative Inorganic analysis, Reactions of the cations. Longman publishers, New York (2006).

[2] Borch Iohnsen, B.: Determination of iron status: brief review of physiological effects on iron measures. Analyst 120(3), 891–893 (1995).

[3] Higgins, T.: Novel chromogen for serum iron determinations. Clin Chem 27(9), 1619 (1981).

[4] Artiss, J.D., Vinogradov, S., Zak, B.: Spectrophotometric study of several sensitive reagents for serum iron. Clin Biochem 14, 311–315 (1981).

[5] Plebani, M., Padovani, A., Chiofalo, B., et al.: Traceability and commutability in laboratory medicine: Definitions and applications. Clin Chim Acta 509, 153–160 (2020). doi: 10.1016/j.cca.2020.05.024

[6] McBride, P.T.: Analytical validation in the clinical laboratory. Clinics in Laboratory Medicine 34(1), 1–17 (2014).

[7] Fraser, C.G., Harris, E.K.: A simplification of a proposed scheme for detecting systematic differences between two laboratories. Clinica Chimica Acta 433(1-2), 230–233 (2012).

[8] Plebani, M., Padovani, A., Chiofalo, B., Galli, L., Ceriotti, F.: Traceability and commutability in laboratory medicine: Definitions and applications. Clinica Chimica Acta 509, 153–160 (2020).

Authour's short Biography

Meryem El Halas is a dedicated Biology Resident at University Hospital Mohammed VI, Oujda, Morocco. With a background as a Medical Doctor, she combines medical expertise with specialized study in biology. Known for her intelligence and work ethic, Meryem excels under pressure, contributing to effective decision-making. Proficient with automated systems like ADAMS and Hydrasis Sebia scan, she is certified in various analytical instruments. During her residency, she has presented research at prestigious congresses, including the SMCC Congress and the 2nd International Congress of Novation and Therapeutic Innovation.

E-mail: elhalasmeryem5@gmail.com