ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/25may516

# Verification of Ferritin Assay Methods Evaluation of Analytical Performance by Immunometric Method

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Publication Date: 2025/06/05

➢ ***Introduction:***

**Ferritin is required for the diagnosis of diseases affecting iron metabolism, such as hemochromatosis and iron deficiency anemia. Verification/validation of the in vitro assay method consists in assessing the performance of the analytical process, then comparing it with the criteria in NF EN ISO 15189. The aim was to evaluate the analytical performance of the sandwich chemiluminescence immunometric ferritin assay on a Maglumi® X3 analyzer.**

➢ ***Materials and Methods:***

**Verification of the ferritin assay on SNIBE's Maglumi® X3 analyzer was based on the methods recommended in the Valtec protocol and the GTA-SH 04 technical guide for human health accreditation, for assessing the analytical performance of analyzers for quantitative analysis methods on two different kits from the same batch. The performances tested were repeatability, reproducibility, and inter-sample contamination. Data were processed using method validation software, Microsoft Office Excel and SPSS V20 at 5% risk.**

➢ ***Results:***

**Repeatability quantifying precision and reproducibility quantifying intermediate precision in the first kit were satisfactory, with CV values of 2.16% and 1.82% respectively for the mean level (CIQ Ferritin Target=58.2 ± 5.83 µg/L). For the second Kit, the CV values were 0.60% and 1.05% respectively for the same average level. Supplier CVs were in the order of 3.60% and 5.32%, while SFBC CVs were in the order of 6% and 8% respectively. Inter-sample contamination was deemed satisfactory for routine use of the analyzer.**

➢ ***Conclusion:***

**The analyzer tested meets the analytical performance requirements for the reliable determination of ferritin by sandwich chemiluminescence immunometry on a Maglumi® X3 analyzer.**

***Keywords:*** *Ferritin, Reliability, ISO 15189, Immunoassay Verification.*

**How to Cite:** Hicham Chemsi; Ibrahim Sbai Otmani. (2025). Verification of Ferritin Assay Methods Evaluation of Analytical Performance by Immunometric Method. *International Journal of Innovative Science and Research Technology*, 10(5), 3491-3494. https://doi.org/10.38124/ijisrt/25may516.

## I. INTRODUCTION

The proper performance of results obtained in medical laboratories relies on ongoing assessments carried out in accordance with regulations. Within the framework of NF EN ISO 15189 standard requirements, the clinical laboratories must check that the methods adopted are mastered and used in their field of application, in order to meet the needs of patients/prescribers. This is a scope A verification of methods. The aim of this expert appraisal is to assess the analytical performance of a Maglumi® X3 analyzer using the sandwich chemiluminescence immunometric method for ferritin determination.

## II. MATERIALS AND METHODS

The automated analyzer used in this study is a Maglumi® X3. The instrument is designed for the sandwich chemiluminescence immunoassay of ferritin. The method verification and validation software integrates all current

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requirements, automatically retrieves large amounts of data, and generates reports in accordance with COFRAC recommendations. The verification of the automated ferritin assay was based on the methods recommended in the Valtec protocol [1] and GTA-SH 04 [2-3] Technical Guidance for Human Health Accreditation for evaluating the analytical performance of analyzers for quantitative analytical methods. The patient samples were collected in 5 ml dry tubes. For control reagents, an average concentration of two different reagent kits from the same lot was used. Performance was evaluated for repeatability, reproducibility and sample contaminations in accordance with the requirements of EN ISO 15189. Data were processed using method validation software, Microsoft Office Excel and SPSS V20 at 5% risk.

## III. RESULTS

### A. *Repeatability Study*

For the repeatability study, several values for each mean control level (CIQ ferritin target=58.2 ± 5.83 µg/L) of the different two kits were evaluated. The results of the repeatability study, quantifying the precision, with coefficients of variation calculated for the two kits are 2.16% and 0.60%, respectively. When compared with the coefficient of variation provided by the supplier and the coefficient of variation provided by the SFBC, the results were found to be consistent **(Table 1,2).**

- Ferritin
- Kit n° 0178
- Batch no 028240111
- Target 58.2 ± 5.83 µg/L
- CIQ Internal quality control
- CV Coefficient of variation
- SFBC Société Française de Biologie Clinique

Table 1: Results of Repeatability Study for Kit N° 178

| REPEATABILITY (Applicable) | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Samples** | **Number of Values (n)** | **Mean** | **Standard deviation** | **CV (%)** | **CV (%) Supplier** | **CV (%) SFBC** | **Conclusion** |
| CIQ1 58,2 ± 5,83 µg/L | 5 | 51.7 | 1.12 | 2.16 | 3.60 | 6 | Compliant |

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Table 2: Results of Repeatability Study for Kit N° 179

| REPEATABILITY (Applicable) | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Samples** | **Number of values (n)** | **Mean** | **Standard deviation** | **CV (%)** | **CV (%) Supplier** | **CV (%) SFBC** | **Conclusion** |
| CIQ1 58,2 ± 5,83 µg/L | 5 | 56.2 | 0.34 | 0.60 | 3.60 | 6 | Compliant |

### B. *Intra-laboratory reproducibility study*

The intermediate precision is calculated from several values for the mean control level (CIQ ferritin target=58.2 ± 5.83 µg/L) of the different kits used. The results of the reproducibility study quantifying the intermediate precision, with coefficients of variation calculated for the mean control levels, are in the order of 1.82% and 1.05%, respectively. Comparison of the coefficient of variation provided by the supplier and the coefficient of variation retained by the SFBC showed that the results were in agreement **(Table 3,4).**

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Table 3: Results of Reproducibility Study for Kit N° 178

| REPRODUCIBILITY (Applicable) | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Samples** | **Number of values (n)** | **Mean** | **Standard deviation** | **CV (%)** | **CV (%) Supplier** | **CV (%) SFBC** | **Conclusion** |
| CIQ1 58,2 ± 5,83 µg/L | 15 | 55.4 | 1.01 | 1.82 | 5.32 | 8 | Compliant |

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Table 4: Results of Reproducibility Study for Kit Nº 179

| REPRODUCIBILITY (Applicable) | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Samples** | **Number of values (n)** | **Mean** | **Standard deviation** | **CV (%)** | **CV (%) Supplier** | **CV (%) SFBC** | **Conclusion** |
| CIQ1 58,2 ± 5,83 µg/L | 9 | 57.2 | 0.60 | 1.05 | 5.32 | 8 | Compliant |

*C. Study of Inter-Sample Contamination*

After rinsing the analyzer, a sample with an average value for each kit tested (53.7 µg/L and 56.2 µg/L) is analyzed 3 consecutive times (H1, H2, H3, average mH). The average of each of the values for the two different kits is determined as well as the percentage of inter-sample contamination. There was no inter-sample contamination **(Table 5, 6).**

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Table 5: Results of Inter-Sample Contamination Study for Kit N° 178

| Inter-sample contamination (Applicable) | | | | | |
|---|---|---|---|---|---|
| **Sample** | **Run 1** | **Run 2** | **Run 3** | **Mean (µg/L)** | **Contamination (%)** |
| Mean value (position 1) | 53.7 | 53.7 | 53.7 | | |
| Mean value (position 2) | 53.7 | 53.7 | 53.7 | | |
| Mean value (position 3) | 53.7 | 53.7 | 53.7 | 53.7 | 0 |

- Ferritin
- Kit n° 0179
- Batch no. 028240111
- Target 58.2 ± 5.83 µg/L
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Table 6: Results of Inter-Sample Contamination Study for kit N° 179

| Inter-sample contamination (Applicable) | | | | | |
|---|---|---|---|---|---|
| **Sample** | **Run 1** | **Run 2** | **Run 3** | **Mean (µg/L)** | **Contamination (%)** |
| Mean value (position 1) | 56.2 | 56.2 | 56.2 | | |
| Mean value (position 2) | 56.2 | 56.2 | 56.2 | | |
| Mean value (position 3) | 56.2 | 56.2 | 56.2 | 56.2 | 0 |

## IV. DISCUSSION

Repeatability is an initial and mandatory test that must meet both the criteria already established, by the specifications of the Valtec protocol, and the performances announced by the supplier in others technical documentations [4-5]. The coefficients of variation obtained for the repeatability study are overall excellent, meeting both the supplier's requirements and the criteria of the Valtec protocol (Kit Nº. 178 CV%=2.16; Kit Nº. 179 CV%=0.60). The intermediate results of the SFBC compared to the supplier's values are in line with the decisions taken on the basis of the calculated limits. The coefficients of variation obtained according to Valtec specifications are satisfactory. Our study showed performance with a coefficient of variation of 1.82% (Kit Nº. 178) and 1.05% (Kit Nº. 179) compared to the SFBC value of 8%. No inter-sample contamination was observed as the automated results remained unchanged after 3 consecutive runs of the medium concentrated samples for both kits. In fact, the calculated bias of 0% is below the acceptable limit of 0.5% (SFBC). These results seem to be consistent. The less reliable methods have given way to standardized procedures that require prior verification/validation before use. Scope A verification/validation has been carried out in which the methods recognized as supplier methods are a priori validated in their field of application, within the framework of the NF EN ISO 15189 and 22870 standards [6].

## V. CONCLUSION

The primary objective of this study was to evaluate analytical performance in terms of repeatability, intermediate precision and inter-sample contamination, all of which were found to be satisfactory. It is a suitable analyzer for patient dosing and monitoring, for reliable dosing and accurate response to patients/prescribers.

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/25may516

- **Conflicts of Interest:** The authors declare no conflicts of interest.

## REFERENCES

[1]. Vassault A, Grafmeyer D, Graeve J de, Cohen R, Beaudonnet A, Bienvenu J. Analyses de biologie médicale : spécifications et normes d'acceptabilité à l'usage de la validation de techniques. Annales de Biologie Clinique. 1999 ;57(6) :685-95.

[2]. Document COFRAC SH GTA 04, Guide technique d'accréditation de vérification (portée A) /validation (portée B) des méthodes en Biologie Médicale. 2018

[3]. Document COFRAC SH GTA 14, Guide technique d'accréditation pour l'évaluation des incertitudes de mesure en Biologie Médicale. 2018

[4]. Clark RB, Lewinski MA, Loeffelholz MJ, Tibbetts RJ (2009) Cumitech 31A, Verification and validation of procedures in the clinical microbiology Laboratory. Coordinating ed., Sharp SE, ASM Press, Washington, DC

[5]. CLSI, User Protocol for Evaluation of Quantitative Test Performance; Approved Guideline–second edition, EP12-A2, Vol. 28 No.3, January 2008

[6]. FDA - ORA-LAB.5.4.5. ORA Laboratory Procedure– FDA. Methods, method verification and validation. 2014-08-29 https://www.fda.gov/scienceresearch/fieldscience/laboratorymanual/ucm171877. htm