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Verification of the analytical performance of the serum haptoglobin assay on the Abbott Alinity ci

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Abstract

Introduction: The aim of our study is to evaluate the haptoglobin assay on the Alinity ci automated system. This evaluation is part of an overall approach to verifying the methods used in the central laboratory of the Mohammed VI University Hospital of Oujda , with a view to compiling an accreditation file in accordance with the requirements of standard NF ISO 15189.

Materials and methods: The working methodology adapted by our study is based on the recommendations of the protocol of the COFRAC accreditation technical guide SH GTA 04.

Verification involved assessing the repeatability and reproducibility of Alinity ci .

Results: The results obtained for the various haptoglobin assay verification criteria show satisfactory repeatability for all three levels, with CV1=1.10%, CV2=0.78% and CV3=1.07% respectively. intra-laboratory reproducibility was satisfactory for all three levels, with CV1=1.79%, CV2= 4.2% and CV3=1.62% respectively.

Discussion: Verification of an analytical method is an essential step in guaranteeing that the result obtained is as close as possible to the reference value of a sample. Comparing our results with the CV adopted by the SFBC, we can see that the results are in line with and below the tolerated limits.

Conclusion: We can therefore conclude that the Abbott Alinity ci system meets the requirements set by scientific societies for the determination of haptoglobin.

Keywords: Haptoglobin; Verification; Repeatability; Reproducibility; Alinity ci

1. Introduction

Haptoglobin is a plasma glycoprotein synthesized mainly by the liver, its structure consists of two α-subunits and one beta-subunit linked by disulfide bridges, forming a cloverleaf structure [1].

One of the main functions of haptoglobin is to bind to hemoglobin released during the degradation of red blood cells in the vascular compartment. This binding prevents free hemoglobin from causing tissue and kidney damage by neutralizing its pro-oxidant and inflammatory effects. However, in certain hemolytic conditions, such as sickle cell

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disease, malaria, crush syndrome and severe infections, serum haptoglobin is depleted, leading to an accumulation of free hemoglobin in plasma [1,2,3].

Haptoglobin also acts as an antioxidant, capturing free radicals and preventing oxidative reactions [4].

Haptoglobin is one of the parameters measured in our laboratory on the Abbott Alinity ci automated system. In order to ensure the quality of our serum haptoglobin results, it was essential to embark on a procedure to verify the assay method. In this work, we present the results of a protocol for verifying the analytical performance of the haptoglobin assay method using an Abbot kit on the Alinity ci automated system in the biochemistry laboratory of the Mohammed VI University Hospital of Oujda.

1.1. Interest of Haptoglobin Determination

The determination of haptoglobin is of significant clinical interest due to its association with various diseases. Serum levels vary with certain pathological conditions, making it a potential marker for the diagnosis, monitoring and management of certain diseases.

Serum levels of free haptoglobin rise in acute, sub-acute and chronic inflammatory and infectious conditions, and fall to zero in hemolytic conditions [2,3,5].

1.2. Principle of the assay method

The haptoglobin assay is an immunoturbidimetric assay which measures the increase in sample turbidity caused by the formation of insoluble immune complexes when anti-haptoglobin antibody is added to the sample. The haptoglobin-containing sample is incubated with a buffer and the sample blank is determined before the addition of the anti-haptoglobin antibody. In the presence of an excess of the appropriate antibody, the haptoglobin concentration is measured as a function of turbidity.

2. Material and methods

The biochemistry laboratory of the Mohammed VI University Hospital of Oujda carries out a rigorous verification of the analytical performance of haptoglobin assay kits using the imuno module of the Alinity ci® automated system, in order to assess analytical performance in terms of repeatability and reproducibility using samples from patients hospitalized at the Mohammed VI University Hospital of Oujda, as well as internal quality controls.

Subjects were randomly selected in the usual workflow.

Blood samples were collected in a dry tube and centrifuged at 4000 rpm for 10 minutes at room temperature.

For repeatability, samples were divided into 3 groups: low, medium and high. Each sample was analyzed 30 times under the following conditions: same operator, same batch of reagents, same instrument, same calibration on the same day.

Reproducibility was assessed by running the 3 levels of control daily: low, medium and high, over a 30-day period.

Statistical processing of the data was carried out using the EVM intermediate module from BYG Informatics.

To guarantee the reliability of the results obtained, we compared these measurements with the standards set by the French Society of Clinical Biology (SFBC)[6].

3. Results

3.1. Repeatability results

The results obtained for the different haptoglobin assay verification criteria show satisfactory repeatability for the 3 levels (1: low / 2: medium/ 3: high) with respectively CV1 = 1.1% , CV2= 0.78%, CV3= 1.07% (Table1).

Table 1 Repeatability results for haptoglobin on the Alinity ci automated system

	N	Mean	SD	CV%	CV% SFBC	Conclusion
Level 1	30	0.67 g/l	0.007 g/l	1.10%	4.50%	Validated
Level 2	30	1.00 g/l	0.008 g/l	0.78%	3.75%	Validated
Level 3	30	1.41 g/l	0.015 g/l	1.07%	3.00%	Validated

3.2. Intermediate fidelity results

The results obtained for the various haptoglobin assay verification criteria show satisfactory intra-laboratory reproducibility for the three levels (1: low / 2: medium / 3: high) with respectively CV1 = 1.79%, CV2=4.2%, CV3= 1.62% on 30 samples, as shown in Table 2.

Table 2 Reproducibility results for haptoglobin on Alinity ci automated system

Sample	N	Mean	SD	CV%	CV% SFBC	Conclusion
Level 1	30	0.70 g/l	0.012 g/l	1.79 %	6.00%	Validated
Level 2	30	1.01g/l	0.042g/l	4.2%	5.00%	Validated
Level 3	33	1.44 g/l	0.023 g/l	1.62 %	4 .00%	Validated

4. Discussion

It is essential to check the performance of the analytical system (analyzer and reagent) when it is implemented in the laboratory. This verification confirms the reliability of the results obtained, based on the objectives defined to meet clinical needs. This verification corresponds to one of the elements in the control of the analytical process and applies to all scope A examinations, as specified in COFRAC guide SH-GTA-04 [7,8,9].

The laboratory determines the performance levels obtained from its method. It compares them with the expected reference data available to it (supplier, learned societies, etc.) and concludes as to the acceptability of its method in relation to its needs for the criterion tested. The samples used are specified [7].

Verification of the analytical performance of the haptoglobin assay is of prime importance in clinical laboratories, given its critical role as a key parameter in medical practice. Haptoglobin levels are widely used in the diagnosis and monitoring of various diseases, such as inflammatory conditions (ulcerative colitis, rheumatoid arthritis, heart attacks, severe infections, etc.). Accurate and reliable measurement of haptoglobin is crucial for informed clinical decision-making, treatment planning and monitoring of patient response.

The verification process involves a comprehensive assessment of the assay's performance characteristics, including repeatability and reproducibility [10].

Repeatability testing involves the analysis of a single sample under specific conditions: same operator, same batch of reagents, same instrument and same calibration, all carried out in as short a time as possible. The aim is to determine optimum performance and confirm the correct operation of the system (instrument/reagent) for the analyte concerned [11].

Intermediate precision testing (intra-laboratory reproducibility) involves analyzing the same sample under different conditions, varying at least one of the following factors: time, operator, reagent batches, calibrations [11].

The results of the repeatability and reproducibility study for haptoglobin show satisfactory performance in relation to supplier data and SFBC criteria [6].

The central laboratory of the Mohammed VI University Hospital of Oujda, is a reference center in the eastern region of Morocco, offering a wide range of inpatient and outpatient health services. At the same time, it conducts scientific research aimed at assessing the overall health of the general population [12,13 ,14,15,16,17].

As part of its commitment to quality, our laboratory has adopted a quality strategy incorporating a Scope A method verification procedure and an accreditation process. Carrying out this type of study plays a crucial role in establishing a solid accreditation process for the analyses carried out in our laboratory, ensuring that the results obtained are reliable and accurate.

5. Conclusion

The results of the study are satisfactory and meet the acceptability criteria set by the supplier and the SFBC Valtec protocol. The Alinity c demonstrated reliable analytical performance for the accurate determination of haptoglobin, indicating its reliability for this purpose. The verification process forms the basis for accreditation, improves the quality of patient care and strengthens trust between healthcare providers and patients.

Compliance with ethical standards

Disclosure of conflict of interest

The authors declare no conflict of interest.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study

References

[1] Wan, BN, Zhou, SG, Wang, M., Zhang, X. and Ji, G. (2021). Progress on haptoglobin and metabolic diseases. World Journal of Diabetes , 12 (3), 206.

[2] Naryzhny, S. N., & Legina, O. K. (2021). Haptoglobin as a biomarker. Biomedical Chemistry , 67(2), 105-118.)

[3] Andersen, CBF, K. Stødkilde, KL Saederup, A. Kuhlee, S. Raunser, JH Graversen and SK Moestrup (2017). Haptoglobin. Antioxidants and Redox signaling , 26 (14), 814-831.

[4] Golubeva, M. G. (2023). Role of Haptoglobin in Protection from the Toxic Effects of Extracellular Hemoglobin in Various Pathologies. Biology Bulletin Reviews, 13(4), 293-300.

[5] Thielemans, L., Layton, D. M., & Shovlin, C. L. (2019). Low serum haptoglobin and blood films suggest intravascular hemolysis contributes to severe anemia in hereditary hemorrhagic telangiectasia. Haematologica, 104(4), e127.

[6] de Graeve, J. (1999). Medical biology analyses: specifications and standards of acceptability for use in technique validation. Ann BIOlChn, 57(685), 95.

[7] Technical guide for accreditation, verification (scope A)/validation (scope B) of medical biology methods, Document SH GTA 04, Revision 01, COFRAC.

[8] WILLIAMS, Bethany Jill, KNOWLES, Chloe, et TREANOR, Darren. Maintaining quality diagnosis with digital pathology: a practical guide to ISO 15189 accreditation. Journal of Clinical Pathology, 2019, vol. 72, no 10, p. 663-668.

[9] Quentin Despinasse. Elaboration and implementation of me'méthodes verifications during the renewal of automatons: example of the biochemistry immunoanalysis unit at CHU Grenoble Alpes. Pharmaceutical Sciences. 2020. dumas-02965496 .

[10] ISO - ISO 15189:2012 - Medical laboratories - Requirements for quality and competence [Internet]. [cited 2020 Feb 7]. Available from: https://www.iso. org/fr/standard/56115.html.

[11] Pum, J. (2019). A practical guide to validation and verification of analytical methods in the clinical laboratory. Advances in clinical chemistry, 90, 215-281.

[12] E.-H. Sebbar, M. Choukri, Comparison between two automated immunoassay methods for total 25-hydroxyvitamin D: Architect ci8200 versus Cobas e411, Mater. Today:. Proc. (2022), https://doi.org/10.1016/j.matpr.2022.08.145.

[13] E.-H. Sebbar, M. Choukri, Vitamin D status in the population of Eastern Morocco: Study of vitamin D2 and vitamin D3 by high performance liquid chromatography, Mater. Today:. Proc. (2022), https://doi.org/10.1016/j.matpr.2022.08.076.

[14] SEBBAR, El-Houcine, CHOUKRI, Mohammed. Comparison between two automated immunoassay methods for total 25-hydroxyvitamin D: Architect ci8200 versus Cobas e411, Materials Today: Proceedings, 2022. DOI: https://doi.org/10.1016/j.matpr.2022.08.145.

[15] SEBBAR, El-Houcine, SAALAOUI, Ennouamane, CHOUKRI, Mohammed. Evaluation of vitamin D nutritional intakes in a population of eastern Morocco. Revue Pratiques en Nutrition, 2018, Vol 14 - N 55, p. 44-45. doi : 10.1016/j.pranut.2018.05.012.

[16] SBIBIH, Y., MERIMI, I., SEBBAR, E. H., & CHOUKRI, M. (2023). Verification of the analytical perform ance of the serum albumin assay on the Abbott Alinity ci. Materials Today: Proceedings, 72, 3857-3862.

[17] Yahyaoui, A., Amrani, A., Idrissi, A., Belmahi, S., Nassiri, O., Mouhoub, B., ... & Choukri, M. (2023). Comparative analysis of clinical and biological characteristics of COVID-19 patients: A retrospective cohort study. Clinical Epidemiology and Global Health, 19, 101184.