Research Journal of Surgery
Abbr. Title: Res J Surg
ISSN*(Online)***: XXXX-XXXX**

OPEN ACCESS

Research Article Volume-01 | Issue-01 | 2022

Assay of Urinary Urea: Method verification and Comparative Study Between 2automata Architect Ci8200 from Abbott

*Soumaia Farih*1, Oumaima Nassiri1, Sabrina Belmahi1, El-Houcine Sebbar1, Mohammed Choukri1*

1Laboratory of Biochemistry Central Laboratory, Mohammed VI University Hospital, PB 4806, 60049 Oujda, Morocco, Faculty of Medicine and Pharmacy of Oujda, Mohammed First University, PB 4867, 60049 Oujda, Morocco, & Central Laboratory, Mohammed VI University Hospital, PB 4806, 60049 Oujda, Morocco

Received 12-03-2022

Accepted 16-04-2022

Published 15-05-2022

Abstract: Verification / validation of the methods is a requirement of the NF EN ISO 15189 standard. Its purpose is to produce accurate and reliable measurements, thereby giving confidence to the results obtained. The objective of our study is to evaluate a chemiluminescent micro particle immunoassay (CMIA) method for the quantitative determination of NGAL (Neutrophil Gelatinase-Associated Lipocalin) in human urine on an Abbott Architect® ci8200 system according to the criteria of the scope A of the standard NF EN ISO 15189. The evaluation of the measurement uncertainty was carried out according to the Cofrac recommended QEC / EEQ method. The adapted working methodology is based on the Verification/Validation protocol. The evaluation of the analytical performance in terms of repeatability and intermediate the evaluation of analytical performance in terms of repeatability and intermediate fidelity has been carried out using two levels of quality control. A comparison of method was realized between two automatons Architect 8200.The statistical treatment of the data was realized thanks to the module the statistical processing of the data was carried out using the method validation module of the BYG computer software. The results obtained show a satisfactory repeatability for the 2 levels (1: low / 2: high) with respectively CV1 = 3.17%, CV2= 1.04%, Regarding the intra-laboratory reproducibility was satisfactory for the 2 levels with respectively CV1= 4.9%, and CV2= 3.58%. The average bias between the two automata is about 0.335%, with a linear regression equation Y = 0.998X - 0.017 with a Correlation Coefficient of 0.997, the Mean of the differences is 0.039 g/l and Standard deviation of differences 0.649 g/l.
The results obtained allowed us to verify the performance of the method of determination of the urinary urea to compare them to the analytical objectives set and to meet the regulatory requirements and standards. to meet the regulatory and normative requirements

Keywords: CMIA, QEC, Urinary, patients, COFRAC

INTRODUCTION

Verification / validation of the methods is a requirement of the NF EN ISO 15189 standard. Its purpose is to produce accurate and reliable measurements, thereby giving confidence to the results obtained. Method verification is: "the confirmation, by objective evidence, that the requirements for a specific use or intended application have been met, it is the confirmation that recognized methods are used in their intended field of application, that they meet the needs of the "customers" (patients/prescribers) and that they are mastered by the laboratory"[1]. Recognized methods fall within the scope of a Type A scope [2]. Method Validation is: "the confirmation that non-recognized methods are used in their field of application, that they correspond to the needs of the "clients" (patients/prescribers) and that they are under the control of the laboratory. Recognized methods used outside of their scope and non-recognized methods fall within a Type B scope" [2].This is an act reserved for biologists, which formalizes the assumption of responsibility for the biological act. The method verification is a strategy for the accreditation of marketed methods[3]. A method is defined as: "A set of formalized procedures according to principles, with the aim of acquiring a know-how in accordance with the expected objectives".

The objective of our study is to evaluate urinary urea assay on 2 Architects ® ci8200 according to the criteria of the scope A of the standard NF EN ISO 15189. The evaluation of the measurement uncertainty was carried out according to the Cofrac recommended QEC / EEQ method, to the central laboratory of the University Hospital Mohammed VI of Oujda (Morocco) within the framework of the Accreditation according to the standard iso 15189.

MATERIALS AND METHODS

The SH FORM 43 document [4] presents a synthesis to present the data of the method verification/validation. In order to adapt to the process approach of the 2012 version of ISO 15189, there is only one a single form that summarizes all the necessary items and will be asked to the laboratory by the COFRAC to establish the technical expertise prior to any application for initial accreditation, extension or addition. As required by the ISO 15189 standard and the SH-GTA 04 of the COFRAC, a procedure has been established in which the different steps of the process have been explained how to carry out the

***Corresponding Author:** Soumaia Farih

different steps of the process. The first step, once the method has been chosen, is to write the experimental plan which serves to determine for each parameter the performance criteria to be verified, to define the implementation modalities, and to choose the acceptability criteria. We have adopted the SH FORM 43 scope A document (one for each parameter) based on the supplier data and the data of the method validation module of the validation module of the EVM Middleware (BYG Informatique) in order to obtain the different equations necessary to fill in the verification file. The coefficient of variation obtained our laboratory will then be compared to the reference coefficient of variation obtained from the data provided by the SFBC (French Society of Clinical Biology) / RICOS and ABBOTT records. The internal Quality Controls used in this verification are ready to use controls, "supplier-dependent" controls, developed and manufactured for the specific evaluation of Architect Abbott reagents and supplied separately from the reagent the adapted working methodology is based on the Verification/Validation protocol. The evaluation of the analytical performance in terms of repeatability and intermediate fidelity has been carried out using two levels of quality control. A comparison of method was realized between two automatons Architect 8200.The statistical treatment of the data was carried out using the method validation module of the BYG computer software.

RESULTS

The results obtained show a satisfactory repeatability for two levels (1: low / 2: high) with respectively CV1 = 3.17%, CV2= 1.04%, regarding the intra-laboratory reproducibility was satisfactory for the two levels with respectively CV1= 4.9%, and CV2= 3.58%.

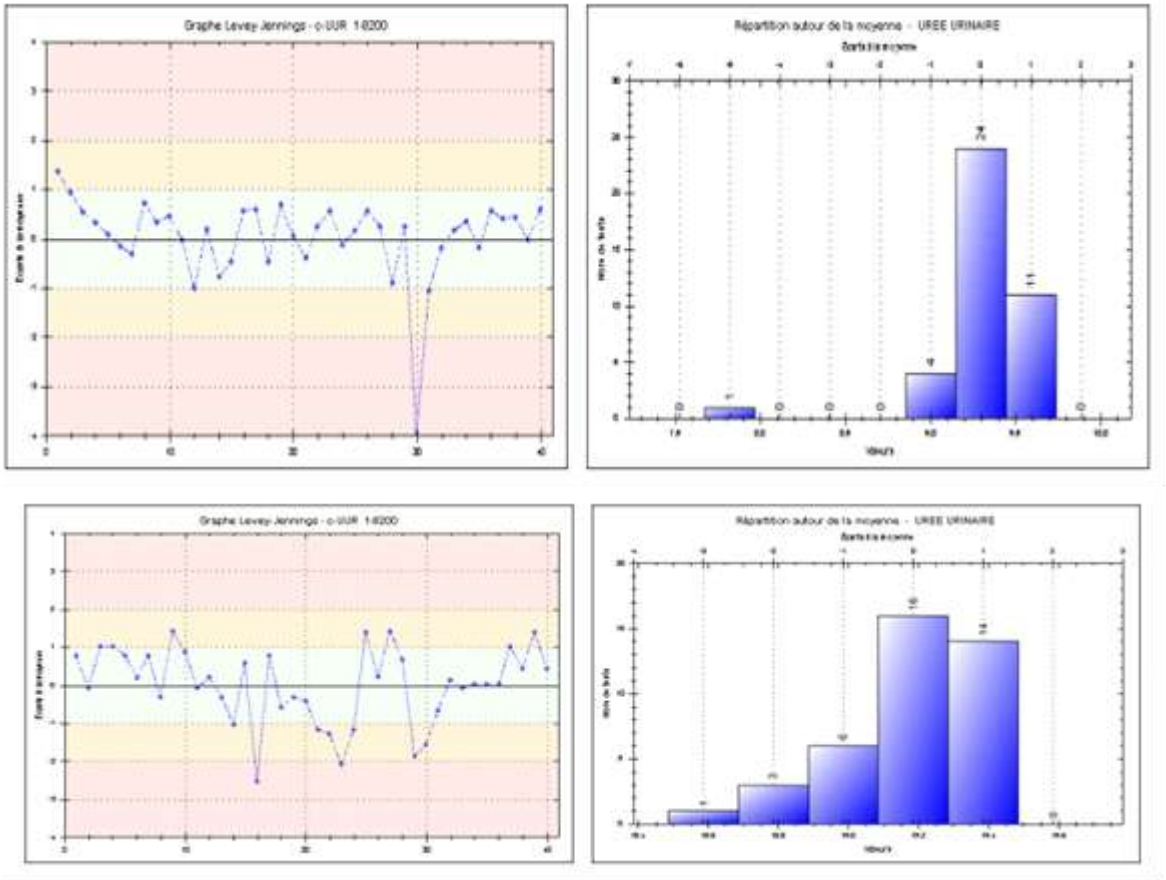

Figure 1: *Repeatability of urinary ureafor two levels (1: low / 2: high)*

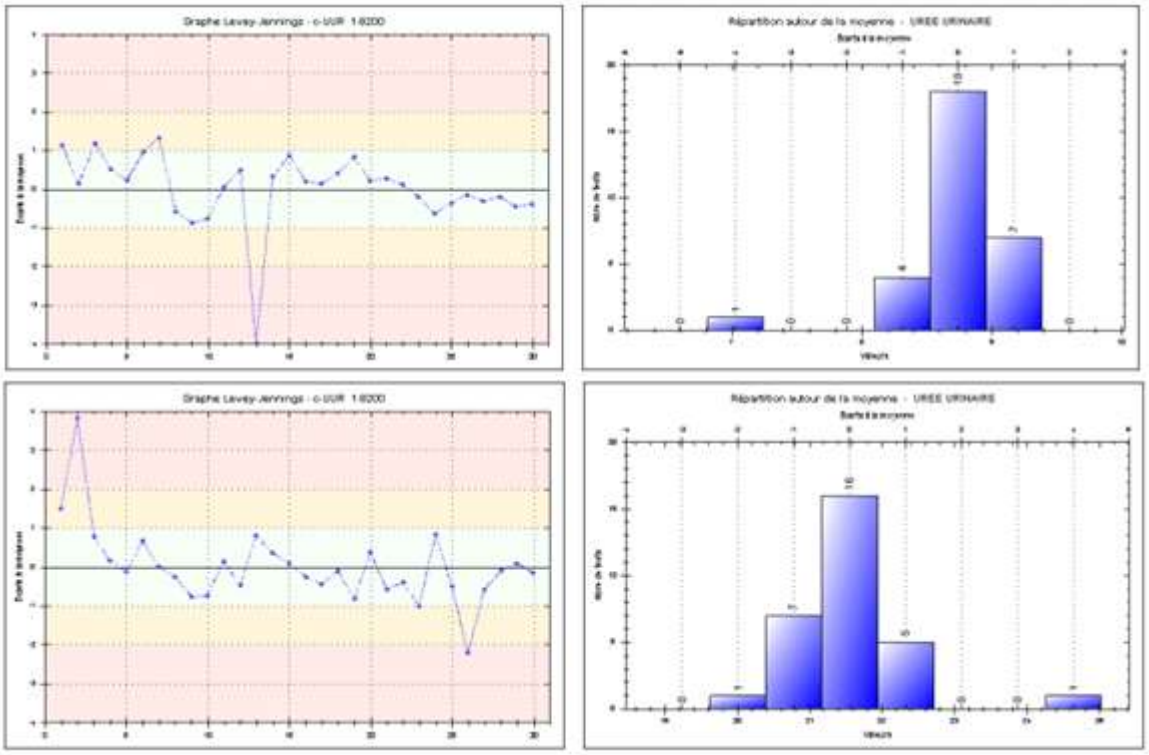

Figure2: *Regarding the intra-laboratory reproducibility of urinary ureafor two levels (1: low / 2: high)*

The average bias between the two automata is about 0.335%, with a linear regression equation Y = 0.998X - 0.017 with a Correlation Coefficient of 0.997, the Mean of the differencesis 0.039 g/l and Standard deviation of differences 0.649 g/l.

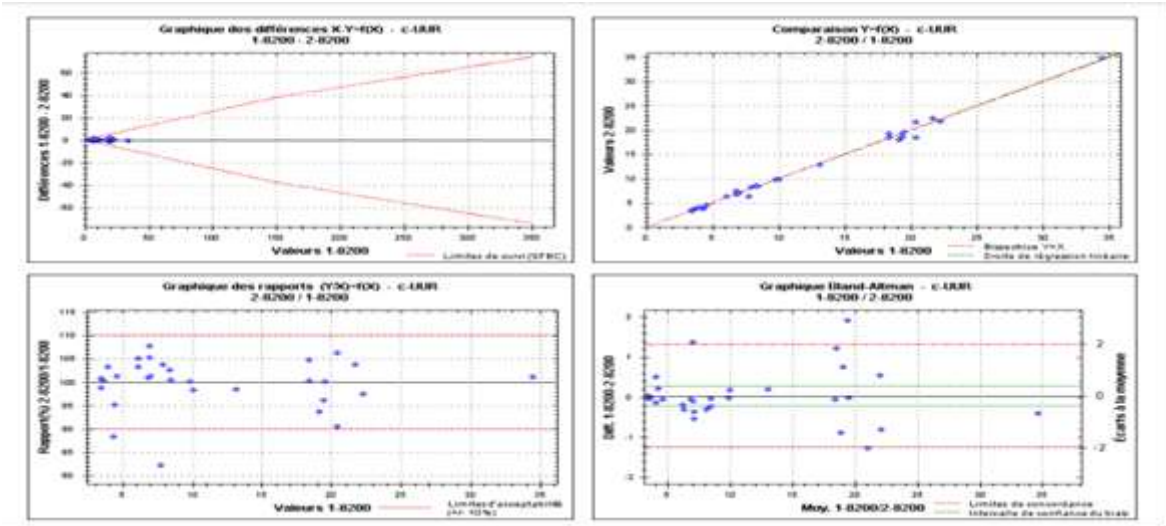

Figure 3. Bland-Altman difference diagram

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DISCUSSION

We have carried out a"method verification" according to Scope A where the recognized methods are validated in their field of application. The ARCHITECT techniques of biochemical parameters are marketed with a CE mark, a mandatory mark to be able to use to use them in medical biology for clinical diagnosis. They are therefore techniques classified in flexible range A for the verification of the method, verification that can be done using the COFRAC guide SH-GTA-04. It will not be necessary to perform a complete method validation method validation, but to perform a method verification in the practices of the laboratory practices. It is not necessary to verify the sensitivity and specificity of

the technique, the stability of the reagents, the robustness and the robustness and comparison with a reference method[5].According to the COFRAC recommendations, we can see that the critical bibliographic verification is very important. The validation/verification file can refer to other documents (bibliography, supplier records, internal laboratory documents...), properly referenced and accessible. On the other hand, the experimental verification on site in scope A is more reduced and relies heavily on the study of performances but also on risk studies or on the competence and qualification of operators. The experimental verifications must be carried out according to a protocol established by the laboratory with defined criteria of acceptability. It must lead to a conclusion and a decision as to the operational validation of the technique, with regard to the specifications initially fixed. We based ourselves on the SH FORM 43 and the method validation module of the EVM middleware (Byg computer system).Method verification/validation is based on statistical analyses to demonstrate the suitability of the method for use in accordance with clinicians' expectations. It is important to have a critical reading of the results obtained in order to be able to interpret them in a correct and relevant way. This interpretation concerns the clinical impact of the result, taking into account the biological variations which can be more or less important according to the compound, but also its representativeness. The aim of method verification/validation is to know the limits of one's methods and therefore to know the relevance of one's method in relation to its clinical use.

Fidelity testing: It concerns the study of fidelity or precision: repeatability and intermediate fidelity (reproducibility) The SH GTA 04 specifies that the minimum is to achieve the performance announced by the supplier in these technical documents.

Repeatability evaluation: It allows to evaluate the dispersion of the results obtained from the same sample in the same series of analysis, for that the repeatability was evaluated on the test serum of the patients and that for the two levels of assay, the coefficient of variation obtained for the repeatability study complies with and is lower than the requirements announced by the supplier and also the COFRAC recommendations. Reproducibility evaluation: It assesses the dispersion of results obtained from the same sample in different analytical runs,the coefficient of variation obtained for the reproducibility study is in conformity and globally meets the requirements issued by the supplier and also the COFRAC recommendations.

Accuracy Assessment: Accuracy was determined using the results of the external evaluation of quality the acceptable limits used are those of RIQAS, the world's largest external quality assessment program with over 50 000 participating laboratories in over 139 countries. They are based on comparison with the Architect peer group participating in the external quality control program, Accuracy was determined for samples from external quality assessments. As for the accuracy approach, we were unable to calculate it due to the lack of outsourcing of our current internal quality controls. Estimation of the uncertainty of measurement This is a parameter which gives an idea of the reliability of the results given by the automaton. Thus, two results close to each other must be interpreted by the clinician taking into account the uncertainty of measurement to conclude whether or not they would be totally different or on the contrary completely identical, for our studied parameter the supplier's tables do not communicate reference uncertainty values. It is therefore not possible to deduce whether the uncertainties of the study comply with the supplier's specifications.

To compare the results of a method Y (to be tested) with those of a method X (used in the laboratory or taken as a reference), at least 30 patient samples are analyzed, homogeneously covering the extent of the pathophysiological field encountered These samples, preferably fresh, are analyzed by both techniques, in the shortest possible time. The results are examined progressively, and it is checked whether the discrepancies (difference between the two methods) are judged to be greater than the pre-established limits calculated for each of the selected pairs x i (X method) and y i (Y method) : Calculate the differences xi - yi and Calculate the ratios yi/ xi Draw the graphs of the differences, (xi - yi) function of xi and (yi / xi) function of xi and plot the selected limits in absolute or relative value on these graphs. Note the number of discordant samples, the possible discordant values will have to be exploited by the laboratory in order to carry out an analysis of the causes and an analysis of impact on the divergences noted between the two tested methods

CONCLUSION

The results obtained allowed us to verify the performance of the method of to compare them to the analytical objectives set and thus to meet the regulatory andto meet the regulatory and normative requirements.

The medical biology act is part of a preventive, diagnostic, prognostic and therapeutic approach. The biologist is responsible for this procedure, which includes taking samples, performing the analysis, validating the results and, if necessary, comparing them with the patient's clinical and biological data. He/she participates by commenting, if necessary, in the interpretation of the results of the medical biology analysis. These results contribute to the diagnosis and the prescription of care. This is why the search for quality must be an essential and constant concern of the biologist and all the laboratory personnel [6]. Quality is defined as the ability of a product, process or service to satisfy the expressed and implicit needs of the user. In the field of medical biology, it is the adequacy between the resources used and the information expected by the prescribing physician, as well as the response to patient expectations. The objective of medical biology accreditation is to guarantee the reliability of medical biology examinations performed and the quality of the medical service provided by a medical biology laboratory. The central laboratory of the Mohammed VI University Hospital Center of Oujda is voluntarily committed to a quality policy that includes an accreditation process. This kind of study will constitute a solid basis for the implementation of an accreditation procedure for the tests used in our laboratory.

Competing Interests

The authors declare that they have no competing interests.

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