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Verification of analytical performance of sodium assay on the Abbott architect ci8200: Experience of the central laboratory Mohammed VI Oujda

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Abstract

Introduction: Sodium is the main extracellular cation. It plays a fundamental role in maintaining osmotic pressure and hydroelectrolyte balance, and is therefore implicated in many pathological conditions. Sodium determination is a basic biochemistry laboratory test.

Objective: the aim of our work is to verify the method of sodium determination by potentiometry on the Architect CI 8200 automated system (Abbott), in order to meet the quality requirements for laboratory accreditation under standard NF ISO 15189. Materials and methods: following the recommendations of NF EN ISO 15189, we evaluated the repeatability, intermediate precision, accuracy and uncertainty of measurement of the serum sodium assay on the Architect CI 8100 automated system, as well as a mirror comparison of the two Architect CI 8100 1 and 2. The CV values obtained were compared with those set by learned societies (SFBC and RICOS).

Results and discussion: The results obtained show satisfactory repeatability for the 3 low, medium and high levels, with CV1= 1.1%, CV2=0.8% and CV3= 0.76% respectively, and satisfactory intra-laboratory reproducibility for the 3 low, medium and high levels, with CV1= 1.05%, CV2= 0.95% and CV3= 0.75% respectively. For comparison, the Bland-Altman diagram showed that the mean bias between the two automata was of the order of 0.29%, the correlation coefficient r= 0.98 with a mean difference of 0.40 mmol/l, a standard deviation of 0.675 mmol/l and a linear regression equation Y = 1.027 X - 4.073. Corrective measures were envisaged to remedy the various errors identified. To solve any malfunction in a sustainable way, it is essential to search for the anomaly by applying the Ishikawa diagram.

Conclusion: The results obtained have enabled us to verify the performance of the sodium assay method and compare it with the analytical objectives set, in order to meet the regulatory and normative requirements to which our laboratory is committed.

Keywords: Sodium; ISO 15189; Verification; Repeatability; Reproducibility; Architect ci8200

1. Introduction

Analytical method verification is a process that involves evaluating an analytical method's performance, quantifying it in accordance with a standard operating procedure, and then contrasting it with standards set by learned societies (RICOS, FSCB). This process gives the laboratory a thorough understanding of its analytical methods, performance, and limitations. It must make sure that these performances are adequate in order to guarantee the precision of the analytical findings and the clinical interpretations that are advantageous to the patient and the prescriber [1] [2]. Through this

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work, we compare two automats: Architect ci8200® of Abbott to present the findings of the protocol of the verification of Sodium 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.

1.1. Reminder on sodium

On average, the human body contains around 60 mmol of sodium per kilogram of body weight. Two-thirds of this sodium is in the form of "exchangeable" sodium (90% of which is located in the extracellular sector and 10% in the intracellular sector) and one-third in the form of "non-exchangeable" sodium, bound to the bone in the form of hydroxyapatite crystals, and in subcutaneous tissue.

1.1.1. Sodium inputs

Sodium is supplied by the diet, mainly in the form of sodium chloride (1 g NaCl = 17 mmol Na). Almost 100% of ingested sodium is absorbed transcellular by the epithelium of the small intestine. Intestinal sodium absorption takes place transcellular, via sodium-proton exchangers (NHE-2, NHE-3, NHE-8), cotransporters coupled to glucose (Sodium-GLucose Transport protein, SGLT-1) or phosphate (NPT2b), and via the epithelial sodium channel ENaC, located at the apical pole of enterocytes. Sodium leaves the enterocyte via the Na+/K+-ATPase pump, located at the basolateral pole.

1.1.2. Sodium outputs

Sodium is excreted via the digestive tract, skin and kidneys In the physiological state and in temperate climates, extra-renal excretion is negligible (5 mmol/d in feces, 10-20 mmol/L in sweat) and is not regulated.In the event of profuse sweating or significant digestive outflow (diarrhea) extra-renal sodium losses may become significant and cause extracellular dehydration, but remain unregulated. Renal sodium outflows, on the other hand, are finely regulated, ensuring a zero "input-output" balance and keeping the total amount of sodium in the body (and therefore the extracellular volume) constant. In physiological conditions, to ensure homeostasis, daily urinary excretion of sodium is equal to the daily dietary intake, except for extra-renal output, which is considered negligible. Consequently, one way of estimating the amount of sodium an individual's diet provides is to measure his or her natriuresis on a 24-hour urine sample. A natriuresis of 170 mmol corresponds to a dietary sodium intake of around 10 g per day (1 g NaCl = 17 mmol). One of the limitations of this method is the difficulty of accurately collecting all the urine over 24 hours, without under or over-collecting. Some authors have proposed formulas for estimating 24-hour natriuresis from the sodium/creatinine ratio of a urine sample, but the precision of these methods remains insufficient to reliably assess an individual's sodium intake [3].

2. Material and methods

2.1. Principle of the assay method

Selective electrodes for sodium, potassium and chloride ions use selective membranes for each of these ions. An electrical potential (voltage) develops across the membranes between the reference electrode and the measuring electrode, in accordance with the Nernst equation. This voltage is compared with the previously determined calibrator voltages and converted into ionic concentration.

Methodology: Dilute ion-selective electrode (indirect) [4]

2.2. Verification procedure

The biochemistry department of Mohammed VI University Hospital of Oujda conducted this comparative descriptive study over a period of 49 days. The working methodology of our study was based on the COFRAC certification technical guide GTA 04 protocol. Sodium was tested on the Architect ci8200 by ion-selective electrode using samples from patients being treated at the Mohammed VI University Hospital in Oujda in addition to internal quality controls as part of the method's verification in order to judge the analytical performance in terms of repeatability and reproducibility. The two Architect ci8200 automatons of Abbott were also compared in terms of their methods. We also used the Bland-Altman diagram, which shows the differences between the two techniques' means. Data was statistically processed using the EVM middleware module of BYG Informatics. The coefficients of variation (CV) values from our study were compared to those set by the learned societies (FSCB and RICOS). Random subjects were chosen from the regular workflow. There were no exclusion standards used.

We conducted our study in two stages. The first step involved determining reproducibility through daily passage of the three levels of control: low, medium, and high over a 49-day period. The next step involved obtaining sodium values

from a group of serum samples that were evenly distributed across the measurement range. Low, medium, and high level sample groups were formed. Each sample was run 30 times to evaluate repeatability. Increase to demonstrate that the candidate method is sufficiently consistent with the reference method by comparing the two automatons.

3. Results

The results demonstrate that repeatability is satisfactory for Architect ci8200 at low, medium, and high levels, as demonstrated by coefficients of variation (CV) of 1.1%, 0.8% and 0.76% respectively, as presented in Table1.

Table 1 Repeatability results for Sodium on Architect ci8200 automaton

Sample	N	Mean	SD	CV%	CV% FSCB	Conclusion
Level 1	37	122.59 mmol/l	1.343 mmol/l	1.1	1.16	Validated
Level 2	30	141 mmol/l	1.129 mmol/l	0.8	0.9	Validated
Level 3	30	162.67mmol/l	1.241mmol/l	0.76	0.82	Validated

The intra-laboratory reproducibility of Architect ci8200ci® was found to be acceptable for levels 1, 2, and 3, with corresponding coefficients of variation (CV) of 1.05%, 0.95% and 0.75% respectively, as shown in Table 2.

Table 2 Reproducibility results for Sodium on Architect ci8200 automaton

Sample	N	Mean	SD	CV%	CV% FSCB	Conclusion
Level 1	49	122.65 mmol/l	1.286 mmol/l	1.05	1.49	Validated
Level 2	33	142.73 mmol/l	1.355 mmol/l	0.95	1.1	Validated
Level 3	38	161.84 mmol/l	1.22 mmol/l	0.75	0.9	Validated

In the comparison analysis using the Bland-Altman diagram (Figure 1), it was observed that the average bias between the two automatons Architect ci8200, is about 0.293 % .The correlation coefficient (r) was 0.979, with a mean difference of 0.40 mmol/l and the standard deviation of the differences is 0.675 mmol/l. The linear regression equation was Y =1.027 X - 4.073 (Figure 2).

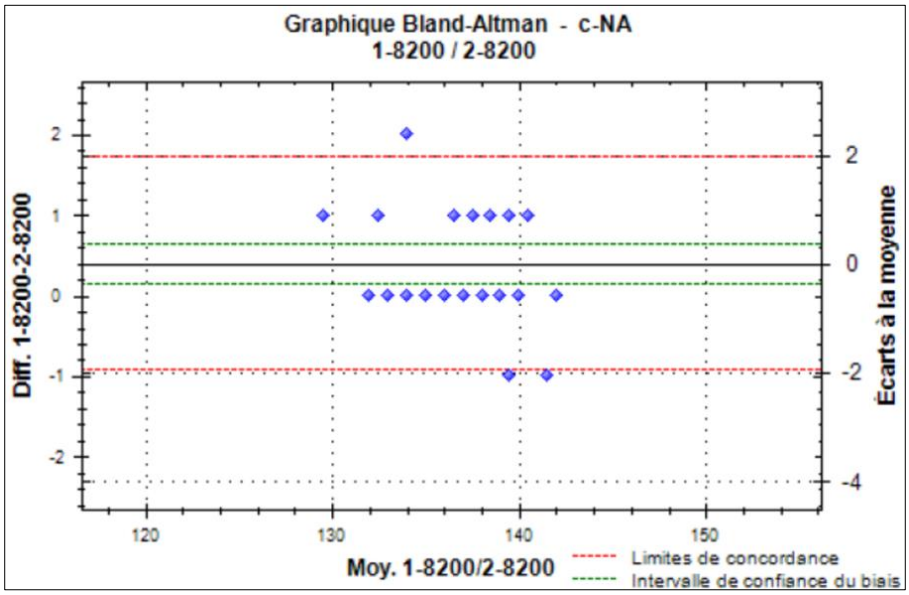

Figure 1 The Bland-Altman diagram for Sodium

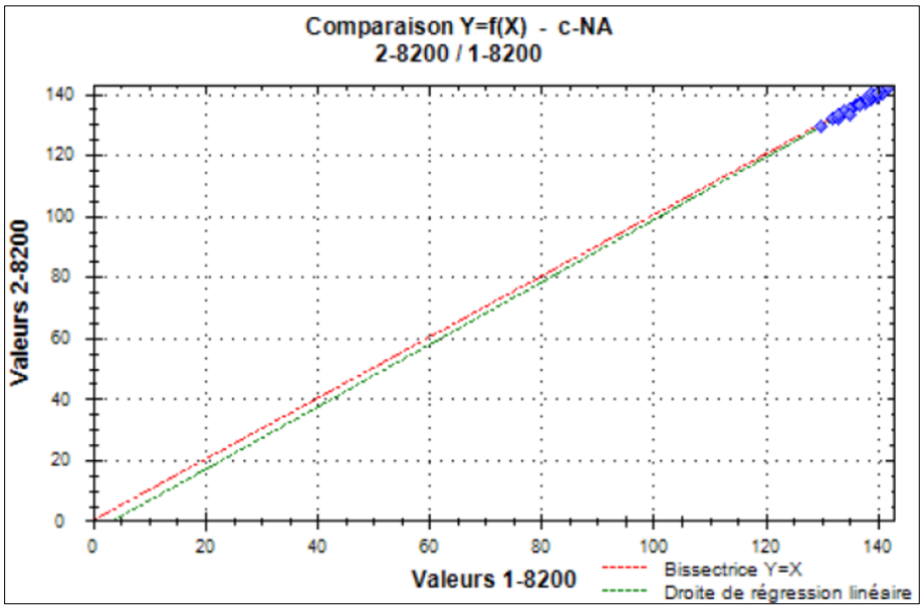

Figure 2 Correlation study for Sodium

4. Discussion

In our "scope A verification/validation" procedure, the recognized methods were a priori validated in their application domain. The Abbott biochemistry techniques bear the CE mark, which is necessary for use in clinical diagnosis in medical biology. Since they can be verified using the COFRAC guide SH-GTA-04, these techniques are classified as flexible range A. Instead of a full method validation, only a method verification will be required for the laboratory procedures. Due to this, it is no longer necessary to confirm the technique's sensitivity and specificity, reagents' stability, robustness, or a comparison with a reference method [1] [5].

The assessment of repeatability creates ideal performance conditions for the parameter under evaluation and confirms that the system is functioning properly, including the use of the proper equipment and reagents. Reproducibility and method faithfulness can be assessed using a variety of factors, including operators, time, reagent batch sizes, and calibrations [6].

It is essential to conduct a critical reading of the results in order to interpret them appropriately and pertinently. In addition to taking into account the result's representativeness and biological variations, which can have varying degrees of significance depending on the compound, this interpretation focuses on the result's clinical significance. Knowing one's limitations and, consequently, the relevance of one's method to its clinical application are the primary goals of method validation and verification [7]. The coefficients of variation obtained for the study of repeatability and intra-laboratory reproducibility are excellent overall and meet the criteria for the Valtec protocol (FSCB) as well as those set forth by the supplier. A technical verification/validation file must be finished if a medical analysis laboratory wants to be accredited under ISO15189 [8]. The repeatability and reproducibility of the Sodium parameter were assessed, and they were found to be satisfactory.

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 [9].

5. Conclusion

The findings of our study enabled us to evaluate the performance of the sodium assay method and evaluate how well it met the analytical goals specified in the accreditation procedure in which our laboratory is currently taking part. The two automatons: Architect ci-8200® are therefore comparable.

Compliance with ethical standards

Disclosure of conflict of interest

The authors declare no conflict of interest.

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