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Electrolytes internal quality control by using ISO 15189 version 2007: Particular requirements for quality and competence for biomedical laboratories

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Abstract

Background: the blood electrolytes analysis is a routine laboratory test which proper execution would help in the diagnosis of hydro-electrolytes disorders. The objective of this work was to assess the internal quality control of the sodium and potassium tests from the pre-pre-analytical phase to the post-analytical phase.

Material and Methods: This was a cross-sectional study which took in the laboratory of biochemistry at the Institute of Cardiology, Abidjan, Ivory Coast from March 1st to March 31, 2009. We used the flame photometer to measure the sodium and potassium electrolytes level in the internal control Exatrol-Normal from Biolabo®. Clinical samples were also taken for the determination of the same electrolytes levels. The pre-pre-analytical quality indicators depending on the physicians order, the pre-analytical quality, the analytical quality and the post-analytical indicators under the control of the laboratory were assessed by using "NF en ISO 15189 version 2007" check list: Particular requirements for quality and competence for biomedical laboratories paragraph 5.4.1, 5.4.2, 5.5 and 5.7. Data were captured into Microsoft Excel [Microsoft Corporation, Redmond, WA] and then imported and analyzed using QI Macros SPC Software for Excel®. The levels of Na^+ and K^+ in the control material Exatrol Normal from Biolabo® were represented as follow: mean (m), Standard deviation (SD). The values of the monthly distribution of Na^+ and K^+ concentrations around the mean were used to draw the Levey-Jennings diagram and Wesgard's rules were used to evaluate the performances of the analytical process.

Results: a total of 112 electrolytes analysis order were received at the biochemistry laboratory. For the pre-pre-analytical phase, the analysis of these requests forms revealed that 81 (72.3%) requests forms carried no clinical information. The non-compliance of the samples were mainly represented by the sampling under tight tourniquet 4 (3.6%), followed by the non-respect of the succession of tubes during multiple sampling process 3 (2.7%). For the analytical phase, the monthly Levey-Jennings diagram showed a dispersion of the two electrolytes Exatrol-Normal Biolabo® levels between the mean plus or minus 2 standard deviations [m ± 2SD]: 139.34 ± 2.84 mmol/L for Na^+ and for K^+, between [m± SD]: 4.2 ± 0.78 mmol/L. The analytical performances assessment for the two Levey-Jennings diagrams by using Wesgard's rules did not found any significant critical deviations with regard to the distribution of Na^+ and K^+ levels. For clinical samples, isolated hyponatremia was the most common disturbance (30.4%) followed by isolated hypokalemia (12.5%). At the post-analytical phase we observed for test execution a mean turnaround time of 34 ± 5.2 minutes with extremes ranging from 23 to 95 minutes. One case (0.9%) of transcription error was noted.

Conclusion: the internal quality control process is applied in the clinical biochemistry laboratory at the Institute of Cardiology, Abidjan. A systematic verification system of the different phases of the analytical process helped to follow quality indicators at all levels of the pre, analytical and post analytical process and corrective actions were taken if

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necessary. Better collaboration between clinicians requesting electrolytes analysis and biologists performing the analysis is necessary to improve the pre-pre-analytical phase and, beyond that, improve the patient outcome throughout a comprehensive care.

Keywords: Analytical phase; Blood electrolytes; Internal Quality Control; Pre-analytical phase; Post-analytical phase

1. Introduction

Sodium is the main extracellular cation and its balance is essential for several activities involved in maintaining the homeostasis of hydroelectrolyte functions [1]. Hyponatremia are electrolyte disorders that are defined as a plasma sodium concentration < 135 mmol/L and can be classified as moderate (130 to 134 mmol/L), intermediate (120 to 129 mmol/L) and severe (< 120 mmol/L) [2]. They occupy a place of choice especially in patients with cardiovascular diseases [3-4]. The pathophysiological mechanisms explaining the occurrence of hyponatremia and potentially life-threatening in these patients have been described. These mechanisms range from neurohormonal disorders involving arginine vasopressin (AVP) to iatrogenic hyponatremia induced by the use of diuretics [3, 5]. Several studies have demonstrated the existence of an association between hyponatremia, morbidity and intrahospital mortality in patients with cardiovascular disease [6-8]. An accurate biological diagnosis is therefore essential for their adequate management. The quality assurance process for biological analysis results recommends the use of ISO 15189 standards [9]. These standards involve the use of internal quality control, statistical methods to minimize systematic and random errors and, if necessary, actions to be taken to correct them [10-11]. There are several types of internal quality control and statistical methods used for the analysis of their stabilities. These statistical methods are generally based on the analysis of the dispersion of the values of the internal control material around the mean. They use the mean values plus or minus two standard deviations (m±2SD) as the alert threshold and the values m± 3ET as alarm threshold. The analysis of the stability of these methods based on the standard deviations (sigma metric methods) is done according to multiple pre-established rules including those described by Wesgard JO [12-14] offer a good precision of the biological results when they are used appropriately. The objective of this work was to assess the internal quality of the electrolytes analysis from its request to the results with an emphasis on the pre-analytical, analytical, post-analytical stages and the internal quality control based on the sigma metric method at the Institute of Cardiology, Abidjan.

2. Material and methods

2.1. Study design

This was a cross-sectional study which took in the laboratory of biochemistry at the Institute of Cardiology, Abidjan, Ivory Coast from March 1st to March 31, 2009. Analysis request forms coming from the clinical departments and sample receipt sheets were used to determine the pre-pre-analytical and pre-analytical quality indicators. Approximately 4 mL of blood was taken in heparinized tube from each fasting patient at least 8 to 12 hours at the elbow crease. After sampling, the tubes were subject to computer processing with a view to assigning an identification number. Whole bloods were centrifuged at 3000 G per minute for 15 minutes. The plasmas obtained after this separation were transported to the technical room for the execution of the analysis. Exatrol Normal from Biolabo® was used as the internal quality control material. We used the flame photometer to measure sodium and potassium electrolytes levels in Exatrol Normal® and in the clinical samples. The pre-pre-analytical quality indicators depending on the physicians order, the pre-analytical quality, the analytical quality and the post-analytical indicators under the control of the laboratory were determined by using ISO 15189 version 2007 check list: Particular requirements for quality and competence for biomedical laboratories paragraph 5.4.1, 5.4.2, 5.5 and 5.7.

2.2. Principe of flame photometer

The principle of this photometer is based on the measurement of the radiation intensity emitted when the excited atoms pass from the energy level E_0 to the energy level E_1. Indeed, the atoms of the element to be assayed (Na^+ and K^+) receive an external energy provided by the flame which makes it possible to produce an atomic vapor of the element. These element leave from the fundamental energy level E_0 to a higher energy level E_1. When these atoms return to the ground state, they emit radiation characteristic of the electrolyte to be assayed (589 nm for Na^+, 767 nm for K^+ and 671 for lithium). These emitted radiations will undergo a selection through a filter. The selected rays will be picked up by a photoelectric cell which will transform them into an electric signal. The electrical signal obtained will be proportional to the level of the electrolyte initially present in the sample according to Plank-Einstein equation: $E= E_1-E_0 = h.\gamma = h.c/\lambda$. The flame photometer incorporates into the test portion an internal standard of known concentration which is a lithium salt (15 mmol/L) whose signal is measured separately and automatically subtracted from the other results. The concentration of this standard must be the same at the end of the assay. This makes it possible to control unpredictable

fluctuations during the measurement, in particular the instability of the flame and the flow of fluids working solution, standard and test sample.

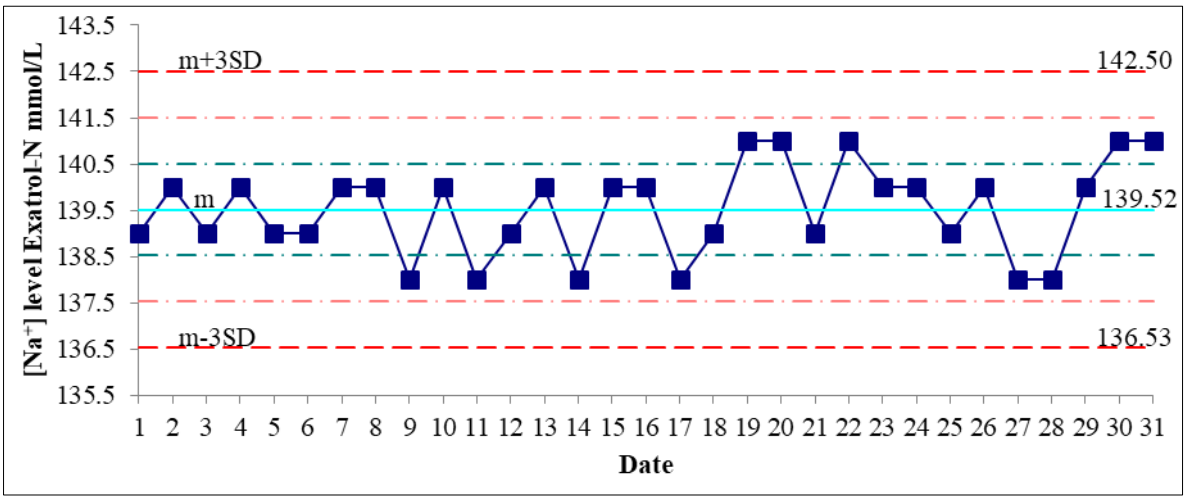
2.3. Data collection analysis

Data were captured into Microsoft Excel [Microsoft Corporation, Redmond, WA] and then imported and analyzed using QI Macros SPC Software for Excel®. Quantitative data normality were assessed by using Shapiro-Wilk test. Descriptive statistics including mean, frequency, and standard deviation (SD) were determined for all variables and expressed as mean ± SD for variables with normally distribution or median plus inter quartile range (IQR) for not normally distributed variables both for clinical data and for data from Exatrol-Normal Biolabo®. For categorical parameters, Chi-square or Fisher exact tests were used. The levels of Na^+ and K^+ in the control material Exatrol Normal from Biolabo® were represented as follow: mean (m), Standard deviation (SD). The values of the monthly distribution of Na^+ and K^+ concentrations around the mean were used to draw-up the Levey-Jennings diagram and Wesgard's rules were used to evaluate the performances of the analytical process. The statistical significance threshold was set at $p \leq 5\%$.

2.4. Ethical consideration

The study was approved by the laboratory director. Verbal informed consent was obtained from all subjects. In particular, subjects were informed of the anonymous nature of the study.

3. Results



CL	n	31
139.516	Mean	139.5161
Stdev	Stdev	0.99569
0.996	Min	138
Max		141
%CV		0.713673

Figure 1 Levey-Jennings diagram of Exatrol-Normal Sodium. Flame photometer, Calibrator: SEAC® Control: EXATROL®-NORMAL

A total of 112 electrolytes analysis order were received at the biochemistry laboratory. For the pre-pre-analytical phase, the analysis of the requests forms coming from the clinical departments revealed that 81 (72.3%) requests carried no clinical information. There were no non-conformities concerning the other items of the pre-pre-analytical phase (Table 1). There was a difference between the different clinical departments regarding the presence of clinical information on their analysis request forms, $p = 0.01$ (Table 2). The pre-analytical phase non-compliances of the samples were mainly represented by the sampling under tight tourniquet 4 (3.6%), followed by the non-respect of the succession of tubes in multiple sampling process 3 (2.7%). Collection errors in an inappropriate tube (coming from the clinical departments) 2/112 (1.8%) and insufficient volume collection errors (coming from the clinical departments) 1/112 (0. 9%) were the

other non-compliances of the pre-analytical phase. The remain of the items of quality indicators of the pre-analytical phase were absent or their follow-up was not possible due to the non-availability of information on it (Table 1). For the analytical phase, the monthly Levey-Jennings diagram showed a dispersion of the Exatrol-Normal® values between the mean plus or minus 2 standard deviations [m ± 2SD]: 139.34 ± 2.84 mmol/L for sodium (Na^+) (Figure 1). For the potassium (K^+), the values of Exatrol-Normal® were between [m± SD]: 4.2 ± 0.78 mmol/L (Figure 2). The analytical performances assessment of the two Levey-Jennings diagrams by Wesgard's rules did not found any significant critical deviation with regard to the distribution of Na^+ and K^+ levels. For clinical samples, the mean of plasma Na^+ was 137 ± 5.7 mmol/L with extremes ranging from 112 to 156 mmol/L. For K^+ the mean was 4.0 ± 2.1 mmol/L with extremes ranging from 2.1 to > 7 mmol/L (Table 3).

Table 1 Pre-analytical quality indicators of the study

Analytical quality indicators	N	%
Pre-pre-analytics depending on the department of clinical		
Request forms without clinical information	81	72.3
Inappropriate request according to the clinical information	NA	NA
Patient identification errors	0	0
Patient identification error detected before result	0	0
Patient identification error detected after result	0	0
Collection at an inappropriate time (postprandial, diuretics, NaCl infusion)	NA	NA
Pre-analytical under laboratory control		
Recording error concerning the identification of the prescribing physician	0	0
Unintelligible recording error regarding the request	0	0
Error registering less than request	0	0
Save error in addition to request	0	0
Misinterpretation of the request during recording	0	0
Sample taken under tight tourniquet	4	3.6
Error of succession of tubes during multiple sampling	3	2.7
Sample identification error during collection	0	0
Inappropriate sample collection error	0	0
Collection error in an inappropriate tube (from the clinical department)	2	1.8
Insufficient volume collection error (come from the clinical department)	1	0.9
Sample destroyed during transport (from clinical service to laboratory)	0	0
Sample transported in inappropriate time	NA	NA
Sample transported under inappropriate temperature condition	NA	NA
Sample in bad storage condition during the transport	NA	NA
Sample lost during the transport	0	0
Anticoagulant-sample ratio not respected	1	0.9
Hemolyzed sample	3	2.7
Clotted sample	0	0
Lipemic sample	2	1.8
Icteric sample	1	0.9

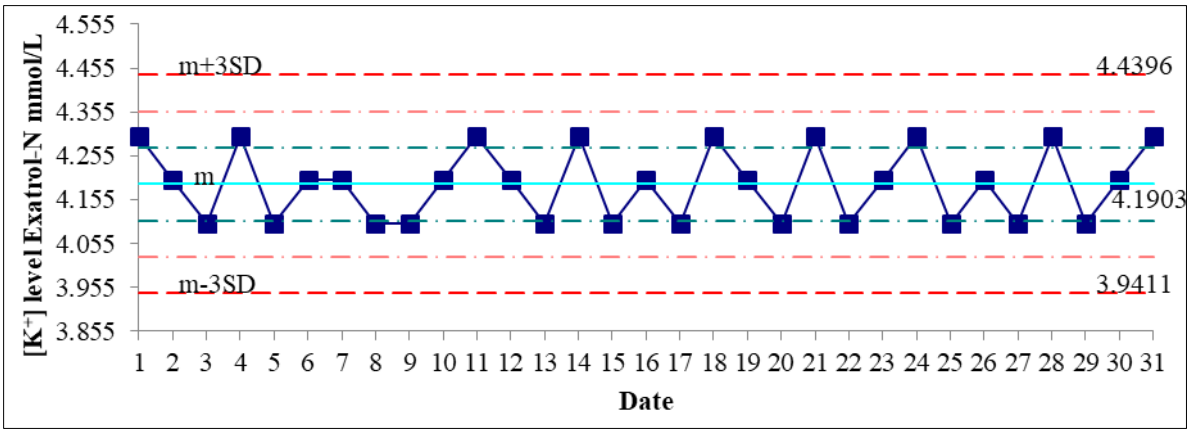
The electrolytes analysis results was normal in 52 patients (46.4%). Isolated hyponatremia was the most common disturbance (30.4%) followed by isolated hypokalemia (12.5%). Hyperkalemia was found in 2 patients (1.8%) while the mixed form hyponatremia plus hypokalemia was found in 9 patients (8.0%). Finally, hyponatremia and

hyperkaliemia were present in one patient (0.9%) (Table 4). Concerning the post-analytical phase, the mean turnaround time (TAT) for the execution of tests was 34 ± 5.2 minutes with extremes ranging from 23 to 95 minutes (Table 5). One case (0.9%) of transcription error was noted (Table 6). We did not observe any loss of the patient results and miss interpretation of the patient's results during our study.

Table 2 Presence of clinical information on the department's analysis request forms

Analysis request departments	N	Presence of clinical information on the request forms	Absence of clinical information on the request forms
Emergency unit	16	2(12.5%)	14(87.5%)
Department of Medicine	11	2 (18.2%)	9 (81.8%)
Intensive care unit	10	4 (40.0%)	6 (60.0%)
Surgery	5	4 (80.0%)	1 (20.0%)
Outpatients	66	16 (24.2%)	50 (75.8%)
Cardio-pediatrics department	4	3 (75.0%)	1 (0.25%)
Total	112	31 (27.7%)	81 (72.3%)

Fisher exact test, $p = 0.01$



CL	n	31
4.190	Mean	4.190323
Stdev	Stdev	0.083086
0.083	Min	4.1
Max		4.3
%CV		1.982799

Figure 2 Levey-Jennings diagram of Exatrol-Normal Potassium (K^+). Flame photometer, Calibrator: SEAC® Control: EXATROL®-NORMAL

Table 3 Descriptive variables of electrolytes in the study population

Electrolytes	N	Minimum	Maximum	Mean	Standard deviation
Sodium (Na^+)	112	112	156	137.2	5.7
Potassium (K^+)	112	2.1	> 7	4.0	0.7

Table 4 Distribution according to electrolytes disturbances

Electrolytes disturbances	N	Pourcent
normal	52	46.4
hyponatremia	34	30.4
hypokaliemia	14	12.5
hyperkaliemia	2	1.8
hyponatremia + hypokaliemia	9	8.0
hyponatremia+ hyperkaliemia	1	0.9
Total	112	100.0

Table 5 Turnaround time (TAT) of the patient's samples

Descriptive statistics of time spent on tests	Min	Mean	Sd	Max
TAT (minute)	23	34	5.7	95

Table 6 Post-analytical quality indicators

Post-analytical quality indicators	N	Pourcent (%)
Loss of results	0	0
Transcription error	1	0.9
Miss interpretation of the results	0	0

4. Discussion

We carried out a cross-sectional study to highlight the internal quality control of electrolytes in the biochemistry laboratory of the Institute of Cardiology of Abidjan (ICA). This study involved 112 requests for blood electrolyte determination between March 1st and March 31, 2009. The main objective of the study was to assess the internal quality control (IQC) of plasma electrolytes dosage method. Flame photometry method was used for the determination of Na^+ and K^+ levels in the control material (Exatrol-Normal Biolabo and in the patients plasma. The sex-ratio was 1.5. We observed the absence of indication of sex on 3 request forms (2.7%). With regard to age, we observed its absence on 5 requests for electrolytes analysis (4.5%). The mean age was 46.48 ± 2 years with the extremes ranging from 1 to 90 years. The age groups of 51-60 and < 30 years were the most represented with 28.6% and 20.5%, respectively. Damorou F et *al*., reported a sex-ratio of 1.9 and an average age of 56.9 ± 1 years with extremes ranging from 20 to 97 years [15].

Arterial hypertension was the most observed information about 11 requests forms of electrolytes analysis (9.8%), followed by preoperative and postoperative request forms each accounting for (2.7%), respectively. We observed the absence of information on 81 requests forms of electrolytes which accounted for 72.3% making it difficult to safely manage the biological results. This pattern was difference between requesting clinical departments *p-value* = 0.01. Our result was in line with those obtained by Alphonsine K.M et *al*., who reported 74.7% of overall non-compliance of analysis requested at the Institute Pasteur of Abidjan, Ivory Coast with a difference between the requesting clinical departments [16]. We used Exatrol-Normal from Biolabo® as the material for the IQC. Levey-Jennings diagrams and Wesgard's rules were used to assess the results of IQC. According to Levey-Jennings, the control values must oscillate around the mean value of analyte level in the control material and be at most between m± 2 SD to allow the validation of the control series and subsequently of the clinical results of the patients. Wesgard JO et *al*., [12-14] add that if a control run results are between m ± 2SD and m ± 3SD, then the run results should be interpreted based on previous results. In 1981, Dr. James O Wesgard published the standard guideline for assessing Levey-Jennings diagrams for analytical quality performance. Wesgard's rules respond to a specific semantical and syntaxial numerical notation like A_L where A is the number of measures taken into account and L the limit used. For instance, the rule 1_{2s} corresponds to one value of measure beyond m ± 2SD and this is an alert but does not require the rejection of the series of measures. On the other

hand, the rule 1_{3s} means that one measure is beyond m ± 3SD and the series must be rejected. The rule 2_{2s} means that 2 consecutive measures exceed m ± 2SD on the same side and the series of measures must be rejected. The rule R_{4s} violation comes when 2 measurements of the control exceed 2SD on either side of the mean and is also a rejection motif of the series of measure. The rule 4_{1s} violation means that 4 consecutive control values exceed the 1SD limit. The rules 10_x: Violation happen when 10 consecutive values are on the same side of the mean. In practice, if the results are between m ± 2SD, the series can be validated and the patient results are validated. If the results deviate from m ± 3SD, the series is not validated the patient results of the series are ~~not~~ also not validated. Analyze the type of errors and consider corrective action if necessary. If the results are between m ± 2SD and m ± 3SD, the rules defined by Wesgrad are used for the assessment of analytical performance of Levey-Jennings diagram based on the previous results [17].

In our study, the Na^+ IQC series results were all within m ± 2 SD (139.34 ± 2.84 mmol/L) thus, we did not observe no violations of Wesgard's rules such as (1_s, 2_{2s}, 1_{3s}, R_{4s}, 1_{4s} and 10_x). About K^+, the results of the IQC series were all between m ± SD (4.2 ± 0.78 mmol/L), also no violations of Wesgard's rules were observed. The Na^+ and K^+ means of the control serum used are comparable to the target values as described by Poh DKH et al., 2021[18]. These results consolidate the technical validation of electrolytes analysis according to Levey-Jennings diagram and the rules defined by Wesgard [13]. According to certain authors, rule out the IQC over at least 20 days is mandatory [19-20], however in our study the control was carried throughout the month of March which confers a broad coverage of the month.

Natremia in patients fluctuated between 112 to 146 mmol/L with an average value of 137.2 mmol/L. Serum potassium ranged from 2.1 to > 7 with an average of 4.0 mmol/L. These means are all within the reference limits obtained by Yapo et *al*., [20] in the presumed healthy Ivorians. This observation could be explained by the high rate of normal results of the electrolytes analytes 52/112 (46.4%) and the very narrow distribution of electrolytes results materialized by restricted standard deviations.

Isolated hyponatremia was observed in 34/112 patients (30.4%). Hyponatremia was also reported by Claiton J.A et *al*., in patients followed in the department of cardiology. However, the rate of hyponatremia in our study was higher than that of Claiton J.A et *al*., who obtained (13.7%) [21]. Isolated hypokalaemia was found in 14/112 patients (12.5%). This result is also different from that obtained by Claiton J.A et *al*., who reported 8.5% of isolated hypokalemia [21]. We did not find any association between age, gender, clinical information and electrolytes disturbances. On the other hand, a significant association was observed between the requesting service and the disturbance of electrolytes *p-value* = 0.02. These results are different from those obtained by Claiton J.A et *al*., who found that age correlated significantly with serum K^+ and that there was a significant association between these two variables. We observed 2/112 cases of hyperkaliemia (1.8%), 9/112 cases of hyponatremia + hypokalaemia (8%) and 1/112 case of hyponatremia + hyperkaliemia (0.9%). In our series, only 31/112 requests forms of analysis carried clinical information (27.7%). We found among these 11 hypertensive patients 2 cases of hypokalaemia + hyponatremia and 1 case of hypokalaemia + normal natremia. It was difficult to evaluate these results given the lack of the clinical information on the requests forms of analysis. However, one could consider the use of antihypertensive treatment or any other treatment that would induce natriuresis and K^+ leakage [22].

Given the importance of electrolytes analysis it is a frequently requested laboratory test in the department of cardiology and intensive care units because of the role that electrolytes play in cardiac activity and in water and electrolytes homeostasis in the body. Its good technical performing is therefore essential for a better care for patients. At the time of our study, the use of flame photometry for electrolytes analysis was still topical. Nowadays, this device has been abandoned in all laboratories in favor of device which uses the principle of indirect and direct potentiometry [23]. This last technique represents the advantage of being insensitive to pseudo hyponatremia induced by hyperlipidemia and hyperproteinemia. In addition, they use less bulky equipment devoid of the dangerous environment created by butane gas, the flame and *in fine*, they are easily automated [24-25].

5. Conclusion

Electrolytes analysis is a frequently laboratory test in cardiology and intensive care units because of the role that these electrolytes play in cardiac activity and electrolyte balance. The internal quality control allowed the technical validation of the flame photometry use in Na^+ and K^+ plasma level determination, the assurance of metrological control of this this method of dosage and the validation of the patients clinical samples. A systematic verification of the different of analytical phase's process makes it possible to assess the quality indicators at all stage of the analytical process and to take corrective action if necessary. Better collaboration between physicians requesting electrolytes analysis, biotechnologists and clinical laboratory scientist performing the analysis is necessary to improve the pre-pre-analytical phase and, beyond that, better patient care. The quality assurance manager of the laboratory must ensure the complete

implementation of all the normative requirements of the NF standard in ISO 15189 version 2007 for total control of the measurement of electrolytes.

Compliance with ethical standards

Acknowledgments

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Disclosure of conflict of interest

Author and co-authors certify that there is no actual or potential conflict of interest in relation to this article.

Statement of informed consent

Each participant gave fully verbal consent prior to his or her enrollment. The research protocol was reviewed and approved by the laboratory director.

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