

## Research Article

# External Evaluation of the Quality of the Four Emergency Biochemical Parameters in Antananarivo

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### Abstract

The External Evaluation of the Quality is an important procedure for assessing the performance of a laboratory. The aim of the present study is to assess the performance of the the biochemistry laboratory of Joseph Ravoahangy Andrianavalona by the dosage of

the most prescribed 4 emergency biochemical parameters. It is a retrospective evaluative study of the performance of the biochemistry laboratory of Joseph Ravoahangy Andrianavalona University Hospital Center on a period of 4 months from January 2019 to April

2019 involving 8 samples of External Evaluation of the Quality provided by the Quality Insurance Association of the clinical Biology Laboratories in France. Serum creatinine, blood glucose, uremia and serum electrolytes were dosed on the 8 samples which carried out 32 dosages. During a period of 4 months the accuracy was 94% for the 32 carried out dosages. The precision had been 97% if the Variation Coefficient Ratio (VCR) was below 1.50. The monthly assessment of the 3 studied parameters: serum creatinine, blood glucose and uremia were always good during the 4 months. The imprecision (VCR >1.50) concerned the disease control of the sodium levels in February. The University Hospital Center Joseph Ravoahangy Andrianavalona Biochemistry laboratory was efficient during the External Evaluation of the Quality. Therefore, these results were reliable and contribute to the improvement of the diagnosis, the monitoring and the aftercare of the patients. Every laboratory for medical analysis ought to organize a periodical External Evaluation of the Quality to monitor and improve biological analysis results.

**Keywords:** Accreditation; Quality control; Performance

## 1. Introduction

Medical analysis laboratories had a very important part to play in the disease diagnosis, monitoring and management. Biological analysis results should be reliable for patients well-being. Therefore, inter-laboratories comparison was necessary in order to control the results and the eventual errors which might happen. The External Evaluation of the Quality (EEQ) was a procedure for performances assessment of a laboratory through an inter-laboratories comparison realised by an organiser who substantially respected the requirement of ISO 43-11 (cf. § 5, 6, 4) and the current regulation with a sample from unknown controls. The realisation of an EEQ was a part of one of the six

preliminary works to establish the aims of analytic performance [1, 2]. The biochemistry laboratory of Joseph Ravoahangy Andrianavalona University Hospital Center (CHUJRA) was yearly registered at the EEQ program of the Quality Insurance Association of France Clinical Laboratories (ASQUALAB). Therefore, the aim of this study was to assess the performance of the CHUJRA biochemistry laboratory through the dosage of four emergency biochemical parameters which were the most prescribed (serum creatinine, uremia, blood glucose and serum electrolytes) on the automaton Mindray BS 300®.

## 2. Materials and Methods

It was a retrospective evaluative study of CHUJRA biochemistry laboratory performance during a period of four months, from January 2019 to April 2019 through the 8 samples from EEQ BIOLABO®, with unknown values, at two levels: a normal level and a pathologic level, provided by the association ASQUALAB in France. These 8 samples were tested on biochemical automaton Mindray BS 300® by dosing the 4 most prescribed emergency biochemical parameters (serum creatinine, blood glucose, uremia and serum electrolytes). The EEQ BIOLABO® samples were multi-parameter lyophilized blood serum at two levels presented as special boxes intended for the EEQ of clinical biochemical parameters provided by the association ASQUALAB in France. The results of all EEQ samples were included in this study and consisted of the 4 routinely most prescribed parameters.

The EEQ BIOLAB® samples which were used had different number for each month:

- In January 2019 : BS 1901 and BS 1902
- In February 2019 : BS 1903 and BS 1904
- In March 2019 : BS 1905 and BS 1906
- In April 2019 : BS 1907 and 1908.

Before each step, EEQ BIOLABO samples were reconstituted by 5ml distilled water as it was recommended by the supplier. The dosage was done once only for each level and for each parameter. The results were collected on results sheets. Then they were sent on ASQUALAB website to be analysed. ASQUALAB sent the EEQ report one month after, once the results were analysed. The results were reported in a tabular summary form and a bar graph for each control level.

Concerning the data analysis method, the parameters for the evaluation of the precision and the accuracy were measured. The parameters for the evaluation of the method dispersion (precision) consisted of the average, the Variation Coefficient (VC) that is to say the dispersion measurement of calculated results, the Standard Error (SE) and the Variation Coefficient Ratio (VCR) [3]. The study of these parameters allowed us to identify random errors. VCR was the ratio between the laboratory VC and the peer group VC. Concerning its interpretation,  $VCR < 1$  means the laboratory precision is better than that of the peer group;  $VCR > 1$  means imprecision;  $VCR > 1.5$  needs the search of the imprecision causes;  $VCR > 2$  means maintenance and compulsory corrective action [3].

The parameters for the evaluation of the measurement accuracy were formed by calculating the bias and the Z-score or SEI (Standard Error Index) [4]. Z-score gave the deviation between the measured value and the target value. These latter allowed the search for possible factual errors. Regarding the interpretation, Z-score S means satisfactory accuracy; Z-score D means questionable accuracy requiring attention; Z-score I means unsatisfactory accuracy requiring action [4]. Each of the participants results were assessed compared to the general average of the results provided by the other participating laboratories or to the general average

from those who used the same device (peer group). If the results showed anomalies in relation to the defined acceptability criteria, the participants were alerted [5]. The results should be first of all interpreted with data comparison for all the techniques [4] then with the peer group the laboratories of which were ranked according to the used method, depending on the methods principles, on instruments and devices, on reagents and calibration [6]. These criteria were mentioned on the results report for the EEQ results interpretation. The study was realised after the validation of the plant manager and the Merieux Foundation.

### 3. Results

For the results of the EEQ, the accuracy of the analysis results was 94% with an inaccuracy of kaliemia in March 2019. This evaluation of the accuracy of each parameter assessed by the Z-score is represented in Tables 1, 2, 3, 4 for the months of January, February, March and April. The last column represents the evaluation of the biochemical analysis. For each analysis, the comment takes into account the results obtained for each of the two samples evaluated in relation to the general average and to the bias. The assessment was good if the calculated bias is within the range of the acceptability limits specific to each analysis. The systematic error (SE) is displayed if the results of the 2 samples are affected by an error of the same sign. This comment is accompanied by a "+" sign if the results are above the high acceptability limit or by a "-" sign if the results concerned are below the low acceptability limit. Concerning the precision, it was 97% with imprecise natremia level in February 2019 according to Table 5. Table 5 represents the summaries of the variation coefficient ratio (VCR) of the 6 parameters analyzed compared to the peer group. Random error (RE) has been observed if one of the 2 results deviates from the acceptability limits or both, but the biases are not of the same sign.

Parameters	BIO1901							BIO1902							
	Our results	Number of participants	overall average	CV %	Bias %	Z-score		Our results	Number of participants	overall average	CV %	Bias %	Z-score		Evaluation
Uremia mmol/l	15.8	83	14.7	7.2	7.5	1.04	S	18.9	84	18.0	5.8	5.0	0.86	S*	good
peer group		65	14.8	6.8	6.8	0.99	S		65	18.2	5.2	3.8	0.74		good
Creatinine μmol/l	364	118	349	9.4	4.3	0.46	S	245	118	243	9.2	0.8	0.09	S	good
peer group		63	338	9.5	7.7	0.81	S		63	236	9.3	3.8	0.41	S	good
Glucose mmol/l	14.8	109	13.9	3.7	6.5	1.75	S	12.9	108	11.8	3.6	9.3	2.59	D*	good
peer group		28	14.1	5.4	5.0	0.92	S		26	12	4.7	7.5	1.60	S	good
Natremia mmol/l	153	85	152	3.0	0.7	0.22	S	154	85	152	2.4	1.3	0.55	S	good
peer group		17	150	2.2	2.0	0.91	S		16	150	2.1	2.7	1.27		good
Kaliemia mmol/l	5.7	89	5.78	4.0	-1.4	-0.35	S	4.1	89	3.90	3.4	5.1	1.51	S	good
peer group		17	5.67	3.0	0.5	0.18	S		17	3.81	4.0	7.6	1.90	S	
Chloride mmol/l	102	74	107	4.9	-4.7	-0.95	S	104	76	108	4.3	-3.7	-0.86	S	good
peer group		11	109	6.2	-6.4	-1.04	S		10	112	8.7	-7.1	-0.82	S	

\*S: Satisfactory D: Debatable

**Table 1:** External Evaluation of the Quality (EEQ) results for samples BIO1901-BIO1902 in January 2019.

Parameters	BIO1903							BIO1904							
	Our results	Number of participants	overall average	CV %	Bias %	Z-score		Our results	Number of participants	overall average	CV %	Bias %	Z-score		Evaluation
Uremia mmol/l	22	93	21.1	6.3	4.3	0.68	S	12.1	93	11.5	6.5	5.2	0.80	S	good
peer group		73	21.2	5.9	3.8	0.64	S		73	11.5	5.4	5.2	0.97	good	
Creatinine μmol/l	212	128	204	7.3	3.9	0.54	S	32	122	44	24.6	-27.3	-1.11	S	-
peer group		75	202	6.6	5.0	0.75	S		70	40	24.3	-20.0	-0.82	S	
Glucose mmol/l	3.30	119	2.9	5.6	13.8	2.46	D	10.7	119	10.3	4.8	3.9	0.81	S	good
peer group		5	3.3	7.5	0.0	0.00	S		3	10.4	9.7	2.9	0.30	S	
Natremia mmol/l	141	91	139	2.8	1.4	0.51	S	131	90	133	3.4	-1.5	-0.44	S	good
peer group		21	138	3.1	2.2	0.70	S		21	130	2.0	0.8	0.38	good	
Kaliemia mmol/l	3.50	97	3.5	3.9	0.0	0.00	S	5.40	95	5.34	4.9	1.1	0.23	S	good
peer group		22	3.48	4.8	0.6	0.12	S		22	5.22	4.3	3.4	0.80	S	
Chloride mmol/l	97	79	102	4.7	-4.9	-1.04	S	84	79	89	4.8	-5.6	-1.17	S	good
peer group		140	100	4.7	-3.0	-0.64	S		14	89	4.3	-5.6	-1.31	S	

Table 2: External Evaluation of the Quality (EEQ) results for samples BIO1903-BIO1904 in February 2019.

Parameters	BIO1905							BIO1906							
	Our results	Number of participants	overall average	CV %	Bias %	Z-score		Our results	Number of participants	overall average	CV %	Bias %	Z-score		Evaluation
Uremia mmol/l	2.8	84	2.8	7.1	0.0	0.0	S	30.2	83	28.9	5.6	4.5	0.80	S	good
peer group		66	2.8	6.3	0.0	0.0	S		65	29	4.9	4.1	0.84	S	good
Creatinine μmol/l	124	122	108	8.4	14.8	1.76	S	494	121	501	8.4	-1.4	-0.17	S	good
peer group		62	108	8.7	14.8	1.70	S		62	488	8.1	1.2	0.15	S	good
Glucose mmol/l	7.7	113	6.9	5.2	11.6	2.23	D	7.0	112	6.2	4.8	12.9	2.69	D	good
peer group		26	7.1	5.0	8.5	1.69	S		26	6.4	5.3	9.4	1.77	S	
Natremia mmol/l	148	78	145	2.7	2.1	0.77	S	128	77	122	3.3	4.9	1.49	S	
peer group		160	145	3.3	2.1	0.63	S		16	121	3.5	5.8	1.65	S	
Kaliemia mmol/l	2.50	81	1.94	6.2	28.9	4.66	U*	2.70	83	2.47	4.7	9.3	1.98	S	SE
peer group		150	1.97	11.8	26.9	2.28	D		150	2.41	5.9	12.0	2.04	D	SE
Chloride mmol/l	105	71	107	5.5	-1.9	-0.34	S	81	68	84	7.1	-3.6	-0.50	S	good
peer group		110	106	5.1	-0.9	-0.18	S		110	85	5.7	-4.7	-0.83	S	Good

\*U: Unsatisfactory

**Table 3:** External Evaluation of the Quality (EEQ) results for samples BIO1905-BIO1906 in March 2019.

Parameters	BIO1907							BIO1908							
	Our results	Number of participants	overall average	CV %	Bias %	Z-score		Our results	Number of participants	overall average	CV %	Bias %	Z-score	Evaluation	
Uremia mmol/l	6.1	113	7.0	6.8	-12.9	-1.89	S	6.9	113	7.3	8.1	-5.5	-0.68	S	-
peer group		4	6.7	16.1	-9	-0.56	S		4	7.8	13.9	-11.5	-0.83	S	
Creatinine μmol/l	115	167	103	11.7	11.7	1.00	S	196	166	185	6.9	5.9	0.86	S	good
peer group		5	98	12.7	17.3	1.37	S		5	180	8.0	8.9	0.11	S	
Glucose mmol/l	5.5	140	5.2	5.1	5.8	1.13	S	20.3	139	19.9	4.5	2.0	0.45	S	good
peer group		37	5.2	7.7	5.8	0.75	S		37	19.8	8.0	2.5	0.32	S	
Natremia mmol/l	122	110	127	3.6	-3.9	-1.09	S	158	110	161	3.6	-1.9	-0.52	S	good
peer group		24	125	2.7	-2.4	-0.89	S		24	160	3.6	-1.3	-0.35	S	
Kaliemia mmol/l	3.80	125	3.81	5.0	-0.3	-0.05	S	4.40	125	4.39	4.1	0.2	0.06	S	good
peer group		24	3.78	3.7	0.5	0.14	S		24	4.37	3.9	0.7	0.18	S	
Chloride mmol/l	80	90	88	4.3	-9.1	-2.11	D	110	89	120	3.7	-8.3	-2.25	D	-
peer group		15	87	5.9	-8.0	-1.36	S		14	117	5.6	-6.0	-1.07	S	

**Table 4:** External Evaluation of the Quality (EEQ) results for samples BIO1907-BIO1908 in April 2019.

Parameters	January		February		March		April	
	BIO 1901	BIO 1902	BIO 1903	BIO 1904	BIO 1905	BIO 1906	BIO 1907	BIO 1908
Glucose mmol/l peer group	0.68	0.76	0.75	0.49	1.04	0.90	0.66	0.56
Creatinine $\mu$ mol/l peer group	0.98	0.98	1.1	1.01	0.96	1.03	0.92	0.86
Uremia mmol/l peer group	1.05	1.11	1.06	1.20	1.12	1.14	0.37	0.58
Natremia mmol/l peer group	1.36	1.14	0.9	1.70	0.81	0.94	1.33	1
Kaliemia mmol/l peer group	1.33	0.85	0.81	1.13	0.52	0.79	1.35	1.05
Chloride mmol/l peer group	0.79	0.49	1	1.11	1.07	1.24	0.72	0.66

**Table 5:** Summary of Variation Coefficient Ratio (VCR) for the 6 parameters analyzed in relation to peer groups.



#### 4. Discussion

The realisation rhythm of EEQ program was a periodical one. It is admitted that from twice to 4 times yearly participation corresponded to a reasonable rhythm [7, 8]. The CHUJRA chemistry laboratory was able to realise once a month the passage of EEQ solutions according to the recommendations of the ASQUALAB assessment program and others too [6, 9]. In this present study, 4 parameters were chosen; they were mostly prescribed in emergency. Nevertheless in our daily practice, 29 routine biochemical parameters were monthly assessed thanks to ASQUALAB such as transaminases and serum calcium levels. Several EEQ organisations used the Z-scores in the participants return reports. But the analysis of VCR was also important [10]. Concerning this present study results, the accuracy was appreciated by Z-score. It was 94% in this study. An inaccuracy was reported for kaliemia in March 2019. It was a systematic error or a bias one. It could be related to the deterioration of automaton lamp, the progressive accumulation of remnants into the tubing or on the electrodes, the reagents aging, the progressive deterioration of the control components, or the optical fibre integrity. Similarly, the lamp failure, its sudden variation or the change of reagents package could be the responsible of this error [11].

After the accuracy, the precision was estimated by the VCR. This precision was 97% in the present study. However an imprecision was reported for natremia in February 2019. According to the literature, imprecision could be linked to an incorrect operation of the analytical process concerning the reagents, the equipment, the staff, the calibration procedures and the internal control [12]. VCR analysis was not very informative and not very sensitive. It was a second line security indicator [6]. The EEQ results encouraged to establish approaches for curative and / or preventive actions [5, 9]. But late reception (1 month after the input

of results) of EEQ report results did not allow to develop a preventive action or an immediate correction but rather a healing action. Therefore it was recommended to keep a volume increment of each EEQ for moving again samples at the report return in order to make verification [10].

The present study allowed us to check up the reliability of the biochemical analysis results in CHUJRA. We found that the analysis performance was good in the majority of the cases. Therefore biologists and technicians in this laboratory were assured that the validated analysis results corresponded to the patients state of health and these latter will be properly supported by clinicians. Similarly, diseases were well diagnosed and their monitoring was improved. The present study highlighted the importance of EEQ which should be performed by all medical analysis laboratories. It was true that ASQUALAB EEQ cost rather expensive (300 € per year). Nevertheless, when lacking adequate amount of financial resources, medical analysis laboratories could perform inter-laboratories comparisons of their biological tests and could correct one another. The main thing was to be able to check if the daily performed biological tests were in standards. In short, as healthcare worker, our aim was always to look for ways to improve patient care. So, the patient life expectancy would be extended.

#### 5. Conclusion

EEQ was an assessment procedure of a laboratory performance. It allowed the laboratory to know if the results of biological tests were reliable and also allowed to perform corrective actions in order to improve the reliability of these results. CHUJRA biochemical laboratory was efficient during the External Evaluation of Quality. So, these results of biochemical tests were reliable and contribute to the diagnosis improvement, to the monitoring and to the aftercare of the patients. Every

laboratory of medical analysis ought to organise a periodical External Evaluation of Quality results in order to monitor and to improve the results of the biological tests.

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### Conflict of Interest

None

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