

External evaluation of the quality of the seven biochemical parameters in Antananarivo in 2020

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Abstract

The aim of the present study is to assess the performance of the biochemistry laboratory of Joseph Ravoahangy Andrianavalona by the dosage of the most prescribed 7 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 6 months from January 2020 to June 2020 involving 12 samples of External Evaluation of the Quality provided by the Quality Insurance Association of the clinical Biology Laboratories in France. Uremia, Serum creatinine, blood glucose, natremia, kaliemia, chlorure and were dosed on the 12 samples which carried out 84 dosages. During a period of 6 months the accuracy was 97.61%. The precision had been 100% if the Variation Coefficient Ratio (VCR) was below 1.50. This participation in the External Evaluation of the Quality program can then improve the quality of the laboratory. It is a step towards the accreditation process.

Key words: accreditation; antananarivo; biochemistry; quality control; performance

Introduction

According to the requirements of the ISO 15189 standard, each laboratory must continuously validate the assay methods by carrying out an external quality assessment (EEQ) [1-3]. According to the requirement of Clinical Laboratory Improvement Amendments (CLIA), the measurement methods of a medical biology examination must provide a certain minimum level of quality as well as a certain level of analytical performance for each analytical system [4]. Thus, biologists must carry out this evaluation [3], in order to guarantee the reliability of the results and gain the trust of prescribers.

The realisation of an EEQ was a part of one of the six preliminary works to establish the aims of analytic performance [5, 6]. 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 seven biochemical parameters which were the most prescribed (uremia,

serum creatinine, blood glucose, natremia, kaliemia, chloremia and albuminemia) on the automaton Mindray BS 300®.

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Materials and methods

It was a retrospective evaluative study of CHUJRA biochemistry laboratory performance during a period of six months, from January 2020 to June 2020 through the 12 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 12 samples were tested on biochemical automaton Mindray BS 300@ by dosing the 7 most prescribed biochemical parameters. 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 7 routinely most prescribed parameters.

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

- In January 2020 : BS 2001 and BS 2002
- In February 2020 : BS 2003 and BS 2004
- In March 2020 : BS 2005 and BS 2006
- In April 2020 : BS 2007 and BS 2008
- In May 2020 : BS 2009 and BS 2010
- In June 2020 : BS 2011 and BS 2012

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 [1].

The parameters for the evaluation of the measurement accuracy were formed by calculating the bias and the Z-score or SEI (Standard Error Index) [2]. Z-score gave the deviation between the measured value and the target value. These latter allowed the search for possible systematic 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 [2].

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 [7]. The results should be first of all interpreted with data comparison for all the techniques [2] 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 [8]. 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 Mérieux Foundation.

Results:

For the results of the EEQ, the accuracy of the analysis results was 97.61% with an inaccuracy of chloremia in February 2020, it was a systematic error. This evaluation of the accuracy of each parameter assessed by the Z-score is represented in tables 1, 2, 3, 4, 5, 6 for the months of January, February, March, April, May and June. 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.

Parameters	BIO2001							BIO2002							Evaluation
	Our results	Number of participants	overall average	CV %	Bias %	Z-score		Our results	Number of participants	overall average	CV %	Bias %	Z-score		
Uremia mmol/l	2.8	69	2.8	8.5	0.0	0.0	S	22.2	70	21.1	7.4	5.2	0.70	S	good
peer group		53	2.8	7.2	0.0	0.0	S		53	21.1	6.3	5.2	0.83	S	good
Creatinine $\mu\text{mol/l}$	111	96	111	7.6	0.00	0.00	S	220	96	206	7.1	6.8	0.96	S	good
peer group		44	112	8.1	-0.9	-0.11	S		44	200	8.2	10.0	1.22	S	good
Glucose mmol/l	7.0	89	6.7	3.7	4.5	1.21	S	3.0	89	2.9	5.2	3.4	0.66	S	good
peer group		24	6.9	4.3	1.4	0.34	S		23	3.0	7.5	0.0	0.00	S	good
Natremia mmol/l	142	67	145	3.3	-2.1	-0.63	S	135	68	138	2.8	-2.2	-0.78	S	good
peer group		14	145	4.4	-2.1	-0.47	S		15	138	3.4	-2.2	-0.64	S	good
Kaliemia mmol/l	1.80	69	1.94	6.2	-7.2	-1.16	S	3.30	71	3.47	4.3	-4.9	-1.14	S	good
peer group		14	2.00	10.1	-10	-0.99	S		15	3.44	5.2	-4.1	-0.78	S	good
Chloride mmol/l	102	58	107	5.2	-4.7	-0.90	S	94	59	101	4.4	-6.9	-1.58	S	good
peer group		10	108	5.2	-5.6	-1.07	S		11	103	4.3	-8.7	-2.03	D*	-
Albuminemia g/l	46.0	63	48.4	4.8	-5.0	-1.03	S	36.0	63	35.8	4.9	0.6	0.11	S	good
peer group		6	43.3	14.4	6.2	0.43	S		6	34.6	18.9	-	-	S	-

Table 1: External Evaluation of the Quality (EEQ) results for samples BIO2001-BIO2002 in January 2020

Parameters	BIO2001							BIO2002							Evaluation
	Our results	Number of participants	overall average	CV %	Bias %	Z-score		Our results	Number of participants	overall average	CV %	Bias %	Z-score		
Uremia mmol/l	12.1	80	11.6	5.5	4.3	0.76	S	26.9	80	28.6	8.0	-5.9	-0.74	S	good
peer group		56	11.5	4.8	5.2	1.09	S		56	28.5	6.8	-5.6	-0.83	S	good
Creatinine µmol/l	29	113	46	20.4	-37.0	-1.81	S	433	113	491	11.1	-11.8	-1.06	S	good
peer group		50	41	22.3	-29.3	-1.31	S		50	476	10.8	-9.0	-0.84	S	good
Glucose mmol/l	10.1	99	10.1	4.6	0.0	0.00	S	6.4	99	6.1	4.4	4.9	1.12	S	good
peer group		26	10.0	5.0	1.0	0.20	S		27	6.2	5.5	3.2	0.59	S	good
Natremia mmol/l	132	79	132	3.7	0.0	0.00	S	119	79	122	3.3	-2.5	-0.75	S	good
peer group		14	131	4.0	0.8	0.19	S		15	121	3.5	-1.7	-0.47	S	good
Kaliemia mmol/l	5.60	82	5.37	4.6	4.3	0.93	S	2.50	82	2.48	6.3	0.8	0.13	S	good
peer group		14	5.37	4.4	4.3	0.97	S		15	2.54	8.2	-1.6	-0.19	S	good
Chloride mmol/l	78	64	88	5.1	-11.4	-2.23	D	72	65	84	6.2	-14.3	-2.30	D*	ES* ES
peer group		10	93	8.8	-16.1	-1.83	S		11	87	8.5	-	-2.03	D	
Albuminemia g/l	21.0	65	19.2	9.4	9.4	1.00	S	26.0	65	23.2	8.3	12.1	1.45	S	good
peer group		34	19.8	8.5	6.1	0.71	S		34	23.9	8.0	8.8	1.10	S	good

Table 2: External Evaluation of the Quality (EEQ) results for samples BIO2003-BIO2004 in February 2020

Parameters	BIO2005							BIO2006							Evaluation
	Our results	Number of participants	overall average	CV %	Bias %	Z-score		Our results	Number of participants	overall average	CV %	Bias %	Z-score		
Uremia mmol/l	7.3	88	7.0	7.8	4.3	0.55	S	19.4	88	18.1	5.8	7.2	1.24	S*	good
peer group		59	6.9	5.5	5.8	1.05	S		59	17.9	5.2	8.4	1.61	S	good
Creatinine µmol/l	114	131	104	8.9	9.6	1.08	S	225	131	240	10.1	-6.3	-0.62	S	good
peer group		58	100	9.3	14.0	1.51	S		59	235	10.4	-4.3	-0.41	S	good
Glucose mmol/l	5.4	110	5.1	3.9	5.9	1.51	S	12.1	110	11.6	3.9	4.3	1.11	S	good
peer group		31	5.2	4.7	3.8	0.82	S		32	11.6	6.3	4.3	0.68	S	good
Natremia mmol/l	125	89	126	3.0	-0.8	-0.26	S	151	89	151	3.2	0.0	0.00	S	good
peer group		17	124	2.5	0.8	0.32	S		17	151	3.3	0.0	0.00	S	good
Kaliemia mmol/l	3.90	91	3.79	4.3	2.9	0.67	S	3.80	91	3.85	3.7	-1.3	-0.35	S	good
peer group		17	3.71	4.2	5.1	1.22	S		17	3.82	3.1	-0.5	-0.17	S	good
Chloride mmol/l	78	72	88	5.5	-11.4	-2.07	D	100	73	108	4.2	-7.4	-1.76	S	-
peer group		11	89	8.3	-12.4	-1.49	S		11	108	5.1	-7.4	-1.45	S	good
Albuminemia g/l	20.0	73	18.7	8.7	7.0	0.80	S	33.0	73	31.2	5.9	5.8	0.98	S	good
peer group		36	18.8	9.5	6.4	0.67	S		36	31.4	5.6	5.1	0.91	S	good

Table 3: External Evaluation of the Quality (EEQ) results for samples BIO2005-BIO2006 in March 2020

Parameters	BIO2007							BIO2008							Evaluation
	Our results	Number of participants	overall average	CV %	Bias %	Z-score		Our results	Number of participants	overall average	CV %	Bias %	Z-score		
Uremia mmol/l	7.8	87	7.3	7.6	6.8	0.90	S	22.8	86	21.1	6.3	8.1	1.28	S*	good
peer group		57	7.2	6.4	8.3	1.30	S		56	21.1	5.3	8.1	1.52	S	good
Creatinine µmol/l	186	128	187	8.0	-0.5	-0.07	S	198	127	207	8.5	-4.3	-0.51	S	good
peer group		60	185	7.6	0.5	0.07	S		59	204	7.7	-2.9	-0.38	S	good
Glucose mmol/l	20.2	97	19.7	4.7	2.5	0.54	S	3.0	97	2.9	6.6	3.4	0.52	S	good
peer group		33	19.6	9.1	3.1	0.34	S		33	3.0	8.4	0.0	0.00	S	good
Natremia mmol/l	157	80	160	2.6	-1.9	-0.72	S	138	79	138	2.5	0.0	0.00	S	good
peer group		14	158	2.0	-0.6	-0.32	S		14	137	2.9	0.7	0.25	S	good
Kaliemia mmol/l	4.50	87	4.34	3.4	3.7	1.08	S	3.70	87	3.46	4.1	6.9	1.69	S	good
peer group		14	4.34	3.5	3.7	1.05	S		14	3.45	3.0	7.2	2.42	D*	good
Chloride mmol/l	112	69	119	3.7	-5.9	-1.59	S	95	69	102	4.4	-6.9	-1.56	S	good
peer group		10	119	5.2	-5.9	-1.13	S		10	105	9.1	-9.5	-1.05	S	good
Albuminemia g/l	33.0	74	33.2	7.7	-0.6	-0.08	S	36.0	74	36.3	7.2	-0.8	-0.11	S	good
peer group		36	33.6	7.9	-1.8	-0.23	S		36	36.7	7.6	-1.9	-0.25	S	good

Table 4: External Evaluation of the Quality (EEQ) results for samples BIO2007-BIO2008 in April 2020

Parameters	BIO2009							BIO2010							Evaluation
	Our results	Number of participants	overall average	CV %	Bias %	Z-score		Our results	Number of participants	overall average	CV %	Bias %	Z-score		
Uremia mmol/l	2.8	90	2.9	11.9	-3.4	-0.29	S	15.1	90	14.8	6.9	2.0	0.29	S*	good
peer group		61	2.8	8.8	0.0	0.00	S		60	14.7	4.7	2.7	0.58	S	good
Creatinine µmol/l	124	125	113	10.4	9.7	0.94	S	349	124	346	10.8	0.9	0.08	S	good
peer group		60	113	9.3	9.7	1.05	S		59	337	10.4	3.6	0.34	S	good
Glucose mmol/l	6.7	99	6.6	4.7	1.5	0.32	S	13.9	98	13.4	4.6	3.7	0.81	S	good
peer group		33	6.7	5.5	0.0	0.00	S		32	13.5	5.3	3.0	0.56	S	good
Natremia mmol/l	142	82	144	2.9	-1.4	-0.48	S	151	81	151	3.4	0.0	0.00	S	good
peer group		16	144	2.0	-1.4	-0.69	S		16	151	3.7	0.0	0.00	S	good
Kaliemia mmol/l	2.10	91	1.95	7.1	7.7	1.08	S	5.90	90	5.68	4.3	3.9	0.90	S	good
peer group		16	1.96	11.6	7.1	0.62	S		16	5.63	2.3	4.8	2.09	D	good
Chloride mmol/l	98	71	107	5.0	-8.4	-1.68	S	103	70	108	4.8	-4.6	-0.96	S	good
peer group		12	108	6.0	-9.3	-1.54	S		12	109	3.7	-5.5	-1.43	S	good
Albuminemia g/l	47.0	73	48.0	6.6	-2.1	-0.32	S	27.0	72	26.8	7.9	0.7	0.09	S	good
peer group		37	48.3	6.0	-2.7	-0.45	S		37	27.7	8.7	-2.5	-0.29	S	good

Table 5: External Evaluation of the Quality (EEQ) results for samples BIO2009-BIO2010 in May 2020

*S: Satisfactory D: Debatable

Parameters	BIO2011							BIO2012							Evaluation
	Our results	Number of participants	overall average	CV %	Bias %	Z-score		Our results	Number of participants	overall average	CV %	Bias %	Z-score		
Uremia mmol/l	8.1	90	7.3	8.0	11.0	1.37	S	30.0	90	28.1	8.8	6.8	0.77	S	good
peer group		61	7.3	6.6	11.0	1.66	S		61	28.2	8.4	6.4	0.76	S	good
Creatinine μmol/l	176	136	186	7.5	-5.4	-0.72	S	419	135	490	9.9	-14.5	-1.46	S	good
peer group		61	187	8.3	-5.9	-0.71	S		61	478	9.5	-12.3	-1.30	S	good
Glucose mmol/l	20.3	111	19.8	3.5	2.5	0.72	S	6.4	111	6.1	3.8	4.9	1.29	S	good
peer group		35	19.5	4.5	4.1	0.91	S		35	6.2	3.5	3.2	0.92	S	good
Natremia mmol/l	155	86	161	3.6	-3.7	-1.04	S	119	86	121	3.3	-1.7	-0.50	S	good
peer group		15	160	3.8	-3.1	-0.82	S		15	119	3.4	0.0	0.00	S	good
Kaliemia mmol/l	4.30	93	4.35	4.3	-1.1	-0.27	S	2.60	93	2.47	5.2	5.3	1.01	S	good
peer group		15	4.31	3.6	-0.2	-0.06	S		15	2.43	6.2	7.0	1.13	S	good
Chloride mmol/l	111	73	120	4.6	-7.5	-1.63	S	76	72	86	7.0	-11.6	-1.66	S	good
peer group		11	120	5.0	-7.5	-1.50	S		11	87	7.6	-12.6	-1.66	S	good
Albuminemia g/l	33.0	74	33.2	5.5	-0.6	-0.11	S	24.0	74	23.4	7.9	2.6	0.32	S	good
peer group		37	33.3	6.4	-0.9	-0.14	S		37	23.6	9.5	1.7	0.18	S	good

Table 6: External Evaluation of the Quality (EEQ) results for samples BIO2011-BIO2012 in June 2020

*S: Satisfactory

Parameters	January		February		March		April		May		June	
	BIO 2001	BIO 2002	BIO 2003	BIO 2004	BIO 2005	BIO 2006	BIO 2007	BIO 2008	BIO 2009	BIO 2010	BIO 2011	BIO 2012
Uremia μmol/l	1,18	1,17	1,14	1,17	1,42	1,11	1,19	1,19	1,35	1,47	1,21	1,05
Creatinine mmol/l	0,93	0,86	0,91	1,03	0,96	0,97	1,05	1,10	1,12	1,04	0,90	1,04
Glucose mmol/l	0,86	0,69	0,92	0,80	0,83	0,62	0,52	0,78	0,85	0,87	0,78	1,08
Natremia mmol/l	0,75	0,82	0,92	0,94	1,20	0,97	1,30	0,86	1,45	0,92	0,95	0,97
Kaliemia μmol/l	0,61	0,83	1,04	0,76	1,02	1,19	0,97	1,36	0,61	0,87	1,19	0,84
Chloremia mmol/l	1	1,02	0,58	0,73	0,66	0,82	0,71	0,48	0,83	1,30	0,92	0,92
Albuminemia g/l	0,33	0,25	1,10	1,04	0,91	1,05	0,97	0,95	1,10	0,91	0,86	0,83

Table 7: Summary of Variation Coefficient Ratio (VCR) for the 7 parameters analyzed in relation to peer groups

Concerning the precision, it was 100 % if the Variation Coefficient Ratio (VCR) was below 1.50 and 63.09 % if the Variation Coefficient Ratio was below 1 according to table 7.

Table 7 represents the summaries of the variation coefficient ratio (VCR) of the 7 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.

No random error was observed in this study.

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 [9, 10].

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 [8, 11]. In this present study, 7 parameters were chosen; they were most commonly prescribed analysis. Nevertheless, in our daily practice, 29 routine biochemical parameters were monthly assessed thanks to ASQUALAB such as transaminases, bilirubinemia, serum calcium levels... Several EEQ organisations used the Z-scores in the participants return reports. But the analysis of VCR was also important [3].

Concerning this present study results, the accuracy was appreciated by Z-score. It was 97.61% in this study. An inaccuracy was reported for chloremia in February 2020, while in March 2019, the inaccuracy affected the kaliemia [12]. It was a systematic error or a bias one [13]. 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 [13].

After the accuracy, the precision was estimated by the VCR. This precision was 100% in the present study, compared to 97% in 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 [14]. VCR analysis was not very informative and not very sensitive. It was a second line security indicator [8].

The EEQ results encouraged to establish approaches for curative and / or preventive actions [7, 11].

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.

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.

During the first 6 months of 2020, accuracy was 97.61%. The precision had been 100% if the Variation Coefficient Ratio (VCR) was below 1.50.

This participation in the External Evaluation of the Quality program can then improve the quality of the laboratory. It is a step towards the accreditation process.

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Conflict of Interest

None

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