



INTERNAL QUALITY CONTROL IN CLINICAL CHEMISTRY DEPARTMENT IN NATIONAL LABORATORY FOR PUBLIC HEALTH IN KHARTOUM STATE 2017

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ABSTRACT

Quality control is a measurement of precision, or how well the measurement system reproduces the same result over time and under varying operating conditions. This cross-sectional study aimed to assess internal quality control in the clinical chemistry department in the national laboratory for public health. The study was conducted in 2017 based on analysis of commercially available normal and pathological control sera. Validation was made for 5 analyses: urea, Calcium, Magnesium, Total protein and Alanine aminotransferase. Analysis repeated 20 times by using auto analyzer Selectra E. The results of normal control sera for urea, Calcium, Magnesium, Total protein and Alanine aminotransferase results were within the range with mean $\pm$ SD: (28.75 $\pm$ 2.36, 8.98 $\pm$ 0.44, 4.87 $\pm$ 0.33, 41.20 $\pm$ 2.57, 1.53 $\pm$ 0.16) respectively. Also pathological control sera for urea, Calcium, Magnesium, Total protein and Alanine aminotransferase results were within the range with mean $\pm$ SD: (136.95 $\pm$ 10.86, 14.10 $\pm$ 0.76, 8.10 $\pm$ 0.59, 145.20 $\pm$ 7.65, 3.26 $\pm$ 0.31) respectively.

The clinical chemistry department results meet the criteria of quality control by means of accuracy and precision.

KEY WORDS: quality assurance, accuracy, precision, control sera, Levy—Jennings chart.

INTRODUCTION

The first essential in setting up internal quality control (IQC) of a test procedure in the clinical laboratory is to select the proper IQC procedure to implement, i.e. choosing the statistical criteria or control rules, and the number of control measurements, according to the quality required for the test and the observed performance of the method^[1].

The purpose of internal quality control (IQC) is mainly to verify the stability of laboratory estimates at the time of testing, and it is essentially a control on imprecision. IQC programs have various procedures, but all are based on the use of selected control sera samples which are analyzed in each analytical series. Differences in the various programs depend upon the number of control samples required and on the data presentation. In clinical chemistry, control samples have generally two concentration levels (normal and pathological)^[2]. The analytical quality within clinical chemistry should be recognized in order to select proper analytical methods including internal quality control systems, which in principle could guarantee the analytical quality. This can be achieved by following rules of good laboratory practice (GLP). Good laboratory practice includes among other things laboratory management, organization and

education of the staff, written instructions for all laboratory procedures, regular check of instruments, reagents and utensils, careful laboratory work, proper reports to the clinician and discussions with the clinician whether the laboratory service is sufficient^[3].

Internal quality control at the chemical analytical laboratory involves a continuous, critical evaluation of the laboratory's own analytical methods and working routines. The control encompasses the analytical process starting with the sample entering the laboratory and ending with the analytical report. The most important tool in this quality control is the use of control charts. The basis is that the laboratory runs control samples together with the test samples. The control values are plotted in a control chart. In this way it is possible to demonstrate that the measurement procedure performs within given limits. If the control value is outside the limits, no analytical results are reported and remedial actions have to be taken to identify the sources of error, and to remove such errors^[4]. Levy—Jennings chart is the most important control chart in laboratory quality control. It can be used in internal quality control. It detects all kinds of analytical errors (random and systematic) and is used for the estimation of their magnitude. Error detection can be done very easily by

using quality criteria. The most widely used are the so called Westgard rules.

MATERIALS AND METHODS

Study design: This was a cross sectional study.

Study area: The study was conducted in clinical chemistry department in the National laboratory of public health, Khartoum state, Sudan.

Study period: From January 2017 – May 2017.

Ethical consideration: The study protocol was approved by research committee of Alneelain University, college of medical laboratory science, clinical chemistry department and the general manager and monitor of the national laboratory of public health, with consent obtained from the head department of clinical chemistry.

Control Materials: The commercially Normal Lot (080) and Pathological Lot (072) lyophilized control sera From Biosystem manufacture were used.

Methods: Five parameters urea (two point), Calcium (end point), Magnesium (end point) ,Total protein (end point), Alanine aminotransferase (kinetics) from control materials were analyzed by auto analyzer Selectra E for 20 days .data obtained were recorded then analyzed.

Data analysis: SPSS computer program version 21 was used for mean, standard deviation (SD) and coefficient of variation (CV%) calculation, then each selected parameter results plotted on Levy—Jennings chart following the westgard rules of acceptance and rejection to exclude errors from reagent preparation.

RESULTS

Normal and Pathological control sera results of urea, Calcium, Magnesium, Total protein and Alanine aminotransferase mean $\pm$ SD were within the range. (Table 1)and (Table 2) respectively.

After plotting all control results on Levy—Jennings chart Figures 2, 5, 6, 7 Shows one result exceed 2SD 1 2 S (Warning -One result more than 2SD from target) , Figure 4 Shows two results exceed 2SD(Warning)and Figures 1, 3, 8, 9, 10 Shows no bias.(no error).

Table 1: Normal control sera results.

	Urea	Ca	Mg	T.P	ALT
Ranges	22-37	7.8-10.5	1.2-1.8	4-5.8	33-47
Mean $\pm$ SD	28.75 $\pm$ 2.36	8.98 $\pm$ 0.44	1.53 $\pm$ 0.16	4.87 $\pm$ 0.33	41.20 $\pm$ 2.57
C.V (%)	8.21%	4.90%	10.40%	6.70%	6.23%
Units	mg/dl	mg/dl	mg/dl	g/dl	IU/L

Table 2: Pathological control sera results.

	Urea	Ca	Mg	T.P	ALT
Ranges	107-172	13-15.6	2.4-4.2	7.2-8.8	119-170
Mean $\pm$ SD	136.95 $\pm$ 10.86	14.10 $\pm$ 0.76	3.26 $\pm$ 0.31	8.10 $\pm$ 0.59	145.20 $\pm$ 7.65
C.V (%)	7.93%	5.40%	9.53%	7.31%	5.27%
Units	mg/dl	mg/dl	mg/dl	g/dl	IU/L

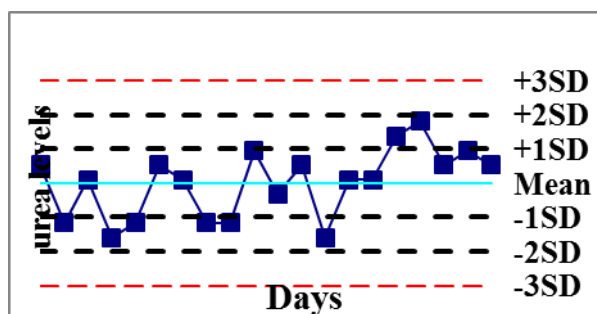


Figure 1: Normal control sera of Urea (mg/dl).

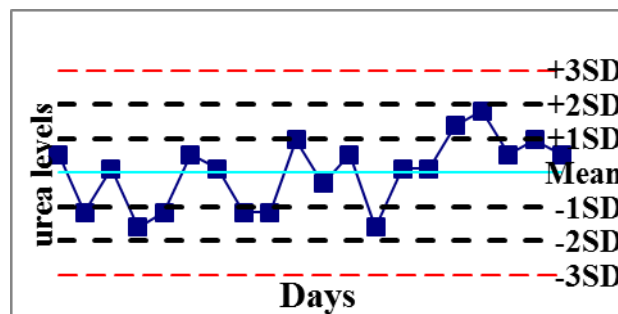


Figure 6: Pathological control sera of Urea (mg/dl).

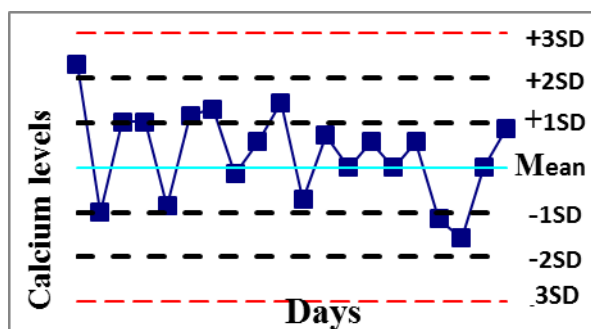


Figure 2: Normal control sera of Calcium (mg/dl)

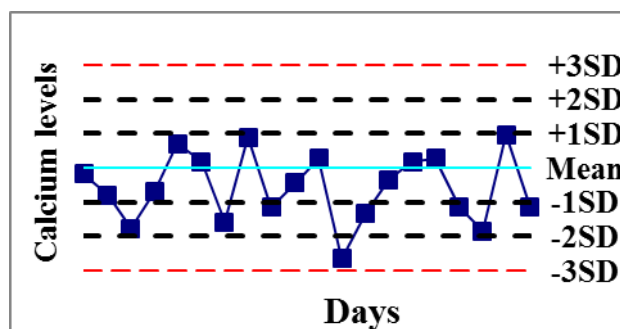


Figure 7: Pathological control sera of Calcium (mg/dl)

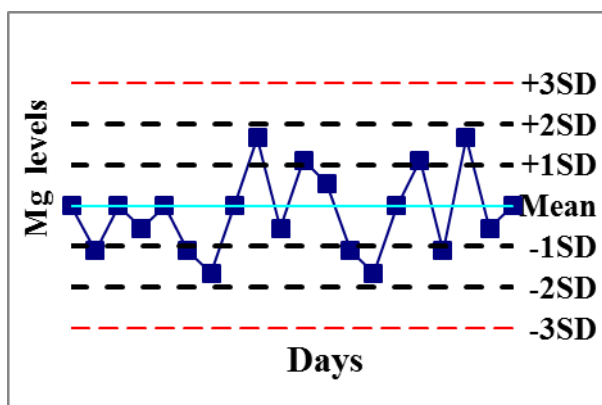


Figure 3: Normal control sera of Magnesium (mg/d).

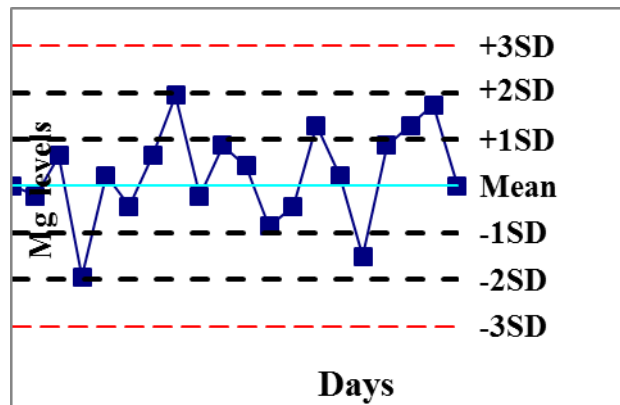


Figure 8: Pathological control sera of Magnesium (mg/dl).

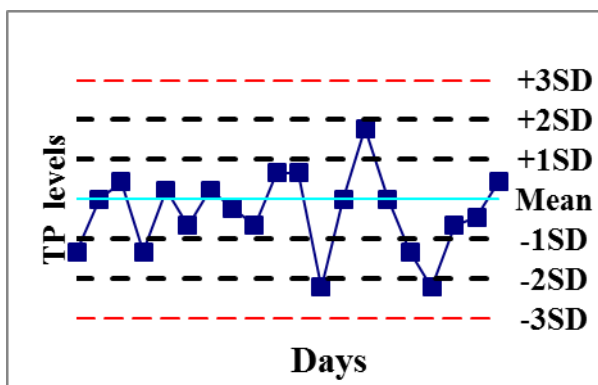


Figure 4: Normal control sera Total protein (g/dl)

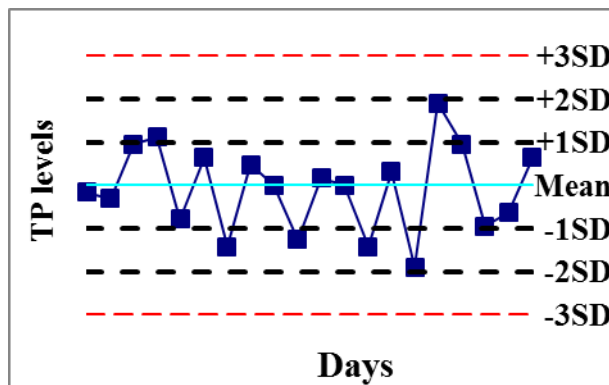


Figure 9: Pathological control sera of Total protein (g/dl)

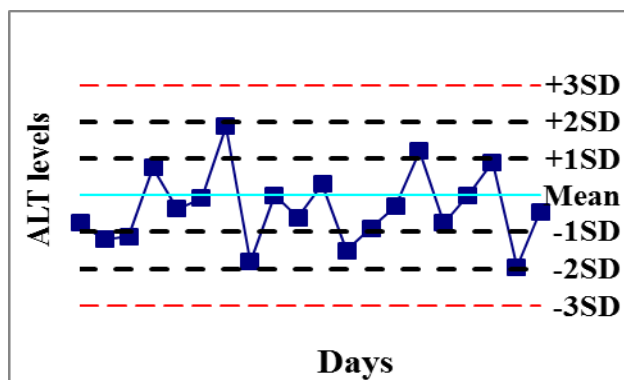


Fig 5: Normal control sera ALT (IU/L).

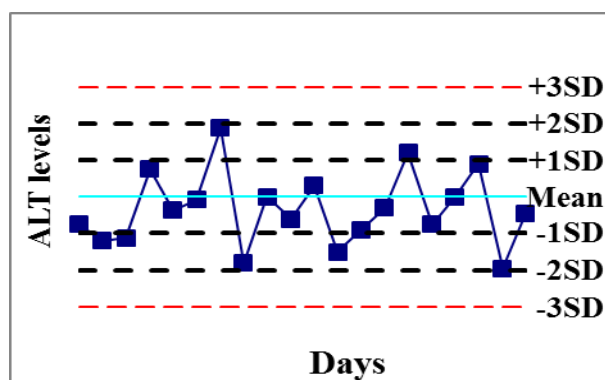


Fig 10: Pathological control sera of ALT (IU/L).

DISCUSSION

Internal quality control is one of the important elements for decision of accepting or rejecting an analytical series^[5]. In the present study results of normal and pathological Control sera from biosystem manufacture were within the range of control sera. This finding disagreed with study done by Siddig et al on The Accuracy and Performance of Different Clinical Laboratory Classes in the Sudan in eight States^[6] which reported significant decrease of (Class C) mean glucose level as end point mode, while insignificant difference was observed in(Class B) in comparison with highly quality and well equipped reference (Class A). Fixed timed mode which presented by mean creatinine level showed significant decreases of both classes B and C. The results of this study agreed with results of Rukhsana et al^[7] who noted that the internal quality control of the clinical chemistry section of AKUH laboratory based on the analysis of commercially available Beckman normal and abnormal range control sera. In the present study results after repeated estimations, mean values of all constituents were established for both normal and abnormal sera. The contradicted of the finding with other study could be due to validity of reagents, good training of staff, good quality system and regular maintenance of instruments.

CONCLUSION

Management of quality control can ensure accuracy and precision of both quality and patient results. Management of matrix effects and calibration misalignment are important aspects to observe shifting of L-J charts and adjustments of accuracy over time.

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