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Preparation of Low Cost Clinical Chemistry Internal Quality Control Material for Clinical Laboratories in Kiambu County, Kenya

Mary Wangui Mwangi[1], Dr. Stanley Kinge Waithaka[2], Dr. Ronald Maathai[3]

[1,2,3]Mount Kenya University, PO BOX 342-O1000, Thika, Kenya

Corresponding Author:** ***Mary Wangui Mwangi, *Mount Kenya University, PO BOX 342-O1000, Thika, Kenya*

Abstract

Internal quality control analysis is a key step in clinical chemistry laboratory. This ensures the results generated are accurate and precise. Many laboratories are faced with a heavy burden in purchasing the quality control material from the manufacturing industries. There was need to develop a low cost and easily available, locally prepared internal quality control material. Internal quality control material was prepared using plasma harvested from 497 donated blood. The prepared internal quality control material had the following characteristics for mean and quality control range: ALT mean 21.9 iu/l, range (2.7-41) iu/l, AST mean 21.3 iu/l, range (4.8-37.8) iu/l, γ GT mean 57 iu/l, range (1.1-113) iu/l, ALP mean 116 iu/l, range (5- 227) iu/l , TP mean 68 g/L, range (52-83) g/L, ALB mean 43 g/L, range (33.6-52.4) g/L, TBILI mean 14.5 µmol/L, range (3.5-25.4) µmol/L, DBILI mean 6.5 µmol/L, range (1.7- 11.3) µmol/L, BUN mean 4.2 mmol/L, range (1.4- 7.0) mmol/L, CREAT mean 78.2 µmol/L, range (20.4 - 136) µmol/L, POT mean 3.8 (mmol/L), range (2.8- 4.9) mmol/L, SOD mean 147 (mmol/L), range (135- 158) mmol/L, CHLO mean = 102 mmol/L, range (94-110) mmol/L, CAL mean 2.1 mmol/l ,range (1.6-2.6) mmol/L, PHOS mean 1.2 mmol/l, range (0.4-2) mmol/L and UA mean 293 µmol/L, range (103- 482) µmol/L. In conclusion, the current study has developed a low cost internal quality control material for conveniently use in clinical chemistry laboratories to ensure the results generated are accurate and precise. The internal quality control material affordability and availability has been assured.

1. INTRODUCTION

The quantitative analytical work performed in clinical laboratories play a very important role in the delivery of health care services. In order to diagnose and manage the various pathological disorders, the results generated must be accurate and precise at all times. Every clinical laboratory strives to achieve this honorable responsibility by embracing the internal quality control programme. Many laboratories are known to have a very vibrant internal quality control programmes (**Mishra B., *et.al*, 2023**). Some clinical laboratories where both qualitative and quantitative analytical work is performed are yet to achieve the aspect of internal quality control programme. Quality control materials produced by various reagents production companies are very expensive. This high cost of quality control materials contributes to the failure of some clinical laboratories to have an internal quality control programme **(Elvar T., *et.al*, 2016)**. It is important to recognize that a laboratory irrespective of the level or size the test results produced are very important and should be accurate and precise; therefore, adherence to quality control programme requirement is mandatory. A clinical laboratory is as good as the quality of results that it generates for the purposes of diagnosing, management and determination of the clinical status of a client. Majority of laboratory tests are requested by health providers in order to establish the suspected pathological disorder that affects a patient. It is paramount therefore that the laboratory personell must be keen on the results generated from the laboratory to ensure that these results are of good quality and beneficial to the clients and the other health providers **(Holt H & Freedman D.B, (2016).** . Laboratory personell must also be aware of the repercussions of generating erroneous results. These repercussions include: wrong diagnoses, wrong treatment, lengthy stay in hospital for in-patients, death, wastage of resources eg specimen collection tools, reagents and wastage of man power. In order to avoid these repercussions, it becomes important to introduce a system that controls the activities of a clinical laboratory. This system is what is referred to as quality assurance system (**Wheeler, S. *et.al*.,**

(2023). Quality assurance system is a galaxy of plans, policies and procedures that collectively provides an administrative structure for a clinical laboratory efforts to a achieve quality goals. Quality assurance involves virtually everybody and everything in a clinical laboratory. Any diversion from the set of activities during the collection, processing, analysis of specimens and reporting of a laboratory test can cause the invalidation of the analysis and leads to a laboratory falling short of attaining quality goals (**Alain, N. *et.al*, 2020**).

Quality assurance system has very strong pillars that put together all the activities in a clinical laboratory whose ultimate goal is the generation of quality and reliable tests results. These strong pillars includes: commitment, facilities, resources, technical competence, quality assurance procedures and problem solving mechanisms (**Plebani, M, 2022)**.Clinical laboratory personnel have to be committed and dedicated in the provision of quality services. Managerial decisions made in clinical laboratory must put into consideration the quality aspect since a decision made otherwise may compromise other plans and practices of attaining quality laboratory goals. The best way that laboratory personell demonstrate that they are committed to their clinical laboratory work is the creation of a culture of quality and satisfaction of the clients that they serve. Laboratory personnel are conversant with their responsibilities and act in an appropriate manner through the processes that are laid out in their clinical laboratory management system. Dedication to achieving quality clinical laboratory becomes the driving force to all the laboratory personell. Laboratory personell are bound emotionally and intellectually to their work and this leads to production of quality clinical laboratory results (**Mishra B., *et. al*, 2023).**

Clinical laboratory with existing quality control programmes requires encouragement to maintain and even improve on the quality reports. Clinical laboratories without any prove of quality control programmes require maximum mentorship through education on the benefits of quality assurance systems and cheap and easier availability of quality control materials. This can only be achieved through preparation of the quality control materials using locally acquired material since the commercially prepared quality control materials are very expensive for some clinical laboratories to acquire. The main objective of this study was to produce a low cost internal quality control material for quantitative analysis in clinical chemistry laboratories in Kiambu County, Kenya.

2. Materials & Methods

The site of the study was Thika Level Five Referral Hospital in Kiambu County, Kenya

A total of 497 blood donors were recruited in the study

2.1. Clinical Chemistry Laboratory Procedures

Plasma Preparation

Blood specimen in the heparinized vacutainer was centrifuged at 3000g using a centrifuge. Plasma obtained was separated from the centrifuged blood using a pasteur pippete. The collected plasma was first used for screening for the following viral infection; HIV, HBsAg, HCV and VDRL Only those specimens which tested negative for the viral and bacterial screening were used for the current study. Approximately 4mls plasma was divided into two portions of 2mls each. Approximately 2mls of plasma was put in each vial. These were identified using the blood donor's study number. One vial was stored at -20oC and the content was what was to be used to prepare the internal quality control material. The other two milliliters of plasma in the other vial was taken to clinical chemistry laboratory and used for establishment of the normal level internal quality control ranges.

The parameters that were analyzed on the above specimens were categorized under the following profiles (1)Liver function profile: [total protein(TP), albumin(ALB), aspartate aminotransferase (AST), alanine aminotransferase(ALT), Alkaline phosphatase (ALP)],gamma glutameta transamines (γ GT), Total Bilirubin (TBIL), Direct Bilirubin (DBIL), (2) kidney function profile: [blood urea nitrogen (BUN), creatinine (CREAT), potassium (K+), sodium (NA+), chloride(CL-) , (3) bone metabolism: [calcium (CAL), phosphorus (PHOS) and uric acid (UA).

Plasma Analysis

The collected plasma was analyzed for the parameters mentioned above using an automated clinical chemistry machine. All reagents for the auto analyzer machine which are commercially acquired were

prepared to fit the required volumes and concentration. To ensure that the values recovered from the patient sample assayed were both accurate and precise, the parameters were calibrated using a commercially acquired multi calibrator. The assayed normal quality control multisera reagent was used for the quality control of the analytical work during the study period. The QC multisera was supplied in lyophilized form and was reconstituted as per the manufacturer's preparation guide. For internal quality control assessment, the prepared QC multisera was analyzed any time specimens for the study were being analyzed. The standard operating procedures for handling and analyzing specimens were adhered to.

2.2. Preparation of Quality Control Materials

All the remaining plasma after the screening and analysis of the biochemical parameters from the entire study subject was harvested from the vials and pooled together. Approximately 1500 mls of pooled plasma was obtained and used for the preparation of the internal quality control material. Fifty milliliters of 70% ethyl alcohol (ethanol) was added to the pooled plasma to act as a preservative. ten milliliter of each internal quality control sera was aliquoted into a specific vial with the following information on the label: (i) quality control type (ii) manufacturing date (iii) expiring date (iv) volume (v) laboratory number (vi) storage conditions. The prepared internal quality control material (plasma) was named as KENTROL which means Kenya Control as indicated in table 2 below.

3. Data Analysis

The cleaned data obtained from the individuals was subjected to normality distribution testing using Kolmogorov-Smirnov Test. The data that was found to be normally distributed was computed using parametric approach methods, whereby the lower and upper limits of the quality control materials was obtained using the following formula:

x – 1.96SD, x + 1.96SD where x = Mean and SD = standard deviation.

The collected analytical data was entered into the Excel spread sheet, cleaned and then exported to the Statistical Package for Social Sciences version 26 (SPSS) for analysis.

4. Results

4.1. The Study Internal Quality Control report

In order to ensure that the analytical results for the specimens used to come up with the internal quality control material were accurate and precise, daily quality control serum was analyzed in thirty-three analytical sessions. The study means for the analyzed parameters were very close to that of the assigned quality control means. It can also be noted that the study internal quality control range results were a sub set of the assigned quality control range as shown in table 1 below.

Table 1. *Study internal quality control report*

	Assigned QC report				Study QC report		
	Session	QC range	SD	Mean	Mean	SD	QC range
ALB (g/L)	33	29-37	2	33	36	1	34-38
ALT (IU/L)	33	119-151	8	135	136	5	126-146
AST (IU/L)	33	48-60	3	54	54	2	50-58
ALP (IU/L)	33	106-134	7	120	122	5	112-132
GGT (IU/L)	33	35-45	2.5	40	35	0.5	34-36
D-BILI (µmol/L)	33	40-52	3	46	42	1	40-44
T-BILI (µmol/L)	33	11-19	2	15	13	0.5	12-14
TP (g/L)	33	48-56	2	52	53	1	51-55
BUN (mmol/L)	33	5.4-6.6	0.3	6	6.5	0.05	6.4-6.6
CL (mmol/L)	33	85-105	5	95	92	3	86-98
CREAT (µmol/L)	33	94-118	6	106	106	4	98-114
POT (mmol/L)	33	1-7	1.5	4	4.2	1	2.2-6.2
SOD (mmol/L)	33	110-150	10	130	132	8	116-148
CA (mmol/L)	33	0.9-2.3	0.1	2.1	2	0.05	1.9-2.1
PHOS (mmol/L)	33	1.2-1.6	0.1	1.4	1.4	0.05	1.3-1.5
UA ((µmol/L)	33	229-301	18	265	260	15	230-290

4.2. Prepared Internal Quality Control Material Report

The internal quality control material was developed using the plasma harvested from the 497 study subjects. The mean, lower and upper concentrations of each of the sixteen clinical chemistry analytes was generated to represent the IQC mean, IQC lower limit, IQC upper limit and IQC range as shown in table 2 below. These analytical results formed the information contained in the developed internal quality control insert.

Table 2. *Internal quality control material report*

Analyte	Analytical Method	IQC Mean	Statistical 1 SD	IQC Lower Limit	IQC Upper Limit	IQC Range
ALT (IU/L)	**Zero/1st order UV kinetic**	21.9	9.6	2.7	41	**2.7-41**
AST (IU/L)	**Zero/1st order UV kinetic**	21.3	8.3	4.8	37.8	**4.8-37.8**
TP (G/L)	**Biuret end point reaction**	68	7.8	52	83	**52-83**
ALB (G/L)	Bromocresol green end point reaction	43	4.7	33.6	52.4	**33.6-52.4**
TBIL (µmol/L)	Diazonium end point reaction	14.5	5.5	3.5	25.4	**3.5-25.4**
DBIL (µmol/L)	Diazonium end point reaction	6.5	2.4	1.7	11.3	**1.7-11.3**
GGT IU/L)	Zero/1st UV kinetic	57	28	1.1	113	**1.1-113**
ALP IU/L)	Zero/1st order UV kinetic	116	56	5	227	**5-227**
UREA (mmol/L)	Berthelot reaction/glutamate dehydrogenase	4.2	1.4	1.4	7.0	**1.4-7.0**
CREAT (µmol/L)	Modified rate Jaffes	78.2	29	20.4	136	**20.4-136.**
UA (µmol/L)	Uricase end point reaction method	293	95	103	482	**103-482**
POT (mmol/L)	Ion selective electrode	3.8	0.5	2.8	4.9	**2.8-4.9**
SOD (mmol/L)	Ion selective electrode	147	5.8	135	158	**135-158**
CHLO (mmol/L)	Ion selective electrode	102	4	94	110	**94-110**
PHOS (mmol/L)	Ammonium molybdate	1.2	0.4	0.4	2.0	**0.4-2.0**
CAL (mmol/L)	o-cresolphthalein /arsenazo iii	2.1	0.25	1.6	2.6	**1.6-2.6**

5. Discussion And Conclusion

The current study established that all the laboratories that had evidence of internal quality control programme were using commercially prepared quality control material from different agents of international manufacturing companies. The current study is the first to produce an internal quality control product in Kenya. Similar studies have been carried out elsewhere to prepare and use locally prepared quality control material. One such a study was carried out in India by **Sweta *et al,* 2020.** Their study was on determining the "efficacy of pooled serum internal quality control in comparison with commercial internal quality control in clinical biochemistry laboratory'. A similar study carried out in Africa was done in Ethiopia by **Haile *et al*, 2020**. Their study was on" preparation of in-house quality control human serum for urea and its use in clinical chemistry laboratory".

The current study successively analyzed sixteen clinical chemistry parameters that reflected three main metabolisms ie liver, kidney and bone. The sixteen parameters that were targeted for the inclusion in the internal quality control insert, are those routinely analysed parameters in clinical chemistry laboratories in Kenya. The blood specimens used were from the healthy blood donors who were included in the study after a through screening procedures to determine their suitability to be involved in the study. Out of the target five hundred blood donors, only three who did not meet the laid down criteria to join the study. These three were immunologically compromised thus their blood specimen could not be used for the study. The use of healthy blood donors in this current study was similar to a study by **Vera R, *et al*, 2020** whose study was on "Blood donors' preferences for blood donation for

biomedical research" transfusion medicine whose study was on "the attitude of blood donors towards the use of their samples and information in biomedical research"..

The major pillar of the current study was to develop locally prepared internal quality control material to be used in clinical chemistry section in our clinical laboratories. This locally prepared internal quality control material was identified as Kentrol which meant that the control was the first to be locally prepared in Kenya. The stability of the locally prepared internal quality control was assured during the time of preparation by the addition of 70% ethyl alcohol (ethanol). This solution was added to the pooled plasma to act as a preservative. It ensured that the quality material sera does not under go any sort of deterioration from the time of preparation all through the process of analyzing. The use of ethyl alcohol as a preservative for plasma specimen in the current study is in agreement with a study by **Penetar *et al*, 2008**. Our current study and that of Penetar and his colleagues are in agreement that 70% ethanol preserves the blood and blood products to ensure that the parameters do not change and will remain the same during the time of storage and the time of analysis. It is worthy to note that the current study did put into consideration the requirements and the stages that locally prepared internal quality control must undergo.

In conclusion, the current study has developed a low cost internal quality control material for conveniently use in clinical chemistry laboratories in Kiambu County, Kenya, to ensure the results generated are accurate and precise. The internal quality control material affordability and availability has been assured.

6. Ethical Consideration

Permission to under-take the proposed study was sought from the following authorities: (i) Mount Kenya University research review committee, (ii) Thika Level Five Referral Hospital ethical review committee (iii) NACOSTI. (iv) Kenya Medical Laboratory Technician and Technologist Board (KMLTTB) and Director General Ministry of Health and Kenya National Blood Donor Services. Consent to take blood specimen and use for the intended study was sought from the study subjects.

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