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# Validation of In-House Prepared Internal Quality Control Material Using Commercially Prepared IQC Materials in a Clinical Chemistry Laboratory in Kiambu County, Kenya

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**Abstract**

*Due to the high cost of purchasing commercially prepared internal quality control material, efforts have been put in place to prepare in-house internal quality control materials. Validation of in-house prepared internal quality control is important before the introduction and utilization of this product. The objective of this study was to validatein-house internal quality control with a internationally commercially prepared internal quality control material. The in-house prepared internal quality control material was identified as Kentrol whilst the international internal quality control was identified as Cypress. Gamma glutamate transferase and potassium were considered for the comparison process. Cypress gamma glutamate transferase had a mean, 1SD and control range of 37.5 iu/l, 3.5 iu/l and (30.8-44.8)iu/l respectively. Cypress potassium had a mean, 1SD and control range of 3mmol/l, 0.375 mmol/l and (2.25-3.75) mmol/l respectively. Kentrol gamma glutamate transferase had a mean, 1SD and control range of 57 iu/l, 28 iu/l and (1.1-113)iu/l respectively. Kentrol potassium had a mean, 1SD and control range of 3.8 mmol/l, 0.5 mmol/l and (2.8-4.9) mmol/l respectively. The daily Gamma glutamate transferase SD for Cypress for 31 days were:(0,-0.4,-0.4,0,1.4,1.4,-1.4, 0.6, 1.1, 1.4, 0, 0.6, 0, -0.6, 0, 1.1, 1.4, 0, 0, -0.6, 0.3, 0, 3, 0.3, 0.6, 0.6, 0.6, 0, -1.4, -1.4 and 0) iu/l. The daily Gamma glutamate transferase SD for Kentrol for 31 days were: (-0.1, -0.3, -0.6, -0.6, -0.4, -0.6, -0.3, 0.1,-0.1, 0.1, 0.1, 0.5, 1, 1.4, 1.5, 1.5, 1.5, 1.2, 1, 0.5, 0.3, 0.1,-0.1,-0.3, -0.1, -0.1, 0.1, 0.3, 0.1, 0.3, 0.26 (iu/l). The daily potassium SD for Cypress for 31 days were:(0, -1.3, -0.3, 0.5, 1, 1, 1.5, 1, 0.5, -0.3, 0.3, 1, 1.3, 2, 1.5, 1, 1, 0.5, 1.3, 1.5, 2, 1, 1, 1.5, 1.3, 1, 0.5, 0.5, 0, 0.5, 0) mmols/l. Daily potassium SD for Kentrol for 31 days were: (0.6, 0, 0, 0, -0.4, -0.4, 0.4, 0.4, 1.2, 0.6, 0.8, 0, -0.6, -1.6, 0, 0.4, 1.6, 0.8, 0.4, 1.6, 0.8, 0.4, 1.6, 0.8, 0.4, 0, 0, 0.4, 1, 0.4, 0.4, 0.8, 0.4, 0, -0.6, -1.2, -1.6) mmol/l.*

*In conclusion, clinical laboratories should prepare their own in-house internal quality control material thus cut down on the cost to purchase the commercially prepared internal quality control material.*

## 1. INTRODUCTION

The quality assurance system encompasses two programmesie internal quality control and external quality control. The internal quality control programme ensures that that results generated from any clinical laboratory are accurate and precise. The qualitative analysis uses positive and negative control to determine the accuracy of a test report whilst in quantitative analysis internal quality material is used to determine the precision and accuracy of the laboratory report. External quality control programme ensures there is harmonization in the clinical laboratory results generated in various clinical laboratories performing same analytes and using the same analytical report. To implement these two important quality programmes clinical laboratories have to use quality control materials, which are purchased from reagents manufacturing companies **(Karkalousos, 2007).** The types of quality control material used to under-take internal quality control are of three levels namely: abnormally low, normal and elevated controls. Clinical laboratories are expected to set aside some funds for purchasing these types of quality control materials from reagents manufacturing industries. Due to high cost of these quality control materials, not all the clinical laboratories are able to successively meet the requirements of quality control programmes **(Yago M and Alcover S.2016).**

Most of the analytical work in clinical laboratories is based on quantitative techniques and the use of internal and external quality control materials purchased from the manufacturing industries are widely used. These quality control materials are purchased independent of the other analytical tests reagents. Most of the analytical tests that are performed using qualitative analytical techniques have the internal

quality control material incorporated within the reagent strips. The only limitation of qualitative analytical techniques is that results cannot express the actual concentration of the analytes being investigated **(Miller G, 2011).** The implementation of internal and external quality control programmes in the clinical laboratories requires constant assessment to ensure that the quality of work is never compromised. Laboratories that are not able to implement the requirements of internal and external quality control programmes require mentorship and provision of quality control materials in an easier and a cheaper way. 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 in house prepared internal quality control material require validation using an existing commercially prepared internal quality control material. This forms the base of the current study i.e. validation of in-house prepared internal quality control material with commercially prepared internal quality control material at Thika level five referral county hospital, Kiambu 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. Preparation of in-House Internal Quality Control Material

In-house internal quality control was prepared from plasma specimen of blood collected from 497 healthy blood donors. Before pooling the plasma, each plasma specimen was analyzed for sixteen clinical chemistry analytes. An automated clinical chemistry analyzer was used for analysis. The standard operating procedures for analysis clinical chemistry specimens were adhered too. This included analyzing the specimens once the internal quality control for the analytes were within each analyte quality control range. After the analysis, the plasma specimens were pooled and preserved using fifty milliliters of 70% ethyl alcohol (ethanol). 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 1 below.

### 2.2. Validation of the in-House Quality Control Material

Two analytes i.e. gamma glutamate transferase and potassium were selected from the sixteen analytes indicated in the in-house quality control and used for validation purposes. These two analytes acted as a representation of the other analytes.

## 3. RESULTS

The two analytes used for validation process had the following information indicated in each specific internal quality control insert. Cypress gamma glutamate had a mean, 1SD and quality control range of 37.5 iu/l, 3.5 iu/l and (30.8-44.8) respectively. The potassium for Cypress) had a mean, 1SD and quality control range of 3 mmol/l, 0.375 mmol/l and (2.25-3.75) mmol/l respectively. On the other hand, Kentrol gamma glutamate had a mean, 1SD and quality control range of 57 iu/l, 28 iu/l and (1.1-113) iu/l respectively. The potassium for Kentrol had a mean, 1SD and quality control range of 3.8 mmol/l, 0.5 mmol/l and (2.8-4.9) mmol/l respectively as shown in table 1 below.

**Table 1.** *Internal quality control report for the analytes used for validation process*

| Quality control material | Analyte (units) | Mean | 1sd | Control range |
|---|---|---|---|---|
| Cypress | ggt(iu/l) | 37.5 | 3.5 | 30.8-44.8 |
| | $K^+$(mmol/L) | 3 | 0.375 | 2.25-3.75 |
| Kentrol | ggt (iu/L) | 57 | 28 | 1.1-113 |
| | $K^+$ (mmol/L) | 3.8 | 0.5 | 2.8-4.9 |

## 4. VALIDATION REPORT

Daily internal quality control results were converted to internal quality control standard deviation for 31 days used for validation process. The daily gamma glutamate transferase SD for Cypress for 31 days were as follows: ((0, -0.4, -0.4, 0, 1.4, 1.4, -1.4, 0.6, 1.1, 1.4, 0, 0.6, 0, -0.6, 0, 1.1, 1.4, 0, 0, -0.6,

-0.3, 0, 3, 0.3, 0.6, 0.6, 0.6, 0, -1.4, -1.4 and 0) iu/l. The daily gamma glutamate transferase SD for kentrol for 31 days were: (-0.1, -0.3, -0.6, -0.6, -0.4, -0.6, -0.3, 0.1, -0.1, 0.1, 0.1, 0.5, 1, 1.4, 1.5, 1.5, 1.5, 1.2, 1, 0.5, 0.3, 0.1, -0.1, -0.3, -0.1, -0.1, 0.1, 0.3, 0.1, 0.3, 0.26 (iu/l).The daily Potassium SD for Cypress) for 31 days were:(0,-1.3,-0.3,0.5,1,1,1.5,1,0.5,-0.3, 0.3, 1, 1.3, 2, 1.5, 1, 1, 0.5, 1.3, 1.5, 2, 1, 1, 1.5, 1.3, 1, 0.5, 0.5, 0, 0.5 and 0) mmols/l. On the other hand the daily potassium SD for Kentrol for 31 days were: ( 0.6,0,0,0,-0.4,-0.4,0.4,0.4,1.2,0.6,0.8,0,-0.6,-1.6, 0, 0.4, 1.6, 0.8, 0.4, 1.6, 0.8, 0.4, 1.6, 0.8, 0.4, 0, 0, 0.4, 1, 0.4, 0.4, 0.8, 0.4, 0, -0.6, -1.2 and-1.6) mmol/l. All the above results are presented in table 2 and in levy Jennings internal quality control chart for eachanalyte in figures 1-2 below.

**Table 2.** *The gamma glutamate transferase and potassium daily internal quality control standard deviations for Cypress and Kentrol*

| DAY | Gamma glutamate transferase | | Potassium | |
|---|---|---|---|---|
| | Cypress SD | Kentrol SD | Cypress SD | Kentrol SD |
| 1 | 0 | -0.1 | 0 | -0.6 |
| 2 | -1.4 | -0.3 | -1.3 | 0 |
| 3 | -1.4 | -0.6 | -0.3 | 0 |
| 4 | 0 | -0.6 | 0.5 | 0 |
| 5 | 1.4 | -0.4 | 1 | -0.4 |
| 6 | 1.4 | -0.6 | 1 | -0.4 |
| 7 | -1.4 | -0.3 | 1.5 | 0.4 |
| 8 | -0.6 | 0.1 | 1 | 0.4 |
| 9 | 1.1 | -0.1 | 0.5 | 1.2 |
| 10 | 1.4 | 0.1 | -0.3 | 0.6 |
| 11 | 0 | 0.1 | -0.3 | 0.6 |
| 12 | 0.6 | 0.5 | 1 | 0 |
| 13 | 0 | 1 | 1.3 | -0.6 |
| 14 | -0.6 | 1.4 | 2 | -1.6 |
| 15 | 0 | 1.5 | 1.5 | 0 |
| 16 | 1.1 | 1.5 | 1 | 0.4 |
| 17 | 1.4 | 1.5 | 1 | 1.6 |
| 18 | 0 | 1.2 | 0.5 | 0.8 |
| 19 | 0 | 1 | 1.3 | 0.4 |
| 20 | -0.6 | 0.5 | 1.5 | 0 |
| 21 | -0.3 | 0.3 | 2 | 0 |
| 22 | 0.3 | 0.1 | 1 | 0.4 |
| 23 | 0.3 | -0.1 | 1 | 1 |
| 24 | 0.6 | -0.3 | 1.5 | 0.4 |
| 25 | 0.6 | -0.1 | 1.3 | 0.4 |
| 26 | 0.6 | -0.1 | 1 | 0.8 |
| 27 | 0 | 0.1 | 0.5 | 0.4 |
| 28 | -1.4 | 0.3 | 0.5 | 0 |
| 29 | -1.4 | 0.1 | 0 | -0.6 |
| 30 | 0 | 0.3 | 0.5 | -1.2 |
| 31 | 0 | 0.26 | 0 | -1.6 |

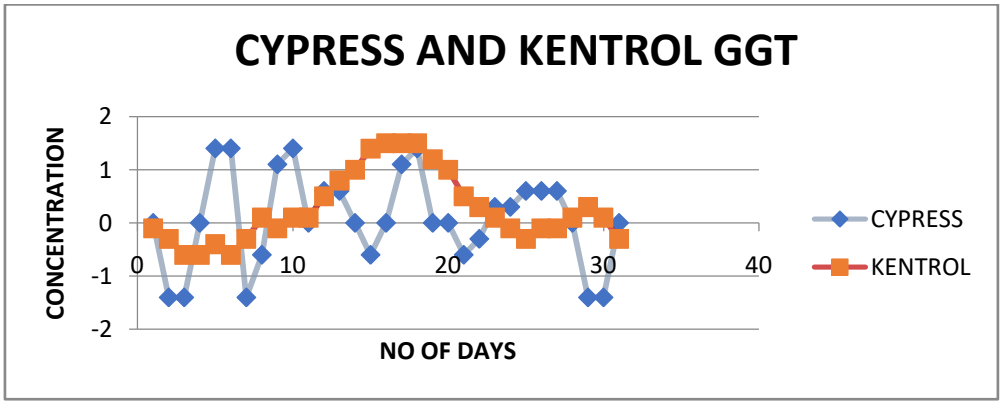


**Figure 1.** *Validation using gamma glutamate transferase*

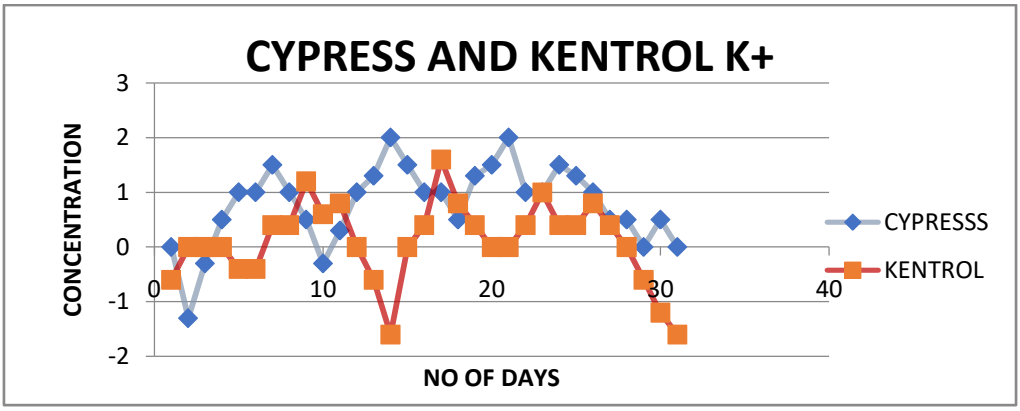


**Figure 2.** *Validation using gamma glutamate transferase*

## 5. Discussion, Conclusion And Recommendation

The locally prepared quality control material in this study was analysed together with the commercially acquired quality control material. One type of commercially acquired quality control material were identified being used in the clinical chemistry laboratory where the study was carried on. For the purpose of this current study, these commercially acquired quality control was identified as: Commercial internal quality control (Cypress. This commercially prepared quality control sera had the same analytes as those for their house prepared quality control material. Another similarity was the analytical methods for the specific parameters. One major difference noted in the two quality control materials was the analytes quality control ranges. The current study is in agreement with a study by **Kulkarni *et. al*, 2020** in terms of daily quality control values within the quality control range. The only difference between these two studies is that the current study used plasma as the quality control material whilst the study by Kulkarni used serum as the quality control material. The in house prepared internal quality control in the current study can replace the commercially prepared internal quality in ensuring analytical accuracy and precision in clinical chemistry laboratory. This is in agreement with a study by **Veru *et. al*, 2022.**

In conclusion in-house prepared internal quality control performance is equal to commercially prepared internal quality control and clinical laboratories are therefore encouraged to prepare and use the same in the clinical laboratories. The other major advantage of in-house internal quality control is cheaper than commercially acquired internal quality control. Adapting the procedures used in the current study will even make the cost of producing the in-house internal quality control material cheaper and affordable. Both plasma and serum are suitable specimens of choice to be used for the preparation of in house internal quality control.

## 6. Recommendation

1. Current study recommends the preparation and use of in-house prepared internal quality control material in clinical laboratories.
2. The current study has prepared the internal quality material using the human plasma. The study recommends more studies to be carried out by using animal plasma/serum which is easily available with less ethical issues.
3. Current study recommends the validation of in house quality control material before using it in the clinical laboratories.

## 7. 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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