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Research Article

Efficacy of In-House Quality Control Material Compared to Commercially Available Quality Control for Thyroid Hormone

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Abstract: Laboratory results in clinical laboratories are being generated by automated analyzers. The constant use of commercial control materials is not economically feasible for many countries because of the non-availability or high cost of those materials. Therefore, the preparation of in-house quality control serum will be cost-effective for use in the laboratory. The commercial quality control for immunoassay is costlier and as per NABL 112 criteria, at least two levels of quality control should be run every day for a laboratory with a large sample load. To overcome this problem our study aims to evaluate the efficacy of in-house pooled serum quality control in comparison with commercial internal quality control samples in thyroid hormone tests. We prepared in-house quality control from leftover samples of subjects tested for thyroid profile after being screened for HIV, HCV, and HBsAg by pooling them together in a glass jar serum and kept in a deep freezer at -20°C. Pooled serum was aliquot into 20 vials each containing 500 µl. Every day along with commercial internal QC, one aliquot of pooled serum was analyzed for thirty days for the following parameters: TSH, FT3, FT4. After getting thirty values for each parameter, mean, standard deviation, and coefficient of variation were calculated for both IQC commercial sample and pooled serum sample.**:** In-house prepared quality control material performed as well as commercial quality control for thyroid profile. Therefore, prepared in-house quality control can be a good substitute for commercial quality control for thyroid profile.

Keywords: In-House Quality Control, Commercial Internal Quality Control, Pooled Serum and Thyroid Hormone.

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1. INTRODUCTION

Quality control (QC) is an essential component in every clinical laboratory which maintains the excellence of laboratory standards, supplementing to proper disease diagnosis, patient care and resulting in overall strengthening of the health care system,[1] With increasing automation in Clinical Laboratories, the requirements for quality control material is more useful for monitoring laboratory performance[2]. Assessment of QC material will be done based on the sample load, when instrument undergoes major maintenance, breakdown or calibration, change in reagent lot or company, and even sometimes inappropriate patient result.[3] These reasons increase the utility of QC material, which is not feasible for low and middle-income countries.[4,5] Even developed country laboratories were advised to use feasible control sera to cut down their cost because many laboratories spend more on the purchase of control sera and calibration serum per patient sample analyzed for better performance in terms of precision of analytical results.[6-8] Major disadvantages in commercial QC material are vial to vial variation and manual error occurs when they are reconstituted.[9] NABL recommends at least two times per day and two levels for hormone assays. As a result, in our laboratory we started to prepare pooled serum. Which was used as an internal QC material for immunoassays especially for thyroid hormones. This in-house pooled serum was prepared to form human serum, the matrix effect and concentration will be similar to population and ethnicity. For the preparation of quality control samples, several methods, including a variety of starting materials, have been proposed in the literature. On consideration of the World Health Organization Document LAB/81.47[10, 11] which encourages the local production of quality control material, we have utilized the leftover serum sample from healthy Master health check-up patients as in house quality control material and its efficacy will be compared with commercial internal quality control. Additional advantages of the homemade serum include easy preparation using normal laboratory expertise. It is inexpensive and very cost-effective resulting in saving precious foreign exchange for the import of commercial serum[12,13]. We prepared in-house pooled frozen serum for thyroid profile (TSH, FT3, and FT4) in the mean range of the reference intervals used in our laboratory. Frozen stabilized sera are more consistent than lyophilized serum as there is always reconstitution error which can vary results from vial to vial. So, we compared between in-house internal quality control sample and commercial internal quality control sample.

2. METHODOLOGY

This study was conducted at Central Clinical Laboratory, Mahatma Gandhi Medical College & Research Institute, SBV, Pondicherry. The study was approved by the Institution Research Committee and Institutional Human Ethics committee (MGMCRI/IRC/06/2020/IHEC/15). The study was done in accordance with declaration of Helsinki. The leftover serum samples of patients tested for thyroid function levels whose TSH value was less than 5 uIU/ml and tested negative for HIV, HBsAg, and HCV antibodies were pooled for the study. The lipemic, icteric, hemolysed, and biohazard samples were excluded from the study. Every day after analysis leftover serum samples approximately 10 sample per day and serum volume between 250 to 500 microliters from each samples were pooled in a glass jar and kept in a deep freezer at -20^0 C.

2.1 Preparation of Aliquots

The serum sample was collected for twenty days and pooled together, mixed gently on vortex mixture, then cooled and kept in a deep freezer until analysis. The pooled serum was aliquoted in 30 vials for 30 days. Every day along with commercial internal QC, one aliquot of pooled serum was analyzed for 30 days for TSH, FT3, and FT4. Before, that pooled serum sample was analyzed 20 times in the same day within and between batches to calculate the precision and accuracies of the sample. After analyzing for 30 days, mean, standard deviation and coefficient of variation were calculated for both commercial QC sample and pooled serum sample.

3. STATISTICAL ANALYSIS

The quantitative data of the study parameters was entered into an Excel sheet. And the data was analyzed using JASP v 0.84. The data was presented in the form of mean & SD for quantitative variables. Co-efficient of variation (CV)% was calculated by using formula.

$$CV\% = SD/Mean \times 100$$

4. RESULTS

We prepared a house quality control sample by pooling all the serum samples for 20 days with patients' TSH levels less than 5 IU/L. The total pooled serum volume was 25 ml then it was aliquot into 50 deep freezer storage vials each consisting of 500 µl of pooled serum. In that 30 vials were used as quality control material for 30 days along with a commercial quality control sample and the remaining 20 vials were used to check for precision and accuracy of pooled for both within and between runs.

Table 1: Comparison of in house quality control material initial values with end of 30 day values

PARAMETERS	Initial Run [N = 20 replicates]		End of 30 day [single run each day]		P VALUE
	MEAN ± SD	CV %	MEAN ± SD	CV %	
TSH	2.24 ± 0.03	1.33	2.23 ± 0.06	2.69	0.566
FT3	3.17 ± 0.04	1.26	3.17 ± 0.04	1.26	1.000
FT4	1.32 ± 0.04	3.03	1.29 ± 0.10	7.75	0.254

Table 1: shows the comparison of in-house quality control material initial values with the end of 30-day values in terms of mean, standard deviation (SD), and coefficient of variation (CV) for thyroid profile for a month.

Table 2: Comparison of in house quality control material initial values with commercial quality material values

PARAMETERS	Pooled serum [N = 30]		Commercial QC [N = 30]	
	MEAN ± SD	CV %	MEAN ± SD	CV %
TSH	2.23 ± 0.06	2.69	0.501 ± 0.03	5.98
FT3	3.17 ± 0.04	1.26	3.07 ± 0.17	5.54
FT4	1.29 ± 0.10	7.75	0.844 ± 0.05	5.92

In table 2 we have compared the pooled serum sample which has been analyzed for one sample per day for 30 days with commercially available quality control for the same 30 days. The result showed a significant difference, even though both pooler serum and commercial QC value are at level 1 i.e. normal range.

Figures 1 to 3 show the commercial quality control results for the period under study. These are the Levy- Jenning charts where the middle heavy line indicates zero standard deviation from the mean. The figures mentioned at the left are the concentrations of TFT and the figures at the bottom indicate the number of days of the internal quality control sample analyzed in the laboratory. Each 'X' indicates the deviation of that sample concentration from the true value, either on the positive or negative side of the middle line. The '0'S (whose constituent level can be seen directly under a specific concentration) indicates the value of positive or negative standard deviation from the true concentration.

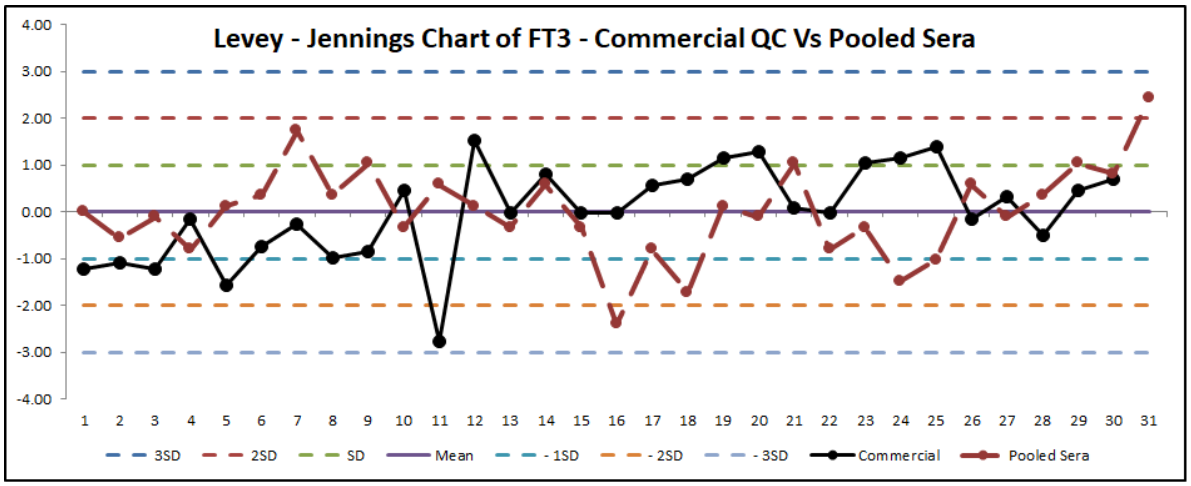

Fig 1 showing Comparison of LJ chart of FT3 between Commercial QC versus Pooled Serum

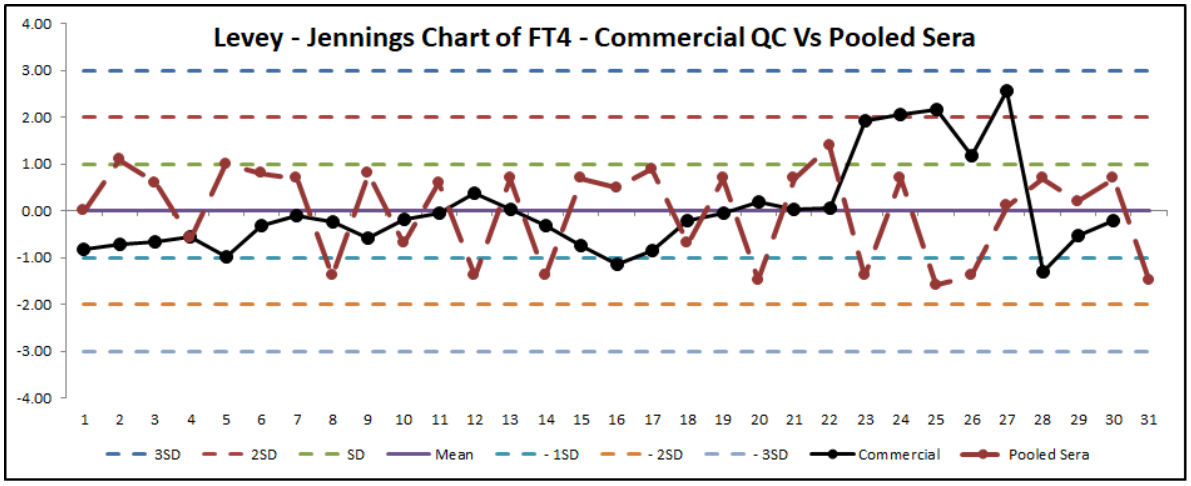

Fig 2: Comparison of LJ chart of FT4 between Commercial QC versus Pooled Serum

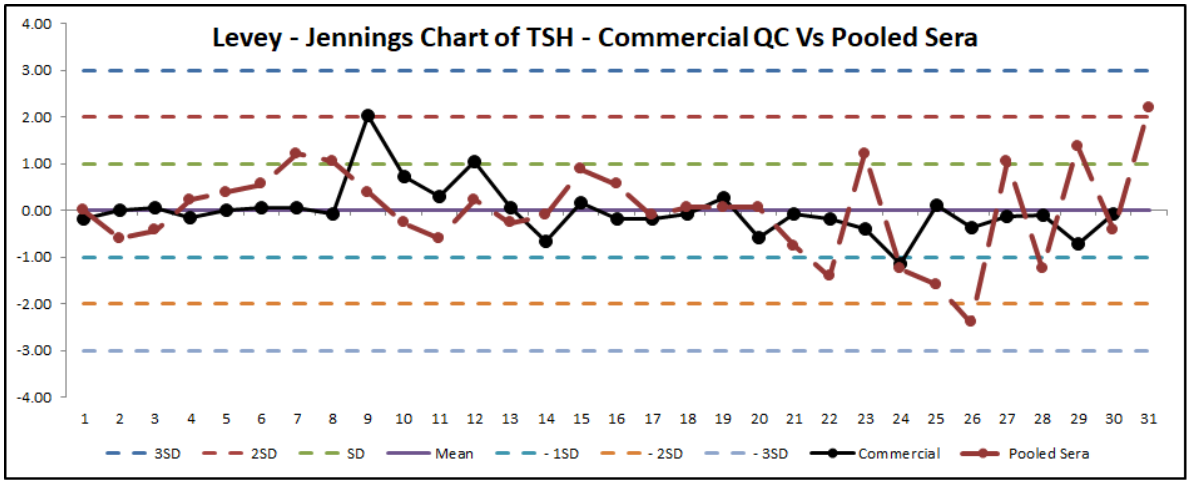

Fig 3: Comparison of LJ chart of TSH between Commercial QC versus Pooled Serum

Figures 1 to 3 show the in-house quality control material [pooled serum] results for the period under study. These are the Levy- Jenning charts where the middle heavy line indicates zero standard deviation from the mean. The figures mentioned at the left are the concentrations of TFT and the figures at the bottom indicate the numbers of days of the in-house prepared internal quality control sample analyzed in the laboratory. Each 'X' indicates the deviation of that sample concentration from the true value, either on the positive or negative side of the middle line. The '0'S (whose constituent level can be seen directly under a specific concentration) indicates the value of positive or negative standard deviation from the true concentration. The narrower coefficients of variation in the homemade serum versus the commercial sera imply a lesser vial to vial variation of the constituent analytes in the homemade serum translating into the better potential for error detection in the normal ranges.

5. DISCUSSION

The clinical laboratory plays an indispensable role in making a clinical diagnosis. This in turn increases the quality of maintenance of day-to-day accuracy of patient reports. Due to the increase in usage of automation in clinical laboratories, usage of QC material also increases. The constant use of commercial QC is not affordable for many laboratories in under and developing countries. WHO document LAB/81.47 records the importance of homemade quality control material and provides guidelines, to prepare different types of local QC material. We prepared our pooler sera from the leftover serum sample of patients given their sample for thyroid function test with TSH value less than 5 IU/L after screening for biohazards such as HIV, HbsAg, and HCV. LJ chart of thyroid function test in pooled sera shows stability throughout the study period. Total allowable error was kept at 5% and appropriate statistical analysis was selected. Results show statistically significant CV% of thyroid hormone levels in pooled sera when compared with commercial QC material. Figure 1 to 3 shows the linearity of the concentration of thyroid hormone in pooled sera with commercial QC material. This implies effectiveness of preparation of home-made QC material as well as its stability over the commercial QC. Rukbsana et al[14] report that there was a 69% decrease in commercial QC expenses annually when they used pooled sera. Results showed that in-house quality controls used for the study parameters TSH, FT3, and FT4 were accurate and CV% less than commercial quality control. There is no statistical difference between them. Lanani et al[5] in their study have shown that homemade quality QC from polycythemia patients is better than commercial QC. Bowes et al[15] in their studies has shown that pooled serum QC is more stable and low cost when compared to commercial QC. Khatri et al[16] has shown in their study by using the patient sample that the reliability and validity of test reports will be better when compared to commercial quality control. Kulkarni S et al [17] in their study reported that in house pooled quality control efficacy is better than commercial quality control. Hence in our study, we found that in-house QC can be used for hormone assay also. Regardless of all efforts, hormone analysis methods in research studies are frequently given surprisingly little consideration[18]. However, considering the quality of the hormone measurement methods in these research findings is critical, as this recognition to methods may avoid wrong conclusions and improper follow-up studies. Hence in this work, we have done the same to decrease the cost.

6. CONCLUSION

We concluded that in-house quality control is very cost-effective and good for use in clinical Biochemistry laboratories when compared with commercial internal quality control for parameters like thyroid hormone assays also because their parameters CV% of in-house quality control are less than commercial IQC. In-house quality control is a good substitute for commercial quality control, especially in developing countries.

7. CONFLICT OF INTEREST

Conflict of interest declared none.

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