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EVALUATING THE STABILITY OF INHOUSE QUALITY CONTROL MATERIAL – IN A TERTIARY CARE HOSPITAL - A PERSPECTIVE STUDY

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ABSTRACT

INTRODUCTION: A good laboratory report must be accurate, reliable and reported timely to be useful in clinical or public health set up. Internal Quality control (IQC) ensures the analytic part error in a patient's report before it is released. Commercial Quality control material procurement, transportation, reconstitution, storage and stability maintenance are tedious. Developing countries like India can make an attempt to prepare inhouse quality control material at low cost and find the alternative source of QC at all times.

MATERIALS & METHODS: About 150mL of Serum was pooled from left over samples in 24 hrs Clinical Biochemistry lab, centrifuged, the supernatant of this serum was aliquoted in 75 sample storing cups of 1.5 mL capacity and stored at -20°C. Initially 4 aliquots of serum were run every day for 5 days along with samples. The lab mean, Standard Deviation (SD), Coefficient of variance (CV%) were calculated from the data obtained from 20 values as said above. Daily morning one serum aliquot was processed as sample and all biochemical analytes were determined in a fully automated analyzer. Levy Jenning chart was drawn for these analytes, Mean, SD, CV were derived from data.

RESULTS: All 60 days values for the inhouse quality control material stored at -20°C were compared with the baseline lab mean, SD & CV%. Most of the analytes did not show statistically significant difference in values between the initial and final day except bilirubin and phosphorus.

CONCLUSION: Based on our observation in the study we recommend that in house QC material from pooled serum is an economical and cost effective way to adopt for the assessment of quality assurance in clinical biochemistry laboratories. It can also be used as alternative at times of unavailability of IQC during emergency situation.

INTRODUCTION

A good laboratory report must be accurate, reliable and reported timely to be useful in clinical or public health set up. In order to achieve the highest level of accuracy and reliability, it is essential to perform an Internal quality control in all processes and procedures in the laboratory in a best possible way. Automation in laboratory has increased the utilisation of Quality Control material (QCM) liberally as WHO guidelines insists on using QCM at least twice a day [1]. Internal Quality control (IQC) ensures the analytic part error as well as reliability and timeliness of patient's results before it is released. It also helps in assessing the laboratory standard in Proficiency Testing with peer group [2]. Commercial Quality control material procurement, transportation, reconstitution, storage and stability maintenance are practically a tedious procedure. India being a developing country with rich human resource, low cost in- house preparation of quality control material will be a good initiative in tertiary care hospitals to reduce the expenditure and also it is a better alternative during the period of QCM unavailability. Having this background, we started a study to evaluate the stability of inhouse quality control material in a Tertiary care Government hospital with serum pooled from left over processed samples which really helped us during pandemic curb.

MATERIALS & METHODS:

After the Institutional Ethics committee approval, the study was conducted in 24hrs Clinical Biochemistry lab, Govt. Stanley Hospital with left over serum samples after all test requests were performed. About 150mL of Serum was pooled, centrifuged, the supernatant of this serum was aliquoted in 75 sample storing cups of 1.5 mL capacity and stored at -20°C. HIV, HBsAg, HBcAg were ruled out by screening an aliquot of the pool. All analytically interfering factors like hemolysis, Icterus, lipemia were excluded. Initially 4 aliquots of serum were run every day for 5 days along with samples. The lab-mean, Standard Deviation (SD), Coefficient of variance (CV%) were calculated from the data obtained from 20 values as said above. From then, daily morning one serum aliquot was processed as sample and all biochemical analytes were determined in a fully automated analyzer Beckman Coulter AU480 and recorded continuously for a month. After a month, it was repeated periodically at an interval of 10 days (on day 40, 50, 60). During those days, temperature was strictly maintained at -20°c and thawing done properly. Levy Jenning chart was drawn for these analytes, Mean, SD, CV were derived from those data.

CV: Coefficient of Variance with 20 data:

S.NO	ANALYTE	MEAN	SD	CV%	CLIA (2019) TV+/-
1	GLUCOSE	138.29	2.82	2.06%	8%
2	UREA	29.5	1.58	5.3%	9% (2mg)
3	CREATININE	1.76	0.075	4.3%	10% (0.2mg)
4	CHOLESTEROL	187.9	8.54	4.542%	10%
5	TRIGLYCERIDES	166.30	3.7	2.2%	15%
6	TOTAL PROTEIN	6.8115	0.11	1.59%	8%
7	ALBUMIN	3.765	0.08	2.13%	8%
8	AST	20.45	0.51	2.5%	15%
9	ALT	18.92	1.12	5.9%	15%
10	TOTAL BILIRUBIN	0.383	0.023	6%	20%
11	CALCIUM	9.64	0.04	2.05%	1mg
12	PHOSPHORUS	3.795	0.17	4.4%	10% (0.3mg)
13	URIC ACID	5.08	0.27	5.13%	10%

Table 2: Comparing the CV% on various days with Lab CV%

S.NO	ANALYTES	40days	50days	60 days	Lab CV%
1	GLUCOSE	2.07%	2.07%	2.1%	2.06%
2	UREA	5.05%	5.31%	5.3%	5.3%
3	CREATININE	6.86%	6.95%	6.85%	4.3%
4	CHOL	4.49%	4.482%	4.59%	4.542%
5	TGL	2.71%	2.698%	2.68%	2.2%
6	T.PROTEIN	1.64%	1.63%	1.64%	1.59%
7	ALB	2.21%	2.2%	2.2%	1.89%
8	AST	3.11%	3.22%	3.17%	2.5%
9	ALT	6.4%	7.067%	7.97%	5.9%
10	T.BIL	9.67%	14.43%	17.6%	6%
11	CAL	1.62%	1.59%	1.66%	2.05%

12	PHOS	8.9%	9.47%	9.23%	4.44%
13	URIC ACID	7.16	7.042%	7.06%	5.13%

RESULTS:

All 60 days values for the inhouse quality control material stored at -20°C were compared with the baseline lab mean, SD & CV%. Most of the analytes did not show statistically significant difference in values between the initial and final day except bilirubin and phosphorus. The variation in value between first aliquot and last aliquot recorded were well within the Total allowable Error. CV% of every analyte were compared with CLIA 2019 guidelines and found no great difference.transferase.

Abbreviations:

AST: Aspartate amino transferase, ALT: Alanine amino

Table 3: Significant P Value For All Analytes

S.NO	ANALYTES	F test	P-value
1	GLUCOSE	0.864	0.46
2	UREA	0.56	0.65
3	CREATNINE	0.113	0.95
4	CHOLESTEROL	0.062	0.98
5	TRIGLYCERIDE	1.6	0.17
6	PROTEIN	0.6	0.62
7	ALBUMIN	0.56	0.643
8	TOTAL BILIRUBIN	5.321	0.002[a]
9	AST	1.151	0.331
10	ALT	0.984	0.41
11	CALCIUM	0.303	0.82
12	PHOSPHOROUS	3.221	0.024[a]
13	URIC ACID	0.553	0.65

[a] show significant changes, P< 0.05 statistically significant

DISCUSSION:

In the era of evidence-based medicine, handling patient's sample in a medical laboratory is always a complex procedure. Frajola et al [3] has made the first attempt of preparing the in-house QCM and in India the first attempt by Premachandra and et al [4] and the WHO guidelines by Browning DM et al [5] has laid the pathway for the procedures to follow in our study except using preservative. Our study has shown a good stability trend for most of the analytes including End point and Kinetic assay throughout the observation period. The values obtained at the end of 30th day were very close to the lab mean and this implies that though commercial lyophilized sample gives a commutable matrix, freshly prepared QC material from local samples are much reliable and promising too. Similar study conducted by Sweta Kulkarini et al showed in house preparation to be stable for 12 weeks and much better than commercial preparation [6]. Even after 30 days the stability of analytes were maintained within the Total Allowable Error by CLIA 2019 recommend ation.

The reason for inconsistency in the stability of Total Bilirubin and its poor stability could be due to photolytic or photo isomerization process. The nature of the stability of serum bilirubin is largely influenced by the exposure of ambient light to the sample prior to analysis and also by the analytical method applied to some extent and our findings are supported by several other groups [19,20,21,22] .

Poor stability of phosphorus having statistically significant value could be possibly due to the time delay in separation of serum from blood cells in the blood collection tube. In Gómez Rioja et al study they have produced a detailed report on the stability of phosphorus in different storage conditions[10]. The day-to-day stability of calcium in our study showed satisfactory results, however there are many other studies which reported several interfering factors which markedly affects calcium estimation using photometric method [11,23,24,25].

The study by Kulkarini et al and Lalani et al in finding the stability of homemade Quality control serum prepared from Polycythemia patients also showed that the routine biochemical analytes were stable in comparision with the commercially available QC material on long term storage [6,7]. The QCM obtained from human resource is very easy in collection, processing, storage and stability integrity and much better than animal serum [7]. The Batch and lot number of QCM has to be maintained for a long run to have a control over the performance in the laboratory. This variability in vial to vial in commercial QCM is also low in human serum if prepared in house in a large quantity [8]. The developing countries like Bhutan also have started this effort to reduce the expenditure and avoid unavailability of QCM in emergency [9]. The day-to-day stability of liver enzymes was satisfactory although poor stability of enzymes on long term storage due to the freeze thaw cycles has been well studied earlier [14,11,12]. The stability of serum urea is satisfactory, the percentage variation did not show any statistical significant difference. Nonetheless it is important to analyze the storage condition thoroughly, as in few studies they have reported a significant change in the stability of urea when stored at -20 °C [11,12].

In our study daily variation of serum glucose in in-house qc sample was considerably satisfactory throughout the study. However we recommend that several pre-analytical factors which could influence the stability of glucose for long term storage which must be taken in to consideration when a pooled sera is used for IQC assessment [16,17,18].

Even though the stability of total protein and albumin was found stable, repeated freeze thaw cycle tends to decrease their stability on long term storage[15].

In our study the stability of creatinine and uric acid in frozen pooled serum were found to be moderately less which could be influenced by various indiscernible factors affecting the analytical concentration and assay however the inconsistency in stability did not cause any obvious statistically significant differences. This observation is dissimilar to the findings of other groups [6,7,9,] However the findings of Marjani and other groups stated that creatinine is only stable for 24 and 48 hours [13,14].

This study emphasizes on preparing inhouse quality control material at low cost in tertiary care Centre where large scale serum can be pooled and can be used as an alternative in emergency situations.

CONCLUSION:

Robust internal quality control (IQC) practices are fundamental to detect errors in the analytical phase and thus improves the quality of patient care. Based on our observation in the study we recommend that in house QC from pooled serum is an economical and cost-effective way to adopt for the assessment of quality assurance in all Clinical Biochemistry laboratories instead of micro and small size resource limited clinical biochemistry laboratories. The precision and accuracy are up to par with the commercially available QC material without compromising patient test results.

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