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Original Article

Assessment of Clinical Chemistry Analytes Using Sigma Metrics in Diagnostic Laboratory of a Tertiary Care Hospital in Lahore

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ABSTRACT

Objective: To observe the quality of laboratory analytical process using sigma metrics, identify the reasons for low sigma values and then take corrective action for improving quality of lab results.

Study Design: Analytical cross-sectional study

Place and Duration of Study: Combined Military Hospital Lahore, Pakistan from May to Oct 2024

Methodology: 23 biochemical analytes were analyzed by Automated Chemistry analyzer Cobas c501 (Roche Diagnostics). Two levels of control samples were run daily. The internal quality control (IQC) data included the mean, standard deviation (SD), and coefficient of variation (CV) of six months from May to Oct 2024. Bias was calculated from analysis of 4x quarterly NEQAPP samples that were received from Armed forces institute of pathology between Oct 2023 to Oct 2024. The sigma value (σ) for the analytes was calculated using the formula (σ) = Total allowable error (TEa) (%) – Bias (%)/ (CV%)

Results: According to categorization by sigma metrics; most of the analytes were in Good ($4 \leq \sigma < 5$) and Marginal ($3 \leq \sigma < 4$) category. While Amylase, Creatine Kinase and Gamma Glutamyl Transferase were world class ($\sigma > 6$). Using quality goal index (QGI) for analytes with $\sigma < 3$ identified Imprecision issues (QGI<0.8) for sodium while Inaccuracy (QGI >1.2) was the main problem identified for other analytes.

Conclusion: Clinical laboratory performance assessment by sigma metrics analysis has become an objective method for quantifying the quality of lab results. It can be conveniently derived from routine QC data without incurring additional costs.

Keywords: Bias, Cobas c501, Coefficient of Variation, Clinical Laboratory, Diagnostic Errors, Inaccuracy, Quality Control, Six Sigma.

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INTRODUCTION

Clinical laboratories play a pivotal role in providing reliable, reproducible, and precise diagnostic services to patients, which in turn has an impact on decisions related to management.[1] Because the quality of laboratory services directly impacts health care, inaccurate laboratory results can result in incorrect diagnosis, further unnecessary diagnostic testing and over or under treatment.[2] Laboratory testing is broadly classified into pre-analytical (before analysis), analytical phase (analysis of sample) and post-analytical phases. Errors at any stage of this testing process can compromise laboratory results. A dependable method for detecting errors within the laboratory testing framework is essential to guarantee accurate outcomes.[3] The quality of the laboratory results can be assessed in terms of accuracy, precision, sensitivity, and specificity. In clinical laboratories, sigma metrics are utilized to monitor and evaluate the parameters and measurement processes mentioned above in an objective and quantitative manner.[4]

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Motorola Corporation was the first organization to introduce the six-sigma model. Nevalainen and colleagues, then applied the concept of six-sigma in medical laboratories.[5] The six-sigma is calculated using three variables: coefficient of variation (CV), bias and total allowable error (TEa). Bias indicates accuracy and CV measures imprecision. Bias, obtained from proficiency testing (PT) results and CV, derived from internal quality control (IQC) represent the analytical performance of the laboratory system. TEa, on the other hand is a quality goal adopted by the laboratory itself.[6] Sigma metrics assist clinical laboratories in establishing quality objectives and to ensure compliance with required standards so that quality of patient reports can be maintained.[7]

The Sigma metric is the only method to accurately quantify errors in the analytical phase rather than relying solely on internal and external quality control data. Higher Sigma metric values indicate fewer analytical errors and a lower likelihood of questionable test results being accepted. Achieving a six-sigma level in the laboratory's analytical process means that 99.99966% of the results are free from errors, so, the chance of errors is only 3.4 per one

million tests, and the laboratory has been assumed to reach the "world-class" level.[8]

Studies conducted across different countries have highlighted the importance of sigma metrics in enabling laboratories to produce test results of the highest quality. Kanani F calculated sigma metrics of 27 analytes of clinical chemistry and 12 immunoassay analytes on Alinity C and Alinity I systems. They inferred that the sigma metric was a useful tool for monitoring IQC practices.[9] An international study used Cobas 6000 and C311 analyzers to evaluate 21 biochemical analytes. The authors documented that for level 1 IQC, 10 analytes on Cobas 6000 and six analytes on C311 showed σ 3-6. For level 2 IQC, eight analytes on Cobas 6000 and four analytes on C311 were found to achieve σ 3-6. The remaining analytes were above 6σ 5.

As Six Sigma is a relatively new concept in pathology diagnostic laboratories, very few studies in Pakistan have used it to monitor the quality of their lab results. To the best of our knowledge, sigma metrics have not been used for the analysis of biochemical analytes on the Cobas 6000 series Automated Chemistry Analyzer c501. Therefore, objective was to observe the quality of lab analytical process within the boundary of sigma metrics and identify the reasons for low sigma matrix values, if any, and then take corrective action to improve the quality of our lab results.

METHODOLOGY

This analytical cross-sectional study was carried out from May 2024 to October 2024, at the Department of Chemical Pathology and Endocrinology, Combined Military Hospital Lahore, a tertiary care hospital. Approval for the study was granted by Research institutional review board vide no 526/2024, dated 14/05/2024.

Inclusion Criteria: Only data of lyophilized Quality control (QC) materials and analyzed on Automated Chemistry analyzer of Cobas 6000 series, Cobas c501 (Roche Diagnostics, Germany), was included in the study

Exclusion Criteria: Data generated from already constituted control materials, control materials provided by vendors other than Roche and those analyzed on Automated analyzers other than Cobas c501 were excluded from the study

Sample size calculation was done by the formula: $n= z^2 \times p \times (1-p/e^2)$, with Confidence Level: 95% (Z=1.96), Margin of Error: 5% (E=0.05) and Expected Proportion of analytical errors: 10% (p=0.10).[4]

The IQC data included the mean, standard deviation (SD), and CV of six months from May 2024 to October 2024 for 23 biochemical analytes. The following parameters were included in this study: Amylase, Alkaline Phosphatase (ALP), Aspartate aminotransferase (AST), Alanine aminotransferase (ALT), Albumin, Creatinine, Creatine kinase (CK), Calcium, Glucose, Gamma glutamyl transferase (GGT), Magnesium (Mg), Phosphate, Potassium, Iron, Lactate dehydrogenase (LD), Total Cholesterol, High density lipoprotein (HDL) cholesterol, Sodium, Total bilirubin, Triglycerides (TG), Total protein, Uric acid (UA) and Urea.

The laboratory was enrolled in a quarterly external proficiency programme, national external quality assurance programme Pakistan (NEQAPP) managed under the administration of AFIP. The 4xNEQAPP samples were received and subsequently analyzed from October 2023 to October 2024.

The lower sigma value indicated that there were higher numbers of quantitative defects and vice versa. The QGI was also evaluated for analytes which had a sigma value of <3, followed by determination of Imprecision and Inaccuracy.

The SD, CV and bias of the IQC and proficiency testing data were entered into Microsoft Excel 2016 (Microsoft Corporation). All the calculations were done manually. The TEa values for the analytes under study were obtained from the Clinical Laboratory Improvements amendment (CLIA) 2018. The database of biological Variation (BV) was consulted for analytes not covered in the CLIA.[10] The following formula was used to calculate the CV: CV% = SD/Mean × 100. Bias was calculated as follows; Bias =Lab PT result- Peer group mean / peer group mean. The sigma value for all the analytes was calculated using the formula (σ) = TEa (%) – Bias/CV%. Formula used for calculation of QGI was: QGI = % Bias/1.5 x CV%. QGI value of <0.8 suggests towards Imprecision, QGI between 0.8-1.2 indicates presence of both Imprecision and Inaccuracy and QGI value >1.2 points towards Inaccuracy.[11]

RESULTS

A total of 23 biochemical analytes were analyzed by Automated Chemistry analyzer Cobas c501 (Roche Diagnostics). The mean Bias, CV% and sigma values of chemistry parameters, for level 1 and level 2 controls, are displayed in Table-I and Table-II respectively. For

both level 1 and 2 QC on Cobas c501, three analytes showing world class performance (σ>6) were Amylase, CK and GGT while ALP, AST, Mg, and UA showed good performance (4< σ <5). Marginal performance (3< σ <4) was shown by ALT, total bilirubin, Glucose, iron, LDH, protein, and triglycerides. For level 2 QC, AST, Mg, total bilirubin, and GGT showed good performance (4 < σ < 5). Marginal performance (3 < σ <4) was shown by ALT, glucose, iron, protein, LD, potassium and protein. Albumin and total cholesterol did not achieve the minimum sigma performance at both IQC levels. Categorization of analytes according to sigma metrics performance is shown in Table-III. QGI values for analytes with Sigma value less than 3 are also shown in Table-III. Only sodium with QGI value less than 1.2, was having imprecision. Rest of the analyses with σ <3 were having QGI >1.2, so they were having inaccuracy issues. Comparison of sigma values of all the chemistry analytes for both level 1 and level 2 controls is shown in Figure.

Table-I: Mean Bias, CV%, TEa and Sigma metrics of level-1 control for chemistry analytes on Cobas c501 automated chemistry analyser (n=23)

Parameter	NEQAPP Round 1 (Bias)	NEQAPP Round 2 (Bias)	NEQAPP Round 3 (Bias)	NEQAPP Round 4 (Bias)	Mean (Bias)	TEa %	Mean CV %	Sigma value
Albumin	-0.38	4.86	-3.96	-1.18	-0.66	8	5.14	1.68
ALP	1.09	8.7	5.15	1.43	4.09	20	3.85	4.13
ALT	2.96	1.64	-4.28	-3.87	-0.887	15	4.24	3.74
Amylase	4.06	5.37	-0.11	-6.5	0.705	30	4.34	6.75
AST	2.52	1.07	-0.36	-4.49	-0.315	15	3.31	4.6
Bilirubin (total)	1.45	2.55	-0.86	-2.51	0.157	20	6.11	3.24
Calcium	-0.17	4.84	4.41	-7.05	0.507	11	4.42	2.37
Cholesterol (total)	2.45	5.04	3.3	-2.59	2.05	10	4.7	1.69
CK	-1.31	2.36	-0.85	-1.04	-0.21	30	3.57	8.64
Creatinine	-3.5	2.43	1.28	-5.86	-1.41	10	5.37	2.12
GGT	-6.67	-0.32	-7.32	0.82	-3.37	22	4.24	6.38
Glucose	-1.31	4.37	-4.44	-2.08	-0.86	10	3.99	3.22
Iron	2	0.42	2.9	-7.99	-0.66	20	6.76	3.35
LDH	1.23	1.51	-1.07	-1	0.17	20	5.40	3.67
Mg	2.23	1.22	5.6	-4.75	1.075	25	5.63	4.63
PO4	7.1	1.64	2.65	-0.88	1.62	10.7	4.02	2.36
Potassium	-0.82	3.72	0.98	-0.15	0.93	10	4.17	2.58
Protein	0.52	2.67	1.4	-2.84	-0.69	10	3.25	3.29
Sodium	0.65	2.44	-0.66	-2.23	0.05	5.0	2.39	2.40
Triglyceride	3.63	4.49	-7.61	-1.16	-0.65	15	4.41	3.56
Urea	-1.71	8.34	0.8	-4.42	0.75	9	3.99	2.47
Uric acid	-1.9	6.35	2.66	-2.61	1.12	17	4.16	4.06

NEQAPP - National external quality assurance program Pakistan, TEa - Total allowable error, Mean CV% - Derived from monthly CV% from May 2024 to October 2024

DISCUSSION

Performance assessment by sigma metrics analysis has become an objective method for "Quantifying" the quality of lab results. It can be conveniently derived from routine QC data generated in laboratories without incurring additional costs. Furthermore, it serves as a valuable tool by reducing the daily frequency and number of controls, thereby lowering costs.

Table-II: Mean Bias, CV%, TEa and Sigma Metrics of Level 2 Control for Analytes on Cobas c501 Automated Chemistry Analyser (n=23)

Parameter(s)	NEQAPP Round 1 (bias)	NEQAPP Round 2 (bias)	NEQAPP Round 3 (bias)	NEQAPP Round 4 (bias)	Mean (bias)	TEa %	Mean CV%	Sigma value
Albumin	-0.38	4.86	-3.96	-1.18	-0.66	8	5.08	1.70
ALP	1.09	8.7	5.15	1.43	4.09	20	3.08	5.16
ALT	2.96	1.64	-4.28	-3.87	-0.887	15	4.47	3.55
Amylase	4.06	5.37	-0.11	-6.5	0.705	30	4.38	6.68
AST	2.52	1.07	-0.36	-4.49	-0.315	15	3.23	4.74
Bilirubin (total)	1.45	2.55	-0.86	-2.51	0.157	20	6.11	4.52
Calcium	-0.17	4.84	4.41	-7.05	0.507	11	4.29	2.44
Cholesterol (total)	2.45	5.04	3.3	-2.59	2.05	10	4.66	1.71
CK	-1.31	2.36	-0.85	-1.04	-0.21	30	3.17	9.52
Creatinine	-3.5	2.43	1.28	-5.86	-1.41	10	5.14	2.2
GGT	-6.67	-0.32	-7.32	0.82	-3.37	22	6.05	4.19
Glucose	-1.31	4.37	-4.44	-2.08	-0.86	10	3.46	3.13
Iron	2	0.42	2.9	-7.99	-0.66	20	6.06	3.41
LDH	1.23	1.51	-1.07	-1	0.17	20	6.08	3.31
Mg	2.23	1.22	5.6	-4.75	1.075	25	5.60	4.27
PO4	7.1	1.64	2.65	-0.88	2.62	10.7	3.79	2.13
Potassium	-0.82	3.72	0.98	-0.15	0.93	10	2.97	3.05
Protein	0.52	-2.67	1.4	-2.84	-0.69	10	2.84	3.76
Sodium	0.65	2.44	-0.66	-2.23	0.05	5.0	2.38	2.08
Triglyceride	3.63	4.49	11.61	-1.16	4.64	15	4.21	2.46
Urea	-1.71	8.34	0.8	-4.42	-0.75	9	4.08	2.39
Uric acid	-1.9	6.35	2.66	-2.61	1.12	17	5.09	3.2

NEQAPP - National external quality assurance program Pakistan, TAE - Total allowable error (derived from CLIA 2018), Mean CV% - Derived from monthly CV% from May 2024 to October 2024

Table-III: Categorization of Biochemical Analytes according to their Sigma Metrics Performance and Root causes Analysis Of Analytes With σ<3

Sigma metrics	Level 1	Level 2	QGI Value	Root cause analysis
World class (σ ≥ 6)	Amylase, CK, GGT	Amylase, CK	NA	NA
Excellent (5 ≤ σ < 6)		ALP	NA	NA
Good (4 ≤ σ < 5)	ALP, AST, Mg, Uric acid	AST, Total Bilirubin, GGT, Mg	NA	NA
Marginal (3 ≤ σ < 4)	ALT, Total Bilirubin, Glucose, Iron, LDH, Protein, Triglyceride	ALT, glucose, Iron, LDH, Potassium, Protein, Uric acid	NA	NA
Poor (2 ≤ σ < 3), and	Calcium, Creatinine, Phosphate, Sodium, Potassium - Urea	Calcium, Creatinine, Phosphate, Sodium, - Triglyceride Urea	1.450 4.831 6.619 0.103 2.294 2.04 13.022	Inaccuracy Inaccuracy Inaccuracy Imprecision Inaccuracy Inaccuracy Inaccuracy
Unacceptable (σ < 2)	Albumin, Cholesterol	Albumin, Cholesterol	2.235 6.368	Inaccuracy Inaccuracy

QGI - Quality goal index, σ - symbol of six sigma

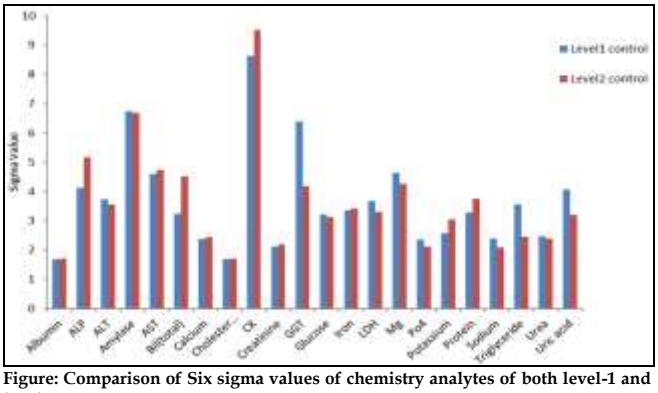


Figure: Comparison of Six sigma values of chemistry analytes of both level-1 and level-2

*Controls: *Y axis – sigma value, X axis – name of analytes*

For both level 1 and 2 QC on Cobas c501, three analytes showing world class performance (σ>6) were Amylase, CK and GGT while ALP, AST, Mg, and UA

showed good performance (4 < σ < 5). Marginal performance (3 < σ <4) was shown by ALT, total bilirubin, Glucose, iron, LDH, protein, and triglycerides. For level 2 QC, AST, Mg, total bilirubin, and GGT showed good performance (4 < σ < 5). Marginal performance (3 < σ <4) was shown by ALT, glucose, iron, protein, LD, potassium and protein. Albumin and total cholesterol did not achieve the minimum sigma performance at both IQC levels. The calculated QGI and root cause analysis indicated inaccuracy, as QGI >1.2.

Zhou *et al.*, investigated the performance of 19 analytes on modular analyzer AU5800 (Beckman Coulter). They also documented different sigma values for each level of quality control. In their study, out of 19 analytes, 11 demonstrated a sigma performance of at least 4σ for level 1 QC. For QC level 2, 12 of the 19 analytes had a sigma value of at least 4σ. Inferences by Zhou *et al.*, are consistent with the findings of our study. In their study, Imprecision was the main cause for marginal performance of five analytes (TP, ALT, Ca, BUN, and Cl), while three analytes (Creatinine, Alb, and P) exhibited both inaccuracy and imprecision, for both QC levels .[12]

In our study, although some analytes showed similar performance for both QC levels (Amylase, Ck, Mg, ALT, glucose, iron, LDH, protein, Calcium, Creatinine, PO4) but disparities in values of sigma metric were also noted between two different QC levels for other analytes (GGT, ALP, uric acid, bilirubin, potassium and urea). However, this observation was not specific to our study as this finding has also been reported by other studies.[13,14] The observed discrepancies between the two material levels were partly attributed to the methodologies used for certain analytes, which may perform better with either normal or abnormal QC material concentrations.

In our study, 60% of the analytes exhibited a sigma score of >3, for both levels of QC material. Similar findings were noted in a study conducted by Moodley *et al.*, in four laboratories with diverse analytical capabilities, in South Africa. In that study, 26 biochemical analytes were analyzed using Siemens Dimension and Siemens Atellica. Approximately 50% of the analytes achieved a sigma score of more than 3 across the three levels of controls in all four laboratories.[4]

In our study 03 analytes showed sigma value >6. Inaccuracy was the main problem identified, for the analytes with σ < 3. In a study by Kumar BV *et al.*, 16 biochemical parameters were analysed using the Vitros 4600 automated biochemical analyzer. Of them, four analytes demonstrated sigma value of > 6. For analytes with a sigma level <3, QGI was <0.8, suggesting that the area needing improvement was imprecision.[15] In a study by Geto *et al.*, the performance of 21 chemistry analytes was evaluated utilizing the Roche Cobas 6000 analyzer. Excellent performance (6 sigma) was observed for 07 tested parameters. Similar to our findings, urea, Creatinine, cholesterol and chloride were < 03 sigma, for both QC levels.[1] A retrospective observational study conducted at laboratory of a public Hospital, in Hyderabad, India reported similar findings to our study. The study presented data of 16 parameters analyzed on the Beckman Coulter analyzer AU-5800. Two of the analytes achieved a sigma score of >6 while most parameters were in sigma 3-4 range.[16] Another observational study in a reference laboratory in Ethiopia, used Cobas 6000 analyzer for analyzing 18 biochemical analytes. The study reported low sigma values for Urea and Chloride. The results of Ethiopian study support the findings of our study.[17] A retrospective study in Turkey, using Cobas c702 analyzer, analyzed 21 chemistry parameters.[18] The findings aligned with our study, showing sigma metrics for creatinine below 3, indicating inaccuracy at both 1 and 2 IQC levels.

In contrast to our findings, a prospective study carried out at King Abdulaziz Hospital, Saudi Arabia evaluated sigma metrics on the Cobas 6000 analyzer for 25 chemistry parameters. Creatinine performance (σ =4.7 at level 1 and σ=5.10 at level 2 IQC) did not match our results but results for sodium, potassium, and chloride (σ<3) matched our study.[19]

A limitation of our study was the variations observed in sigma values for certain analytes between our study and others. This may be attributed to differences in methodology, the traceability of calibrators, the instruments used, the quality control materials employed, and other pre analytical and analytical conditions.

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CONCLUSION

The Six Sigma methodology serves as an effective evaluation system for the routine chemistry parameters

analyzed in a clinical laboratory, optimizing QC procedures for each analyte and providing a problem-solving strategy. Sigma metric analysis offers a benchmark for designing IQC protocols and addressing poor assay performance.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

NUK & MZR: Data acquisition, data analysis, critical review, approval of the final version to be published.

STAG: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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