Original Article

Driving Analytical Excellence in Biochemistry: A Four-Month Six Sigma Performance Assessment

Shahid Ali[1], Sana Alam[1,*], Jaspreet Kaur[1]

[1]Department of Biochemistry, Hamdard Institute of Medical Sciences and Research, New Delhi, India

***Correspondence:** sana2k2@gmail.com

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Abstract

Background: Ensuring the accuracy of biochemical tests in clinical labs is crucial for diagnosis. Six Sigma evaluates test result deviation from targets; higher values indicate fewer errors. Some tests perform poorly with sigma values below 4. This study uses Six Sigma, the Quality Goal Index (QGI), and Root Cause Analysis (RCA) to identify and improve performance issues.

Methods: Data were collected daily for IQC at two levels and monthly for external assessments over four months. CV, bias, and Total Allowable Error were used to calculate sigma values for 16 biochemical analytes. QGI analysis identified discrepancies, and RCA uncovered reasons for poor results.

Results: Urea, protein, phosphate, high-density lipoprotein, alanine aminotransferase, and iron had sigma values $\leq$4.0. Glucose, creatinine, albumin, uric acid, and triglyceride in Level 1, and albumin, triglyceride, and alanine aminotransferase in Level 2, showed sigma values of 4–5. Level 2 glucose, creatinine, uric acid, and cholesterol were in the 5–6 sigma range. Ten analytes across Levels 1 and 2 had sigma values $\geq$6. For $\sigma < 4$ analytes, QGI showed inaccuracy. IQC reconstitution, storage temperature, and air bubbles affected performance.

Conclusion: Six Sigma methodology improves laboratory testing quality. Regular monitoring and addressing root causes lead to more accurate results and better patient care.

Keywords: clinical laboratories; internal quality control (IQC); six sigma; quality goal index (QGI); root cause analysis (RCA)

Introduction

Clinical laboratories are fundamental to modern healthcare, with approximately 70% of medical decisions relying on laboratory test results.[1] These laboratories play a critical role in diagnosing, treating, and monitoring diseases, from chronic conditions like diabetes to acute infections, providing essential data that guide clinical decisions and public health strategies. However, the increasing complexity of diagnostic technologies and the growing demand for high-quality healthcare services have placed laboratories under greater scrutiny. Even at minimal levels, errors in testing can lead to significant consequences, including misdiagnosis, delayed treatment, and inappropriate interventions, underscoring the importance of robust quality management systems to ensure precision and reliability of the test results. To ensure accurate and dependable results, laboratories strive to implement robust quality assurance programs. While pre-analytical and post-analytical phases are prone to errors, the analytical phase typically experiences fewer mistakes. However, despite the lower frequency of analytical errors, rigorous monitoring of quality control (QC) during this phase remains essential to maintain the precision and reliability of laboratory testing. The error rate across the total testing process is estimated to range between 30% and 75% in the pre-analytical phase, 4% to 30% in the analytical phase, and 9% to 55% in the post-analytical phase. Therefore, maintaining strict quality control measures is crucial to ensure consistent results and support enhanced patient care.[2]

Internal Quality Control (IQC) serves as the first line of defense, involving daily monitoring of test performance using control samples to detect and correct analytical errors before they affect patient results. Complementing IQC, External Quality Control (EQC) or proficiency testing involves periodic evaluation of laboratory performance through comparison with peer laboratories, ensuring standardization and accuracy across different setups. Central to these processes are the Westgard rules, a set of statistical guidelines that aid in the interpretation of IQC results. These rules help identify potential errors in test systems by analysing trends and shifts, allowing laboratories to take corrective actions promptly. Together, IQC, EQC, and Westgard rules form an integrated quality assessment framework, minimizing errors, enhancing reliability, and building confidence in laboratory results, ultimately supporting better clinical decision-making and patient outcomes.

One of the most effective tools for evaluating laboratory performance is the Six Sigma methodology, which quantifies the efficiency and error rates of processes. Six Sigma was first developed in 1986 by Motorola Company to reduce industrial waste. A sigma value of 6 corresponds to near perfection, with only 3.4 defects per million opportunities.[3] This method not only identifies areas of improvement but also provides a structured framework for achieving higher standards of excellence. Despite these advancements, challenges such as reagent quality, sample handling, and environmental factors continue to impact test reliability, underscoring the need for ongoing quality assessment and improvement.

The calculation of Six Sigma in clinical laboratories involves assessing the performance of an analytical process using three critical parameters: bias, Total Allowable Error (TEa), and the coefficient of variation (CV). Bias refers to the difference between the mean of test results and the true or target value, representing the systematic error in a method. TEa is the maximum permissible error in a test result without affecting clinical decision-making, serving as a benchmark for acceptable performance. These metrics are procured through regular quality control activities, including internal quality control (IQC) data and external quality assessments (EQA), which provide insight into the accuracy and precision of testing processes.[4]

The Six Sigma value is calculated using the formula: Sigma = (TEa – Bias%) / CV%[5]

Here, CV represents the relative standard deviation of the test, reflecting its precision. A higher sigma value indicates fewer errors and better reliability in the analytical process. Accurate determination of bias requires the use of reference materials or proficiency testing programs, while TEa is typically defined by regulatory guidelines or clinical needs. The relationship between these factors is critical—low bias and CV relative to TEa result in higher sigma values, indicating robust performance. Laboratories utilize these metrics to monitor and improve their processes, ensuring reliable and accurate results for patient care.

This study focuses on the application of Six Sigma methodology to assess the performance of biochemical analytes, identify suboptimal areas, and implement corrective measures. By highlighting the importance of precision and quality in clinical laboratories, this research aims to contribute to the development of more reliable diagnostic practices that enhance patient care and safety.

Materials and Methods

Study setting

This study was conducted at the Clinical Biochemistry Laboratory of Hakeem Abdul Hameed Centenary (HAHC) Hospital, Hamdard Institute of Medical Sciences and Research (HIMSR), New Delhi. This was a prospective observational study.

Data collection

Internal Quality Control (IQC) data were systematically gathered over a four-month period, from June to September 2024, utilizing Bio-Rad QC materials. These materials were used at two levels: Level 1 (L1) and Level 2 (L2), to ensure a comprehensive evaluation across a range of clinical scenarios.

The 16 analytes assessed are the most common analytes done in a clinical biochemistry laboratory; these included Glucose, Urea, Creatinine, Total Bilirubin, Total Protein, Albumin, Phosphate (Phos), Uric Acid, Total Cholesterol, Triglycerides, High density lipoprotein (HDL), Aspartate aminotransferase (AST), Alanine aminotransferase (ALT), Alkaline phosphatase (ALP), Amylase, and Iron.

Serum Electrolytes were not included as their Total Allowable Error were not standardized by CLIA 2024 Guidelines.

Testing was conducted on the Beckman Coulter AU480 analyzer, a robust platform known for its precision and reliability. This process allowed for daily monitoring of analytical performance, promptly identifying trends and deviations to maintain laboratory results' accuracy.

External Quality Control (EQC) data were sourced through the Randox International Quality Assessment Scheme (RIQAS),

a globally recognized proficiency testing program. Monthly validations of the same 16 analytes were carried out using this scheme, providing an external benchmark to complement internal monitoring. RIQAS ensured that the laboratory's performance was aligned with international standards and allowed for peer comparison, fostering continuous improvement.

To evaluate analytical performance, Total Allowable Error (TEa) thresholds were adopted based on the 2024 Clinical Laboratory Improvement Amendments (CLIA) guidelines. These benchmarks served as the gold standard for acceptable performance, ensuring that the test results met the clinical expectations for precision and accuracy. By combining the IQC and EQC data with the TEa standards, the laboratory established a robust quality assurance system, minimizing errors and delivering reliable results to support patient care.

Coefficient of variation

CV% was calculated using IQC values taken at two levels, Level 1 and Level 2, with the formula: (SD/Mean) x 100.[6] Where the coefficient of variation (CV), shown as a percentage (%CV), is a simple way to measure the consistency and variation in laboratory test results.

Bias

Bias in biochemical analytes refers to the systematic deviation of laboratory test results from the true or actual values.

Bias% = (Measured value in our laboratory – Determined value given by EQAS) $\times$ 100% / (Determined value given by EQAS)[7]

Here for each parameter, External Quality Assessment results were taken from monthly EQAS data from Randox International Quality Assessment Scheme (RIQAS).

Sigma calculation

Six Sigma Matrices for each were calculated using the CV%, Bias, and TEa that we adopted from CLIA 2024 guidelines for both levels. Sigma was calculated as $\Sigma = (TEa - Bias\%)/CV\%$ [5]. The results were then grouped based on sigma grades [8]: World Class for $\sigma \geq 6$; Excellent for $5 \leq \sigma < 6$; Good for $4 \leq \sigma < 5$; Marginal for $3 \leq \sigma < 4$; Poor for $2 \leq \sigma < 3$; and Unacceptable for $\sigma < 2$.

Quality Goal Index

The Quality Goal Index (QGI) was calculated for each parameter with a sigma grade less than 4 using the formula: QGI = Bias% / (1.5 $\times$ CV%)[8]. This index categorizes results into three groups: Imprecision for a QGI Score < 0.8, Inaccuracy for a QGI Score > 1.2, and Both for $0.8 \leq$ QGI ≤ 1.2.

Assisting us to make the root cause analysis using the Fishbone Diagram.

This helped us pinpoint the root cause of the errors occurring and the improvement needed to have a better outcome.

The diagram uses five customized categories (Environment, Personal, Method, Material, Equipment) to dissect QC failures, focusing on actionable issues like temperature control and operator skills—directly relevant to prediabetes sample handling (e.g., avoiding hemolysis or degradation). It promotes systematic root cause analysis over generic checklists. This approach enhances traceability, reduces bias in error attribution, and supports evidence-based interventions, as recommended in lab accreditation standards.[8]

Results

Tables 1 and 2 show the CV%, Bias%, and six-sigma values of the 16 analytes for levels 1 and 2, respectively. All runs were performed using a Beckman Coulter AU480 autoanalyzer with an ISE module. The values for TEa were extracted from CLIA 2024. The performance of the analytes was graded into six categories based on the sigma level.

Table 3 classifies the sigma values in terms of grades and the analytes falling under those categories for both level 1 and level 2 IQC data.

The Quality Goal Index (QGI) was calculated for analytes with $\sigma < 4$. Table 4 shows the QGI values for the level 1 IQC runs. It has been seen all the four analytes showed problem in precision.

Table 1: Sigma metrics for level 1 internal quality control for analytes. TEa – total allowable error; CV – coefficient of variation; CLIA – Clinical Laboratory Improvement Amendment.

S.No	Analytes	TEa	TEa source	Bias%	CV%	Sigma
1	Glucose	10	CLIA 2024	0.27	2.26	4.3
2	Urea	9	CLIA 2024	1.41	2.82	2.68
3	Creatinine	10	CLIA 2024	-5.11	2.8	5.39
4	Total Bilirubin	20	CLIA 2024	2.7	2.1	8.23
5	Total Protein	5	CLIA 2024	-2.33	3.31	2.21
6	Albumin	10	CLIA 2024	-0.4	2.11	4.92
7	Phosphate	10	CLIA 2024	2.83	2.89	2.47
8	Uric Acid	10	CLIA 2024	0.36	1.85	5.18
9	Total Cholesterol	10	CLIA 2024	-0.55	1.67	6.29
10	Triglyceride	15	CLIA 2024	0.94	2.73	5.13
11	High density lipoprotein (HDL)	10	CLIA 2024	1.96	2.96	2.7
12	Aspartate aminotransferase (AST)	15	CLIA 2024	0.45	2.33	6.24
13	Alanine aminotransferase (ALT)	15	CLIA 2024	1.91	3.09	4.23
14	Alkaline phosphatase (ALP)	20	CLIA 2024	-4.75	2.98	8.3
15	Amylase	20	CLIA 2024	-0.15	2.49	8.08
16	Iron	15	CLIA 2024	-1.43	2.1	7.81

Table 2: Sigma metrics for level 2 internal quality control for analytes. TEa – total allowable error; CV – coefficient of variation; CLIA – Clinical Laboratory Improvement Amendment.

S.No	Analytes	TEa	TEa source	Bias%	CV%	Sigma
1	Glucose	10	CLIA 2024	0.26	1.88	5.17
2	Urea	9	CLIA 2024	1.41	2.68	2.82
3	Creatinine	10	CLIA 2024	-5.11	2.6	5.79
4	Total Bilirubin	20	CLIA 2024	2.7	2.22	7.76
5	Total Protein	5	CLIA 2024	-2.33	3.52	2.07
6	Albumin	10	CLIA 2024	-0.4	1.87	5.56
7	Phosphate	10	CLIA 2024	2.83	2.53	2.83
8	Uric Acid	10	CLIA 2024	0.36	1.55	6.2
9	Total Cholesterol	10	CLIA 2024	-0.55	1.89	5.57
10	Triglyceride	15	CLIA 2024	0.95	2.75	5.09
11	High density lipoprotein (HDL)	10	CLIA 2024	1.96	2.23	3.59
12	Aspartate aminotransferase (AST)	15	CLIA 2024	0.45	2.02	7.19
13	Alanine aminotransferase (ALT)	15	CLIA 2024	1.91	2.61	5
14	Alkaline phosphatase (ALP)	20	CLIA 2024	-4.75	2.72	9.09
15	Amylase	20	CLIA 2024	-0.15	1.57	12.82
16	Iron	15	CLIA 2024	-1.43	4.22	3.89

Table 3: Sigma grades of analytes for internal quality control (IQC) level 1 and level 2.

Sigma Grades	Analytes (IQC-L1)	Analytes (IQC-L2)
World class ($\sigma \geq 6$)	Total bilirubin (TBIL), Total Cholesterol, Aspartate Aminotransferase (AST), Alkaline Phosphatase (ALP), Amylase, and Iron	Total bilirubin (TBIL), uric acid (UA), Aspartate Aminotransferase (AST), Alkaline Phosphatase (ALP), Amylase
Excellent ($5 \leq$ sigma< 6)	Creatinine (Creat), Uric acid (UA), Triglyceride	Glucose, Creatinine, Albumin, Total Cholesterol, Triglyceride, Alanine aminotransferase (ALT)
Good ($4 \leq$ sigma< 5)	Glucose, Albumin, Alanine aminotransferase (ALT)	–
Marginal ($3 \leq$ sigma< 4)	–	High-density lipoprotein (HDL), Iron
Poor ($2 \leq$ sigma< 3)	Urea, Total Protein, Phosphate, High-Density Lipoprotein (HDL)	Urea, Total Protein, Phosphate
Unacceptable ($\sigma < 2$)	–	–

Table 4: Quality Goal Index (QGI) of analytes for level 1 (L1) IQC run. IQC: internal quality control.

Analytes	QGI (L1)	Problem
Urea	0.3	Imprecision
Total Protein	0.46	Imprecision
Phosphate	0.65	Imprecision
High-Density Lipoprotein (HDL)	0.43	Imprecision

Similarly, Table 5 shows the QGI values for the level 2 IQC runs. It had five analytes with all showing problem in precision.

Table 5: Quality Goal Index (QGI) of analytes for level 2 (L2) IQC run. IQC: internal quality control.

Analytes	QGI (L2)	Problem
Urea	0.3	Imprecision
Total Protein	0.44	Imprecision
Phosphate	0.74	Imprecision
High Density Lipoprotein (HDL)	0.58	Imprecision
Iron	0.22	Imprecision

Root cause analysis was performed based on potential factors that can lead to low performance of analytes and low sigma values: environmental factors, personal factors, method followed for different analytes, materials used for both L1 and L2 IQC, and finally, equipment-related error. Errors such as IQC reconstitution, Storage Temperature fluctuation, and differences in thawing time and air bubbles while processing the QC were more common causes of poor performance.

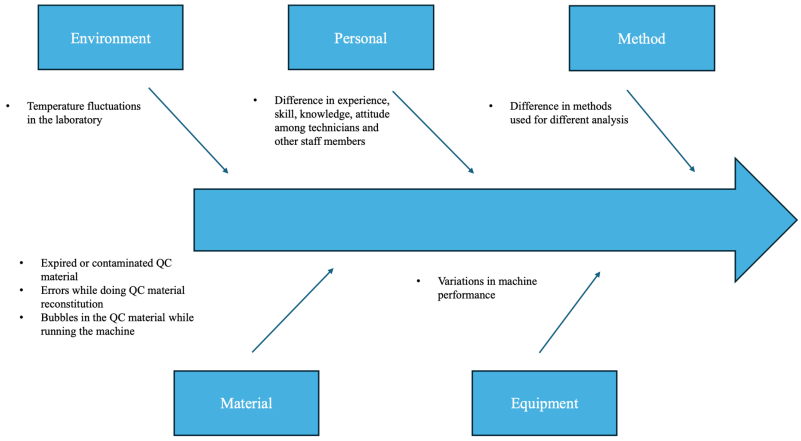

Figure 1: Fishbone diagram illustrating root cause analysis of quality control failures across five categories: environment, personal, method, material, and equipment.

Discussion

This study highlights how Six Sigma helps monitor test quality in clinical biochemistry labs. Of the 16 analytes examined, most had strong sigma scores, showing the lab process is generally accurate and consistent. However, some analytes like urea, total protein, phosphate, HDL, and iron had sigma scores below 4. This means not all tests on the same equipment perform equally well. Some need more frequent quality checks, while others can be monitored less often. Focusing resources this way helps address problem areas without wasting effort.

Finding analytes with low sigma scores has important clinical effects beyond just lab quality numbers. Inaccurate test results can affect clinical decisions, especially when results are close to key thresholds. High imprecision can cause repeated tests to vary for no clear reason, making it hard for doctors to tell if changes are real or just due to testing. This can delay diagnoses, lead to extra tests, or cause wrong changes in treatment, which can harm patient safety and care quality.

For example, if glucose measurements are inaccurate, results may move around important cut-off points, which can lead to mistakes in diagnosing or managing diabetes. Inconsistent creatinine results can make it harder to assess kidney function, possibly leading to wrong disease staging or medication errors. Imprecise sodium or potassium results might hide real imbalances or suggest problems that aren't there, causing delays or unnecessary treatments. Variability in liver enzyme tests

like ALT and AST can either hide real disease changes or falsely suggest liver damage, affecting decisions about further tests or treatments.

By connecting sigma metrics and Quality Goal Index (QGI) analysis to these clinical situations, the study shows how lab issues can affect patient care. Fixing imprecision with better quality control, regular instrument maintenance, and staff training improves lab performance and makes test results more reliable. Improving precision is key to making sure lab data supports accurate diagnosis, proper treatment, and the best outcomes for patients.

Clinical labs play a key role in healthcare, with about 70% of medical decisions based on lab results.[9] They are vital for diagnosing, managing, and monitoring diseases, from chronic conditions like diabetes to acute infections. Labs provide important data for clinical decisions and public health efforts.

Sigma is a quality management tool that helps labs continuously monitor and improve how well their tests perform.

Using Six Sigma in clinical labs is a strong way to improve test quality and make lab processes better. By reducing variability and mistakes, Six Sigma makes test results more reliable and helps labs run more efficiently.

A main benefit of Six Sigma in labs is that it lets staff measure test quality with numbers. The Sigma metric, aiming for 3.4 defects per million, helps labs check how well their tests and equipment work. It also shows if problems like bias or imprecision are present, so staff can take steps to fix them.

For example, by looking at sigma values for different tests, labs can decide how often and how closely to check quality. This helps keep standards high without doing extra, unnecessary tests.

A lab might find that some tests need more frequent quality checks because they vary more, while others work well with less monitoring.

Optimizing Quality Control

Six Sigma supports creating quality control plans that fit each test's needs. By using sigma values, labs can make flexible QC strategies that use resources wisely and cut down on unnecessary testing. This boosts efficiency and makes sure important tests get enough attention, lowering the chance of errors.

Also, by finding and fixing errors from things like reagent quality, instrument calibration, or how staff run tests, labs can improve their accuracy and reliability.

Reducing errors and improving patient outcomes

There is a strong link between high sigma scores and fewer lab errors. When labs reach higher sigma levels, they report fewer questionable results. This reliability helps doctors trust the results more, leading to better patient care.

Continuous improvement culture

Bringing Six Sigma into lab work encourages a culture of ongoing improvement. Labs are urged to regularly review their processes and results, making staff responsible for quality. This proactive mindset helps labs handle current issues and get ready for future changes in healthcare.

For example, as new technologies and testing needs come up, sticking to Six Sigma helps labs stay flexible and ready to adapt.

Case studies and real-world application

Many labs have used Six Sigma to make big improvements. For example, some clinical labs have reached Six Sigma levels for lost or damaged specimens, showing that this method can bring great results even in complex settings.

Law enforcement forensic labs have also used Lean and Six Sigma to cut down on testing backlogs, showing these methods work well in many types of labs.

Conclusion

This study shows that Six Sigma is not just a theory; it is a practical tool for improving laboratory test quality. This helps identify which tests are performing well and which need work. In this study, we found that the main problem for lower-performing analytes was imprecision rather than bias. This means that instead of changing the whole testing method, we can focus on reducing result variation by improving procedures and working conditions. When combined with QGI and root cause analysis, Six Sigma becomes a clear guide for deciding which changes will have the biggest impact on quality.

The larger message here is that the regular use of Six Sigma can help laboratories produce more accurate and reliable results and reduce the chance of errors that could affect patient care. It also helps laboratories use their resources better, focusing more on problem areas and avoiding unnecessary work on tests that are already performing well. Most importantly, it builds a culture in which the staff are always looking for ways to improve. To maintain these gains, laboratories need to continuously monitor their processes, regularly train their staff, and update their methods when necessary. In the long run, this approach increases trust in laboratory results, supports better clinical decisions, and improves the quality of healthcare for patients.

The integration of Six Sigma methodologies into clinical laboratory operations marks a significant and forward-thinking leap toward achieving excellence in patient care. This approach, rooted in structured, data-driven strategies, not only supports the identification and reduction of errors but also instills a mindset of continuous quality improvement in the laboratory environment. By methodically assessing each facet of the laboratory workflow, minimizing variability, and implementing well-targeted corrective actions, Six Sigma enables laboratories to achieve higher standards of analytical performance, use their resources more efficiently, and reduce the likelihood of diagnostic inaccuracies.

The benefits of adopting Six Sigma in clinical laboratory settings are both measurable and meaningful. These include quicker turnaround times for test results, increased consistency and reliability of processes, stronger staff involvement and motivation, and, most importantly, enhanced diagnostic precision. These improvements play a pivotal role in shaping better clinical decisions, which in turn leads to improved patient outcomes, an essential benchmark for measuring success in modern healthcare systems.

Moreover, as the healthcare landscape continues to grow in complexity—with rising patient expectations, technological advancements, and tightening regulatory standards, laboratories that implement Six Sigma are far better equipped to respond and adapt. These labs can not only meet these evolving demands but can do so while maintaining high standards of quality, safety, and compliance.

Looking ahead, clinical laboratories that aim to remain at the forefront of diagnostic excellence will need to make Six Sigma a sustained part of their operational philosophy. This involves investing in the ongoing education and training of staff, cultivating a culture that embraces innovation and critical thinking, and making full use of advanced data analytics to guide decision making. Ultimately, by embedding Six Sigma into the framework of their organizations, laboratories can ensure long-term efficiency, reinforce patient and clinician trust, and make a meaningful contribution to the broader mission of delivering high-quality, patient-centered healthcare.[10]

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