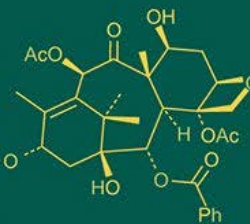
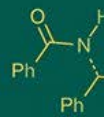
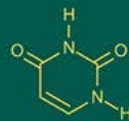
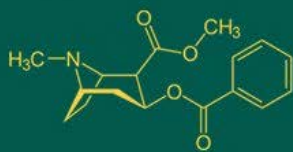


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Evaluation of analytical performance in renal biochemistry laboratory using Six Sigma Metrics

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Abstract

Introduction: Quality management in the healthcare system continues to be a central theme of discussion due to its direct impact on patient outcomes. Laboratory measurements inherently exhibit variability resulting from both random and systematic influences. Advances in precision medicine have increased the demand for highly accurate laboratory processes, necessitating more rigorous evaluation tools.

Materials and Methods: Quality control data were collected retrospectively from July 2024 to June 2025. Six Sigma metrics were calculated for 20 biochemical parameters analyzed using the Cobas C311 system, based on the coefficient of variation (CV%), bias, and total allowable error (TAE).

Results: Approximately 90% of the biochemical parameters fulfilled the Six Sigma criteria, while 10% required improvement.

Discussion: Our study results for sigma metrics showed excellent performance for 8 L1 QC and 9 L2 QC parameters; very good performance for 1 L1 QC and 7 L2 QC parameters; good performance for 5 L1 QC and 1 L2 QC parameters; satisfactory/acceptable performance for 3 L1 QC and 2 L2 QC parameters; and poor sigma metrics for 3 L1 QC and 1 L2 QC parameters. Although most modern laboratories are automated, ensuring accurate and precise laboratory results remains a challenge.

Conclusion: The implementation of Six Sigma metrics across laboratory processes enables the identification of errors and the introduction of innovative approaches for cost reduction without compromising quality. By systematically evaluating Six Sigma metrics, areas of strength and opportunities for improvement were clearly identified

Keywords: Quality control, Accuracy, Precision, Bias, Total Allowable Error, Six Sigma

Introduction

Quality management in the healthcare system continues to be a central theme of discussion, given its direct impact on patient outcomes. ^[1] Among various healthcare services, clinical laboratory testing plays a particularly essential role, with an estimated 70% of medical decisions relying on laboratory results. ^[2] The total testing process comprises three distinct phases—pre-analytical, analytical, and post-analytical—each contributing differently to overall laboratory error rates. Reported error frequencies range from 30–75% in the pre-analytical phase, 4–30% in the analytical phase, and 9–55% in the post-analytical phase. ^[3] These figures highlight the critical need for robust quality control practices to ensure the reliability of test results and to enhance patient care.

Laboratory measurements inherently exhibit variability due to random and systematic influences. ^[4, 6] Bias, defined as the systematic deviation of a test result from the true value, can significantly affect diagnostic accuracy, prognosis estimation, and healthcare costs. ^[7-9] Quality in laboratory medicine is therefore defined as conformance to user requirements, ^[10] forming the basis for analytical accuracy and precision. Quality control (QC) practices are traditionally divided into external quality assessment (EQA) and internal quality control (IQC). ^[11] While EQA provides periodic evaluation through comparison with external reference laboratories, IQC ensures continuous monitoring of analytical performance. Together, these systems help maintain result reliability prior to report release.

Advances in precision medicine have increased the demand for highly accurate laboratory processes, necessitating more rigorous evaluation tools. This has brought increasing attention to the Six Sigma management methodology as a means to reduce errors, enhance process capability, and support continuous improvement. ^[12] Originally developed by Bill Smith at

Motorola and later introduced in China in the late 1990s, Six Sigma principles began finding application in healthcare management after 1991.^[13]

Six Sigma employs a structured framework consisting of five stages: Define, Measure, Analyze, Improve, and Control (DMAIC). Mathematically, sigma represents standard deviation, reflecting the degree of variation in a process.^[14] Six Sigma metrics quantify errors in terms of defects per million opportunities (DPMO) and provide a standardized scale for assessing process performance.^[15] As an evolution of Total Quality Management (TQM), sigma metrics offer a more objective and quantitative method to identify errors, evaluate analytical quality, and guide process optimization within clinical laboratories.^[14]

The corresponding sigma levels and expected defects per million (DPM) tests are summarized below:

Table 1: DPM at Various Sigma Level

Six Sigma Level	Percentage Accuracy	Defects per Million (DPM)
6	99.9997%	3.4
5	99.98%	233
4	99.4%	6,210
3	93.3%	66,807
2	69.1%	308,537
1	31%	698,000

Given the high diagnostic value of renal biochemical testing and the need for optimal analytical performance, the present study was undertaken to assess quality system processes in a Renal Biochemistry Laboratory using Six Sigma metrics and to implement corrective actions aimed at improving analytical quality.

Aim: To retrospectively evaluate and analyze the quality control (QC) procedures in a Renal biochemistry laboratory and to implement corrective measures to improve analytical performance using the Six Sigma scale.

Materials and Methods

This retrospective study was conducted in the accredited Shankara Laboratories Abhiramapuram, Chennai, Tamil Nadu, India. Internal Quality Control (IQC) and External Quality Assurance Scheme (EQAS) data from July 2024 to June 2025 were analyzed for 20 Biochemical parameters.

As per the laboratory's QC policy, two levels of controls were used: Level 1 (normal) and Level 2 (abnormal). Biochemical parameters were analyzed on the Cobas C311 system using Bio-Rad control QC materials. Levy-Jennings charts were verified for QC deviations. Corrective actions, if required, were taken prior to processing patient samples and releasing reports.

Results

Table 4: (CV1) Coefficient of variation (CV)% of level 1 IQC for 12 months (July 2024 to June 2025)

S.no	Parameter	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	March	April	May	June	Mean
1	Albumin	1.48	1.65	1.64	1.33	1.54	1.82	2.25	1.82	1.1	1.75	1.98	1.4	1.65
2	ALP	1.19	1.53	1.84	1.28	1.93	1.64	1.29	1.66	1.46	2.13	1.76	0.96	1.56
3	ALTL	5.97	6.18	3.1	5.37	4.35	3.54	6.27	4.04	4.93	6.67	5.15	4.26	4.99
4	ASTL	3.22	3.54	4.98	6.15	5.05	4	2.58	4.18	2.9	4.13	2.04	2.04	3.73
5	BIL D	3.71	2.74	3.11	3.23	5.42	4.44	2.78	2.97	3.72	3.47	2.8	2.95	3.45

Six Sigma Metrics

The Six Sigma metrics for each parameter were calculated using imprecision (CV%), bias, total allowable error (TAE) and Quality Index Goal (QGI) as described below:

Coefficient of Variation (CV%)

$$CV\% = \frac{\text{Standard Deviation (SD)}}{\text{Laboratory Mean}} \times 100$$

Bias (%)

Bias was determined from monthly EQAS results provided by Bio-Rad peer group data:

$$\text{Bias (\%)} = \frac{\text{Peer Group Mean} - \text{Laboratory Reported Value}}{\text{Peer Group Mean}} \times 100$$

Total Allowable Error (TAE)

TAE incorporates both imprecision and bias (trueness) to assess the acceptability of a test method. TAE values were obtained from the Clinical Laboratory Improvement Amendments (CLIA) 2025 proficiency testing criteria (16). For parameters not listed in CLIA, equivalent data from the Royal College of Pathologists of Australasia (RCPA) guidelines were used.

Six Sigma Calculation

The sigma metrics were calculated using the following formula:

$$\sigma = \frac{\text{TAE} - \text{Bias\%}}{\text{CV\%}}$$

Table 2: Performance of Sigma Metrics

S.No	Sigma Metrics	Performance
1	>6	Excellent
2	<6 - >5	Very good
3	<5 - >4	Good
4	<4 - >3	Satisfactory
5	<3	Poor

Quality Goal Index (QGI)

It represents the relative extent to which both bias and precision meet their respective goals. It is calculated as follows:

$$QGI = \frac{\text{Bias}}{1.5} \times \text{CV\%}$$

QGI

Table 3: QGI Outcome

<0.8	Imprecision
8 - 1.2	Imprecision & Inaccuracy
> 1.2	Inaccuracy

6	BIL T	4.52	0.85	2.25	1.86	3.4	2.61	2.07	5.18	2.29	2.34	4.28	4.59	3.02
7	Calcium	0.95	1.1	1.25	1.6	1.34	1.37	0.97	0.96	2.05	1.81	1.65	1.09	1.35
8	LDL	1.62	1.62	2.81	1.92	2.76	2.23	1.19	1.27	3.83	5.91	2.5	6.53	2.85
9	HDL	0.96	1.19	1.52	3.86	3.86	1.97	2.58	1.2	1.16	2.31	3.23	1.9	2.15
10	Cholesterol	1.42	1.38	1.11	1.51	1.24	1.04	1.26	1.09	1.66	1.33	2	1	1.34
11	Creat J	2.52	2.55	2.41	2.06	1.83	2.03	1.88	1.86	1.91	1.91	3.5	4.49	2.41
12	Glucose	1.36	1.6	1.61	1.4	1.38	1.37	1.16	1.04	1.65	2.83	2.71	0.56	1.56
13	IRON	1.47	1.32	1	1.03	1.6	1.54	1.85	1.04	1.67	1.42	1.14	0.77	1.32
14	Magnesium	2.94	2.88	2.6	4	2.76	2.56	2.74	2.38	2.59	2.82	2.71	2.81	2.82
15	Phosphorous	2.4	2.32	2.6	3.04	2.21	1.6	1.81	2.25	2.29	1.88	2.26	0.82	2.12
16	T.Protein	2.2	1.38	1.72	2.26	2.85	1.56	1.68	1.2	1.44	1.04	1.26	1.6	1.68
17	TGL	0.83	1.16	1.03	1.12	1.22	1.23	2.09	1.28	2.29	1.83	2.16	0.66	1.41
18	Urea	1.5	1.81	1.49	1.3	1.61	1.29	1.65	1.63	2.56	1.97	2.16	1.63	1.72
19	Uric acid	1.14	1.14	1.35	1.33	0.87	0.87	1.1	1.11	1.34	1.56	1.77	2.19	1.31
20	GGT	2.65	2.91	2.41	2.23	2.56	3.41	1.89	2.09	1.72	3.39	2.41	0.87	2.38

Table 5: (CV2) Coefficient of variation (CV)% of level 2 IQC for 12 months (July 2024 to June 2025)

S. No	Parameter	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	March	April	May	June	Mean
1	Albumin	2.11	3.06	2.21	2.15	1.57	2.33	2.81	1.44	1.88	1.79	1.97	1.84	2.10
2	ALP	1.27	1.05	1.4	1.61	2.02	1.08	0.87	0.97	1.44	4.91	1.86	1.17	1.64
3	ALTL	1.55	1.47	1.58	2.61	2.61	2.16	3.55	1.65	2.19	4.65	2.39	0.83	2.27
4	ASTL	2.71	1.73	1.96	2.72	1.28	0.99	2.22	2.33	1.12	2.5	1.87	0.5	1.83
5	BIL D	1.73	2.39	1.79	2.72	3.04	2.92	1.98	2.43	1.8	2.26	2.98	1.71	2.31
6	BIL T	2.4%	2.25	1.22	1.41	1.51	1.29	2.09	5.24	2.47	1.67	2.96	3.52	2.14
7	Calcium	0.92	0.92	1.5	0.89	1.09	1.42	0.55	0.9	2.07	1.96	1.75	0.59	1.21
8	LDL	1.4	1.73	2.82	1.81	2.96	2.32	1.15	1.46	4.39	5.1	3.71	6.72	2.96
9	HDL	2.13	2.14	1.26	2.93	3.52	0	4.04	0.87	2.11	3.15	3.51	2.11	2.31
10	Cholesterol	1.52	1.4	1.21	1.7	1.49	1.01	1.52	1	2	1.99	2.2	0.8	1.49
11	Creat J	1.8	1.73	1.55	1.56	0.95	1.32	1.26	1.5	1.49	1.47	2.98	4.54	1.85
12	Glucose	1.23	1.44	1.23	1.45	1.16	0.75	1.14	0.93	1.32	2.86	2.5	1.16	1.43
13	IRON	3.21	3	2.6	1.95	2.49	2.19	3.12	4.54	2.06	2.06	2.43	1.8	2.62
14	Magnesium	1.21	1.2	1.3	1.98	1.9	1.46	1.41	1.72	1.3	1.31	1.38	4.7	1.74
15	Phosphorous	1.14	1.43	1.69	1.29	1.35	1.19	1.14	1.59	1.55	1.23	1.65	0.77	1.34
16	T.Protein	1.98	1.51	1.8	2.92	2.84	1.69	2.58	1.9	1.19	1.38	1.79	1.59	1.93
17	TGL	1.38	1.46	1.22	1.71	1.52	1.12	2.55	1.8	2.8	2.87	3.87	3.25	2.13
18	Urea	1.16	1.71	1.15	1.22	1.23	1.24	1.26	1.34	2.02	1.36	2	1.87	1.46
19	Uric acid	0.96	0.95	0.84	1.23	0.92	0.72	0.93	1.14	1.25	1.24	1.33	0.41	0.99
20	GGT	2.22	1.85	1.85	1.89	1.28	1.28	1.22	1.61	1.06	2.29	2.29	1.69	1.71

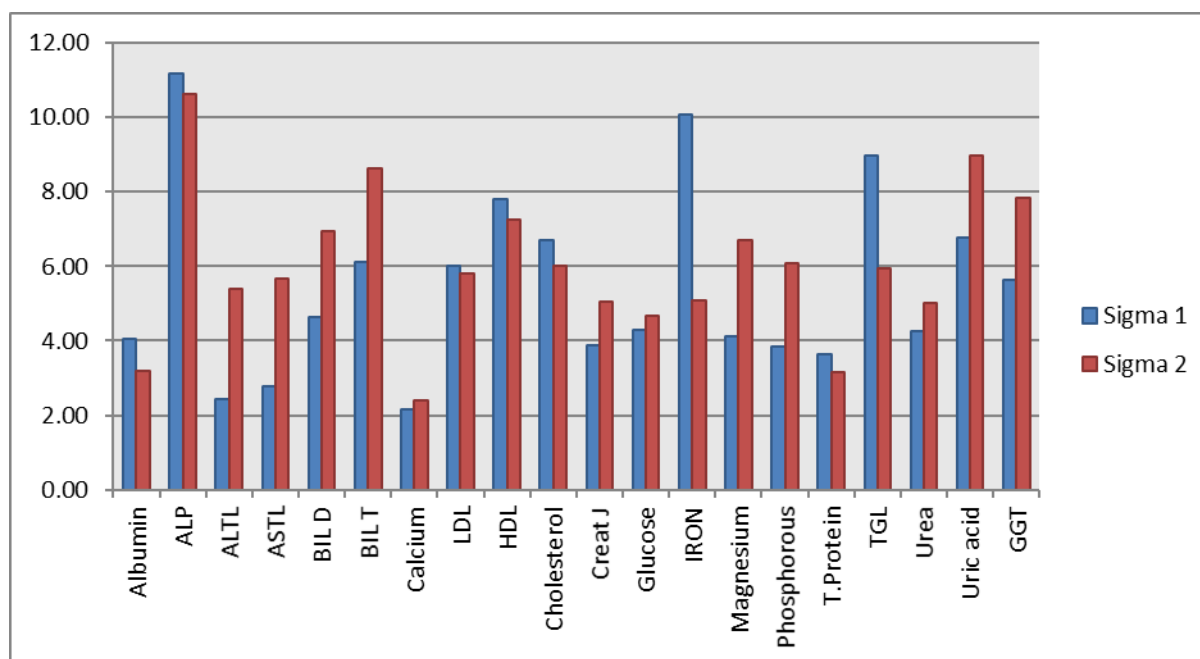
Table 6: Bias% for biochemical parameters Bio-Rad EQAS cycle 16

S. No	Parameter	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	Mean
1	Albumin	0.74	4.14	1.35	1.18	2.72	0.77	1.21	0.55	0.71	0.61	1.23	0.72	1.33
2	ALP	0.22	8.12	0.38	8.58	1.79	1.91	0.33	3.1	1.88	0.48	2.13	1.68	2.55
3	ALTL	3.01	10.23	5.85	1.03	6.73	1.05	2.46	0.08	0.36	0.74	0.72	1.27	2.79
4	ASTL	0.67	35.24	0.2	1.86	5.39	0.68	1.1	0.86	1.61	0.9	1.71	5.51	4.64
5	BIL D	5.27	2	6.1	6.81	0.3	6.84	3.34	3.95	0.63	1.62	10.6	0.63	4.00
6	BIL T	0.15	3.53	0.16	0.17	2.57	3.5	1.29	1.16	2.22	2.59	0.13	1.16	1.55
7	Calcium	1.72	1.37	1.8	1.04	1.05	2.08	2.29	0.08	1.03	0.06	0.17	0.33	1.09
8	LDL	6.97	0.38	2.77	4.52	1.66	0.97	1.83	1.93	2.16	3.36	2.41	5	2.83
9	HDL	2.39	3.33	9.3	0.31	6.78	5.17	0.78	0.01	2.18	5.55	2.27	0.57	3.22
10	Cholesterol	1.34	1.51	1.39	0.38	2.42	1.21	0.24	0.19	0.01	0.48	1.15	2.08	1.03
11	Creat J	0.03	1.46	0.14	0.11	1.16	0.93	0.69	0.5	0.45	0.03	0.43	1.62	0.63
12	Glucose	0.52	1.53	2.11	0.08	1.72	2.33	0.39	0.92	0.98	2.07	1.06	2.27	1.33
13	IRON	0.87	0.06	0.9	2.45	3.1	2.23	0.86	3.53	2.36	0.93	0.49	2.9	1.72
14	Magnesium	1.75	6.49	4.15	1.12	10.4	4.46	2.56	1.65	4.73	0.88	1.63	0.48	3.36
15	Phosphorous	0.73	5.88	3.27	1.19	1.41	1.35	4.38	0.33	1.32	0.67	0.85	1.03	1.87
16	T.Protein	3.6	2.56	0.31	4.37	1.24	3.07	0.16	2.76	0.8	0.89	1.49	1.47	1.89
17	TGL	0.08	3.61	4.91	2.36	5.79	3.07	0.37	0.29	0.86	0.06	0.72	5.89	2.33
18	Urea	0.84	0.65	1.95	1.35	1.05	1.86	0.14	1.46	1.79	1.16	1.46	6.63	1.70
19	Uric acid	2.5	0.4	1.9	0.22	0.13	1.24	1.21	0.91	2.95	1.1	0.6	0.1	1.11
20	GGT	2.35	1.52	2.94	1.99	0.09	0.24	1.27	0.1	1.38	1.39	2.19	3.81	1.61

Table 7: Six Sigma Metrics for level 1 and level 2 IQC

S. No	Parameter	Bias%	CV1	CV2	T A E	Sigma 1	Sigma 2
1	Albumin	1.33	1.65	2.10	8	4.05	3.18
2	ALP	2.55	1.56	1.64	20	11.22	10.64
3	ALT	2.79	4.99	2.27	15	2.45	5.38
4	AST	4.64	3.73	1.83	15	2.77	5.66
5	BIL D	4.00	3.45	2.31	20*	4.64	6.92
6	BIL T	1.55	3.02	2.14	20	6.11	8.62
7	Calcium	1.09	1.35	1.21	4*	2.17	2.41
8	LDL	2.83	2.85	2.96	20	6.03	5.80
9	HDL	3.22	2.15	2.31	20	7.82	7.26
10	Cholesterol	1.03	1.34	1.49	10	6.71	6.02
11	Creat J	0.63	2.41	1.85	10	3.88	5.07
12	Glucose	1.33	1.56	1.43	8	4.29	4.66
13	IRON	1.72	1.32	2.62	15	10.05	5.07
14	Magnesium	3.36	2.82	1.74	15	4.13	6.69
15	Phosphorous	1.87	2.12	1.34	10	3.83	6.07
16	T.Protein	1.89	1.68	1.93	8	3.63	3.16
17	TGL	2.33	1.41	2.13	15	8.99	5.95
18	Urea	1.70	1.72	1.46	9	4.26	5.00
19	Uric acid	1.11	1.31	0.99	10	6.77	8.98
20	GGT	1.61	2.38	1.71	15	5.63	7.83

* TAE Source From RCPA.

**Fig 1:** Average Sigma of analytes Tested**Table 8:** Six sigma performance of 20 biochemical parameters

S. No	Sigma Metrix	Performance	Level 1	%	Level 2	%
1	>6	Excellent	8	40	9	45
2	<6 - >5	Very good	1	5	7	35
3	<5 - >4	Good	5	25	1	5
4	<4 - >3	Satisfactory	3	15	2	10
5	<3	Poor	3	15	1	5

Discussion

Our study results for sigma metrics showed excellent performance for 8 L1 QC and 9 L2 QC parameters, very good performance for 1 L1 QC and 7 L2 QC parameters, good performance for 5 L1 QC and 1 L2 QC parameters, satisfactory/acceptable performance for 3 L1 QC and 2 L2 QC parameters, and poor sigma metrics for 3 L1 QC and 1 L2 QC parameters (Table 8).

In our study, we evaluated the analytical performance of 20 frequently requested renal biochemical parameters. Among these, five parameters—Alkaline Phosphatase (ALP), Bilirubin Total, High-Density Lipoprotein Cholesterol (HDL), Cholesterol, and Uric Acid—showed excellent performance for both L1 and L2 QCs. Seven parameters, namely Bilirubin Direct, Low-Density Lipoprotein Cholesterol (LDL), Iron, Triglycerides (TGL), Magnesium, Phosphorus, and Gamma-Glutamyl Transferase (GGT), showed excellent performance for one level of QC. Five parameters—Albumin, Creatinine (Jaffe), Glucose, Total Protein, and Urea—exhibited satisfactory/acceptable performance for both levels of QC. Aspartate Transaminase (AST), Alanine Transaminase (ALT), and Calcium showed poor sigma metrics (<3), with AST and ALT poor at one QC level and Calcium poor at both QC levels. (Fig. 1)

We performed root cause analysis and calculated the Quality Goal Index (QGI) for these three poor-performing parameters. QGI indicated inaccuracy for both AST and ALT (requiring focus on EQAS). For Calcium, we observed both inaccuracy and imprecision (requiring focus on EQAS and IQC). The inaccuracy for AST and ALT was likely due to bias deviation during August 2024 caused by random error. For Calcium, we decided to strengthen IQC and calibration frequency, and also to explore alternative methodologies such as ionized calcium. Although most modern laboratories are automated, ensuring accurate and precise laboratory results remains a challenge^[17]. Although IQC provides continuous monitoring of analytical methods, the exact number of errors occurring during the analytical phase cannot be fully evaluated^[18]. The analytical phase is

particularly crucial, as it involves personnel, instruments, and methodologies. Method validation studies, the application of QC sampling procedures, and frequent training programs have considerably reduced analytical errors^[19, 20]

Six Sigma metrics integrate both internal and external quality control performance; both components are essential tools for evaluating the quality and stability of the analytical system. The application of Six Sigma metrics is necessary to minimize variance and enhance QC processes, thereby improving compliance with vital quality requirements. Sigma metrics also help assess the use of superior analytical methods to improve overall laboratory performance.

Numerous studies have reported six sigma performance in biochemical parameters, summarized in Table 9.

Table 9: Comparison of Various Indian Studies on Six Sigma Performance

Study	Study Period (months)	No. of Parameters	Instrumentation	CV Source	Bias Source	TAE Source	Sigma L1 and L2		
							>6	3-6	<3
Study 1	6	15	Olympus	Randox	RIQAS	CLIA	4	6	5
Study 2	6	13	Cobas Integra	Bio-Rad	CMC	CLIA	5	4	4
Study 3	4	10	ILAB-650	Bio-Rad	Bio-Rad	CLIA	-	7	3
Study 4	12	12	Cobas Integra 400 plus	Randox	Bio-Rad	CLIA	6	6	2
Study 5	12	16	Vitros 4600	Bio-Rad	Bio-Rad	CLIA	4	7	5
							4	8	4
Study 6	12	23	–	–	–	RICOS	11	10	2
							11	12	-
Study 7	6	16	BC AU5800	Bio-Rad	Bio-Rad	CLIA	2	5	9
Present Study	6	23	Cobas C311	Bio-Rad	Bio-Rad	CLIA	8	9	3
							9	10	1

Details of various Indian studies on six sigma metrics shown in table 6, Study 1 Singh B *et al*^[21], Study 2 Nanda SK *et al*^[11], Study 3 Chaudhary NG *et al*^[22], Study 4 Chauhan KPC *et al*^[23], Study 5 Kumar BV *et al*^[24], Study 6 Lakshnam M *et al*^[25], Study 7 Suresh Babu Ganji *et al*^[26].

A major strength of this study is its 12-month duration, which provided a robust reflection of the data, as accuracy and imprecision estimates improve with larger datasets^[27]. Additionally, third-party QC materials were used. It is recommended that, whenever possible, third-party QC materials be used rather than manufacturer-supplied control materials. When QC materials differ from calibrator materials, they provide an independent and unbiased assessment of the measurement procedure's performance^[28], overall 90% of routine renal biochemistry parameters fulfilled six sigma metrics and 10% required improvement.

Conclusion

Physicians increasingly rely on laboratory-generated information for disease diagnosis, patient monitoring, treatment planning, and evaluation of treatment effectiveness. Laboratories should therefore aim to minimize errors that can negatively affect patient outcomes. The implementation of Six Sigma metrics across laboratory processes enables the identification of errors and the introduction of innovative approaches for cost reduction without compromising quality. By systematically evaluating Six Sigma metrics, areas of strength and opportunities for improvement were clearly identified. This approach not only highlighted the reliability of well-performing assays but also provided a structured framework for corrective action in parameters falling below desirable Sigma metric levels. The Sigma metrics tool has the potential to be a valuable quality-

management instrument for monitoring analytical performance in comparison with world-class standards. Overall, Sigma metrics serves as a valuable tool in clinical laboratories, supporting error reduction, process optimization, and continuous improvement to ensure high standards of patient care and diagnostic reliability

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