DOI: 10.7860/JCDR/2026/85000.22571

Original Article

Biochemistry Section

Evaluation of Non Conformances in the Total Testing Process of a NABL-accredited Clinical Biochemistry Laboratory: An Observational Study

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ABSTRACT

Introduction: Maintaining quality within clinical laboratories is fundamental to patient safety and reliable diagnosis. Every stage of the Total Testing Process (TTP) from sample collection to result reporting, is prone to errors that can affect both clinical decisions and operational efficiency. Systematic identification and analysis of Non Conformances (NCs) form an integral part of accreditation and continual quality improvement.

Aim: To analyse the nature, frequency, and underlying causes of NCs in a National Accreditation Board for Testing and Calibration Laboratories (NABL)-accredited, clinical biochemistry laboratory attached to a medical college

Materials and Methods: An observational study was conducted in the Clinical Biochemistry Laboratory of a tertiary care teaching hospital located in rural Gujarat, India, over a 12-month period, from March 2023 to February 2024. All recorded NCs were reviewed and categorised according to seven domains, including type, recurrence, severity, root cause, and impact. Root Cause Analysis (RCA) was undertaken using the "5 Whys" and Fishbone (Ishikawa) diagram approaches. Data were analysed descriptively and expressed as frequencies and percentages.

Results: A total of 439 NCs were documented. Pre-analytical errors were most frequent (53.30%), followed by analytical (43.51%) and post-analytical (3.19%) errors. Human error (62.18%) and technical factors (36.90%) were the main root causes. Most NCs were isolated (76.77%) and minor (70.16%), chiefly affecting resource utilisation (59.91%) and turnaround time (29.16%).

Conclusion: Pre-analytical weaknesses and human-related factors remain the key contributors to laboratory NCs. Regular monitoring, structured RCA, and continuous staff training are essential to sustain accuracy, efficiency, and quality within clinical biochemistry laboratories.

Keywords: Clinical chemistry tests, Medical laboratory techniques, National accreditation board for testing and calibration laboratories, Patient safety, Quality control, Root cause analysis

INTRODUCTION

Ensuring quality in healthcare involves consistently meeting the expectations and needs of patients, clinicians, and regulatory bodies [1,2]. In clinical laboratories, quality is primarily reflected in the accuracy, timeliness, and reliability of test results, which are critical for effective clinical decision-making [3,4]. Laboratory data influence an estimated 60-70% of key medical decisions, including diagnosis, treatment planning, and patient discharge [5,6]. Consequently, even minor laboratory errors can have significant downstream effects on patient outcomes, underscoring the need for stringent quality practices at every stage of testing [7-9]. To reduce errors and ensure dependable reporting, laboratories have adopted a combination of automation, structured quality control programs, and trained personnel [10]. International agencies such as the World Health Organisation (WHO), the International Organisation for Standardisation (ISO), and the Clinical and Laboratory Standards Institute (CLSI) provide comprehensive frameworks for laboratory quality management [11]. These emphasise not only immediate error correction but also systematic RCA and preventive action as essential components of a mature quality system.

In India, the NABL provides voluntary accreditation, which has become increasingly sought after. Accreditation strengthens institutional credibility, improves stakeholder confidence, and aligns laboratories with international standards [12-14]. The clinical biochemistry laboratory is a cornerstone of hospital diagnostic services. Due to high sample volumes and the multiple steps involved in the Total Testing Process (TTP)-encompassing pre-analytical, analytical, and post-analytical phases-errors can arise at any point [15,16]. The ISO 15189:2022 mandates that laboratories identify, document, and address NCs, defined as deviations from established procedures, across all phases of testing. Reported error rates vary widely, with 30-75% in the pre-analytical, 4-30% in the analytical, and 9-55% in the post-analytical phases [17].

A robust Quality Management System (QMS) is central to achieving and maintaining accreditation. Regular internal audits and systematic evaluation of NCs enable laboratories to identify error patterns, implement corrective and preventive measures, and drive continuous quality improvement. Within this framework, NCs analysis serves as a powerful tool to understand operational weaknesses, reduce variability, and enhance patient safety.

Previous studies from India and other countries have reported NCs across different phases of the TTP, with most highlighting the predominance of pre-analytical and human-related errors [10,18]. However, much of this literature comes from laboratories that are either non accredited or operate on open-channel systems using locally prepared reagents, where workflow and quality practices differ considerably from accredited settings [19]. Many of these studies also provide only limited categorisation of NCs and do not routinely apply structured root-cause analysis tools such as the 5 Whys or the Fishbone method [10,18,19]. In addition, the operational impact of these NCs -such as their effect on turnaround time, resource utilisation, or compliance—is not consistently evaluated [18]. There is very little published evidence from NABL-accredited laboratories

functioning on closed-system, fully automated platforms. This gap highlights the need and novelty of the present study, which analyses NCs in a NABL-accredited, closed-system biochemistry laboratory attached to a medical college.

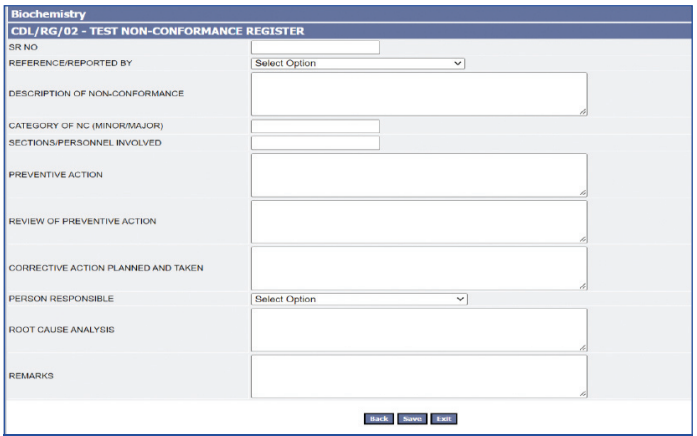
MATERIALS AND METHODS

An observational study was conducted in the Clinical Biochemistry Laboratory of a tertiary care teaching hospital located in rural Gujarat, India, over a 12-month period, from March 2023 to February 2024. The laboratory is accredited by the NABL. Ethical approval for the study was obtained from the Institutional Ethics Committee. (IEC/BU/143/Faculty/43/348/2023).

Study Procedure

Data collection and documentation of NCs

All documented instances of deviations from established standard operating procedures were included. NCs were identified as part of routine quality management activities, including internal audits, quality control checks, and feedback mechanisms. Each event was recorded in the Laboratory Information System (LIS) using a standardised NC reporting form. This form captured a unique identification number, reporting personnel, location and description of the incident, classification as major or minor, details of corrective and preventive actions, and subsequent evaluation of action effectiveness. The format used for documentation is shown in [Table/Fig-1].


Biochemistry

CDL/RG/02 - TEST NON-CONFORMANCE REGISTER

SR NO

REFERENCE/REPORTED BY — Select Option

DESCRIPTION OF NON-CONFORMANCE

CATEGORY OF NC (MINOR/MAJOR)

SECTIONS/PERSONNEL INVOLVED

PREVENTIVE ACTION

REVIEW OF PREVENTIVE ACTION

CORRECTIVE ACTION PLANNED AND TAKEN

PERSON RESPONSIBLE — Select Option

ROOT CAUSE ANALYSIS

REMARKS

Back Save Edit

[Table/Fig-1]: Format used for recording NCs.

Root cause analysis was performed for each NC using two structured approaches: the "5 Whys" method [20] to trace direct causal factors, and Fishbone (Ishikawa) diagrams [21] to identify contributory elements at technical, human, process, and external levels. Findings from the analyses guided corrective and preventive actions, which were implemented and reviewed for their effectiveness over time.

Classification of Non Conformances (NCs)

Each recorded NC was systematically categorised under seven domains to enable structured analysis: (1) analytical procedure classification, (2) type of NC, (3) recurrence pattern, (4) severity grading, (5) root cause classification, (6) impact on results, and (7) source of NC [15-17].

1. **Analytical procedure classification:** NCs were classified according to the specific phase of the total testing process in which they occurred. Pre-analytical deviations comprised errors related to specimen collection, patient identification, labelling, transport, and initial processing before analysis. Analytical NCs included issues arising during the testing phase, such as instrument malfunction, calibration drift, reagent problems, and internal quality control failures. Post-analytical deviations referred to discrepancies during result transcription, verification, report generation, and communication with clinical areas. This phase-wise classification allowed clear identification of where failures most commonly originated within the workflow [15-17].
2. **Type of Non Conformance (NCs):** Non conformances were further grouped based on their nature and underlying characteristics. Equipment-related issues involved analyser malfunction or calibration errors. Procedural deviations reflected departures from established standard operating procedures or testing protocols. Documentation-related NCs included incomplete, inaccurate, or missing entries in technical or administrative records. Personnel-related issues were attributed to inadequate training, execution errors, or lapses in adherence to standard practices. Sample-related NCs included mislabelling, improper storage, haemolysis, insufficient volume, or delays during transport. Environmental factors involved disruptions such as temperature fluctuations, contamination, or workspace-related problems. Supplier-related issues included reagent instability, compromised consumables, or other defects related to externally sourced materials.
3. **Recurrence pattern:** The recurrence of NCs was categorised as isolated (single occurrence with no previous incidents), intermittent (sporadic events without a consistent pattern), or chronic (repeated occurrences indicative of systemic issues).
4. **Severity grading:** Severity was graded as critical (posing immediate risk to patient safety or data integrity), major (causing significant operational impact without immediate patient harm), or minor (administrative or low-impact issues).
5. **Root cause classification:** Root causes were grouped into four categories: technical factors (e.g., equipment malfunction, methodological errors), human error (e.g., execution mistakes, communication gaps), process failures (e.g., procedural gaps, inadequate quality checks), and external factors (e.g., supplier issues, environmental influences, regulatory changes).
6. **Impact on results:** The impact of each NC was assessed in terms of data integrity, turnaround time, resource utilisation, and regulatory compliance.
7. **Source of NC** Sources were classified as Internal Quality Control and External Quality Assurance (IQC/EQA) checks, technical failures, clinical feedback from healthcare providers, resource management deficiencies, sampling errors (e.g., haemolysis, misidentification), internal or external audits, and miscellaneous factors such as housekeeping lapses and accidental spills.

Root Cause Analysis (RCA)

The NCs deemed critical or recurring underwent detailed RCA. The "5 Whys" technique helped identify immediate causal links, while Fishbone diagrams facilitated a broader assessment of systemic issues. The combination of both methods ensured a comprehensive evaluation. Corrective and preventive actions were formulated based on the analysis, documented in the LIS, and followed up to assess their effectiveness in preventing recurrence.

Data Analysis

All NC data were compiled in Microsoft Excel and analysed using descriptive statistics. Frequencies and proportions were calculated for each classification domain, recurrence pattern, severity level, and root cause category. Results were expressed as absolute numbers and percentages to identify trends and priority areas for quality improvement.

RESULTS

A total of 439 NCs were documented during the study period. These NCs were systematically categorised, and their frequency distribution was calculated as percentages.

Out of 439 NCs, 234 (53.30%) occurred in the pre-analytical phase, 191 (43.51%) in the analytical phase, and 14 (3.19%) in the post-analytical phase [Table/Fig-2]. The predominance of pre-analytical errors indicates that most deviations originated before sample testing, primarily during collection, labelling, or transportation.

Type of error	n (%)
Pre-analytical Error	234 (53.30)
Analytical Error	191 (43.51)
Post-analytical Error	14 (3.19)
Total	439 (100)

[Table/Fig-2]: Frequency of NCs related to analytical procedure.

Procedural errors were the most frequent (29.61%), followed by personnel-related (24.60%) and equipment-related issues (19.82%). Environmental (11.62%) and sample-handling (11.39%) NCs were less common, while documentation (2.51%) and supplier-related issues (0.45%) were infrequent [Table/Fig-3].

Type of NC	n (%)
Equipment	87 (19.82)
Procedure	130 (29.61)
Documentation	11 (2.51)
Personnel	108 (24.60)
Sample handling	50 (11.39)
Environmental	51 (11.62)
Supplier	02 (0.45)
Total	439 (100)

[Table/Fig-3]: Frequency of NCs related to type of NC.

Most NCs (76.77%) were isolated incidents, 21.18% were intermittent, and only 2.05% were chronic [Table/Fig-4]. The predominance of isolated events indicates effective corrective action and minimal recurrence of systemic issues.

Occurrence of NC	n (%)
Isolated Incident	337 (76.77)
Intermittent	93 (21.18)
Chronic	09 (2.05)
Total	439 (100)

[Table/Fig-4]: Frequency of NCs related to recurrence.

The majority of NCs were minor 70.16%, 28.02% were major, and only 1.82% were critical [Table/Fig-5]. These findings suggest that while NCs were frequent, most had limited impact on patient safety or data integrity.

Grading of NC	n (%)
Critical	08 (1.82)
Major	123 (28.02)
Minor	308 (70.16)
Total	439 (100)

[Table/Fig-5]: Frequency of NCs related to severity of NC.

Human error was identified as the most common root cause, accounting for 62.18% of NCs, followed by technical factors (36.90%). System failures and external factors contributed minimally (0.46% each) [Table/Fig-6]. These findings highlight the continuing influence of human factors on laboratory quality performance.

The majority of NCs affected resource utilisation (59.91%), followed by turnaround time (29.16%) and data integrity (10.02%). Only 0.91% affected regulatory compliance [Table/Fig-7]. These results indicate that most NCs influenced operational efficiency rather than analytical accuracy.

RCA	n (%)
Technical	162 (36.90)
Human Error	273 (62.18)
System Failure	02 (0.46)
External Factors	02 (0.46)
Total	439 (100)

[Table/Fig-6]: Frequency of NCs related to Root Cause Analysis (RCA).

Impact on result	n (%)
Data integrity	44 (10.02)
Turnaround time	128 (29.16)
resource utilisation	263 (59.91)
Regulatory compliance	04 (0.91)
Total	439 (100)

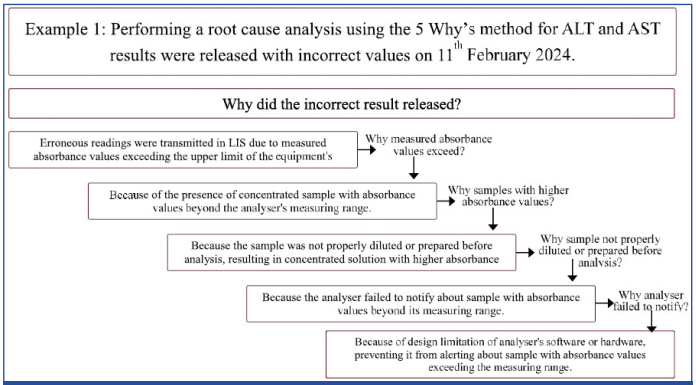
[Table/Fig-7]: Frequency of NCs related to impact on result.

The IQC contributed to 32.35% of NCs, followed by technical issues (29.84%) and sampling errors (27.79%) [Table/Fig-8]. EQA, clinical feedback and audit findings together accounted for less than 10% of all NCs.

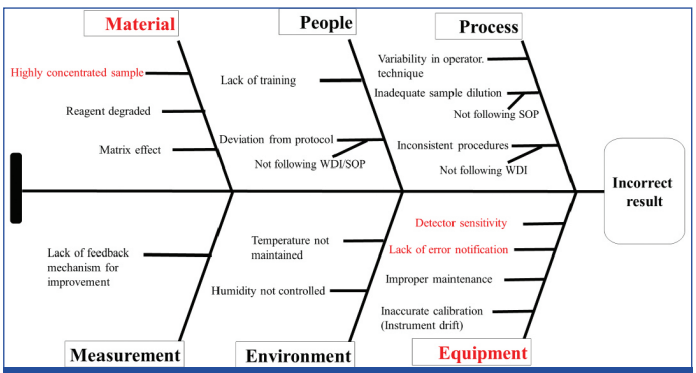
Source	n (%)
Internal quality control (IQC)	142 (32.35)
External quality assurance(EQA)	23 (5.24)
Technical	131 (29.84)
Feedback	05 (1.14)
Inefficient resource Management	03 (0.68)
Sampling error	122 (27.79)
Internal audit	04 (0.91)
External audit	02 (0.46)
Others	07 (1.59)
Total	439 (100)

[Table/Fig-8]: Frequency of NCs related to source.

Root cause analysis was applied to selected critical NCs using both the "5 Whys" and Fishbone diagram approaches [Table/Fig-9,10].



[Table/Fig-9]: RCA of the incorrect result released by 5 Why's method.



[Table/Fig-10]: RCA of the incorrect result released by the Fishbone diagram.

One representative incident involved the release of incorrect Alanine Aminotransferase (ALT) and Aspartate Aminotransferase (AST) results, which were inconsistent with the patient's clinical condition. Investigation revealed a high absorbance error that exceeded the analyser's measurable range. Manual dilution of the affected samples reduced analyte concentration, allowing accurate measurement within the instrument's linear range. The reanalysis confirmed the corrected results.

This event highlighted the importance of manual verification in identifying out-of-range absorbance errors that may not be flagged by automated systems. It also emphasised the need for collaboration with equipment manufacturers to enhance software and hardware mechanisms for detecting and preventing similar events in the future.

Overall, pre-analytical and analytical errors accounted for the majority of NCs, with human error being the leading root cause. Although most deviations were minor and isolated, their cumulative impact was significant in terms of resource utilisation and turnaround time. These findings underline the importance of targeted interventions focusing on staff training, process standardisation, and continual monitoring to strengthen laboratory quality systems.

DISCUSSION

A laboratory can better understand where errors come from and how they impact overall performance by evaluating NCs across the whole testing process. The majority of the aberrations in the current investigation happened during the pre-analytical stage, a pattern that has been repeatedly documented in the literature [10,22]. Due to its heavy reliance on manual processes like collection, identification, and transport, Plebani M has long noted that the pre-analytical stage accounts for over half of all laboratory errors [18]. Goswami B et al., observed a similar pattern, reporting that pre-analytical mistakes accounted for roughly 77% of the errors in their clinical biochemistry laboratory [10].

The study's pre-analytical events, such as incorrect sample handling, mislabelling, insufficient samples, and transport-related gaps, are similar to the issues brought out by other Indian writers. Due to differences in phlebotomy procedures and the participation of several staff categories, Arul P et al., observed that insufficient and clotted samples were significant causes of pre-analytical errors in their context [22]. These parallels support the idea that pre-analytical risks exist in various laboratory configurations regardless of automation.

In the present findings, analytical NCs made up the second-largest percentage. This proportion seems greater than some previous studies, but it probably reflects how strictly NABL-accredited laboratories must record even small changes in quality control, reagent problems, calibration-related issues, and equipment malfunctions. Similar trends were noted by Sodavadiya KB et al., who reported that a significant percentage of their NCs at a government-run, authorised biochemistry laboratory were caused by IQC-related problems [19]. Rather than pointing to subpar performance, the stringent monitoring required by accreditation probably enhances detection.

Although post-analytical NCs were rare, they had operational implications, especially when it came to report verification and result communication delays. The findings emphasise the necessity of prompt contact with clinical teams and consistent documentation, as even little irregularities in this step might affect turnaround time.

Human error continued to be the most frequent underlying cause throughout all stages. Numerous writers have confirmed this finding, attributing a significant percentage of laboratory errors to procedural errors, communication breakdowns, or a lack of familiarity with conventional protocols [10,18,22]. The overall impact on resource utilisation and workflow cannot be disregarded, even if the majority of the NCs in the present study were small and did not directly jeopardise patient safety. Small, frequent disruptions, whether brought on by sample problems, QC shifts, or paperwork issues, add up to a discernible operational cost.

Tsheola EM et al., new work from South Africa (2024) gives the present findings a crucial modern perspective. Document control, audit follow-up, record management, personnel competency records, and equipment-related paperwork were found to be associated with over half of all NCs in internal audit reports from non-accredited public health laboratories [23]. The pattern they describe is remarkably comparable, even though their situation is different from that of the present laboratory context. Additionally, they indicated that medium-severity incidents were less frequent than minor and severe NCs, which is similar to what was seen in present study. Their research demonstrates that even laboratories with well-established procedures still have difficulty meeting ISO 15189's administrative and system-level criteria, underscoring the continuous need for reliable documentation procedures, prompt remedial action, and committed quality control [23].

Fishbone diagrams and the 5-Whys are two structured analytical methods that have proven quite helpful in pinpointing the precise causes of some recurrent phenomena [20,21]. The example of inaccurate ALT and AST values demonstrates how careful RCA can reveal subtle problems that might otherwise go unreported in a completely automated environment, including out-of-range absorbance. The results also highlight areas where equipment manufacturers may help labs by providing better software alerts and mechanical protections.

Overall, the study confirms that the pre-analytical phase and human-dependent procedures continue to provide the greatest risk of error, even in authorised laboratories using automated technologies. Ongoing training, transparent communication, regular competency assessments, and a culture that promotes reporting of even minor deviations are still crucial. Enhancing these areas will enhance turnaround time, resource management, and confidence in the accuracy of laboratory results in addition to lowering the incidence of errors.

Limitation(s)

The present study was conducted in a single NABL-accredited biochemistry laboratory, so the findings may not apply to laboratories with different settings or workflows. The analysis depended on routine documentation, which may include underreporting or variations in how events were recorded. RCA, although structured, can still involve some subjectivity. The study also did not assess the long-term effectiveness of corrective and preventive actions.

CONCLUSION(S)

This study assessed the types, prevalence, and underlying causes of NCs in a clinical biochemistry laboratory accredited by the NABL and examined how they affect overall laboratory performance. Pre-analytical variations were the most common, followed by analytical and post-analytical issues, suggesting that the testing procedure's pre-analytical stage is the most vulnerable. Human factors accounted for the bulk of NCs, underscoring the need for frequent staff training and strict adherence to standard operating procedures. Even though many of the accidents were minor and isolated, their overall impact on workflow and resource utilisation emphasises how important it is to take quick corrective and preventive action. The main takeaway is that regular non conformance monitoring supported by structured RCA is crucial to accuracy, efficiency, and continuous quality improvement in accredited laboratory settings.

REFERENCES

[1] Modi K, Shaherawala J. Turnaround time for common clinical chemistry examinations and root cause analysis for its delay. International Journal of Clinical Biochemistry Research. 2019;6(4):596-600. Doi: 10.18231/j.ijcbr.2019.123.

[2] Chauhan KP, Trivedi AP, Patel D, Gami B, Haridas N. Monitoring and root cause analysis of clinical biochemistry turnaround time at an academic hospital. Indian J Clin Biochem. 2013;29(4):505-09. Doi: 10.1007/s12291-013-0397-x.
[3] World Health Organization. Laboratory quality management system: Handbook. Geneva (Switzerland): World Health Organization; 2011 [cited 2025 Nov 23]. 271 p. Available from: https://www.who.int/publications/i/item/9789241548274.
[4] Westgard JO, Westgard SA, Serrano L, Wildermuth C, Migliarino G, Fernandez E, et al. Basic Quality Management Systems: Essentials for Quality Management in the Medical Laboratory [Internet]. Madison (WI): Westgard QC, Inc.; 2014 [cited 2025 Nov 23]. Available from: https://www.westgard.com/images/stories/BQMS-Preview.pdf.
[5] Badrick T. Evidence-based laboratory medicine. Clin Biochem Rev. 2013;34(2):43-46. PMID: 24151340; PMCID: PMC3799218.
[6] Forsman RW. Why is the laboratory an afterthought for managed care organizations? Clin Chem. 1996;42(5):813-16. PMID: 8653920.
[7] Zima T. Accreditation in clinical laboratories. Biochemia Medica. 2010;20(2):215-20.
[8] Zima T. Accreditation of medical laboratories: System, process, benefits for labs. J Med Biochem. 2017;36(3):231-37. Doi: 10.1515/jomb-2017-0025.
[9] Roy AD, Das D. An evaluation of the errors occurring in pathology and microbiology laboratories of a tertiary care teaching hospital and their root cause analyses. Journal of Health Research and Reviews. 2019;6(3):102-06.
[10] Goswami B, Singh B, Chawla R, Mallika V. Evaluation of errors in a clinical laboratory: A one-year experience. Clin Chem Lab Med. 2010;48(1):63-66. Doi: 10.1515/CCLM.2010.006. PMID: 20047530.
[11] Hong Kong Accreditation Service. Technical criteria for laboratory accreditation (medical laboratories) [Internet]. Hong Kong: The Government of the Hong Kong Special Administrative Region; 2010 [cited 2025 Nov 23]. Available from: https://www.itc.gov.hk/en/quality/hkas/doc/hoklas/HOKLAS015-Abridged.pdf.
[12] Verma M, Kumari A, Dalal D. Hurdles faced in getting a clinical biochemistry laboratory accredited by NABL in government setup: Our experience. Indian Journal of Medical Biochemistry. 2020;24(1):01-03. Doi: 10.5005/jp-journals-10054-0136.
[13] Wadhwa V, Rai S, Thukral T, Chopra M. Laboratory quality management system: Road to accreditation and beyond. Indian J Med Microbiol. 2012;30(2):131-40. Doi: 10.4103/0255-0857.96647. PMID: 22664426.
[14] Kanagasabapathy AS, Rao P. Laboratory accreditation—procedural guidelines. Indian J Clin Biochem. 2005;20(2):186-88. Doi: 10.1007/BF02867425. PMID: 23105558; PMCID: PMC3453827.
[15] Lippi G, Plebani M, Simundic AM. Quality in laboratory diagnostics: From theory to practice. Biochemia Medica. 2010;20(2):126-30.
[16] Sciacovelli L, O'Kane M, Skaik YA, Caciagli P, Pellegrini C, Da Rin G, et al.; IFCC WG-LEPS. Quality indicators in laboratory medicine: From theory to practice. Preliminary data from the IFCC Working Group project "Laboratory Errors and Patient Safety". Clin Chem Lab Med. 2011;49(5):835-44. Doi: 10.1515/CCLM.2011.128. PMID: 21342024.
[17] Bonini P, Plebani M, Ceriotti F, Rubboli F. Errors in laboratory medicine. Clin Chem. 2002;48(5):691-98. PMID: 11978595.
[18] Plebani M. The detection and prevention of errors in laboratory medicine. Ann Clin Biochem. 2010;47(2):101-10. Doi: 10.1258/acb.2009.009222. PMID: 19952034.
[19] Sodavadiya KB, Rajput AS, Patel NR, Patel SM. Impact of developing and implementing nonconformance management system at clinical biochemistry laboratory section of tertiary care hospital run by Government of Gujarat, India. Panacea Journal of Medical Sciences. 2023;13(2):396-401.
[20] Kumah A, Nwogu CN, Issah AR, Obot E, Kanamitie DT, Sifa JS, Aidoo LA. Cause-and-effect (fishbone) diagram: A tool for generating and organizing quality improvement ideas. Glob J Qual Saf Healthc. 2024;7(2):85-87. Doi: 10.36401/JQSH-23-42. PMID:38725884; PMCID:PMC11077513.
[21] Serrat O. The five whys technique. In: Knowledge solutions. Singapore: Springer; 2017. p. 307-10. Doi: 10.1007/978-981-10-0983-9_32.
[22] Arul P, Pushparaj M, Pandian K, Chennimalai L, Rajendran K, Selvaraj E, Masilamani S. Prevalence and types of preanalytical error in hematology laboratory of a tertiary care hospital in South India. J Lab Physicians. 2018;10(2):237-240. Doi: 10.4103/JLP.JLP_98_17. PMID: 29692594; PMCID: PMC5896195.
[23] Tsheola EM, Pienaar JA, Kruger W. Analysis of internal audit non-conformances at non-accredited public health laboratories in Gauteng province, South Africa. Journal of Medical Laboratory Science & Technology of South Africa. 2024;6(2):86-91. Doi: 10.36303/JMLSTSA.246.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Oct 22, 2025
- Manual Googling: Dec 25, 2025
- iThenticate Software: Dec 27, 2025 (3%)

ETYMOLOGY: Author Origin

EMENDATIONS: 7

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? No
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Oct 21, 2025**
Date of Peer Review: **Nov 20, 2025**
Date of Acceptance: **Dec 29, 2025**
Date of Publishing: **Mar 01, 2026**