National Journal of Life & Health Sciences
https://njlhs.com/index.php/njlhs/index
ISSN: 3006-5852 & ISSN: 3006-5844
Vol. 5, Issue 1, (2026)

A Comparative Study of Laboratory Protocol Deviations Across Pre-Analytical, Analytical, and Post-Analytical Phases in Public and Private Diagnostic Laboratories

Mohammad Ismail[1], Muhammad Ishaq[1], Bilal Masood[1], Faisal Rehman[1], Muhammad Waseem[1*]
[1]Faculty of Rehabilitation and Allied Health Sciences, Riphah International University, Islamabad, Pakistan.

Article Information

Article Type: Research Article

Dates
Received: Feb 02, 2026
First Revision: May 23, 2026
Second Revision: June 29, 2026
Accepted: July 13, 2026
Available online: Aug 10, 2026

Corresponding Author*
Muhammad Waseem
Faculty of Rehabilitation and Allied Health Sciences, Riphah International University, Islamabad, Pakistan.
Email:
m.waseem@riphah.edu.pk

HOW TO CITE:
Ismail M, Ishaq M, Masood B, Rehman F, Waseem M. A Comparative Study of Laboratory Protocol Deviations Across Pre-Analytical, Analytical, and Post-Analytical Phases in Public and Private Diagnostic Laboratories. National Journal of Life and Health Sciences. 2026 June; 5(1), 7-13.

ABSTRACT

Background: Diagnostic laboratories are important to healthcare, providing critical information for diagnosis, treatment decisions, and patient monitoring. The reliability of laboratory results depends on maintaining quality at every phase of the testing process. Deviation from established laboratory protocols may arise during the pre-analytical, analytical, and post-analytical phases, thereby compromising the quality of laboratory services.

Methods: A multicenter cross-sectional observational study was conducted over a four-month period at designated public and private diagnostic laboratories. Five public laboratories and three private laboratories were integrated. Routine laboratory procedures were evaluated during morning shifts, five days a week, via direct observation utilizing a prepared checklist consistent with established laboratory standards. Observed deviations from standard protocols were noted across the pre-analytical, analytical, and post-analytical processes in the phlebotomy, hematology, clinical chemistry, microbiology, and clinical pathology departments. Data were evaluated descriptively using frequencies and percentages.

Results: Protocol deviations were more prevalent in public laboratories, especially during the pre-analytical phase. Pre-analytical variations accounted for almost 60% of the detected discrepancies in public laboratories, compared with 10% in private laboratories. Frequent discrepancies in public laboratories included inadequate compliance with phlebotomy protocols, limited use of appropriate specimen-collection materials, insufficient antiseptic measures, specimen-identification challenges, and nonadherence to standard operating procedures (SOPs), while in private laboratories, excellent efficiency had been observed in accurately use of sterile containers for sample collection, proper labelling, barcoding, and a standardized way of preparation and processing.

Conclusion: The pre-analytical phase is crucial and requires improvement, particularly in public laboratories. Strengthening conformity with SOPs, ensuring resource availability, and establishing rigorous quality monitoring may improve laboratory results and patient safety.

Keywords: Diagnostic laboratories, protocol deviations, pre-analytical phases, public laboratories, private laboratories, Pakistan

INTRODUCTION

The diagnostics Laboratories are a fundamental part of healthcare systems. It gives an important information for the diagnosis of different diseases, decisions regarding treatment, and patient management and care. Given that about 70% of clinical decision-making processes are determined by laboratory reports, it is essential to maintain reliable performance and precision to safeguard patients and ensure proper clinical care.[1,2] The laboratory quality management system (QMS) includes the whole testing approach, involving the collection of specimens, their analysis, interpretation, and finally reporting, dispatching and regular assessment of laboratory proficiency.[3]

Laboratory testing is frequently divided into three main phases: pre-analytical, analytical, and post-analytical. ISO 15189:2012 defines the pre-analytical phase as the period from the physician's request for investigation to patient preparation, sample collection, and transportation to the laboratory for further examination. The second phase is the analytical phase, which includes

specimen examination, method validation, equipment calibration, internal quality control (IQC) and proficiency testing, while the post-analytical phase involves test result validation, interpretation, and reporting to the clinician.[4,5]

Laboratory disparities are deviations that occur at any phase of the laboratory analysis process, which may discredit the reliability, accuracy, and interpretation of results.[6,7] Although laboratory errors are infrequent, their implication can substantially affect patient treatment and care. To effectively prevent laboratory-related deviations or errors, it is crucial to identify high-risk procedures, continuously observe vulnerable sections in laboratory workstations, and follow rigorous quality improvement strategies throughout all phases of laboratory analysis.[8] In recent years, laboratory quality indicators have served as important tools for analyzing laboratory procedures and performance, inspecting key activities to improve efficiency, and monitoring indicators related to specimen quality and turnaround time (TAT).[9]

Literature has shown that the majority of lab errors, with incidence ranging from 46% to 68%, occur predominantly during the pre-analytical period and are frequently linked with patient identification, specimen collection, labeling, transportation, and handling protocols.[10] Factors such as workload, infrastructure, personnel practices, resource availability, and the implementation of Quality Management Systems (QMS) may influence the incidence of laboratory deviations.[11]

Additionally, disparities between public and private diagnostic laboratories can affect laboratory procedures in resource-constrained healthcare systems. While private laboratories usually have better access to standardized workflows, monitoring systems, and quality improvement techniques, public laboratories sometimes manage large patient volumes with few resources.[12,13] However, there is little comparative research, particularly in Pakistan, regarding differences in laboratory procedures between public and private diagnostic centers.

IQC, external quality assessment (EQA), proficiency testing (PT), and adherence to standard operating procedures (SOPs) are all necessary for continuous monitoring of laboratory quality.[14] These approaches support corrective actions, improve laboratory practices, and make it easier to identify flaws. The purpose of this study is to assess and contrast identified protocol deviations in public and private diagnostic laboratories during the pre-analytical, analytical, and post-analytical stages.

Materials and Methods

Study Design and Study Period

A multicentric cross-sectional observational study was conducted over a four-month period to analyze laboratory deviations at each analytical phase in both public and private laboratories.

Study Setting and Laboratory Selection

This study covers eight laboratories, including three private and five public diagnostic laboratories. Selected laboratories function as independent diagnostic facilities, ensuring quality patient care. Private laboratories were diagnostic centers that maintained predefined protocols, although public laboratories served as larger-scale healthcare facilities.

Observation Procedure and Data Collection Tool

Data were collected directly through observation using the laboratory's standardized protocols during the morning shift, five days a week, for four months. Under the supervisor's supervision, we prepared a thorough observation checklist that contained defined laboratory protocols for sample collection, processing, and reporting.

The research group had been split into subgroups, and observers were distributed across distinct laboratory sections. Observations were made without interfering with routine standard laboratory procedures; only deviations from standard protocols were reported.

Assessment and Classification of Laboratory Protocol Deviations

During this research study, protocol deviations were defined as any activities that violated recognized laboratory standard operating procedures when carrying out routine laboratory procedures.

The observed variations were categorized based on all three laboratory testing stages:

Pre-analytical stage

Test ordering, patient preparation, sample collection, sample labeling, transportation, and handling before analysis.

Analytical stage

Processing of sample, testing procedures, quality control, calibration standards, and result generation.

Post-analytical stage

Result validation and verification, reporting, interpretation, storage and disposal of sample.

Sections of the laboratory included: phlebotomy, hematology, clinical chemistry, Clinical pathology, and microbiology. The histopathology and blood

bank sections were not included. Laboratory sections included phlebotomy, hematology, clinical chemistry, microbiology, and clinical pathology.

Data Analysis

All the observed deviations were classified on the basis of laboratory class, stage, sections, and category of deviations.

Data were analyzed using percentages and frequencies. The findings were presented as a typical distribution of error rate on all laboratory samples.

Ethical Considerations

Ethical approval had been issued by the Committee of Research Ethics of Riphah International University prior to the beginning of the project. Permission to conduct observations was obtained from the relevant healthcare institutions. The study involved observing standard laboratory procedures without direct involvement, and no identifiable information about patients or personnel was collected. The confidentiality of the data collected was maintained throughout the investigation.

Results

Over the four-month observation period, standard laboratory practices were evaluated via direct observation in five public and three private diagnostic laboratories. Protocol deviations were observed in the pre-analytical, analytical, and post-analytical phases. Compliance with standardized laboratory protocols was identified between private and public laboratories, while public laboratories reported a higher incidence of protocol deviations.

The analysis of reported protocol deviations during laboratory testing phases indicated that the pre-analytical phase was the primary cause of departure, especially in public laboratories. Pre-analytical aberrations accounted for around 60% of the detected discrepancies in public laboratories, whereas a smaller proportion was observed in private laboratories. Fig. 1 shows the observed deviations in the pre-analytical, analytical, and post-analytical phases, with pre-analytical showing the greatest deviations among all.

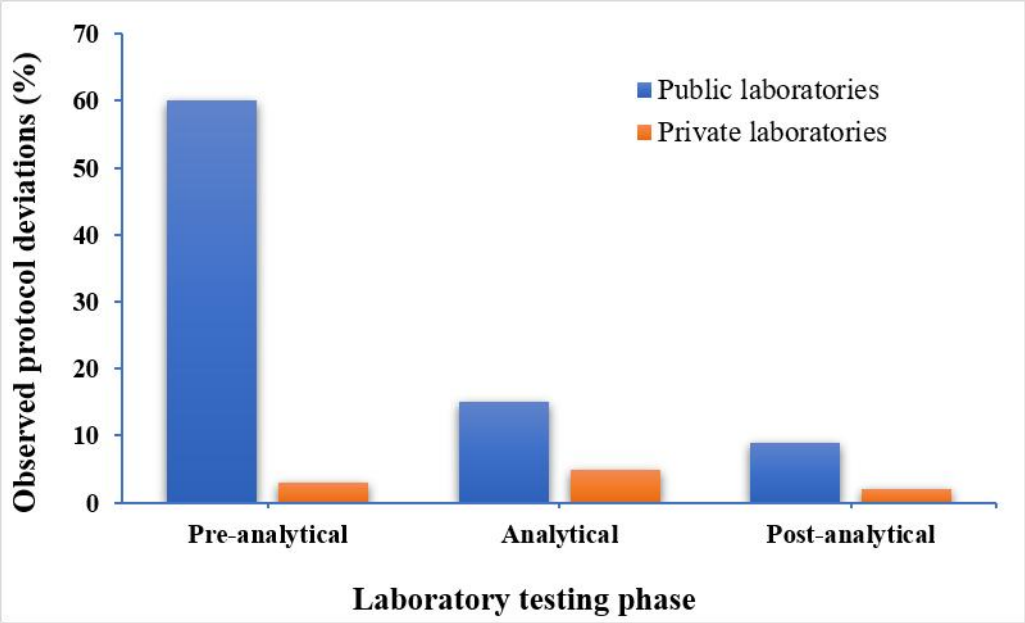

Figure 1. The occurrence of reported observed deviations in protocol among the pre-analytical, analytical, and post-analytical phases between private and public laboratories

A detailed examination of sample collection and the handling protocols showed substantial variations between private and public laboratories. In public laboratories, widespread variations were observed in standardized sample collection SOPs, including inappropriate use of tourniquets, incorrect use of antiseptic before venipuncture, poor collection practices, lack of proper labelling of samples, lacking of barcoding, non-sterile containers for urine, poor mixing of blood specimens after collecting and incorrect transfer of blood specimens from the syringes to the tubes, Meanwhile, private laboratories showed higher compliance with defined handling and specimen collection techniques. The observed techniques involved the use of personal protective equipment (PPE), robust antiseptic use, recommended phlebotomy patient positioning, sterile containers

for sample collection, barcoding of the tubes for patient identification, gentle mixing of blood, and good handling practices. Table 1 demonstrates a comparison of reported observed sample collection and handling methods between private and public laboratories, as illustrated in Fig 2.

Table 1. Comparison of Observed Specimen Collection and Handling Practices Between Public and Private Laboratories

Observed practice	Public laboratories	Private laboratories
Tourniquet use during venipuncture	Inconsistent use and deviation from recommended practice were observed	Appropriate use according to routine procedure was observed
Skin antisepsis before blood collection	Antiseptic application is frequently not observed	Consistent antiseptic practice observed
Patient positioning during blood collection	Variable practices observed	Standardized positioning followed
Use of gloves during specimen collection	Inconsistent practice observed	Routine use observed
Specimen labeling and identification	Labeling errors and incomplete identification practices were observed	Proper identification and labeling are maintained
Barcode-based identification system	Not routinely observed	Routinely applied
Urine specimen collection containers	Non-standard containers observed	Sterile containers used
Blood sample mixing after collection	Inadequate mixing practices were observed	Gentle and appropriate mixing performed
Transfer of blood from the syringe to the collection tube	Forceful transfer practices observed	Standard specimen transfer procedures followed
Use of a vein finder for venipuncture	Not observed	Observed in some laboratories

Evaluations showed that the phlebotomy section was the most significant and major source of reported observed variations, subsequently followed by hematology, clinical chemistry, microbiology, and clinical pathology sections, as represented in Fig 3. A significant number of variations found in phlebotomy were associated with sample handling and collection SOPs, emphasizing the relevance of the pre-analytical stage for ensuring laboratory quality.

The subsequent observed evaluation between the pre-analytical and post-analytical stages found variations in laboratory operating protocols, quality control standards, document records, validation of the result, and reporting processes. Meanwhile, these variations occurred less frequently relative to those found during the pre-analytical phases.

Discussion

A consistent framework for laboratory quality that can detect, track, and reduce aberrations in diagnostic testing is necessary to guarantee patient safety. The three interconnected stages of laboratory testing are pre-analytical, analytical, and post-analytical. Previous studies and the current study support the idea that the pre-analytical period is the most vulnerable stage for laboratory errors.[8,15]

This study found that the pre-analytical stage was the main cause of protocol deviations, accounting for over 60% of changes found in public laboratories. Inadequate patient preparation, inconsistent application of appropriate collection techniques, incorrect specimen identification and labeling, inappropriate management of collected specimens, and noncompliance with established laboratory practices were the main causes of the discrepancies found. These findings align with a recent study showing that the pre-analytical phase plays a significant role in quality assurance problems; further studies have shown that a large proportion of laboratory errors occur prior to sample analysis.[16,17] The use of many manual procedures and strict compliance with established guidelines is the main cause of this phase's vulnerability.

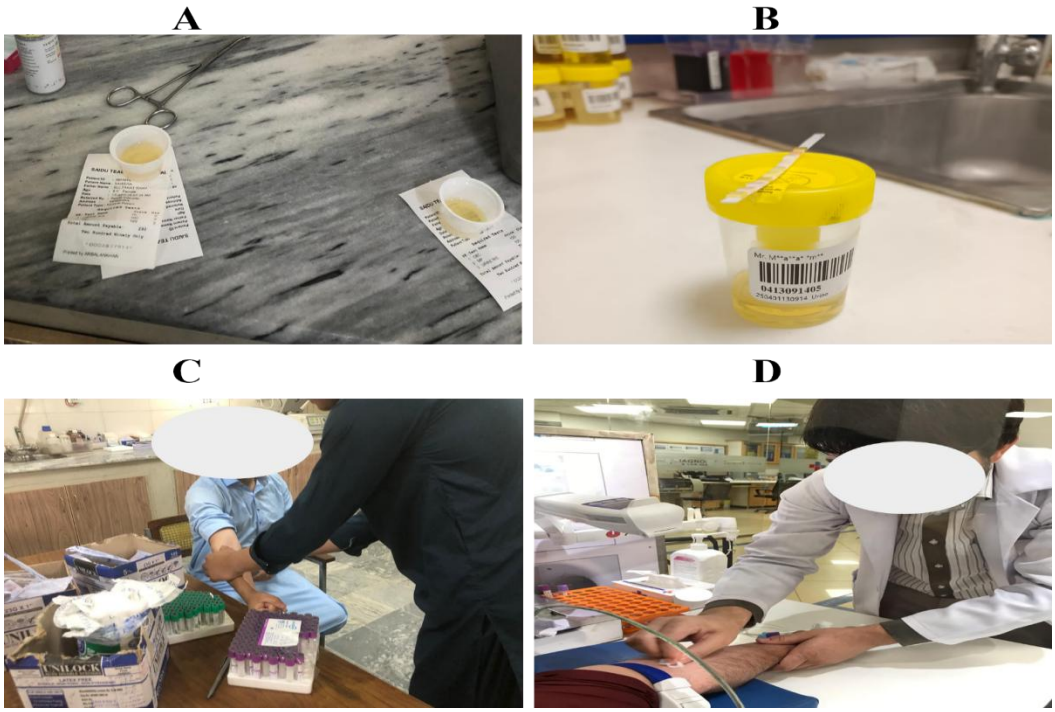

Figure-2: Comparison of sample collection and handling practices between public and private laboratories. A) Urine sample collected in an unsterile and open container and examined without centrifugation in a public laboratory. (B) Urine sample collected in a sterile and close container, and also barcoded. (C) In a public laboratory, blood was collected without a tourniquet and antiseptic swab, violating specimen collection SOPs. (D) The private laboratory shows standard SOPs for using tourniquets, antiseptic swabs, and a vein finder for easy blood draw.

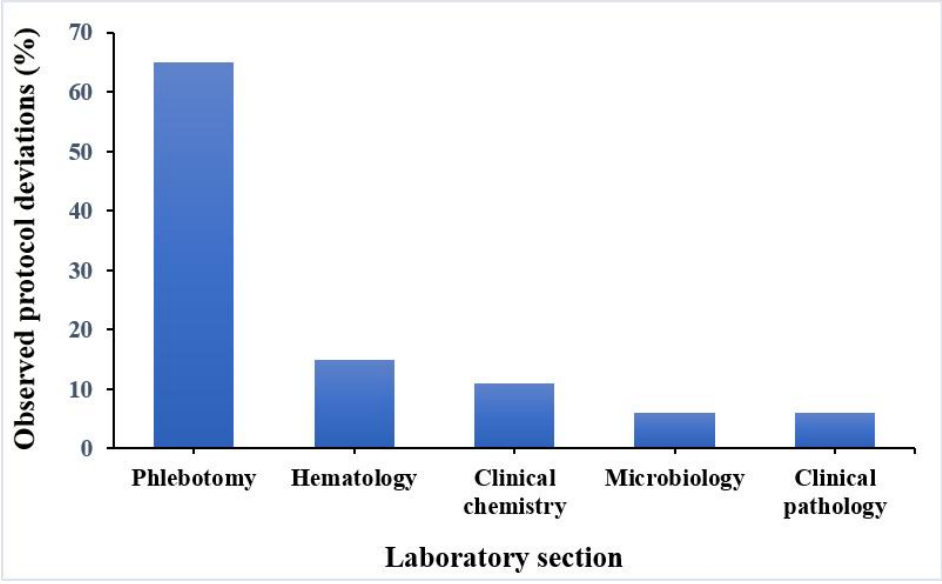

Figure 3. Representation of reported observed deviations of protocols among all laboratory sections

Various variations in sample collection and handling techniques between public and private laboratories were also observed throughout the analysis. Deviations from standard protocols and SOPs were commonly observed in public laboratories in the phlebotomy section: inadequate antiseptic use, manual labeling of samples or no labeling, non-sterile containers, inadequate blood sample mixing, and no proper protocols for transferring samples from collection areas to the laboratory and for sample storage. On the other hand, private laboratories follow standard protocols, including rigorous and precise sample collection procedures, a barcoding system, and more efficient procedures. These disparities may stem from differences in organizational monitoring procedures, workload categorization, quality management system implementation, and resource accessibility rather than solely personnel-related factors.

Previous research indicates similar variations in laboratory quality standards and performance across hospital settings, highlighting the importance of staff training, infrastructure and resource availability, and adherence to SOPs for laboratory reliability.[18] Common challenges faced by public laboratories are heavy patient flow and workload, lack of resources and funding, and poor-quality improvement strategies. All these findings emphasize the urgent need for systemic changes rather than relying solely on personal performance. A strong quality system, daily monitoring and constant improvement are needed to advance laboratory operations.

These findings underline the urgency of implementing targeted measures to strengthen pre-analytical quality management. To minimize avoidable deviations, continuous competency-driven training strategies, efficient SOP implementation, regular monitoring using laboratory quality parameters, and upgrades to sample-handling approaches need to be implemented. Qualitative indicators can provide fundamental information on compromised procedures, helping laboratories deploy preventive and corrective actions. In addition, adopting automated and modern technologies, sample barcoding, and laboratory information systems (LIS) may strengthen record-keeping, minimize human error, and increase overall laboratory performance.

Future research should focus on the successful outcomes of certain quality development programs, specifically in large-scale public laboratories. Further research encompassing more laboratories, longer observation periods, and assessment of intervention-related consequences may improve knowledge of the actions required to address gaps in laboratory protocols. Furthermore, exploring the significant impact of laboratory automation, LIS, and continual professional development efforts may contribute to the establishment of sustainable approaches for patient safety and accurate diagnostics.

Limitations

This paper found that violations of standard protocols were more common in public laboratories than in private laboratories. The pre-analytical phase was recognized as the main challenge. The limited number of laboratories included in this study may affect the generalizability of the outcomes across multiple laboratories. Collected data were limited to morning shifts; thus, protocol deviations in the evening and night shifts are likely unless properly observed. This study noted protocol deviations yet neglected to evaluate the immediate effect on diagnostic accuracy. Additional multicentric research among morning, evening and night shifts needs to evaluate their implications while improving standardized protocols.

Conclusion

The techniques used for sample collection and handling, notably in phlebotomy SOPs, greatly contribute to the observed deviations. These deviations across multiple laboratories show the importance of further strengthening adherence to SOPs, developing sample collection protocols, and implementing standard quality control procedures. Competency-specific learning, resource optimization, and improved quality assurance could decrease these deviations and further strengthen diagnostic accuracy and enhance patient safety.

Informed Consent Statement: Not applicable.

Data Availability Statement: All the data will be provided on reasonable request.

Conflicts of Interest: The authors declare no conflict of interest.

Author contributions

Conceptualization: Muhammad Waseem. Mohammad Ismail, Muhammad Ishaq, Bilal Masood, Faisal Rehman. Formal analysis: Muhammad Waseem. Mohammad Ismail. Investigation: Muhammad Waseem, Mohammad Ismail, Muhammad Ishaq, Bilal Masood, Faisal Rehman. Methodology: Muhammad Waseem. Mohammad Ismail, Muhammad Ishaq, Bilal Masood, Faisal Rehman. Project administration:

Muhammad Waseem. Mohammad Ismail, Muhammad Ishaq, Bilal Masood, Faisal Rehman. Software: Muhammad Waseem. Mohammad Ismail. Supervision: Muhammad Waseem. Visualization: Mohammad Ismail. Writing original draft: Muhammad Waseem. Mohammad Ismail. Writing review & editing: Muhammad Waseem. Mohammad Ismail

References

1. Sayyar Am, Alzubun Fsm, Alsuwaydaa Yas, Alrashdi Nso, Alghaslan Fyf, Alreshidi Bat, et al. Comprehensive Review of Laboratory Role in Disease Diagnosis and Health Monitoring. Journal of Ecohumanism. 2024 Dec 11;3(8):5317-5325–5317– 5325. doi:10.62754/JOE.V3I8.5162
2. Mulatie Z, Ebrahim E, Alebachew M, Gedefie A, Eshetu B, Tilahun M, et al. Performance Analysis of Clinical Chemistry Laboratory Using Sigma Metrics in the Total Testing Process at Dessie Comprehensive Specialized Hospital, Ethiopia. J Clin Lab Anal. 2025 Dec 1;39(24). doi:10.1002/JCLA.70134 PubMed PMID: 41306004.
3. Raza Jafri T, Swarup A, Pant N, Mishra A. Pre-Analytical Errors In Sample Collection And Their Impact On Laboratory Results. Int J Adv Res (Indore). 2025 Dec 30;13(12):1491–5. doi:10.21474/IJAR01/22485
4. Vermeersch P, Frans G, Meyer A Von, Costelloe S, Lippi G, Simundic AM. How to meet ISO15189:2012 pre-analytical requirements in clinical laboratories? A consensus document by the EFLM WG-PRE. Clin Chem Lab Med. 2021 May 1;59(6):1047–61. doi:10.1515/CCLM-2020-1859 PubMed PMID: 33554545.
5. Althobaiti SM, Alammari FA, Ali A, Alghamdi A, Thakir M, Alghamdi S, et al. Quality Assurance Strategies in Medical Diagnostic Laboratories. Journal of Posthumanism. 2024 Dec 19;4(3):758–69. doi:10.63332/joph.v4i3.3085
6. Tola EK, Dabi YT, Dano GT. Assessment of Types and Frequency of Errors in Diagnostic Laboratories Among Selected Hospitals in East Wollega Zone, Oromia, Ethiopia. Pathol Lab Med Int. 2022 Mar;Volume 14:1–6. doi:10.2147/PLMI.S351851
7. Arifin A, Yusof MM. Error evaluation in the laboratory testing process and laboratory information systems. J Med Biochem. 2022;41(1):21. doi:10.5937/JOMB0-31382 PubMed PMID: 35291500.
8. Alghamdi SMS. Pre-Analytical, Analytical, And Post-Analytical Errors In Clinical Laboratory Testing: A Systematic Review Of Causes And Prevention Strategies. Journal of International Crisis and Risk Communication Research. 2024 Nov 15;3361–75. doi:10.63278/JICRCR.VI.3220
9. Sciacovelli L, Padoan A, Aita A, Basso D, Plebani M. Quality indicators in laboratory medicine: state-of-the-art, quality specifications and future strategies. Clin Chem Lab Med. 2023 Mar 1;61(4):688–95. doi:10.1515/CCLM-2022-1143 PubMed PMID: 36660807.
10. Alcantara JC, Alharbi B, Almotairi Y, Alam MJ, Muddathir ARM, Alshaghdali K. Analysis of preanalytical errors in a clinical chemistry laboratory: A 2-year study. Medicine. 2022 Jul 8;101(27):e29853. doi:10.1097/MD.0000000000029853 PubMed PMID: 35801773.
11. Pillai SP, Fox E. Laboratory quality management system fundamentals. Front Bioeng Biotechnol. 2025 May 21;13:1578654. doi:10.3389/FBIOE.2025.1578654/TEXT
12. 12. Nkengasong JN, Yao K, Onyebujoh P. Laboratory medicine in low-income and middle-income countries: progress and challenges. Lancet. 2018 May 12;391(10133):1873. doi:10.1016/S0140-6736(18)30308-8 PubMed PMID: 29550031.
13. Akpan E, Abdulrahman SA, Pepple N. Comparison of the Level of Adherence to Laboratory Quality Management System between Public and Private Secondary Health Facilities in Southern Nigeria. Glob J Health Sci. 2020 Oct 19;12(12):p27. doi:10.5539/GJHS.V12N12P27
14. Skitek M, Martinello F, Jerin A. How to Really Understand and Improve the System of Internal Quality Control and External Quality Assessment in the Accreditation Process of the Medical Laboratory? EJIFCC. 2022;33(1):23. PubMed PMID: 35645692.
15. Lin Y, Spies NC, Zohner K, McCoy D, Zaydman MA, Farnsworth CW. Pre-analytical phase errors constitute the vast majority of errors in clinical laboratory testing. Clin Chem Lab Med. 2025 Aug 1;63(9):1709–15. doi:10.1515/CCLM-2025-0190 PubMed PMID: 40311145.
16. Nordin N, Ab Rahim SN, Wan Omar WFA, Zulkarnain S, Sinha S, Kumar S, et al. Preanalytical Errors in Clinical Laboratory Testing at a Glance: Source and Control Measures. Cureus. 2024 Mar 30;16(3). doi:10.7759/CUREUS.57243 PubMed PMID: 38559530.
17. Güner Y, Güner EK, Üçüncüoğlu M, Yüksel H. Evaluation of specimen rejection rates in the preanalytical phase and nurses' experiences: a mixed design study. BMC Nursing 2025 24:1. 2025 Jul 1;24(1):705-. doi:10.1186/S12912-025-03426-W
18. Nigatu T, Deress T, Mezgebu B, Adane K. Determinants of quality laboratory service provision amongst government comprehensive specialized hospitals in Northwest Ethiopia. Health Research Policy and Systems 2026 24:1. 2026 Apr 1;24(1):41-. doi:10.1186/S12961-026-01458-5 PubMed PMID: 41923262.