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A Prospective Study on Errors in Pre-Analytical Phase in Central Laboratory: Biochemistry Unit

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Abstract:

- ***Background:***
Pre-analytical errors are a significant source of inaccuracies in clinical biochemistry laboratories, contributing to approximately 60-70% of total laboratory errors. These errors arise during the pre-examination phase, which spans from test ordering to sample analysis. Given the potential impact on diagnostic outcomes, understanding and mitigating these errors is critical to improving laboratory quality.

- ***Objectives:***
The study aims to enumerate and analyze the frequency of pre-analytical errors in a Clinical Biochemistry laboratory, with a particular focus on assessing the effect of hemolysis on blood glucose levels.

- ***Materials and Methods:***
Data were collected across various hospital departments, and the occurrence of pre-analytical errors was assessed. The analysis focused on the impact of hemolysis on test results, particularly blood glucose measurements.

- ***Results:***
The findings reveal significant variation in the frequency of pre-analytical errors across different clinical departments. The Inpatient Department accounted for the highest proportion of errors (50.36%), followed by the Critical Care Medicine department at 43.13%. In contrast, lower rates of errors were observed in the Emergency Department (3.61%) and Outpatient Department (2.89%). Hemolysis was identified as the most prevalent error type, followed by issues such as inadequate sample volume, improper tube selection, labeling errors, and clot formation in serum samples. These findings underscore that pre-analytical errors are particularly common in inpatient and critical care settings, suggesting the need for targeted interventions in these areas.

- ***Conclusion:***
The study highlights the significant role of pre-analytical factors in shaping laboratory test outcomes. Hemolysis, inadequate sample volume, and other procedural errors were found to be the most frequent contributors to inaccurate results. The research emphasizes the importance of adhering to standardized protocols and implementing quality control measures to reduce errors, enhance the accuracy of laboratory testing, and ultimately improve patient care.

Keywords: *Pre-Analytical Errors, Clinical Biochemistry Laboratory, Hemolysis and Quality Control.*

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I. INTRODUCTION

The healthcare system today is grappling with multiple challenges surrounding patient quality outcomes, and while various sectors of the system are focused on improving these outcomes, laboratories have long been at the forefront in ensuring quality in their analytical processes. This commitment to excellence is driven by stringent adherence to standards and a constant drive for improvement, aimed at guaranteeing the accuracy, reliability, and precision of laboratory testing procedures.[1] Quality assessment programs are foundational to the discipline of laboratory diagnostics, with competent laboratory services being vital to modern healthcare. Laboratory testing contributes to nearly 70% of medical diagnoses and treatment decisions.[2] Today's medical practices are deeply rooted in evidence-

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based methods, underscoring the significance of precise laboratory results for effective, timely patient management. Laboratory testing can be divided into three essential phases: the pre-analytical phase, the analytical phase, and the post-analytical phase. The pre-analytical phase, which spans from the collection of a patient's sample to its receipt at the laboratory, is particularly susceptible to errors. Factors such as specimen handling, transport conditions, and processing can all compromise the integrity of the sample, which in turn affects the precision of test results. These pre-analytical errors present a significant challenge as they can introduce biases, reduce assay accuracy, and undermine the clinical relevance of the test results. [4-5] This research delves into the often-overlooked domain of pre-analytical errors in Clinical Biochemistry Laboratories, aiming to explore the complexities, consequences, and possible interventions related to this crucial phase. Accurate laboratory reports are vital for correct disease diagnosis and appropriate treatment, as inaccurate results can lead to misdiagnosis or inappropriate therapies. Therefore, maintaining the highest standards of precision in laboratory reporting is essential to safeguard patient health. [6-10] The objectives of this study are to assess the frequency of pre-analytical errors in Clinical Biochemistry Laboratories, and to evaluate the impact of these errors on test results, and examine how repeating sample analysis can help identify and address derangements caused by these errors.

MATERIALS AND METHODS

- Source of data and study design: It is a Prospective observational study. conducted at central laboratory, National Institute of Medical Science & Research Hospital in Jaipur, Rajasthan. Collaboration was established with all Clinical Departments.
- Study Participants: Complete Enumeration from IPD & OPD samples of National Institute of Medical Science & Research Hospital, Jaipur, Rajasthan.
- Inclusion Criteria: Samples received for routine clinical chemistry analysis were screened for pre-analytical errors in patients aged between 1 – 70 years of both genders.
- Exclusion Criteria: the following patients were excluded from the study.

✓ Patients unwilling to participate,
✓ Individuals less than 1 year of age,
✓ Samples received for other test, other than routine clinical biochemistry,
✓ Urine samples.

➢ *Sample Size Determination:*

We included a total sample during the study period of a complete enumeration at the National Institute of Medical Science & Research Hospital, Jaipur, Rajasthan.

➢ *Data Collection:*

- Data Source: Direct observation and documentation of the sample collection process. This data was meticulously categorized under distinct quality indicators for further analysis.

➢ *Variables:*

- Demographic information (age, gender, etc.).
- Sample type (blood).
- Test requested.
- Details of sample transport.
- Identification and labeling details.

➢ *Identification of Pre-Analytical Errors:*

- **Real-time Monitoring:** A system for real-time monitoring of the sample collection process was implemented.
- **Criteria for Identification:** Established guidelines and protocols were followed for identifying pre-analytical errors.

➢ *Quality Control Measures:*

- Regular checks and audits were conducted to ensure data accuracy and reliability.
- Calibration of equipment and validation of test methods were performed as per standard operating procedures.
- **Sample Collection:** Direct observation and documentation of the sample collection process. This data was meticulously categorized under distinct quality indicators for further analysis.

II. RESULTS

Table 1: Distribution of Pre Analytical Errors in Clinical Biochemistry Laboratory

Pre-Analytical Errors	n = 415	In %
Clot in Serum	13	3.13%
Hemolysed	140	33.73%
Inadequate amount	45	10.84%
Inappropriate tube	36	8.67%
Labelling errors	36	8.67%
Lipemic sample	24	5.78%
Sample from IV running area	17	4.10%
Software errors	11	2.65%
Transport Specimen	29	6.99%
TRF is missing	1	0.24%

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Wrong barcode	32	7.71%
Wrong time for collection	31	7.47%

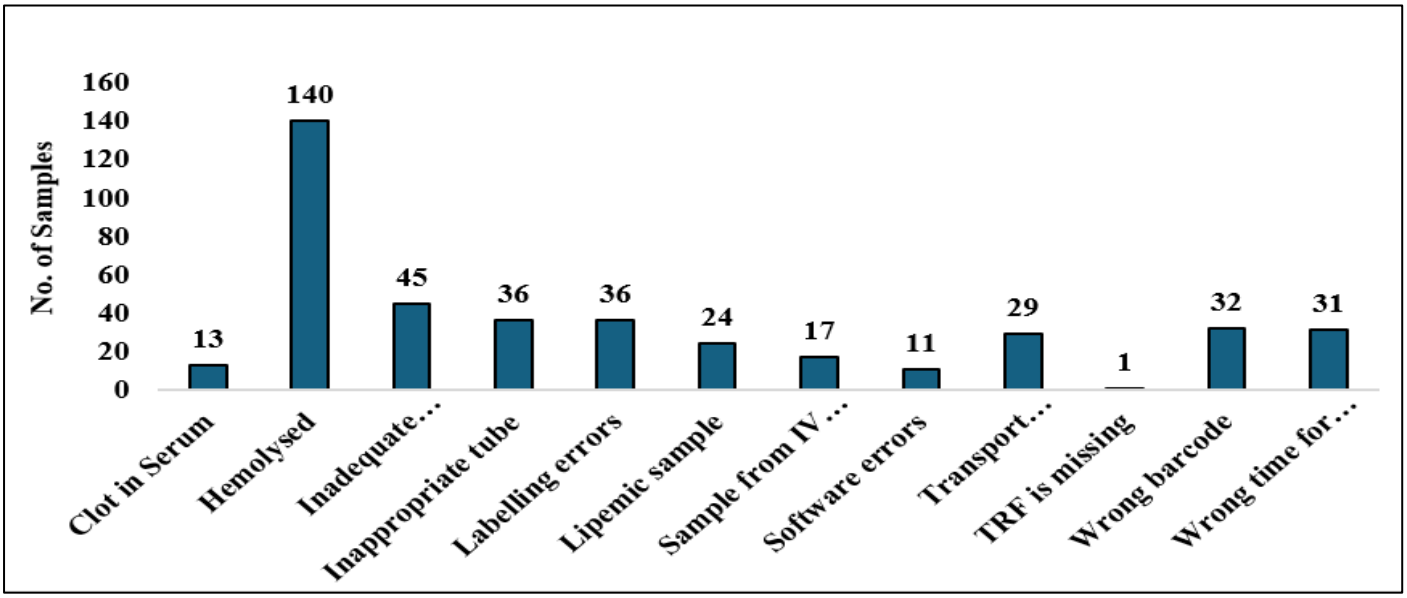

Fig 1: Distribution of Pre Analytical Errors in Clinical Biochemistry Laboratory

Table 1 and figure 1 indicates a range of pre-analytical errors, with varying frequencies observed across different error types. The most prevalent error type is hemolysis, accounting for 33.73% of the total errors identified. Following hemolysis, inadequate sample volume is the next most common error, representing 10.84% of the total errors. Other notable error types include inappropriate tube usage (8.67%), labelling errors (8.67%), and clot formation in serum samples (3.13%). These findings underscore the significance of pre-analytical factors in influencing laboratory testing outcomes. Addressing and mitigating these errors are crucial for maintaining the integrity and accuracy of laboratory results, thereby ensuring quality patient care.

Table 2: Department Wise Distribution of Prevalence Rate of Pre-Analytical Errors in Clinical Biochemistry Laboratory

Department	Total No. of Samples	Pre-Analytical Errors	In %
Emergency Department	2948	15	0.51%
Out Patient Department	19656	12	0.06%
In Patient Department	38921	209	0.54%
Critical Care Medicine	18067	179	0.99%
Total	79592	415	0.52%

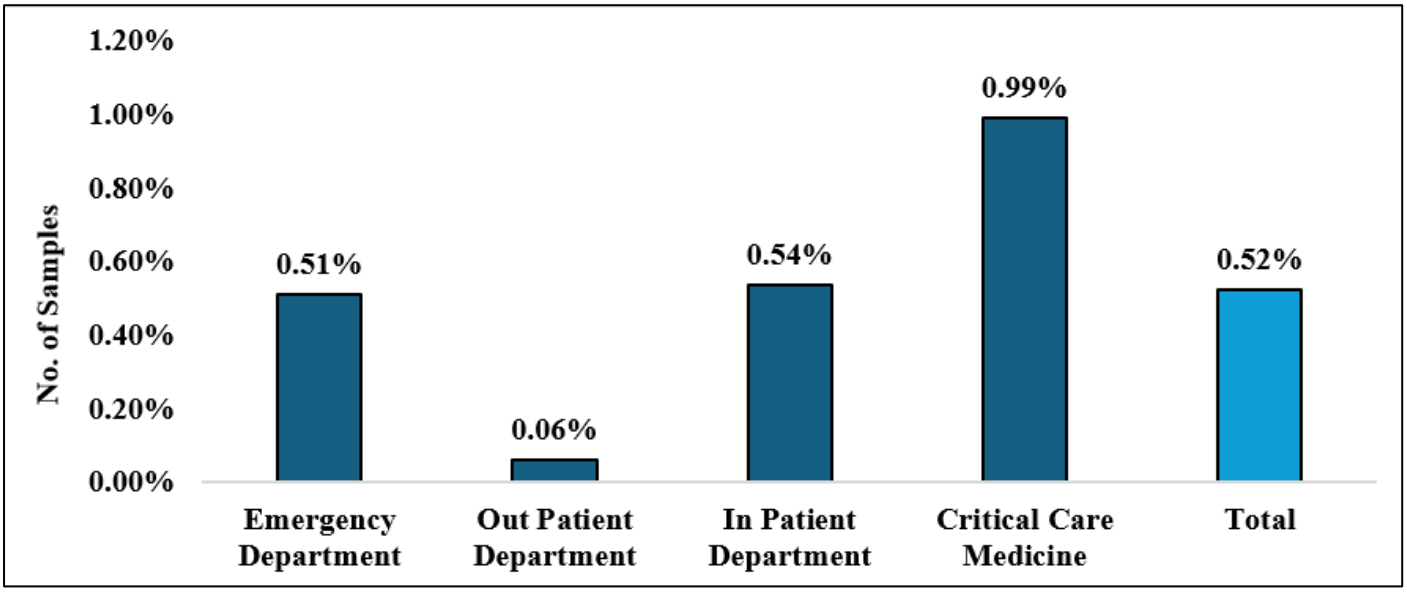

Fig 2: Department Wise Distribution of Prevalence Rate of Pre-Analytical Errors in Clinical Biochemistry Laboratory

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Table 2 and figure 2 presents the department-wise distribution of the prevalence rate of pre-analytical errors in the clinical biochemistry laboratory, based on the total number of samples processed and the corresponding number of pre-analytical errors identified, with a total sample size of 79,592.

The data reveals that pre-analytical errors occur across all departments, albeit at varying rates. Among the departments analyzed, the Critical Care Medicine department exhibits the highest prevalence rate of pre-analytical errors, accounting for 0.99% of the total samples processed. This indicates a relatively higher frequency of pre-analytical errors in critical care settings compared to other departments.

In comparison, the Emergency Department and the Inpatient Department demonstrate similar prevalence rates of pre-analytical errors, with both departments experiencing errors in approximately 0.51% of the samples processed. The Outpatient Department shows the lowest prevalence rate of pre-analytical errors at 0.06%.

Overall, the aggregated prevalence rate of pre-analytical errors across all departments is calculated to be 0.52%.

These findings underscore the importance of department-specific analysis in identifying areas of improvement and implementing targeted interventions to mitigate pre-analytical errors, thereby enhancing the quality and reliability of laboratory testing services.

Table 3: Month Wise Frequency Distribution of Pre Analytical Error Samples

Months	No. of samples received	No. of Pre analytical error samples	In %
Sep-23	12948	43	0.33%
Oct-23	14807	82	0.55%
Nov-23	12489	61	0.49%
Dec-23	13367	91	0.68%
Jan-24	14295	79	0.55%
Feb-24	11686	59	0.50%
Total	79592	415	0.52%

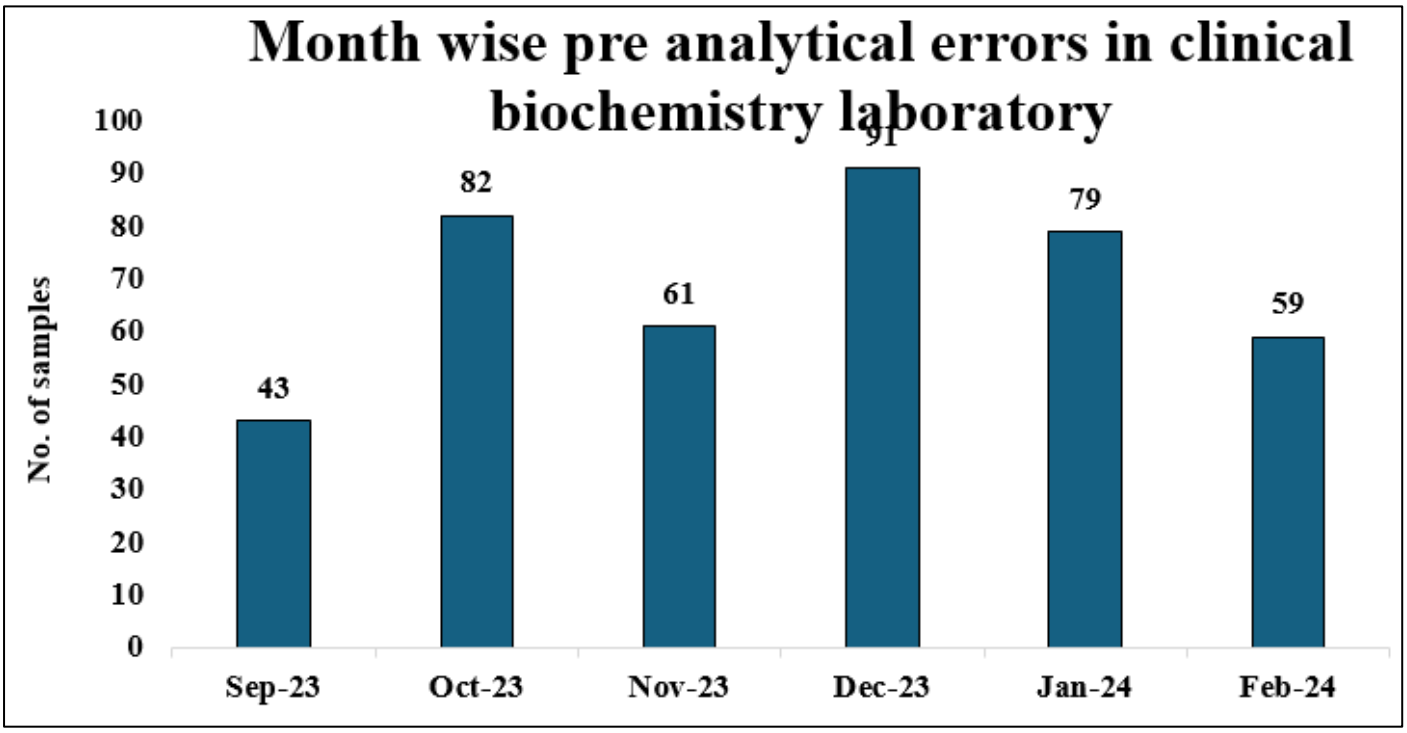

Fig 3: Month Wise Frequency Distribution of Pre Analytical Error Samples

Table 3 and figure 3 illustrates the month-wise frequency distribution of pre-analytical errors in the clinical biochemistry laboratory over a period spanning from September 2023 to February 2024. The table includes the number of samples received during each month, along with the corresponding number of pre-analytical error samples identified, presented both in absolute numbers and percentages.

The data indicates fluctuations in the occurrence of pre-analytical errors across the six-month duration. In September 2023, the laboratory received 12,948 samples, with 43 samples (0.33%) exhibiting pre-analytical errors. The frequency of errors slightly increases in October 2023, with 82 error samples identified out of 14,807 samples received, accounting for 0.55% of the total.

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November 2023 and January 2024 show similar trends, with error rates of 0.49% and 0.55%, respectively. December 2023 stands out with the highest error rate among the months analyzed, where 91 error samples are detected out of 13,367 samples received, representing 0.68% of the total.

February 2024 witnesses a slight decline in error frequency compared to the preceding months, with 59 error samples identified out of 11,686 samples received, constituting 0.50% of the total.

Overall, the aggregated prevalence rate of pre-analytical errors across all months is calculated to be 0.52%, with variations observed in error rates from month to month. These fluctuations may reflect changes in laboratory procedures, workload, or other operational factors during the specified time frame.

The month-wise analysis provided in this table offers valuable insights into temporal trends in pre-analytical error occurrence, facilitating targeted interventions and quality improvement initiatives to address specific challenges identified during each period.

Table 4: Descriptive Statistics of Blood Glucose Parameters of Hemolysed and Actual Samples Received in Clinical Biochemistry Laboratory

Variables		Minimum	Maximum	Median (IQR)	Mean ± SD
Random Blood Sugar (mg/dL)	Hemolysed	78	164	126 (116-144)	126.9 ± 23.5
	Actual	121	197	162 (144-175)	158.8 ± 22.6
Fasting Blood Sugar (mg/dL)	Hemolysed	71	121	92 (85.25-99.75)	93 ± 12.9
	Actual	83	131	103 (97.5-114)	104.7 ± 12.6
Post Prandial Blood Sugar (mg/dL)	Hemolysed	123	173	136 (128.5-145.75)	138.8 ± 14.5
	Actual	134	182	148 (145.25-159.5)	153.2 ± 12.87

Table 4 presents the descriptive statistics of blood glucose parameters for both hemolysed and actual samples received in the clinical biochemistry laboratory. The table includes variables such as Random Blood Sugar, Fasting blood Sugar, and Post Prandial blood Sugar, with their respective minimum, maximum, median (interquartile range - IQR), and mean values ± standard deviation (SD).

Regarding Random Blood Sugar levels, hemolysed samples show a range from 78 mg/dL to 164 mg/dL, with a median of 126 mg/dL and a mean of 126.9 ± 23.5 mg/dL. Actual samples, on the other hand, have a wider range of 121 mg/dL to 197 mg/dL, a median of 162 mg/dL, and a mean of 158.8 ± 22.6 mg/dL.

For Fasting Sugar levels, hemolysed samples range from 71 mg/dL to 121 mg/dL, with a median of 92 mg/dL and a mean of 93 ± 12.9 mg/dL. Actual samples exhibit a wider range of 83 mg/dL to 131 mg/dL, a median of 103 mg/dL, and a mean of 104.7 ± 12.6 mg/dL.

Lastly, in terms of Post Prandial Sugar levels, hemolysed samples range from 123 mg/dL to 173 mg/dL, with a median of 136 mg/dL and a mean of 138.8 ± 14.5 mg/dL. Actual samples have a range of 134 mg/dL to 182 mg/dL, a median of 148 mg/dL, and a mean of 153.2 ± 12.87 mg/dL.

Overall, the descriptive statistics reveal differences in blood glucose parameters between hemolysed and actual samples, with actual samples generally exhibiting higher values across all parameters compared to hemolysed samples. These findings underscore the importance of ensuring sample integrity to obtain accurate blood glucose measurements in clinical practice.

Table 5: Comparing Blood Glucose Parameters between Hemolysed and Actual Sample by using Paired t-Test

Variables	Hemolysed	Actual	Mean Difference (Δ)	Paired t-test	P-Value
Random Blood Sugar (mg/dL)	126.9 ± 23.5	158.8 ±22.6	31.902	-23.34	0.00001
Fasting Sugar (mg/dL)	93 ± 12.9	104.7 ± 12.6	11.714	-16.77	0.00001
Post Prandial Sugar (mg/dL)	138.8 ± 14.5	153.2±12.87	14.429	-11.56	0.00001

Table 5 presents the comparison of blood glucose parameters between hemolysed and actual samples using paired t-tests. The variables analyzed include HbA1c, Random Blood Sugar, Fasting blood Sugar, and Post Prandial blood Sugar, with their respective mean values and standard deviations for both hemolysed and actual samples, along with the mean difference (Δ), paired t-test values, p-values, and significance levels.

Similarly, for Random Blood Sugar, Fasting Sugar, and Post Prandial Sugar levels, hemolysed samples show lower mean values compared to actual samples, with mean differences of 31.902 mg/dL, 11.714 mg/dL, and 14.429 mg/dL, respectively. The paired t-test values are -23.34, -16.77, and -11.56, with p-values of 0.00001 for all parameters, signifying statistical significance.

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Overall, the paired t-tests demonstrate significant differences in blood glucose parameters between hemolysed and actual samples, emphasizing the importance of ensuring sample integrity for accurate glucose level measurements in clinical settings.

III. DISCUSSION

Pre-analytical errors represent a significant challenge in clinical laboratories, as they can directly impact the accuracy and reliability of laboratory test results. These errors occur in the initial stages of the testing process, starting with specimen collection and continuing through transport, handling, and processing. Factors such as improper labeling, delayed transportation, inappropriate sample storage, and inadequate handling techniques are common contributors. Such mistakes can introduce variability in test outcomes, potentially leading to incorrect diagnoses and treatment plans. Notably, pre-analytical errors are difficult to identify once the sample reaches the laboratory, making them harder to address unless strict protocols are in place from the onset. Quality assurance programs and continual training of healthcare staff, especially those involved in phlebotomy and sample collection, can help mitigate the risk of these errors. Implementing modern technologies, such as barcode systems and automated tracking, offers significant potential in reducing human errors related to patient identification and sample misplacement. Regular monitoring of quality indicators and error reports allows laboratories to identify patterns and systemic issues, providing an opportunity for targeted interventions. Despite these advancements, laboratories must remain vigilant and consistently review their procedures to adapt to emerging challenges. Additionally, laboratory professionals should foster a culture of continuous improvement, encouraging open reporting of errors without fear of repercussions. This transparency is essential for long-term quality enhancement. Laboratories that focus on reducing pre-analytical errors can ultimately improve the precision of diagnostic testing, ensuring better patient outcomes and reducing the risk of misdiagnosis or delayed treatment.

IV. CONCLUSION

Pre-analytical errors are a critical concern in clinical biochemistry laboratories, as they significantly influence the accuracy and reliability of diagnostic results. Implementing comprehensive training, utilizing advanced technologies, and monitoring quality indicators can substantially reduce these errors. Through continuous improvement and a proactive approach, laboratories can enhance the overall quality of patient care.

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