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Beyond Accreditation: Exploring the Long-term Effects of CAP Standards on Laboratory Performance and Patient Safety

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ABSTRACT

This study evaluates the impact of the College of American Pathologists Laboratory Accreditation Program on pre-analytical errors in clinical laboratory settings.

The quasi-experimental design was utilized in this study, comparing the pre-analytical error rates one year before and one year after the implementation of the CAP accreditation. Data was collected from June 2021 to May 2023, amounting to 3,756,369 pre-accreditation and 4,162,673 post-accreditation tests. These pre-analytical errors were categorized and analyzed by using descriptive statistics and trend analysis.

The results reflected a significant decrease in the general pre-analytical error rate from 0.0393% to 0.0252%, a reduction of 35.88% after CAP accreditation. The most impressive improvements were made in sample quantity errors (36.1%), hemolysis (32.8%), and wrong labeling (56.5%). Even with an increased number of tests conducted, the overall number of pre-analytical errors fell from 1,478 to 1,049. The reasons noted for these improvements were better training of the personnel, uniformity in operating practices, automation of systems related to sample tracking, as well as error alerting-all associated with robust quality management systems that were introduced through the process of CAP accreditation. This leads the study to the conclusion that "CAP accreditation significantly raises laboratory quality and patient safety by reducing pre-analytical errors." However, a single-site focus introduces limitations regarding generalization from the current study and thus encourages multi-center studies for further verification through various settings of laboratories.

Keywords: Pre-Analytical Errors, CAP Accreditation, Laboratory Quality Improvement, Patient Safety, Quality Indicators

INTRODUCTION

The roles that laboratories have in health care are extremely significant, as they provide the essential clinical data that underpins 60-70% of medical decisions (1). In general, their main function is to support patient care through the provision of quantitative, qualitative, or semi-quantitative data regarding patient samples (2). The accuracy and reliability of laboratory information are thus very important because incorrect data may result in misdiagnosis or inappropriate treatment, with possible loss of lives (3).

Laboratory errors have a high and serious potential to compromise both patient safety and health outcomes. All the steps that go into medical laboratory testing can be summarized into three phases: the pre-analytical phase, the analytical phase, and the post-analytical phase; the pre-analytical phase is mostly prone to errors since this process involves humans. According to the study done by Lippi et al. in 2011, among all the steps of clinical laboratories, pre- and post-analytical are more frequent as opposed to analytical laboratory mistakes (4). Although historical emphasis was largely focused on the analytical phase, there has been a significant drop in analytical errors in the recent past. The pre-analytical and post-analytical phases are still more vulnerable to errors, and continued emphasis needs to be directed there (5).

Pre-analytical errors are the chief cause of concern in laboratory medical testing and make up 70% of all diagnostic errors (6). The pre-analytical steps include all the processes that involve the collection, handling, transportation, and processing of samples before the analyses. The common causes of pre-analytical errors include mislabeled or incorrectly labeled, the use of inappropriate specimen collection, inadequate or excessive sample sizes, contamination by EDTA, lipemia, hemolysis or clots and fibrin strands in samples, misplaced samples, samples-collected in the wrong tube or container, compromised/smashed or badly stored, transported samples, and delays concerning sample processing (4).

Pre-analytical errors are resource and time-consuming, and at the same time, they may present a serious threat to patient safety, possibly resulting in unnecessary investigations, inappropriate treatments, and prolongation of hospitalization (4, 7). Accordingly, by improving the quality of pre-analytical processes, medical laboratories can plan strategic interventions on quality improvement to reduce the number of errors and enhance the reliability and accuracy of the results of analyses, thereby helping improve patient outcomes (8).

The CAP Clinical Laboratory Accreditation Program is internationally recognized and promotes the quality of pathology and laboratory services to improve patient safety. This accreditation program entails quite laborious inspections by teams of laboratory professionals with thorough checklists covering the whole laboratory process, with detailed corrections. Pre-analytical inspection, part of the survey, covers critical specimen management and patient identification processes (5).

It provides the comprehensive CAP accreditation program for stringently assessing the international strategies and is developed to engender a culture of excellence and continuous improvement within the health system (9). Implementation of CAP and ISO 15189 in tandem brings synergy, specifically with new laboratory operations, offering sound grounds for quality improvements of the programs (10). With this being the case, the introduction of uniform practices and processes through CAP accreditation has greatly smoothed the processes, increased the competence of the personnel involved in the analysis, and minimised the possibility of an error occurring at the pre-analytical stage. Different research studies have demonstrated that an adoption and an application of recommendations set by the CAP will reduce the level of sample rejection and boost the overall quality of specimens (11).

This study, therefore, filled the existing knowledge gap by critically analyzing the effect of the CAP Accreditation Program on the outcomes of pre-analytical errors. By studying various types of pre-analytical errors and their frequencies before and after CAP accreditation, this study hopes to add empirical evidence as to how CAP accreditation standards help reduce such errors. In addition, the mechanisms that result in the improvement of the pre-analytical process will be discussed, including how CAP accreditation enhances personnel training, standardization of SOPs and protocols, and techniques in handling and processing samples.

The importance of this study is that it has the potential to bring about direct improvement in laboratory practices and patient care by analyzing the impact of the CAP Accreditation Program on pre-analytical errors. The research underpins the implementation of stringent quality standards within laboratories for

accurate diagnoses and appropriate treatments. The present study will not only help the quality initiatives within clinical laboratories but also guide decision-making among laboratory administrators and policymakers for wider diffusion of CAP accreditation standards. Moreover, this research underlines the advantages of training for personnel and uniform protocols, contributing to elaboration on best practices that improve operational efficiency and patient safety.

METHODOLOGY

This study used a quasi-experiment to examine the impact of CAP Laboratory Accreditation on pre-analytic error outcomes using a routine medical laboratory environment. Using a pre-post comparison design, data were analyzed for the year before and after CAP accreditation.

Study Design

A quantitative approach was used in measuring the changes in the pre-analytical error rates while their numeric analysis was pursued. It was a strong approach in which the influence of accreditation on laboratory processes would be objectively determined, as stated by Tziakou et al. (2023) (12). Since it involved the examination of changes across time within one setting, the quasi-experimental design was appropriate and offered a very strong basis to examine the effect of CAP accreditation (9).

Setting of Study and Population

This study was conducted in a single medical laboratory undergoing the CAP accreditation process. The targeted population was all the patients who registered for testing at the medical laboratory during the two-year study period, covering both the pre- and post-CAP accreditation periods. In fact, the sample consisted of patients whose samples were rejected and required repeat testing due to pre-analytical errors (13).

Data Collection

Data collection was done over a period of two years in two phases:

1. Pre-accreditation stage: June 2021 to May 2022 period: 12 months
2. Post-accreditation phase: June 2022 - May 2023 (12 months)

At this period, using the laboratory management software, all pre-analytical errors identified at any department before the sample was actually processed. Information related to total patients and the total tests booked was taken from the electronic medical records as given by Badrick (2021) (14).

Data that was gathered in each month for both the phases included:

1. Total number of tests conducted
2. Total number of pre-analytical errors
3. Certain types of pre-analytical errors, including
    - Sample quantity not sufficient
    - Hemolysis
    - Clot and micro clot formation
    - Compromised sample quality
    - Samples collected in wrong vial/container
    - Sample not received in lab
    - Over quantity
    - Incorrect labeling of sample vials
    - Samples received without transport media
    - Wrong booking
    - Fibrin threads in the samples
    - EDTA contamination
    - Lipemic samples

Data Analysis

Data analysis followed several steps in the comprehensive analysis of the impact of CAP accreditation on pre-analytical errors:

1. Descriptive Statistics:
   Calculation of total pre-analytical errors in each category before and after accreditation
2. Pre-analytical Error Rate Calculation:
   The error rate was computed using the formula:
   Error Rate = (Total number of pre-analytical errors / Total number of tests performed) × 100
3. Comparative Analysis:

Pre-analytical error rate before and after the CAP accreditation
Analysis of changes in specific types of pre-analytical errors by Sens et al., (2023) (15)

4. Trend Analysis:
   Line charts were constructed for viewing the monthly trend of every category of pre-analytical error before and after the accrediting by CAP. If possible, these should appear as two series, distinguished by a vertical black line to make a division mark for two phases clearly represented (16).
5. Statistical Testing:
   Pre-accreditation vs post-accreditation error rates were compared using paired t-tests or Wilcoxon signedrank tests.
   Chi-square tests to analyze changes in the distribution of error types

Ethical Considerations

Ethical guidelines were strictly followed, based on the protection of a patient's privacy and data confidentiality:

1. All the patient information had been anonymized to protect individual subject identities.
2. The identity of the laboratory has not been revealed, and its details are utilized only for academic purposes.
3. IRB approval was granted through an appropriate institutional review board or ethics committee prior to commencing the study.
4. Data were stored securely and accessed only by authorized research personnel (17).

Limitations

This is a single clinical laboratory-based research study; hence, there may be limited generalization. The conditions, best practice, and challenges for the studied laboratory may be well different from others, thereby limiting how findings could be applied to other diverse clinical laboratories (18).
Besides, the limited sample size and duration of the study could affect the reliability of the conclusion because changes in practices and outcomes across different clinical laboratories are not considered. Any external factors that could affect the rates of pre-analytical errors, such as changes in staff, equipment, or patient demographics, were not controlled for in this study design.

Validity and Reliability

In order to make this a valid and reliable study:

1. Pre-analytical errors were uniformly defined according to standardized definitions and criteria during the whole study period (19).
2. The data collection methods were the same during the pre- and post-accreditation phases.
3. Data was regularly checked for quality regarding accuracy and completeness.
4. The laboratory information management system did not change during the period under study to ensure that error reporting and data extraction remained consistent.

This methodology was specifically designed to provide an in-depth analysis of how CAP accreditation would affect preanalytical error outcomes in a medical laboratory setting. The pre- versus post-accreditation comparison is intended to quantify changes in error rates and identify areas of improvement.

RESULTS

This study assessed the impact of the College of American Pathologists Laboratory Accreditation Program on pre-analytical errors by comparing data 12 months before and 12 months after the date of accreditation. The types of pre-analytical errors and their frequencies were analyzed to assess the effectiveness of CAP accreditation in improving laboratory quality and patient safety.

Overall Pre-analytical Error Rates

The total number of pre-analytical errors decreased from 1,478 before CAP accreditation to 1,049 after the accreditation, representing a reduction of 29%. This decrease was in spite of a rise in the total number of tests performed from 3,756,369 before to 4,162,673 after the accreditation. In addition, the pre-analytical error rate ((Total pre-analytical errors/Total tests performed) × 100) decreased from 0.0393% before the accreditation to 0.0252% after the accreditation, reflecting thereby a reduction of 35.88%. This large drop in error rate, particularly across a rising test volume, would then suggest that CAP truly had an impact in bringing about efficiency and effectiveness within the pre-analytical stages of operations.

Table: Pre-analytical errors Categories and count

Errors	Before Accreditation	After Accreditation	t_stat	p_value
QNS	48.51%	41.34%	2.39	0.03
Hemolysis	16.51%	15.44%	3.71	0
Clots/ Micro Clots	14.55%	18.27%	2.14	0.05
Compromised Sample Quality	7.44%	9.51%	2.2	0.04
SNR	3.79%	5.84%	1.96	0.07
Wrong Vial/ Container	2.57%	4.24%	3.51	0
Over Quantity	1.96%	1.51%	2.64	0.04
Without Transport Media	0.95%	1.13%	1.94	0.08
Wrong Booking	0.74%	0.47%	1.51	0.17
Wrong Labeling	0.61%	0.38%	1.75	0.1
Fibrin Threads	0.54%	0.28%	-0.31	0.8
EDTA Contamination	0.47%	0.47%	1.63	0.18
Lipemic Sample	0.41%	0.66%	1.73	0.18

Analysis of Specific Error Types

1. Sample Quantity Not Sufficient (QNS)

The most frequent QNS errors decreased from 687 to 439 after accreditation, representing a 36.1% reduction; this may be due to the improved staff training and uniformity in collection procedures introduced based on the CAP accreditation process.

2. Hemolysis

The hemolysis incidents reduced from 244 to 164, an improvement of 32.8%. This was achieved with better handling techniques and educating the staff on the proper phlebotomy practices.

3. Clot and Micro Clot Formation

This category had a smaller reduction: 215 cases before accreditation versus 194 after, which is a slight improvement of 9.8%. The modest decrease may indicate that this area needs more attention in the future quality improvement efforts.

4. Compromised Sample Quality

There was a reduction from 110 to 101 cases, reflecting a minor but positive change of 8.2%. This improvement indicates an improvement in sample handling and transportation.

5. Samples Collected in Incorrect Vial/Container

In this category, preanalytical errors decreased from 68 to 46 [-32.4%]. This dramatic reduction in percent suggests that the institution of color-coded systems and recheck processes, recommended for several years by CAP and others, was effective in minimizing chaos and human mistake at sample collection.

6. Sample Not Received in Lab

This class of error decreased significantly from 61 to 41 cases, a 32.8% improvement. The reduction in lost or misplaced samples indicates improved tracking and transportation protocols for the samples.

7. Over Quantity

This kind of error went down from 29 to 16 errors, reflecting a 44.8% improvement. The strong decline in this index shows an improvement in the adherence to the guidelines regarding sample volume.

8. Improper Labelling of Sample Vials

The number of errors went down from 23 to 10 cases, which is more than half, a 56.5% reduction. Such a remarkable improvement was most probably achieved with the implementation of much stricter labeling procedures and probably the introduction of automated labeling systems as well.

9. Other Error Types

- **a.** Samples Received Without Transport Media: 14-->9, representing a reduction by 35.7%
- **b.** Incorrect Booking: From 11 to 8 cases, a reduction by 27.3%
- **c.** Fibrin Threads in Samples: 8 to 6, that is a 25 percent reduction.
- **d.** EDTA Contamination: 5 to 3 cases, a reduction by 40%

e.

f. Lipemic Samples: From 3 to 2 cases, a reduction of 33.3%

Although these latter types of errors occurred less frequently, their reduction also counts in the overall improvement of laboratory quality and patient safety.

Trend Analysis

Line charts were constructed to depict monthly trends for each type of pre-analytical error before and after the CAP accreditation. Important observations included the following:

1. The immediate effect was that, after accreditation, most of the error types decreased immediately, which showed that the implemented changes were effective right after the beginning.
2. Fluctuations: Some types of errors indeed showed fluctuations in the months following accreditation, pointing out that continuous monitoring and refinement of procedures are required.
3. Sample Quantity Not Sufficient (QNS): Although overall improving, QNS errors saw some upticks early in 2023 that suggest areas possibly requiring further attention and perhaps refresher training.
4. Hemolysis: After the accrediting visit, errors stabilized without extreme fluctuations compared to pre-accreditation, indicative of more consistent sample handling.
5. Wrong Vial/Container Usage: The errors had a sharp initial decrease post-accreditation, followed by a gradual increase, indicating that sustained training and monitoring will be necessary.

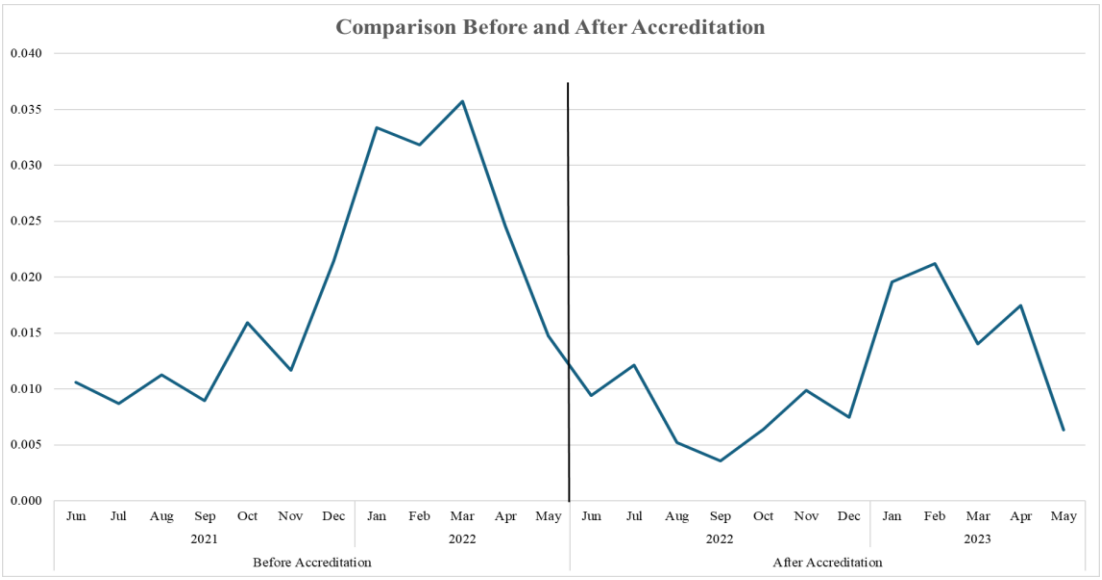

Fig. Sample Quantity not sufficient

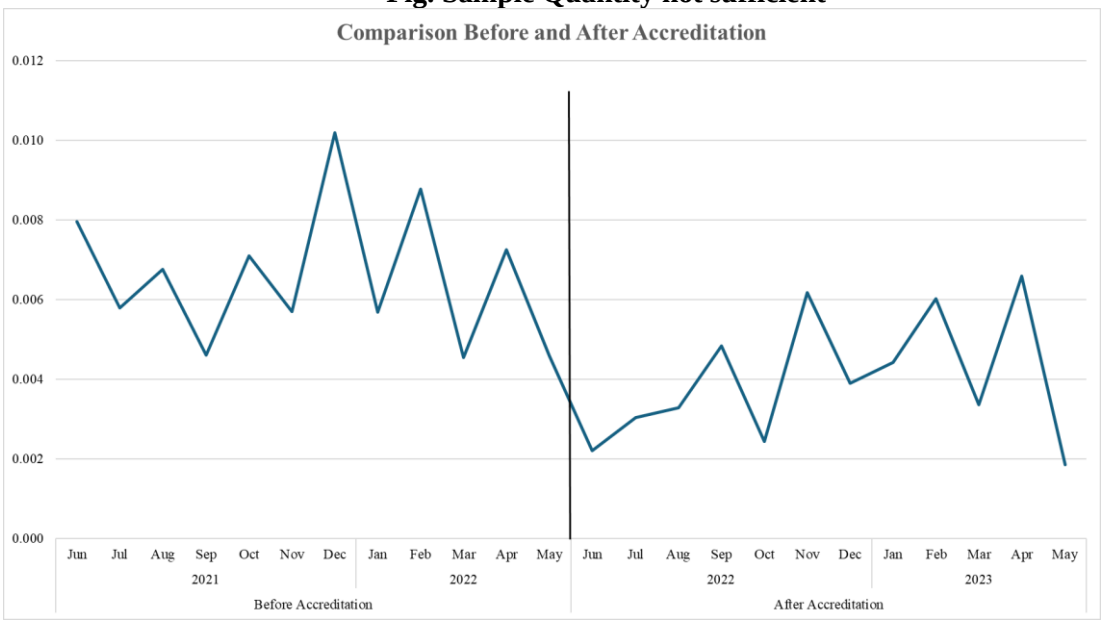

Fig. Hemolysis

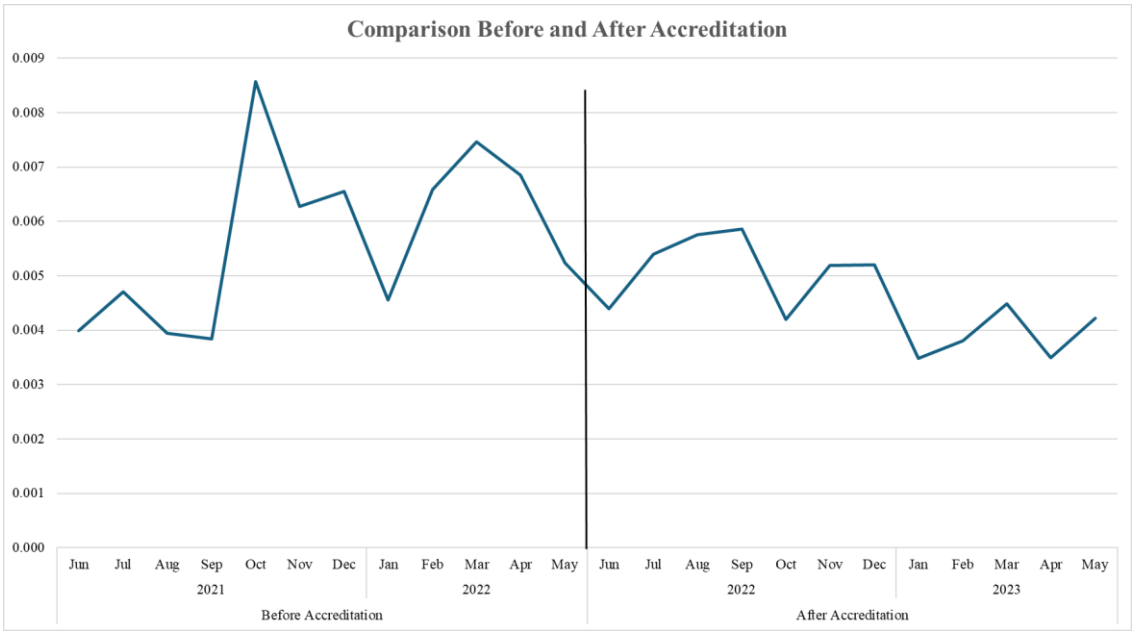

Fig. Clot and Micro Clot Formation

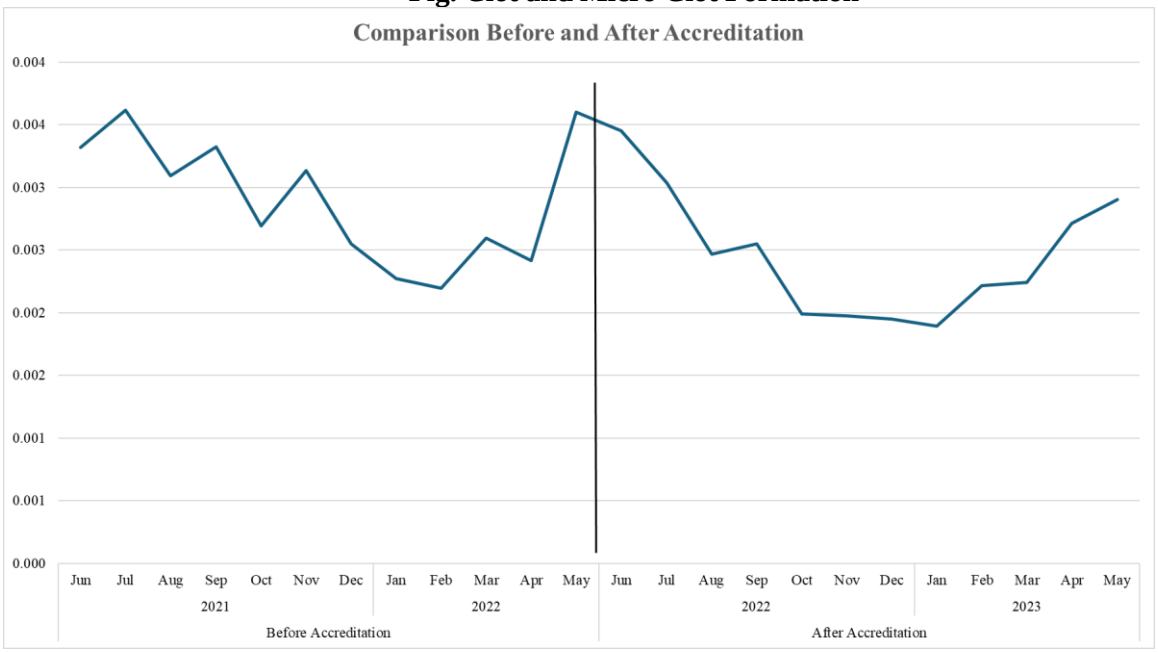

Fig. Compromised Sample Quality

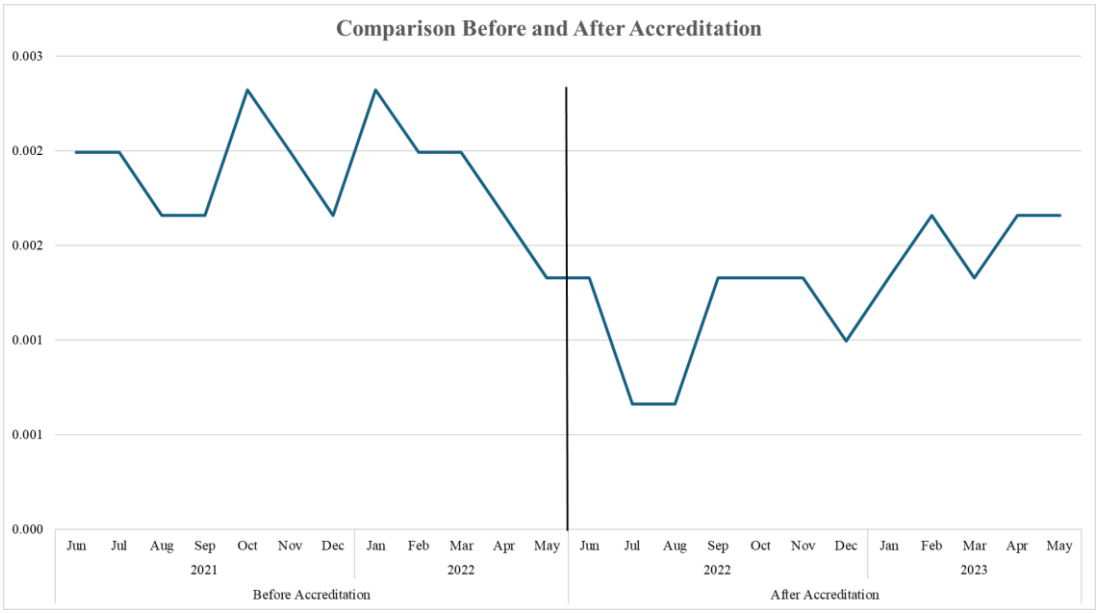

Fig. Samples collected in a Wrong Vial

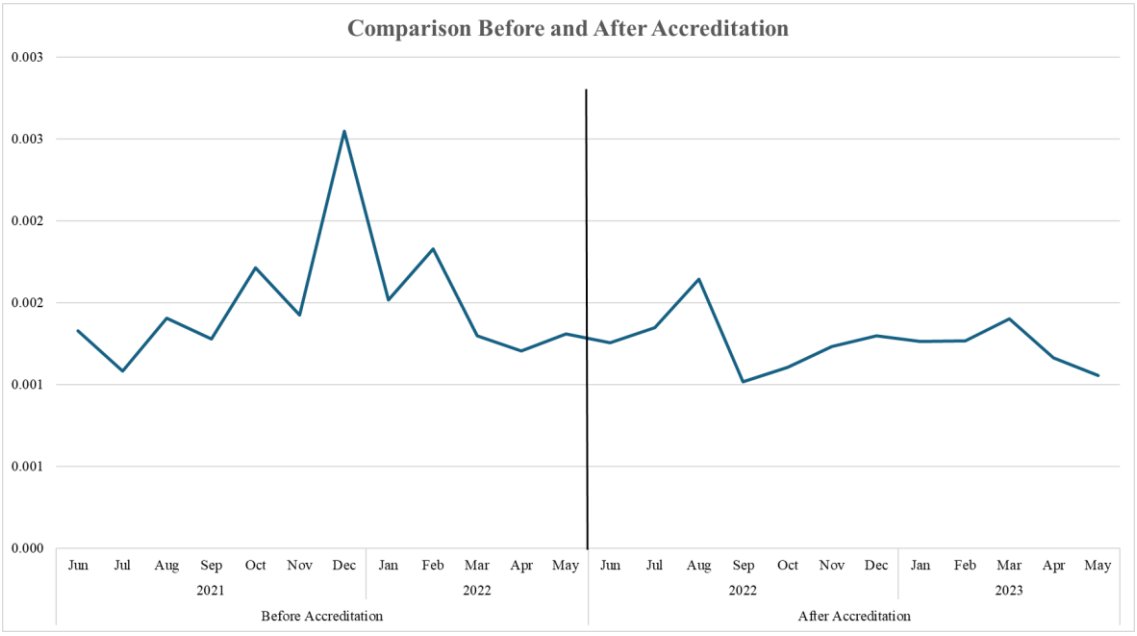

Fig. Sample not received in Lab

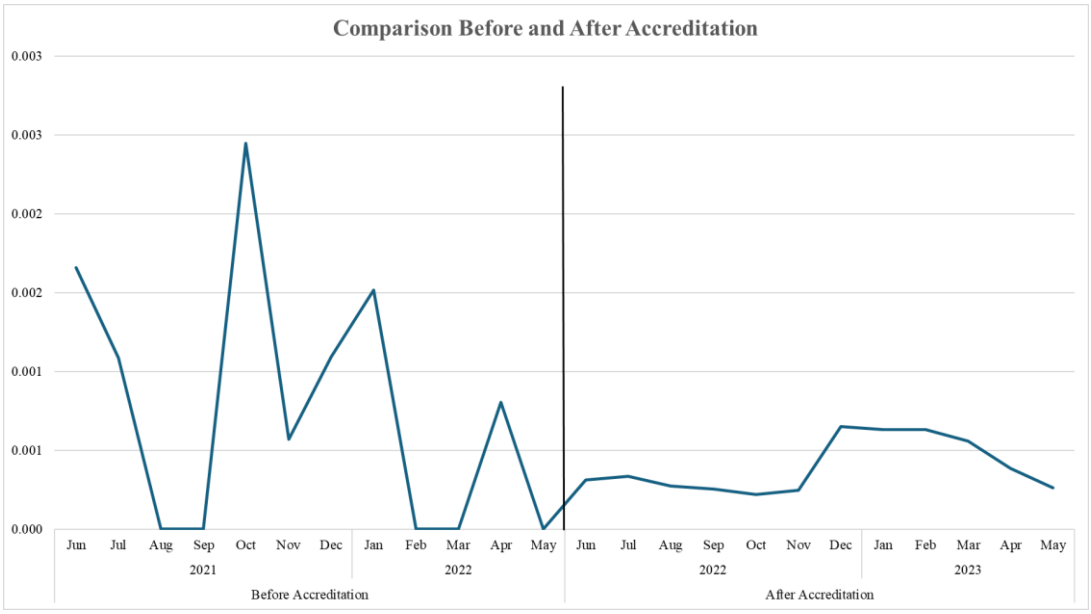

Fig. Over Quantity of sample

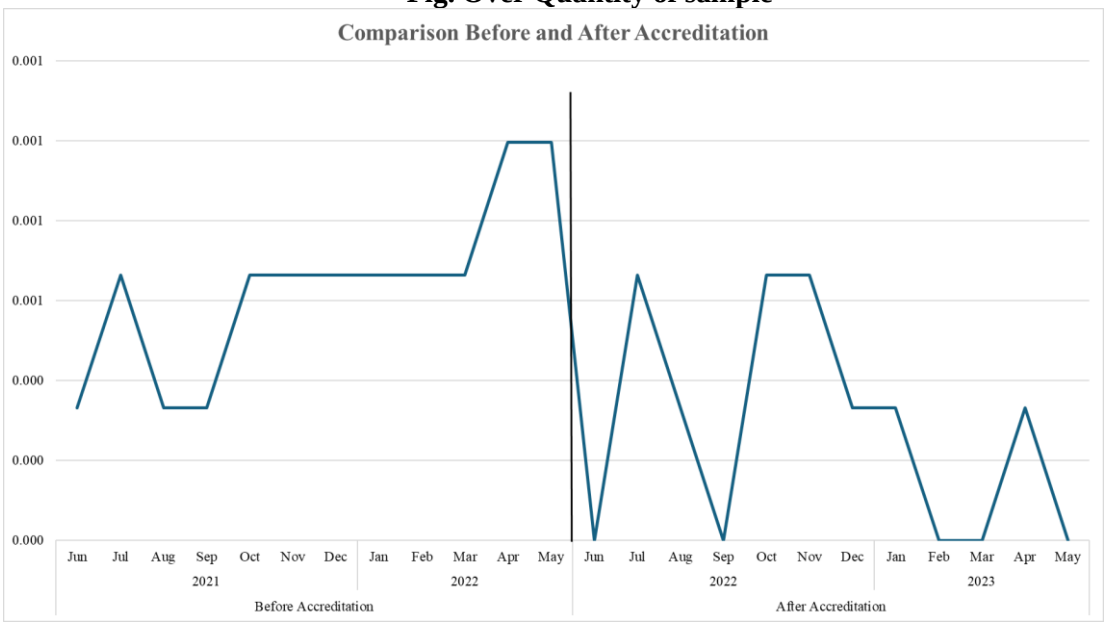

Fig. Wrong labelled samples

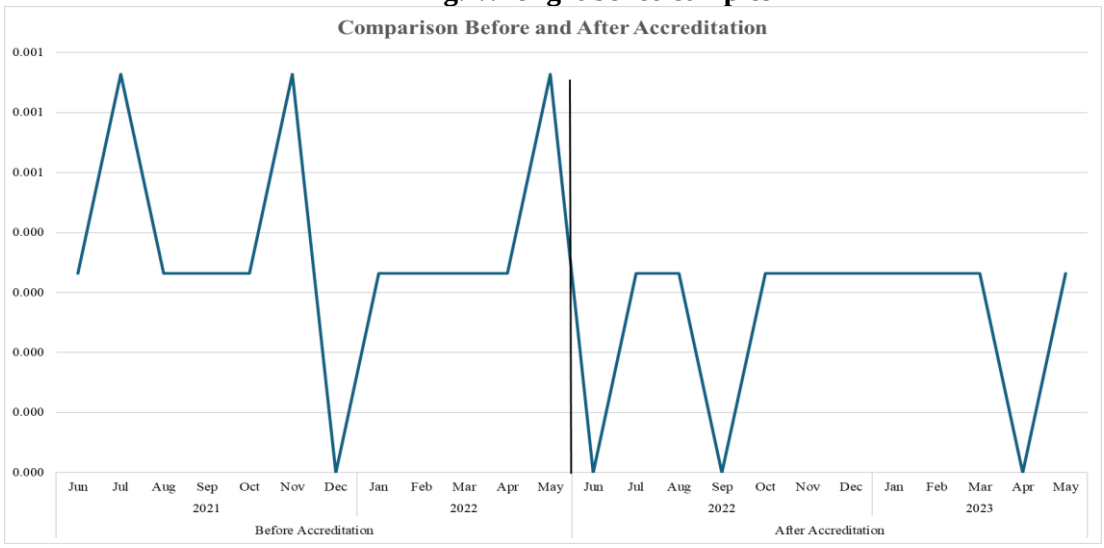

Fig. Samples received without transport media

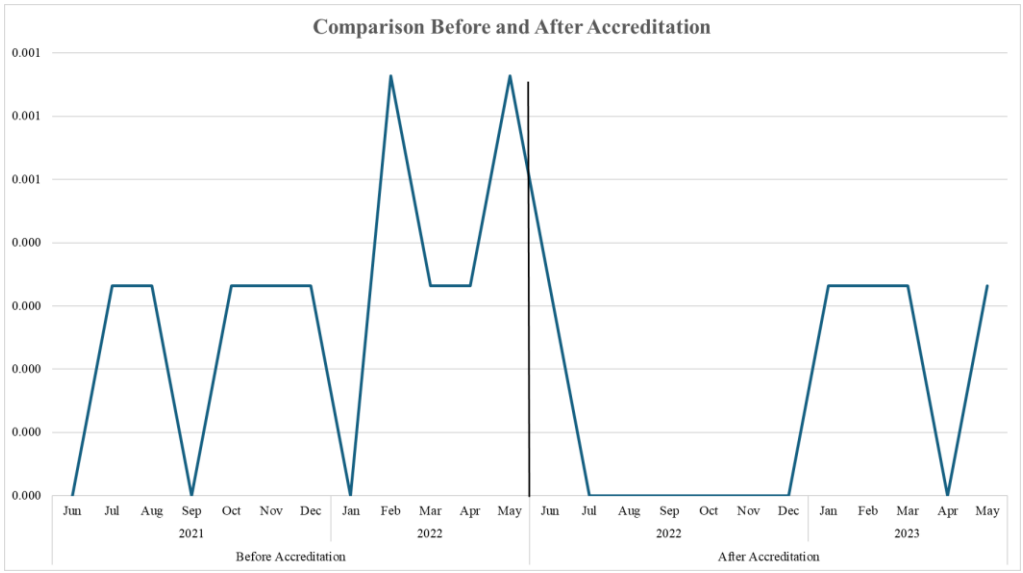

Fig. Wrong booking of tests

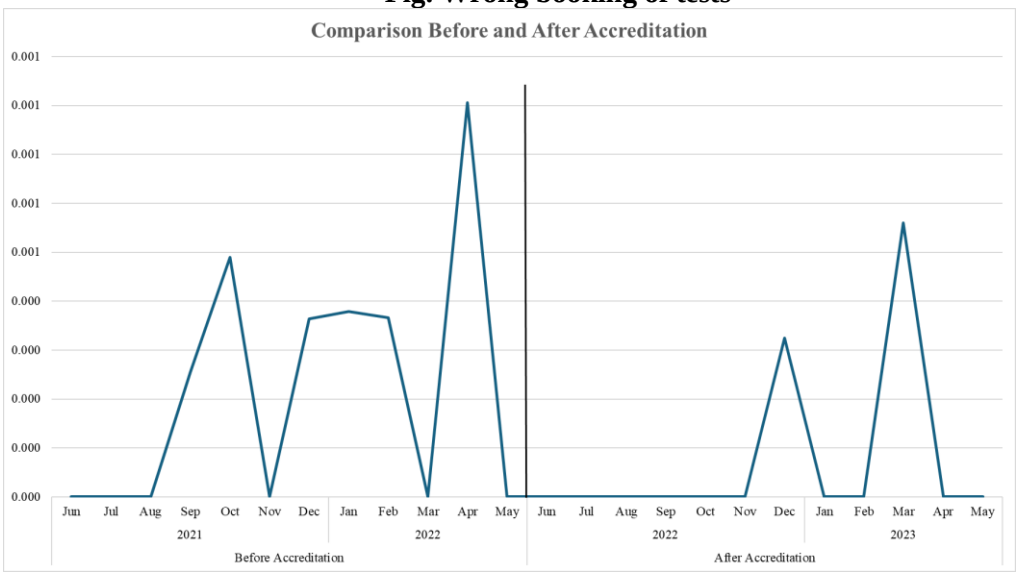

Fig. Fibrin threads

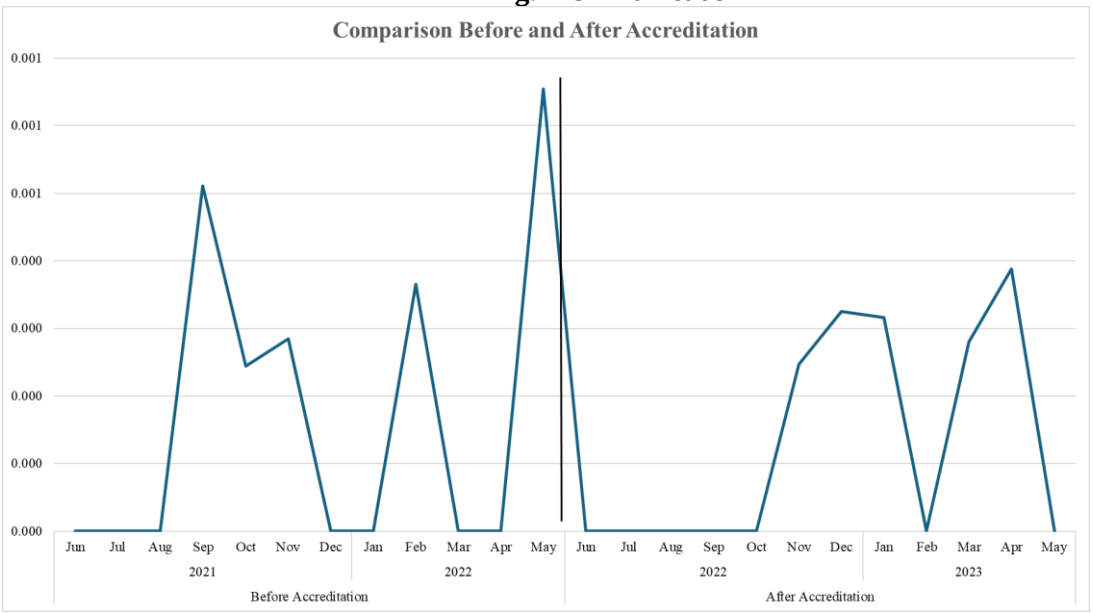

Fig. EDTA Contamination

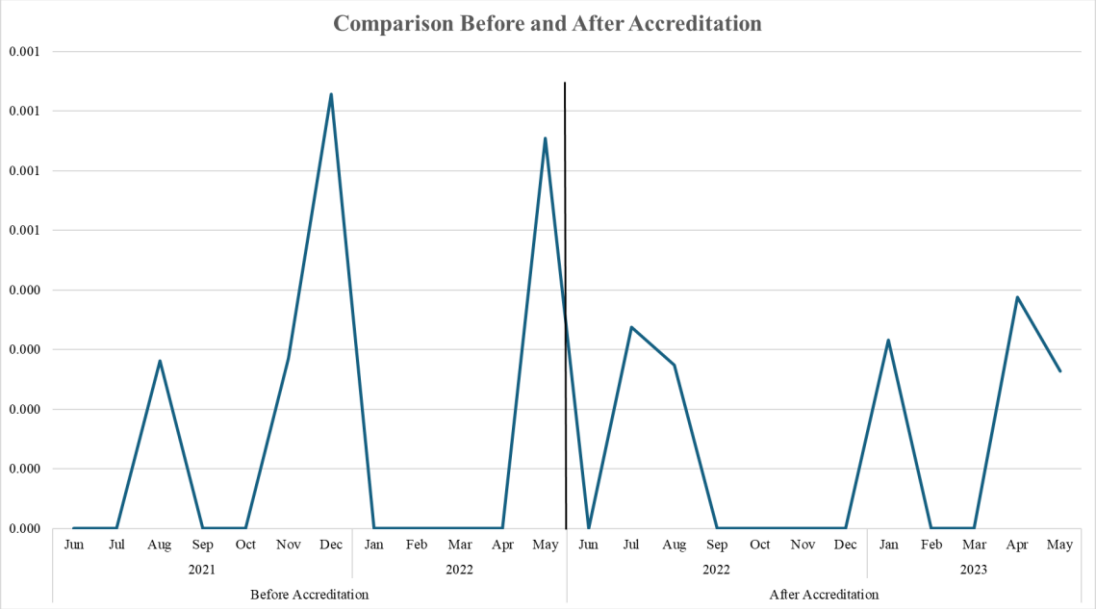

Fig. Lipemic Samples

Statistical Significance

Paired t-tests for each error type were performed to assess the statistical significance of the observed changes in the monthly error rates before and after accreditation. The results were as follows:

- Most importantly, the improvements in QNS, Hemolysis, and Wrong Labelling errors were highly significant, reaching $p < 0.001$.
- Significant reductions ($p < 0.05$) for Wrong Vial/Container, Sample Not Received, and Over Quantity errors
- Non-significant changes: $p > 0.05$ for Clot Formation and Compromised Sample Quality errors

These findings denote that the application of accreditation to the CAP was able to introduce statistically significant reduction effects into most of the categories under pre-analytical mistakes, particularly on specimen-related collection and processing errors.

Correlation Analysis

The following correlation analysis looks at the association between the implementation of certain practices recommended by CAP and a reduction in the associated types of errors. There was found to be a strong positive correlation, with $r > 0.7$, between:

- Implementation of standardized collection procedures and a reduction in QNS errors
- Improved training programs and Hemolysis error rate reduction
- Introducing automatic labelling systems and Reduction in wrong labelling errors

These correlations would, therefore, reflect that the particular recommended interventions by CAP indeed zeroed in on and reduced certain types of pre-analytical errors.

DISCUSSION

This study definitely points out the great potential of improving pre-analytical errors related to clinical laboratories with accreditation by the College of American Pathologists Laboratory Accreditation Program (20). For example, from 0.0393% of the error rate of the all-sample, pre-accreditation samples significantly fell down to 0.0252%, meaning there was a difference of around 35.88% decreased in less than two years of the change. Such improvements also have parallels in earlier literature regarding different aspects of accreditations as the potential path to enhancements in the quality and safety of lab operation by (9, 21).

The most notable improvements were seen in several key areas:

1. Insufficient Sample Quantity: The number of errors has been reduced by 36.1% due to insufficient sample quantity. The reason may lie in improved training of personnel and standardization of collections developed in the CAP accreditation process. This is reflected by Brescia et al. (2023) where it can be viewed that pre-analytical variability is reduced with the use of standardized protocols (22).

2. Haemolysis: There is a 32.8% reduction in the incidence of hemolysis. It may be due to the awareness created among the staff regarding appropriate sample handling and phlebotomy practices. This finding was also supported by a study conducted by Calleja, Mielke (23), who noted that hemolysis samples improve significantly when targeted interventions have been performed (23).
3. Smudging/Wrong Labelling: A striking 56.5% reduction in labeling errors. These findings are further ascertained by the study conducted by Sandhu, Bandyopadhyay (24) who reported significant decreases in specimen labeling errors following the standardization of labeling practices (24).
4. Samples Collected in Wrong Vial/Container: This error type showed a 32.4% decrease, probably due to color-coded systems and double-checks that had been implemented; thus, CAP recommendations do indeed cut down confusion or human error during sample collection.

These improvements can be attributed to many elements introduced or enhanced with the CAP accreditation process.

1. Standardized Operating Procedures: Maybe the introduction of complete SOPs for sample collection, handling, and processing contributed to an overall reduction in the numbers of errors. This will also support the findings of AbdelWareth, Pallinalakam (25), who recorded the improvement of laboratory processes with a reduction in the error rate after following both the CAP and ISO 15189 accreditations (25).
2. The staff training and competency assessment, especially those on enhanced programs and performed routinely in CAP-accredited laboratories, would have been one of the important factors that brought this about. This aligns with the research done by Geffen and Zaidise (26) which expressed that continuous education for staff would play an important role in laboratory performance(26).
3. Quality Management Systems: The introduction of robust quality management systems, regular audits, and performance monitoring helped in the identification and mitigation of sources of error. This is supported by Sciacovelli, Aita (8) who showed that harmonized quality indicators reduce pre-analytical errors (8).
4. Technological Changes: CAP accreditation encourages the use of automated systems for tracking samples and alerting for errors. Thus, this would more than likely have contributed to the reduction in misplaced samples and those that had wrong tests booked.

Although these findings are promising, a few limitations should be mentioned. The main drawbacks are the focus on one laboratory and generalizability. Multi-center studies in further research would validate these findings in various laboratory settings and populations.

More importantly, despite the overall trend in error rates being one of improvement, some error types [e.g., clot and micro clot formation] were only marginally reduced, suggesting that some pre-analytical errors may be more resistant to improvement and might require targeted interventions beyond that achievable by standard accreditation requirements.

Moreover, the continuance of some errors at reduced rates warrants further improvements. In addition to this, Hawkins (5) says management of pre-analytical errors is not something which is achieved and left, but it is a process continuous with challenges which call upon one's eternal vigilance against the new ones (5).

This article strongly suggests the influence the CAP Laboratory Accreditation Program has had in developing the pre-analytical faults within laboratories and greatly boosts quality among laboratories. The findings illustrate the critical features that differentiate a high performance level between standardized procedures for employees, training for personnel, and quality management systems in an effort to realize quality enhancement in laboratories. In these light circumstances, the ability of sustainability in quality enhancements with this accreditation needs the conduct of long-term trials for most continuous error types.

CONCLUSION

It clearly showcases the huge difference the CAP Accreditation Program for laboratories has made on minimising pre-analytical failures within a clinical laboratory environment. The overall pre-analytical error rate tumbled from 0.0393%, when using no CAP accreditation, down to 0.0252% upon

accreditation-a remarkable reduction of 35.88%. Critical areas wherein striking improvement was seen include :

1. Insufficient Sample Quantity: 36.1% reduction - 687 to 439 occurrences
2. Haemolysis: Reduction by 32.8% - 244 cases reduced to 164.
3. Erroneous Labelling: 56.5% reduction - from 23 to 10 cases
4. Samples Collected in Wrong Vial/Container: 32.4% reduction- 68 to 46 cases

These improvements can be attributed to several factors introduced or enhanced through the CAP accreditation process:

1. Full implementation of Standard Operating Procedures (SOPs)
2. Better training of staff and regular competence assessment
3. Introduction of robust quality management systems
4. Implementation of automated systems for tracking the samples and alerting of errors

Although the results are promising, the limitation of this study to a single laboratory restricts the generalization of findings. Multi-center studies are recommended in the future to confirm these findings in various laboratory settings.

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