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Assessment of Pre-analytical and Analytical Performance Using Sigma Metrics and Quality Goal Index: A Case Study on Liver Profile Analysis at Benghazi Medical Center

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ABSTRACT

Background and Objective: This study aimed to assess the performance of the liver function profile including Total Protein (TP), Total Bilirubin (T. Bil), Alkaline Phosphatase (ALP), Aspartate Aminotransferase (AST), and Alanine Aminotransferase (ALT) during the pre-analytical and analytical phases, with a focus on Sigma metrics and the Quality Goal Index at Benghazi Medical Centre, Libya.

Materials and Methods: We collected data through a questionnaire evaluating pre-analytical aspects, such as the eligibility of request forms and sample quality. A total of 200 request forms and 12,256 samples were analyzed by calculating Sigma levels and defects per million opportunities. Additionally, three months of internal quality control data for both normal and pathological levels were reviewed, and Sigma metrics and Quality Goal Index values were determined.

Results and Discussion: The study revealed a high frequency of pre-analytical errors, with 34.6% of request forms deemed ineligible, resulting in a low Sigma level of 1.99. Sample quality was also problematic, with 30% of samples being insufficient, leading to a Sigma level of 2.91. Total protein at level I demonstrated excellent performance with a Sigma value of 5.57, while other markers such as TP at level II, AST at level II, and ALT at level II performed well, with Sigma values ranging from 4.03 to 4.40. However, other analytes displayed marginal to unacceptable performance. The findings highlighted significant pre-analytical and analytical challenges, particularly in achieving the world-class Sigma level of 6, necessitating improvements in both precision and accuracy.

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Abbreviations

ALP, Alkaline Phosphatase; ALT, Alanine Transaminase; AST, Aspartate Transaminase; B, Bias; BVD, Biological Variation Database; CV%, Coefficient of Variation; DPMO, Defects Per Million Opportunities; EFLM, European Federation of Clinical Chemistry and Laboratory Medicine; GGT, Gamma-Glutamyl Transferase; INR, International Normalized Ratio; IQC, Internal Quality Control; LFTs, Liver Function Tests; PT, Prothrombin Time; QC, Quality Control; QGI, Quality Goal Index; RCA, Root Cause Analysis; SM, Sigma Metric; T. Bil, Total Bilirubin; T.P, Total Protein; TEa Total Allowable Error

Introduction

Liver function tests (LFTs) are essential for evaluating the health of the liver, a vital organ responsible for metabolism, digestion, detoxification, and substance elimination. These tests including alanine transaminase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), gamma-glutamyl transferase (GGT), serum bilirubin, prothrombin time (PT), international normalized ratio (INR), total protein, and albumin aid in the detect of liver damage and disease. Abnormal LFT results require further investigation, underscoring the importance of these tests in the timely diagnosis and management of liver-related conditions (1).

Laboratory medicine is a fundamental component of healthcare worldwide. Clinical laboratories contribute 90 % of medical data, influencing 60-70% of clinical decisions (2), with slight ranging from 60 to 80% (3). Thus, the quality of clinical laboratory services impacts not only individual patient care but also the entire healthcare system (4). Over the past two decades, the number of available laboratory tests has doubled, now exceeding 3,500 tests available to healthcare professionals. The global in vitro diagnostics (IVD) market, valued at $87 billion USD in 2021, is projected to grow annually by 4.6%, potentially reaching $135 billion USD within the next ten years (2).

The laboratory process is divided into three main phases: pre-analytical, analytical, and post-analytical. The majority of errors occur during the pre-analytical phase, while errors during the analytical phase are comparatively rare. These errors can be challenging to identify, often resulting in incorrect clinical decisions, delayed diagnoses, prolonged hospital stays, and increased resource utilization (5). The lower incidence of errors in the analytical phase is attributed to automation, advanced technology, standardized assays, and skilled personnel. Nonetheless, errors can still occur, primarily due to insufficient internal quality control within laboratories. This issue can be likened to an iceberg, where most errors remain concealed by minimal quality control measures (6).

Assessing the performance of clinical laboratories is imperative to ensure the precision, accuracy, and consistency of test results. This evaluation is typically achieved using quality control materials with well-defined values, serving as a means to validate the effectiveness of the laboratory's testing systems (7).

Six Sigma is a customer-focused, data-driven quality improvement (QI) methodology aimed at reducing process variation that leads to defects (4). The Six Sigma model, proposed by Bill Smith at Motorola, was applied by Nevalainen et al. in clinical laboratories for quality control and continuous improvement (8).

Six Sigma is a methodology used to measure how closely a process aligns with its intended goal. The term "sigma" represents the process's standard deviation (σ), with a higher value indicating fewer defects. World-class processes aim for Six Sigma performance, characterized by fewer than 3.4 defects per million products (DPMO). The correlation between sigma metric and error is as follows:

1 sigma (σ) corresponds to 690,000 defects or errors per million reports, 2 sigma corresponds to 3,08,000 defects per million reports, 3 sigma corresponds to 66,800 defects per million reports, 4 sigma corresponds to 6,210 defects per million reports, 5 sigma is 230 defects per million reports and 6 sigma is 3.4 defects per million reports (9).

Two main approaches to evaluate the Sigma Metric (SM) – one involves counting defects, while the other entails measuring process variation directly. SM quantifies the number of standard deviations within tolerance limits (TL), which, in laboratory medicine, correspond to the total allowable error (TEa). Importantly, TEa is not influenced by the method or reagents used. In clinical laboratories, Westgard introduced SM with an emphasis on measurement bias (B) as a critical component of the assessment (10).

The sigma metric is based on three variables commonly used in clinical laboratories: total allowable error (TEa), imprecision, and precision. Previous studies have shown that various sources of TEa can lead to significant variations in sigma values of the same analyte (8). According to the recommendations of the Conference of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) in Milan in 2014, the database of "desirable" biological variation was selected as the TEa for the liver profile assays in this study.

The Quality Goal Index (QGI) is an integral component of root cause analysis (RCA), used to pinpoint the cause of a reduced sigma level in an analyte, whether it stems from issues related to precision, accuracy, or a combination of both. The desired QGI score to achieve is 0.0 (11).

A QGI falling within the range of 0.8 to 1.2 suggests that improvements are required in both precision and accuracy. Conversely, a QGI exceeding 1.2 indicates that improvements should focus on accuracy (12).

Currently, the six-sigma model finds widespread application in assessing the performance of various analytes and serves as a guiding framework for the adoption of personalized quality control approaches within laboratory settings (8). The σ metric is also valuable for evaluating the effectiveness of quality control (QC) procedures and methodologies. Therefore, by employing Six Sigma principles and metrics, it becomes feasible to evaluate the quality of laboratory testing processes and determine the necessary QC measures to attain the desired level of quality (13). Therefore, in this study we aimed to assess and compare the performance of liver function parameters, specifically total bilirubin (T. Bil), total protein (T.P), alkaline phosphatase (ALP), alanine transaminase (ALT), and aspartate transaminase (AST), utilizing two distinct automated chemical analyzers within a tertiary hospital setting.

Materials and Methods

Study Design

To the best of our knowledge, this research represent the first study of its kind conducted in the specific geographical context of Libya.

This cross-sectional study, conducted at the Benghazi Medical Center (BMC) between July and September 2023, aimed to assess the performance of liver profile tests, specifically (T. Bil), (T.P), (ALP), (ALT), and (AST), during both the pre-analytical and analytical phases, using Sigma metrics and Quality Goal Index (QGI).

A structured, validated questionnaire developed to systematically collect data related to the evaluation of laboratory processes. This questionnaire consisted of two distinct sections, each focusing on specific aspects of the laboratory workflow. The first section addressed the pre-analysis phase, which further subdivided into two key components: the eligibility of request forms and the quality of the collected samples. The second section of the questionnaire dedicated to gathering results related to both the normal and the pathological levels of internal quality control (IQC) for the specified tests throughout the study period.

All reagents, calibrators, and IQC materials were provided by Ortho Clinical Diagnostics (VITROS®) as a first-party supplier.

The ViTROS® 3600 Immunodiagnostic system is an advanced analytical platform that utilizes the principles of dry chemistry and enhanced chemiluminescence. By immobilizing reagents onto a polyester support, this system offers a unique blend of precision and efficiency. The integration of self-monitoring capabilities further enhances the system's reliability and ease of operation.

Total Protein (TP) was determined using a traditional biuret colorimetric method. This well-established method provides a robust and quantitative measure of protein concentration. In contrast, Total Bilirubin (T. Bil) was assessed using a dual-wavelength endpoint colorimetric assay, enabling precise quantification by distinguishing between conjugated and unconjugated bilirubin. Liver enzymes, including Alkaline Phosphatase (ALP), Aspartate Aminotransferase (AST), and Alanine Aminotransferase (ALT), were evaluated using a kinetic, multi-point rate assay. This method provides greater sensitivity and specificity compared to endpoint assays by monitoring the reaction rate over time (14).

Data Collection

Data collection regarding the eligibility of test request forms and the samples quality was carried out through direct observational and responses to inquiries outlined in (Table 1). During the research period, a comprehensive analysis was conducted on 200 inpatient request forms and 12,256 samples submitted for liver profile testing. Control readings, used to evaluate performance, were obtained from the laboratory information system integrated with the VITROS® V4600 Analyzer, an automated chemical analyzer. In the laboratory, two levels of IQC were daily, seven days a week. Consequently, we collected 90 data points for each analyte at each QC level over three consecutive months.

Table 1. The quality indicators of the pre-analytical phase.

Questions related to the request form quality	
1	Is the date of the test request present on the form?
2	Is the patient's name at least three names?
3	Does the patient's age or date of birth exist?
4	Is there a doctor's signature/doctor's name?
Questions related to sample quality	
5	How many insufficient sample quantities received
6	How many samples collected in wrong test tube
7	How many samples re-collected from the same patient
8	How many samples rejected during the study period

Calculation of Sigma Metrics

Calculation of sigma metrics for pre-analytical phase

As per the insights of Westgard and his son in 2006, a recommended approach for determining the six-sigma level in pre-analytic and post-analytic processes involves examining the process's results, quantifying defects, computing a defect rate per one million, and utilizing a statistical table to translate the defect rate per million into a σ metric (13). Sigma levels and defects per million opportunities (DPMO) for the eligibility of test request forms and the quality of samples (qualitative data) were calculated by online six sigma calculators from the website (https://goodcalculators.com/six-sigma-calculator/).

Calculation and interpretation of sigma metrics and QGI for analytical phase

Regarding the quality control readings (quantitative data), Microsoft excel program was used to calculate the means, standard deviations, coefficient of variation, bias, impression, and total error. The Sigma metrics were calculated by excel using Westgard's equation (Sigma Level= (TEa% - Bias%)/ CV% (15). Total allowable error (TEa) signifies the quality objectives set by laboratories. There are various TEa sources, and no universal international standard exists.

In this study, we have determined TEa values in accordance with the consensus established at the Milan Conference 2014, and the data on desirable biological variation for our study parameters were obtained from the EFLM Biological Variation Database ((BVD) (8).

Measurement bias refers to the consistent, systematic difference between the expected or mean value of multiple test results and the true or accepted reference value. Essentially, it indicates how much a measurement consistently diverges from the actual value due to inherent errors in the testing method. Unlike random errors, bias represents a form of systematic error that affects all measurements in the same way, resulting in a predictable level of inaccuracy (16). In this study the reference values were taken from internal quality control sheets of the manufacturer.

Bias% was determined as (our mean – manufacturer's reference value) / (manufacturer's reference value) x 100 (17). The coefficient of variation (CV%) represents the imprecision of the analytes, which was obtained by accumulating the data during the study period and was calculated for each IQC level by the equation {CV%= SD/meanx100) (8). The Quality Goal index (QGI) was calculated using the formula (QGI= %Bias/(1.5 x CV%) (11). The interpretation of sigma metrics and QGI score were illustrated in Table 2 (18).

Table 2. Interpretation of sigma metrics and quality goal index.

Sigma value	**Indication**
σ value ≥ 6	World-class performance
σ value ≥ 5	Excellent performance
σ value ≥ 4	Good Performance
σ value ≥ 3	Marginal Performance
σ value ≥ 2	Poor Performance
σ value < 2	Unacceptable performance
QGI	**Problem**
<0.8	imprecision
0.8–1.2	imprecision and inaccuracy
>1.2	inaccuracy

Incitation and Bibliography

Mendely Desktop version 1.19.8 was used in references incitation and bibliography.

Limitations

We encountered several limitations during our pre-analysis auditing process. These challenges included the lack of statistical data on sample quality and the difficulty in tracking inspection request forms. Additionally, a larger dataset of control results would have provided more robust and inclusive findings

Results

Pre-analytical phase

The comprehensive evaluation revealed a significant prevalence of pre-analytical errors. As detailed in Table 3, the most frequent error on request forms was the absence of patient age (51%), followed by incomplete patient names (40%), the omission of specific dates (25.5%), and the absence of the doctor's name or signature (22%). Additionally, the study found that 34.6% of request forms were deemed ineligibility, with a Defects per Million Opportunities (DPMO) of 346,250 and a corresponding unacceptable sigma level of 1.99, as presented in Table 5.

Table 3. Distribution of pre-analytical errors in the test requisition form.

Pre-analytical Error	Frequency	%
No Date in request form	51	25.5%
Patient's name less than three names	80	40%
Patient's age or date of birth missed	102	51%
Doctor's signature/ doctor's name missed	44	22%
Total NO. of request form= 200	**277**	

Regarding the quality of collected samples, a notetable pre-analytical error identified was insufficient sample quantity, which affected 30% of the 12,254 samples assessed. In contrast, samples collected in the wrong test tube were rare, representing only 0.02% of cases. The need for sample re-collection was minimal, occurring in a mere 0.06% of instances. Furthermore, 1.7% of samples faced rejection due to pre-analytical errors, as illustrated in Table 4.

Table 4. Distribution of pre-analytical errors in sample collection.

Pre-analytical Error	Frequency	%
Insufficient sample quantity	3676	30%
Samples collected in wrong test tube	2	0.02%
Samples re-collection	7	0.06%
Samples rejected	210	1.7%
Total NO. of request form= 12254	**3895**	

Ultimately, the study determined that the yield of the sample collection process stood at 92.1%. This outcome was associated with a Defects per Million Opportunities (DPMO) of 79,464 and a corresponding sigma level of 2.91 which is poor, as detailed in Table 5.

Table 5. Sigma metric values for the pre-analytical quality indicators.

Pre-analytical quality Indicators	DPU	DPMO	Sigma Value (short-term)	Yield %
Test Requisition Form	1.39	346250	1.99	65.4
Samples Quality	0.318	79464	2.91	92.1

Analytical Phase:

Table 6 illustrate the target value, observed mean, CV%, Bias%, TEa%, and Sigma value for the study parameters estimated using VITROS ® V4600 Analyzer.

Total Protein (TP) at Level I exhibited excellent performance, achieving a sigma (σ) level of 5.57. Additionally, three other parameters including TP at Level II, AST at Level II, and ALT at Level II demonstrated good performance, with sigma levels of 4.40, 4.37, and 4.03, respectively.

Table 6. The observed mean, coefficient of variation, bias, and sigma metrics of liver profile parameters performed by the VITROS® V4600 analyzer

LFT Parameter	I.Q.C Target Value	Observed Mean	Observed CV%	Bias %	TEa %	SM Value	Performance Grade
T. Bil Level I (mg\dl)	1.5	1.39	8.38	7.14	20	1.46	Poor
T. Bil Level II (mg\dl)	14.57	13.69	4.46	6.04	20	3.13	Marginal
T. P Level I (g\dl)	3.79	3.78	1.40	0.21	8	5.57	Excellent
T. P Level II (g\dl)	6.94	6.88	1.62	0.87	8	4.40	Good
ALP Level I (IU\L)	104.5	111.92	3.61	7.10	20	3.57	Marginal
ALP Level II (IU\L)	441	501.21	5.07	13.65	20	1.25	Unacceptable
AST Level I (IU\L)	38	34.72	2.65	8.64	15	2.40	Poor
AST Level II (IU\L)	178	170.28	2.44	4.34	15	4.37	Good
ALT Level I (IU\L)	37	36.67	3.85	0.88	15	3.67	Marginal
ALT Level II (IU\L)	172	163.94	2.56	4.69	15	4.03	Good

T. Bil, Total Bilirubin; T. P, Total Protein; ALP, Alkaline Phosphatase; AST, Aspartate aminotransferase; ALT, Alanine aminotransferase; TEa, Total Allowable Error; SM, Sigma Metric.

However, the performance of the remaining parameters across both IQC levels ranged from marginally acceptable to unacceptably low, as detailed in Table 6.

Quality Goal Indices (QGIs) were calculated specifically for analytes with marginal, poor, or unacceptable sigma metrics, as shown in Table 7. These calculations highlighted potential issues related to either imprecision, inaccuracy, or a combination of both. Our analysis revealed that the low sigma levels were primarily due to imprecision in T. Bil at Level II and ALT at Level I. For the remaining parameters, inaccuracy was identified as the main contributing factor.

Discussion

Pre-analytical phase

This study provides valuable insights into the prevalence and impact of pre-analytical errors in liver profile testing, particularly concerning request forms and sample collection. These errors significantly affect the accuracy and precision of liver profile analysis, as evidenced by changes in sigma metrics. The analysis of 200 request forms revealed a concerning 1.4 defects on average per form, with the most common errors being the absence of patient age, incomplete patient names, date omissions, and missing doctor's names or signatures. This high error rate, resulting in a sigma level of 1.99, suggests a notable risk in laboratory processes. While a Laboratory Information System (LIS) is in place, the study attributes this high error rate to the lack of strict guidelines, standard operating procedures, and a lack of appreciation for the significance of complete information by doctors.

Table 7.QGI calculated for analytes with marginal, poor, and unaccepted sigma level.

LFT Parameter	Observed CV%	Bias %	QGI	Problem
T. Bil Level I (mg\dl)	8.38	39.29	0.54	Inaccuracy
T. Bil Level II (mg\dl)	4.46	6.04	0.90	Inaccuracy + Impression
ALP Level I (IU\L)	3.61	7.10	1.31	Inaccuracy
ALP Level II (IU\L)	5.07	13.65	1.80	Inaccuracy
AST Level I (IU\L)	2.65	8.64	2.18	Inaccuracy
ALT Level I (IU\L)	3.85	0.88	0.15	Impression

QGI, Quality Goal Indices; T. Bil, Total Bilirubin; ALP, Alkaline Phosphatase; AST, Aspartate aminotransferase; ALT, Alanine aminotransferase.

In a comparative perspective, a 2021 Ethiopian study assessed request form errors and found somewhat different yet notably similar findings. The Ethiopian study identified common errors like the absence of patient age 26.9%, no order date 57.5%, and no doctor's signature 77.5%, with exceptionally high defect rates, possibly due to their sample size, having more than 3 defects per request. This contrasts with our study's defect rate (19).

Contrastingly, a Kenyan hospital study showed a relatively higher compliance with essential information on request forms. They assessed 289 forms and consistently found patient's name (100%), age (98.3%), investigation requested (97.6%), and clinician's name and signature (96.9%). This indicates a more comprehensive inclusion of essential information in their hospital with minimal deviations or omissions (20).

In a 2018 study in North-Central Nigeria, which involved 4,178 inpatient request forms, issues with information completeness were noted. Age information was absent in 22.7% of outpatient cases, less than our study. The order date was missing in 2.7% of cases, which was again lower than our study, and the requesting physician's identity was not stated in 3.6% of inpatient cases, also lower than our findings (21).

Regarding sample collection quality, the study achieved a success rate of 92.1%. However, the Defects per Million Opportunities (DPMO) of 79,464 and a sigma level of 2.91 indicate room for improvement. Insufficient sample quantity (30%) was the primary issue, jeopardizing result accuracy.

Errors like wrong test tube use were rare (0.02%), and sample re-collection was infrequent (0.06%). Nonetheless, 1.7% of samples were rejected due to errors, emphasizing the need for rigorous quality control measures. The elevated error rate in sample quantity reveals the urgency of refining collection techniques. Discrepancies highlight the lack of standardized sample quality control procedures. Inadequate sample volume, attributed to phlebitis awareness and challenging patient populations, significantly contributes to sample rejection (22).

In the Saudi study of 55,345 laboratory requests, a higher overall error rate of 12.1% was identified, compared to our study's rate of 7.9%. Notably, they reported a lower incidence of insufficient sample quantity at 1.7%, in contrast to our study's 30%, while the use of inappropriate tubes was higher at 0.2%, compared to our 0.02% (5).

In a separate 2018 study in North-Central Nigeria, involving 11,109 outpatient and 4,178 inpatient forms, higher rates of inappropriate specimen containers were observed in the outpatient group at 1.4%, whereas in the inpatient group, the rate was lower than our study. Additionally, inadequate specimen quantities were found in 7.8% of outpatient cases and 4.6% of inpatient cases, which were lower than our study's findings (21). These results underscore the prevalence of pre-analytical errors in the region, emphasizing the importance of quality control measure.

Analytical Performance

In this study, we aimed to assess the reliability of liver profile examinations, focusing on (T. Bil), (T.P), (ALP), (ALT), and (AST) tests with two levels of Internal Quality Control (IQC). Our findings revealed that none of the analytes achieved a world-class σ level of 6. Total Protein (T.P) at level I had the highest sigma value but didn't reach the benchmark. Alkaline phosphatase level II had the lowest sigma value at 1.25, indicating a need for improvement. Three parameters performed better, with σ levels of 4.40, 4.37, and 4.03. The rest had variable performance. Quality Goal Index (QGI) results highlighted the factors affecting sigma levels, with imprecision and inaccuracy playing key roles.

Upon reviewing these findings, it becomes evident that there is a considerable opportunity for improvement in the performance of liver profile tests. Addressing issues of imprecision and inaccuracy in the analysis process could contribute to enhancing the reliability and overall quality of these essential diagnostic tests, ultimately benefiting patient care and clinical decision-making.

A 2018 Turkish study by and colleagues analyzed four different analytical platforms for 18 biochemical tests, including Beckman Coulter-Olympus AU2700, Abbott-Architect C8000, Roche-Cobas 8000, and Siemens-ADVIA 2400 (23). Their findings had similarities and differences compared to our research. Specifically, their investigation highlighted that Total Protein (T. P) level I exhibited Sigma values ≥ 6 in two analyzers, closely resembling our own findings.

Conversely, for Total Bilirubin (T. Bil), their study revealed Sigma values falling below 3 in both IQC levels on one analyzer, aligning with our observation. In the realm of (ALP), their research reported Sigma values exceeding 6 sigma at two different IQC levels on two analyzers. This contrasts with our results, indicating our lower performance for ALP. Furthermore, Özlem Gülbahar et al. discovered that (AST) and (ALT) level I demonstrated Sigma values ≥ 6 on two analyzers, which stands in opposition to our own findings.

Compared to Ambitkumer's 2021 study (24), our research shows variations in Sigma values for ALT and AST at different IQC levels. Ambitkumer reported lower Sigma values for ALT (2.93 at level I and 2.59 at level II) compared to our study, indicating ALT's better performance in our research. Conversely, for AST, our study demonstrated a notably higher Sigma value of 4.37 at level II, suggesting better performance at this level but slightly lower reliability at level I, compared to Ambitkumer's findings. The disparities in findings could potentially be linked to differences in laboratory equipment, research methodologies, or variations in the populations under study. Additionally, our observation of a low sigma scale for AST level 1 may be attributed to inaccuracies, as indicated by the Quality Goal Index (QGI) result of 2.18, which closely aligns with Ambitkumar's result of 1.74.

In another research study conducted by Bingfei Zhou and his colleagues in 2020 (25) to assess the analytical performance of various biochemical analytes using two distinct models of Beckman Coulter chemical analyzers, notable differences emerged. Specifically, in the case of Total Bilirubin (T. Bil), the two Internal Quality Control (IQC) levels observed on the two analyzers exhibited a performance exceeding six sigma, surpassing our own results. Conversely, our laboratory demonstrated a superior performance in Total Protein (T. P) with sigma values of 5.57 for level I and 4.40 for level II. This performance outperformed the first analyzer's results, which yielded sigma values of 4.29 for level I and 3.87 for level II. In the case of the second analyzer, our T. P level I yielded a higher sigma value (4.67) compared to the counterpart, although our level II demonstrated a lower sigma value (5.12).

When assessing the performance of ALP (Alkaline Phosphatase) and AST (Aspartate Aminotransferase), it is evident that they exhibited exceptional and top-tier performance in both Internal Quality Control (IQC) levels across the two analyzers under consideration. Our study revealed sigma values of 3.67 and 4.03 for ALT (Alanine Aminotransferase) at level I and level II, respectively. These results surpass the performance of ALT observed in the first analyzer, which showed sigma values of 2.94 at level I and 4.01 at level II. Moreover, ALT at level I in the second analyzer yielded a sigma value of 2.57, further highlighting the superior performance demonstrated in our study.

The Seniz Korkmaz research in 2022 (12), explored sigma values and TEa (Total Allowable Error) differences, providing context for our findings. Korkmaz's study, using the Roche Cobas c 501 autoanalyzer, observed sigma levels exceeding 6 for AST and ALT, indicating high analytical performance. Our study showed sigma values for ALT (3.57 at level I and 1.25 at level II) and AST (2.40 at level I and 4.37 at level II) that matched or surpassed Korkmaz's results. However, disparities were found in ALP and T.P sigma values. In Korkmaz's study, ALP and T.P had sigma values below 2, indicating room for improvement. In our study, ALP at level I and T.P at both levels had higher sigma values than Korkmaz's findings but still fell below the 6-sigma threshold. Both studies identified inaccuracy as a key factor affecting sigma values, suggesting the need for optimization.

Conclusion

In this comprehensive evaluation of liver profile tests, focusing on Sigma metrics and the Quality Goal Index (QGI), we identified both strengths and areas for improvement. Our study found that none of the analytes reached world-class performance, defined as a σ level of 6. Total Protein (T.P) at level I achieved the highest sigma value among the parameters tested. While some parameters demonstrated relatively good performance, others fell significantly short of the desired σ level of 6. This discrepancy underscores the necessity for enhanced quality control measures. Addressing issues of imprecision and inaccuracy is crucial to improving the reliability and quality of these diagnostic tests, ultimately benefiting patient care.

Recommendations

Initiate a Lean Six Sigma project aimed at elevating quality control measures, implementing regular training and proficiency testing, benchmarking against international standards, fostering continuous quality improvement, and fostering a culture of ongoing quality enhancement throughout the laboratory.

Declaration

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Not available.

Conflicts of interest/Competing interests

The authors declare no conflict of interest.

Authors' contributions

HH served as the project supervisor and was actively involved in the calculation and writing of the paper. KAA facilitated the administrative processes and assisted with record retrieval and release. HAE and EMA were responsible for collecting pre-analytical data and internal quality control results.

Ethics approval

In accordance with the ethical standards outlined in the Helsinki Declaration and international guidelines, ethical clearance certificate for this research was obtained from the Libyan international Medical University with ID: 1-G-00164. Additionally, a letter of consent was sent to the administration of Benghazi Medical Center to secure their approval for the retrospective analysis of Quality Control (QC) data.

Declaration of Generative AI and AI-assisted technologies

During the preparation of this work, the author(s) used ChatGPT and Paraphraser tools for paraphrasing, grammar checking, and language enhancement. After utilizing these tools, the content was thoroughly reviewed and edited by the author(s), who take full responsibility for the final publication.

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