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MEASURING EXCELLENCE: COLLEGE OF AMERICAN PATHOLOGISTS LABORATORY ACCREDITATION PROGRAM AND QUANTITATIVE PROFICIENCY TESTING OUTCOMES

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ABSTRACT

This research aims to investigate the impact of College of American Pathologists (CAP) accreditation on proficiency testing outcomes in clinical laboratory. The study employs a retrospective design, analyzing historical data from laboratories pre and post CAP accreditation. Proficiency testing metrics, including Standard Deviation Index (SDI) values serve as a primary variable for analysis. The research explores descriptive statistics, normality testing, comparative analyses using Paired sample t-test and Wilcoxon signed-rank test, control chart assessments, and correlation analyses to determine the influence of accreditation. Descriptive statistics disclose an overall improvement in proficiency testing outcomes post-accreditation, with no SDI values exceeding control limits +3SDI. The Shapiro–Wilk test indicates normality in the majority of data, while comparative analyses show statistically significant improvements post-accreditation, except for four analytes. Control charts visually represent the improvement in proficiency testing performance. Correlation analysis reveals a weak negative correlation between SDI and competency assessment scores, the weak correlation could be due to availability of limited data. The scatter plot further explains the correlation results. The study contributes to the literature by emphasizing the continuing influence of CAP accreditation on proficiency testing results, with suggestions for laboratory quality management and patient care. The findings underscore the significance of accreditation in uplifting laboratory performance and ensuring the precision and reliability of test results.

Key Words: CAP Accreditation, Proficiency Testing, Quantitative Analysis, Competency Assessment, Method Validation, Comparative Analysis.

INTRODUCTION:

Clinical laboratories are pivotal to the healthcare system, serving as the primary source of diagnostic data essential for patient care and medical decision-making worldwide. These laboratories provide critical quantitative, qualitative, and semi-quantitative analyses of patient samples. The accuracy and reliability of these results are paramount, as errors in data can lead to misdiagnosis or inappropriate treatment, jeopardizing patient safety.

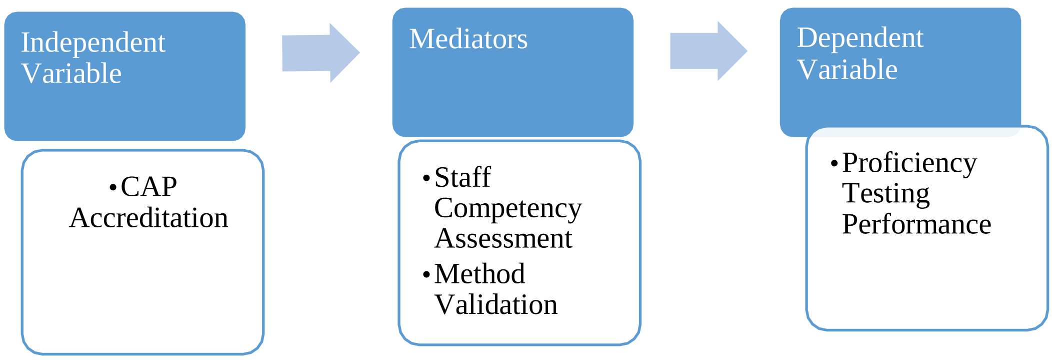
Historically, clinical laboratories have contended with inherent variances in test results. These variances, reflecting discrepancies in results from repeated measures of the same material, were often overlooked until the advent of External Quality Assessment (EQA) surveys. Such surveys, including those conducted by the College of American Pathologists (CAP), have highlighted significant discrepancies across laboratories, underscoring the need for rigorous quality control measures (Scottet al., 2018; Kavsak et al., 2023).

The introduction of EQA programs has been instrumental in addressing these issues by enabling laboratories to identify inconsistencies in their results and improve their processes. Participation in these programs, such as CAP's Proficiency Testing Program, is crucial for ensuring the reliability and accuracy of laboratory analyses. CAP accreditation is particularly esteemed, signifying adherence to high-quality standards and stringent procedural requirements (Gosselin et al., 2019; Harada & Mackinnon, 2023).

This study explores the impact of CAP accreditation on laboratory performance, focusing on Proficiency Testing outcomes. CAP accreditation requires comprehensive evaluations, including staff competency and method validation, which are critical for enhancing analytical precision and accuracy (Davis et al., 2017; Shabir et al., 2007). The laboratory in question, having previously held ISO 15189 accreditation, embarked on a transformative journey by pursuing CAP accreditation to further elevate its quality standards. This transition aims to provide a catalyst for continuous internal improvements, beyond the scope of previous certifications.

Understanding the effects of CAP accreditation on proficiency testing results is essential for assessing its value in improving laboratory practices. This study investigates the changes in proficiency testing outcomes before and after CAP accreditation, focusing on variations in Standard Deviation Index (SDI) from quantitative analyses. By analysing these results, the research seeks to elucidate the impact of CAP accreditation on laboratory performance and explore the roles of staff competency and method validation in driving these improvements.

Directional Relationships:



Literature support:

Medical laboratory services are integral to modern healthcare, underpinning a significant portion of clinical decision-making. Studies indicate that laboratory data influences 60–70% of clinical decisions (Olver et al., 2023), emphasizing the critical role of these services in patient care. Despite this, the frequency of laboratory testing varies, with inpatient settings experiencing higher volumes (Ngo et al., 2017). Early 21st-century reports such as the National Institute of Medicine's "To Err is Human" brought attention to the prevalence of medical errors (Gay, 2017). Although the exact death toll from these errors is debated (Shojania & Dixon-Woods, 2017), the consensus acknowledges their significant impact on patient safety and the need for systemic improvements (Kels & Grant-Kels, 2012; Rodziewicz & Hipskind, 2020). The College of American Pathologists (CAP) has been proactive in addressing these issues through various initiatives (Howanitz, 2005).

Nakhleh et al. (2016) emphasize the importance of case reviews in detecting and preventing diagnostic errors. Perkins (2016) argues for the full disclosure of medical errors, a practice not consistently adhered to in pathology. Plebani (2015) critiques the shift in laboratory priorities from service provision to cost-cutting, which impedes quality and safety. Schultze and Irizarry (2017) highlight the need to address errors across all phases of laboratory testing, not just analytically. These perspectives collectively underline the essential role of CAP in improving laboratory practices and reducing errors. Historical and ongoing efforts to enhance laboratory quality through accreditation and proficiency testing reflect a broader commitment to patient safety and quality assurance (Wu & Steckelberg, 2012; O'Leary, 2000; Hoeltge, 2017).

Quality Assurance:

Accreditation, a formal recognition by a third party, is crucial for maintaining laboratory quality by adhering to predefined standards. It ensures the reliability of test results, which directly impacts patient care and safety (Abhijith et al., 2021; McGrowder et al., 2021). Despite the challenges of accreditation, including financial and logistical demands, the benefits—such as improved customer satisfaction and reduced medical errors—underscore its importance (Zima, 2017). The growth in accredited laboratories over the past two decades reflects this trend (Grochau et al., 2020).

ISO 15189, introduced in 2003, is a quality management standard tailored for medical laboratories. While it builds on ISO 17025 and ISO 9000, it is specifically designed for laboratory environments (Ho, 2004). The CAP's Laboratory Accreditation Program, which predates ISO 15189, has accredited over 8,000 laboratories, highlighting its longstanding role in quality assurance (Schneider et al., 2017). Vance (2011) acknowledges CAP's accreditation as a gold standard, emphasizing its rigorous focus on accuracy and staff competency. Studies have shown that CAP accreditation significantly enhances laboratory practices and patient outcomes (Andiric et al., 2018; Peter et al., 2010; Zima, 2017). Hirano and Ohno (2015) further support this by noting improvements in satisfaction and performance among accredited laboratories.

Proficiency Testing as a Quality Indicator:

Laboratory testing encompasses pre-analytical, analytical, and post-analytical phases, each critical for accurate results (Howanitz, 2005). CAP has pioneered various quality assurance measures, including proficiency testing (PT), to enhance laboratory performance (Hoeltge, 2017).

PT involves sending blind samples to laboratories, allowing for performance comparison and improvement (Ibrahim et al., 2012). CLIA mandates PT as an external quality indicator, crucial for maintaining accuracy and reliability in laboratory testing (Astles et al., 2013). Research supports the efficacy of PT in identifying discrepancies and improving laboratory performance (Sciacovelli et al., 2010; Halim, 2013). Liu et al. (2014) and Middlebrook (2017) demonstrate that CAP-accredited laboratories generally outperform non-accredited ones in PT, highlighting the positive impact of accreditation on testing accuracy.

The Impact of Staff Competency Assessments:

Staff competency assessments are vital for ensuring the accuracy of clinical test results and addressing performance issues proactively (Sharp & Elder, 2004). Accreditation standards emphasize ongoing competency evaluations to ensure laboratory staff proficiency.

Boone (2000) and Ying Li et al. (2014) show a positive correlation between staff competency and reduced laboratory errors. Effective competency assessments not only validate skills but also highlight training needs and areas for improvement (Desjardins & Fleming, 2014). These assessments are crucial for maintaining high standards in laboratory operations.

Method Validation: Ensuring Analytical Precision:

Method validation is essential for confirming the accuracy and reliability of analytical processes. It involves systematically evaluating procedures to ensure they meet predefined criteria under specific conditions (Peris-Vicente et al., 2015). Validation encompasses all stages of the analytical process, from sampling to result reporting (MacNeil, 2012).

Rigorous validation procedures are linked to improved method precision and accuracy (Gupta, 2015; Baruch et al., 2018). Indrayanto (2022) and Lal et al. (2019) further support the importance of method validation in maintaining consistent and accurate results, aligning with accreditation standards.

Challenges and Innovations in Clinical Laboratory Accreditation:

Despite advancements, clinical laboratory accreditation faces challenges such as resource constraints, evolving technology, and regulatory complexities (Girma et al., 2018). Inadequate coordination and follow-up, as well as resource optimization issues, further complicate the accreditation process (Rusanganwa et al., 2019).

Addressing these challenges requires targeted interventions, such as advocacy and mentorship (Makokha et al., 2022), integrating education into laboratory operations, and ensuring regulatory compliance (Al Kuwaiti & Al Muhanna, 2019). Improvements in accreditation practices must address issues related to standards, costs, and human resources (Salehi & Payravi, 2017; Kobayashi & Ayoub, 2010).

Recent Trends and Comparative Studies:

Recent trends in clinical laboratory accreditation include comparative studies evaluating different accreditation processes. Research comparing CAP and ISO accreditation outcomes shows that both standards contribute to quality and performance improvements, though they offer complementary features (AbdelWareth et al., 2018). These comparative analyses provide valuable insights for laboratories to choose accreditation programs that best meet their needs.

Methodology:

This research employs a retrospective study design to assess the impact of College of American Pathologists (CAP) accreditation on proficiency testing outcomes. By examining historical data, this approach facilitates a comprehensive evaluation of laboratory performance before and after the accreditation process. The retrospective design allows for a detailed analysis of changes in proficiency testing results linked to CAP accreditation.

A quasi-experimental design combined with a quantitative approach is utilized for this study. This methodology is appropriate as it allows for the evaluation of proficiency testing performance in relation to the introduction of CAP Accreditation.

The study follows a deductive reasoning framework, focusing on applied research with practical implications for real-world laboratory settings. By comparing proficiency testing outcomes before and after CAP accreditation, the study aims to derive insights that can enhance laboratory practices, improve quality assurance, and inform future accreditation processes.

Ethical considerations were rigorously observed throughout the study. The laboratory's name was anonymized to protect its identity, and it was assured that the data would be used solely for academic purposes. Personnel names involved in the testing were replaced with unique codes to maintain confidentiality and ensure privacy. The sampling process involved the following steps:

Population and Stratified Sampling: The population comprises technical departments within a medical diagnostic laboratory. These departments were first categorized into strata based on the type of analyses they handle, specifically distinguishing between qualitative and quantitative analyses.

Purposeful Sampling: Within the strata, a purposeful sampling approach was employed to select only those quantitative analyses for which proficiency testing included five samples per survey. This selection criterion ensures a focus on analysis with adequate data for analysis. **Sampling Units:** The sampling units are individual analysis within the selected departments.
The analysis selected for this study include:

Blood Gases:	**Chemistry**	**Hematology**	**Special Chemistry**
PCO2 pH PO2	Bilirubin, total Calcium, ionized Calcium, serum Chloride Creatinine Kinase HDL Cholesterol Iron LDL, measured Lipase Magnesium Potassium, serum Sodium, serum Urea	MCH MCHC Platelet Count Red Blood Cell Count	Alpha-Fetoprotein Carbamazepine CEA Complement C3 Cortisol, serum (K) Phenytoin Thyroxine (T4) Triiodothyronine (T3) Vitamin B-12

Data was collected across a defined period, encompassing proficiency testing results from both pre-accreditation and post-accreditation phases. The laboratory receives three cycles of each analyze annually, with each cycle containing five samples.

Four survey cycles were selected for Sub Disciplines Blood Gases, Chemistry, and Special Chemistry, and three cycles for Haematology based on record availability. This approach allows for a direct comparison of proficiency testing outcomes before and after CAP accreditation. Data were collected from proficiency testing evaluation reports maintained by the laboratory. Specifically, thirty analyses were evaluated, with the following details:

Pre-accreditation and Post-Accreditation Phases: Results were gathered for both phases to assess changes attributable to CAP accreditation. Four survey cycles (before and after accreditation) for Blood Gases, Chemistry, and Special Chemistry; three survey cycles for Haematology.

The primary variable of interest is the Standard Deviation Index (SDI) values, which represent the laboratory's performance relative to peer groups. Accreditation status is categorized as an independent variable, indicating whether the laboratory had undergone CAP accreditation at the time of testing.

Data analysis was performed using the Statistical Package for the Social Sciences (SPSS) and Microsoft Excel. Statistical methods were employed to compare proficiency testing outcomes before and after CAP accreditation. The analysis focused on variations in SDI values to determine the impact of accreditation on laboratory performance.

Finding:

Descriptive statistics are essential for summarizing data in an organized manner and are a critical first step in research before conducting inferential analyses.

This approach includes measures of central tendency (mean, median, mode) and dispersion (standard deviation, coefficient of variation).
It simplifies data, making it easier to assess specific populations (Kaur et al., 2018). In this study, descriptive statistics are used to compare Standard Deviation Index (SDI) results from proficiency testing across both phases.

Table 1.1: Descriptive Statistics Before Accreditation After Accreditation

Analytes	Min	Max	Mean	SD		Min	Max	Mean	SD
PCO2	-7.7	2.5	-0.915	2.0628		-1.4	0.8	-0.130	0.6538
pH	-8.4	2.6	-2.365	3.5537	**Blood Gases**	-0.9	1.5	0.040	0.6269
PO2	-5.7	1.3	-1.740	1.7157		-1.1	0.8	-0.350	0.4674
Bilirubin, total	-1.2	3.7	0.700	1.6105		-0.9	1.2	0.295	0.6004
Calcium, ionized	-10.0	11.3	-0.295	3.6957		-1.9	2.2	0.320	1.2805
Calcium, serum	-3.5	4.7	-0.440	1.8554		-1.0	1.9	0.615	0.8774
Chloride	-1.3	4.5	1.545	1.6472		-1.2	2.3	0.485	0.9740
Creatinine Kinase	-0.9	2.2	0.355	1.0390		-1.3	0.5	-0.530	0.5741
HDL Cholesterol	-2.4	1.4	-0.650	1.2693		-1.3	0.3	-0.430	0.4305
Iron	-2.4	0.0	-1.250	0.7494	**Chemistry**	-2.3	0.7	-0.740	0.7598
LDL, measured	-0.1	3.1	0.975	1.0078		-2.5	1.3	-0.565	1.1463
Lipase	-2.3	0.3	-0.745	0.7466		-1.6	2.0	0.160	0.8744
Magnesium	-0.7	3.7	0.775	1.5947		-1.4	0.6	0.020	0.5970
Potassium, serum	-2.8	1.8	-0.575	1.3130		-1.9	1.7	-0.105	1.1157
Sodium, serum	-2.0	2.7	-0.045	1.2659		-1.3	0.9	-0.110	0.5628
Urea	-2.5	0.8	-0.345	0.8941		-1.2	1.3	-0.200	0.7974
Hemoglobin	-4.6	3.5	0.320	3.0388		-0.7	1.2	0.060	0.6967
MCH	-4.0	2.4	-0.653	2.0191		-0.7	1.2	0.127	0.6100
MCHC	-3.3	1.0	-0.960	1.2654	**Hematology**	-2.5	0.4	-1.267	0.7789
Platelet Count	-1.7	3.0	0.353	1.4894		-1.9	1.5	-0.473	0.9610
Red Blood Cell Count	-1.1	3.5	0.927	1.2555		-1.8	1.1	-0.053	0.8374
Alpha-Fetoprotein	-1.0	3.9	0.640	1.5632		-1.3	2.6	-0.140	1.1821
Carbamazepine	-1.2	4.1	0.900	1.6821		-2.6	3.0	-0.280	1.2086
CEA	-2.1	2.2	-0.300	0.9733		-1.3	2.6	0.490	0.9380
Complement C3	-0.6	2.6	0.515	0.7250		-1.8	1.4	-0.380	0.9468
Cortisol, serum (K)	-0.9	1.9	0.575	0.6307	**Special Chemistry**	-1.0	1.2	-0.365	0.6107
Phenytoin	-2.4	1.3	-0.495	1.1114		-1.0	1.6	0.095	0.7480
Thyroxine (T4)	-2.1	0.8	-0.550	0.7756		-1.2	1.2	-0.065	0.5641
Triiodothyronine (T3)	-1.8	0.4	-0.511	0.5812		-1.3	0.9	0.064	0.5310
Vitamin B-12	-1.3	5.6	0.815	1.6050		-1.6	1.2	-0.435	0.6491

Table 1.1 Descriptive statistics clearly depicts that overall performance after CAP accreditation has been improved. Comparing Minimum and Maximum values in both phases indicates that in first phase i.e., before accreditation SDI values exceeds the Upper and Lower Control Limits i.e., +3SDI and -3SDI respectively. However, in second phase most of the values lie within +2SDI and no value surpasses +3SDI.

To assess changes in Proficiency Testing performance before and after accreditation, Paired sample T-Test or Wilcoxon signed-rank test was performed according to the normality of data. Paired-samples t-test is used to compares the mean of a single group, examined at two different points in time. While Wilcoxon signed-rank (WSR) test is a non-parametric statistical test used to conduct a paired difference test of repeated measurements on a single sample. When the data is normally distributed Paired Sample t-test is used otherwise Wilcoxon signed-rank (WSR) test is applied (Rietveld & van Hout, 2017).

Normality Test plays a significant role in determining the measure of central tendency and statistical methods for data analysis. When the data follow normal distribution, parametric tests are used to compare the groups.

However, if the data is not normally distributed nonparametric methods are used. Though number of methods could be used to test normality, but for small sample size (n<50), Shapiro–Wilk test has more power to detect the non-normality and this is the most common and widely used method (Mishra et al., 2019). Thus, Normality of SDI involved in research was checked using Shapiro-Wilk test.

Table 1.2: Normality Statistics of SDIs

Analytes	df	Before Accreditation Shapiro-Wilk		After Accreditation Shapiro-Wilk	
		Statistic	Sig.	Statistic	Sig.
Blood Gases					
PCO2	20	0.849	0.050	0.945	0.299
pH	20	0.914	0.075	0.946	0.316
PO2	20	0.965	0.654	0.944	0.283
Chemistry					
Bilirubin, total	20	0.882	0.053	0.939	0.228
Calcium, ionized	20	0.727	0.000	0.933	0.175
Calcium, serum	20	0.889	0.026	0.931	0.162
Chloride	20	0.923	0.111	0.945	0.295
Creatine Kinase	20	0.877	0.051	0.942	0.259
HDL Cholesterol	20	0.927	0.135	0.963	0.603
Iron	20	0.925	0.123	0.986	0.988
LDL, measured	20	0.818	0.002	0.919	0.093
Lipase	20	0.938	0.215	0.959	0.532
Magnesium	20	0.718	0.000	0.861	0.008
Potassium, serum	20	0.977	0.886	0.937	0.208
Sodium, serum	20	0.939	0.233	0.957	0.482
Urea	20	0.928	0.143	0.907	0.056
Haematology					
Hemoglobin	15	0.819	0.006	0.872	0.073
MCH	15	0.939	0.373	0.943	0.428
MCHC	15	0.949	0.512	0.980	0.968
Platelet Count	15	0.927	0.243	0.973	0.898
Red Blood Cell Count	15	0.979	0.962	0.948	0.489
Special Chemistry					
Alpha-Fetoprotein	20	0.865	0.010	0.788	0.001
Carbamazepine	20	0.884	0.021	0.935	0.191
CEA	20	0.935	0.195	0.984	0.973
Complement C3	20	0.920	0.100	0.954	0.437
Cortisol, serum (K)	20	0.959	0.515	0.849	0.005
Phenytoin	20	0.943	0.272	0.959	0.517
Thyroxine (T4)	20	0.987	0.990	0.984	0.972
Triiodothyronine (T3)	20	0.948	0.338	0.918	0.091
Vitamin B-12	20	0.884	0.021	0.948	0.342

In Table 1.2 Sample Size (df) indicates the degrees of freedom representing the number of observations. Significance (p-value) indicates the probability of obtaining a test statistic as extreme as the one observed, assuming the null hypothesis that the data follows a normal distribution.

Table 1.2 demonstrates that p-value (Sig.) in before accreditation phase, is greater than 0.05 for 22 analytes from Shapiro-Wilk tests. Hence, the data is considered as normally distributed and is compared with Paired Sample T-Test for these analytes. For other 8 analytes (Calcium, ionized; Calcium, serum; LDL, measured; Magnesium; Hemoglobin; Alpha-Fetoprotein; Carbamazepine and Vitamin B-12) p-value is less than 0.05. Hence, the data cannot be considered as normally distributed, so is compared with Paired Sample T-Test as well as Wilcoxon Signed Ranks Test.

In After Accreditation phase, p-value (Sig.) is greater than 0.05 for 27 analytes while it is observed to be smaller in 3 analytes (Magnesium; Alpha-Fetoprotein and Cortisol, serum (K)). Hence only Paired Samples T-Test was performed for normally distributed data and Wilcoxon Signed Ranks Test is performed in addition for analytes having Sig. value less than 0.05. All significant values less than 0.05 is highlighted in grey color for distinction.

Paired Samples t-Test {SDI (B-A) - SDI (C-A)}

Paired Sample t-test is performed for comparison of Absolute SDI in before-accreditation and after-accreditation phase, considering the data is normally distributed.

Table 1.3: Paired Sample t-test of SDIs Group (Before-Accreditation and After-Accreditation)

Analyte	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% CI of the Difference				
				Lower	Upper			
Blood Gases								
PCO2	0.9350	1.7939	0.4011	0.0954	1.7746	2.331	19	0.031
pH	2.6550	2.8891	0.6460	1.3029	4.0071	4.110	19	0.001
PO2	1.5500	1.3725	0.3069	0.9077	2.1923	5.051	19	0.000
Chemistry								
Bilirubin, total	0.7150	1.3248	0.2962	0.0950	1.3350	2.414	19	0.026
Calcium, ionized	0.9850	3.0507	0.6822	-0.4428	2.4128	1.444	19	0.165
Calcium, serum	0.3250	1.5824	0.3538	-0.4156	1.0656	2.631	19	0.016
Chloride	0.9100	1.8937	0.4235	0.0237	1.7963	2.149	19	0.045
Creatine Kinase	0.8850	1.5062	0.3368	0.1801	1.5899	2.628	19	0.017
HDL Cholesterol	0.7100	0.7355	0.1645	0.3658	1.0542	4.317	19	0.000
Iron	0.3800	0.7374	0.1649	0.0349	0.7251	2.305	19	0.033
LDL, measured	1.5400	1.1170	0.2498	1.0172	2.0628	6.165	19	0.000
Lipase	0.1450	0.7480	0.1672	-0.2051	0.4951	2.768	19	0.012
Magnesium	0.7550	1.4940	0.3341	0.0558	1.4542	2.260	19	0.036
Potassium, serum	0.2800	1.1606	0.2595	-0.2632	0.8232	1.079	19	0.294
Sodium, serum	0.5150	0.8561	0.1914	0.1143	0.9157	2.690	19	0.014
Urea	0.0250	0.6904	0.1544	-0.2981	0.3481	0.162	19	0.873
Haematology								
Hemoglobin	2.1800	1.2633	0.3262	1.4804	2.8796	6.683	14	0.000
MCH	1.1800	1.2072	0.3117	0.5115	1.8485	3.786	14	0.002
MCHC	0.3067	1.4469	0.3736	-0.4946	1.1079	0.821	14	0.425
Platelet Count	0.3467	1.1594	0.2993	-0.2954	0.9887	1.158	14	0.266
Red Blood Cell Count	0.9800	1.1851	0.3060	0.3237	1.6363	3.203	14	0.006
Special Chemistry								
Alpha-Fetoprotein	0.3400	1.6191	0.3620	-0.4178	1.0978	0.939	19	0.359
Carbamazepine	1.1800	2.0585	0.4603	0.2166	2.1434	2.564	19	0.019
CEA	0.0400	0.8450	0.1890	-0.3555	0.4355	2.330	19	0.031
Complement C3	0.8950	1.3938	0.3117	0.2427	1.5473	2.872	19	0.010
Cortisol, serum (K)	0.9400	0.7976	0.1784	0.5667	1.3133	5.270	19	0.000
Phenytoin	0.4000	0.6951	0.1554	0.0747	0.7253	2.574	19	0.019
Thyroxine (T4)	0.3250	0.6373	0.1425	0.0267	0.6233	2.281	19	0.034
Triiodothyronine (T3)	0.2251	0.5478	0.1225	-0.0313	0.4815	3.071	19	0.006

Analyte	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% CI of the Difference				
				Lower	Upper			
Vitamin B-12	1.2500	2.0122	0.4499	0.3083	2.1917	2.778	19	0.012

In Paired Sample t-test; Mean Difference indicates the average change in analyte level of After Accreditation from Before Accreditation variable. Standard Deviation indicates the variability or spread of the differences. Standard Error Mean provides information about the precision of the mean difference. Confidence Interval (95% CI) of the Difference provides a range within which we can reasonably expect the true population mean difference to fall. Degrees of Freedom (df) represents the number of paired observations minus 1 and is used in the calculation of the t-statistic. t-statistic measures the difference between the mean difference in analyte levels and zero, normalized by the standard error. A higher absolute t-value suggests a greater difference relative to the variability. Significance (p-value) indicates the probability of observing a t-statistic under the assumption that the true mean difference is zero. A low p-value suggests that the observed difference is unlikely to be due to random chance.
In Table 1.3, it is noteworthy that the p-value (Sig.) is less than 0.05 in 24 analytes out of 30, indicating a significant difference between the two variables (SDI B-A and SDI C-A). For other 6 analytes (Calcium, ionized; Potassium, serum; Urea; MCHC; Platelet Count and Alpha-Fetoprotein) although the p-value is not statistically significant but the Positive mean difference indicates that on average SDI Before Accreditation (B-A) is higher than SDI After CAP Accreditation (C-A) in all analytes. All significant values higher than 0.05 is highlighted in grey colour for distinction.

Wilcoxon Signed Ranks Test {SDI (C-A) - SDI (B-A)}
In few parameters, Shapiro-Wilk test gives doubt that either the data is normally distributed or not. Thus, Non-parametric test i.e., Wilcoxon Signed Ranks Test is followed for these parameters.

Table 1.4: Wilcoxon Signed Ranks Test of SDIs Group (Before-Accreditation and After-Accreditation)

Analyte	Z	Asymp. Sig. (2-tailed)
Chemistry		
Calcium, ionized	-0.917	0.359
Calcium, serum	-2.709	0.007
LDL, measured	-3.543	0.000
Magnesium	-0.101	0.029
Haematology		
Hemoglobin	-3.295	0.001
Special Chemistry		
Alpha-Fetoprotein	-1.942	0.052
Carbamazepine	-2.157	0.031
Cortisol, serum (K)	-3.443	0.001
Vitamin B-12	-2.540	0.011

In Wilcoxon Signed Ranks Test, Z score measures the number of standard deviations a data point is from the mean. Asymp. Significance (p-value) indicates the probability of observing a Z score as extreme as the one calculated, assuming the null hypothesis that the true mean difference is zero. A low p-value suggests that the observed difference is unlikely to be due to random chance.
In Table 1.4, it is observed that Z score of all analytes is negative that leans towards SDI After Accreditation (C-A) tending to be smaller than SDI Before Accreditation (B-A) for all. However, p-

value for Calcium, ionized and Alpha-Fetoprotein is greater than 0.05 suggesting that these two analytes are not statistically significant at a conventional significance level of 0.05. All significant values greater than 0.05 is highlighted in grey colour for distinction.

Control Charts:

Afterwards results were compared with Control Chart. Control charts are the tools in control processes to determine whether a process is in a controlled statistical state. It is used to study process changes over time. Data in Control chart have a Central Line of average (Mean), an upper line of upper control limit and a lower line of lower control limit which are usually set at three-sigma (standard deviations) from the mean. If the data lies within control limit, it indicates that process is under control and no changes are required to be made to the parameter of process control. However, any data points that fall outside these limits, or unusual patterns (determined by various run tests) on the control chart, suggest a special cause (Tennant et al., 2007).Control Chart of each analyte is representing the data for both phases, separated by a vertical black line indicating the transition from before accreditation to after accreditation. Left side of chart shows before accreditation phase values while right side shows the after-CAP Accreditation values. Gray line indicates Central Line (i.e., 0). Red lines indicate the Lower and Upper Control Limits (LCL and UCL). If any result crosses LCL and UCL it might consider as unacceptable as evaluation criteria for most of the analyte is + 3SDI. Green lines indicate + 2SDI, if any value crosses these lines, it may indicate warning of systematic or random errors. Data lying within + 2SDI is considered as acceptable. In Horizontal axis, BA- S{n} stands for Before-Accreditation Survey number while CA-S{n} stands for CAP Accreditation Survey number

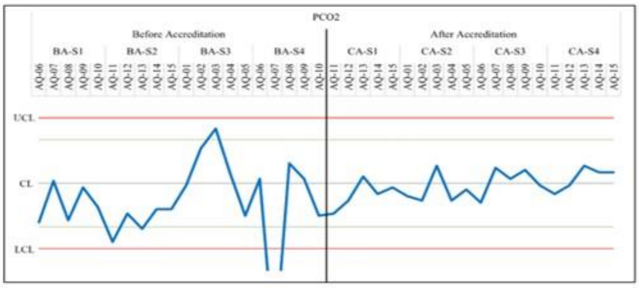
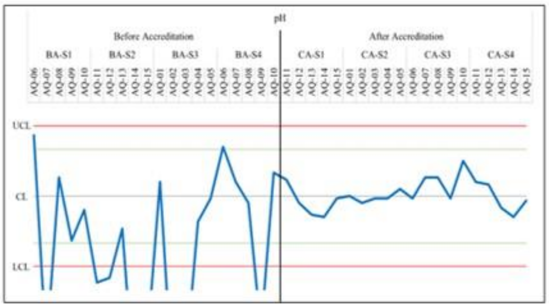
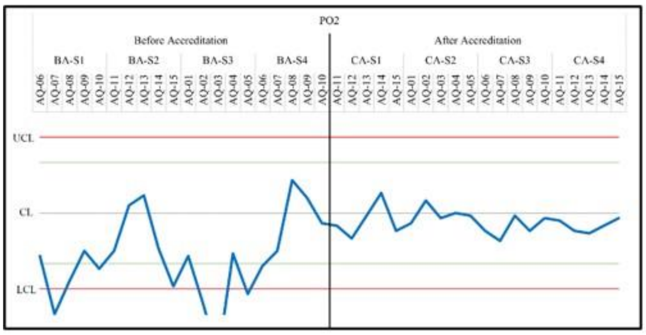
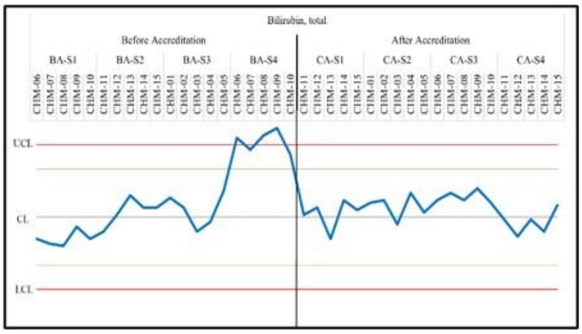
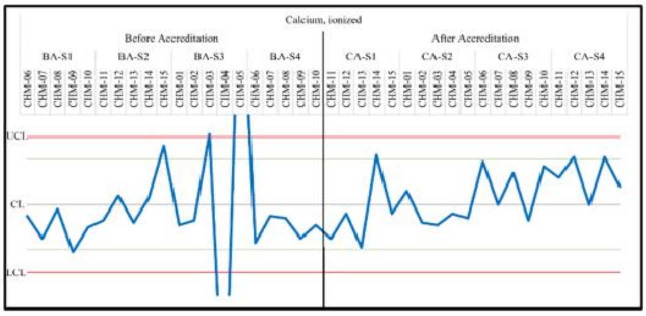


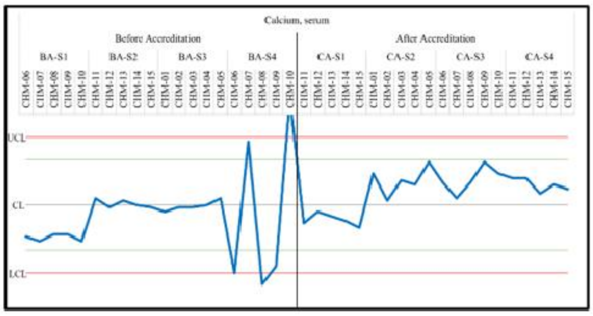
Figure 4.2: Control Chart for Analyte pH

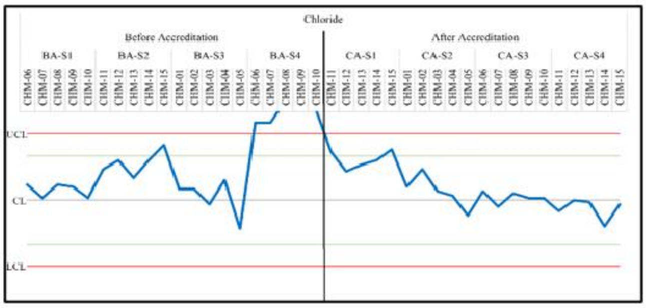


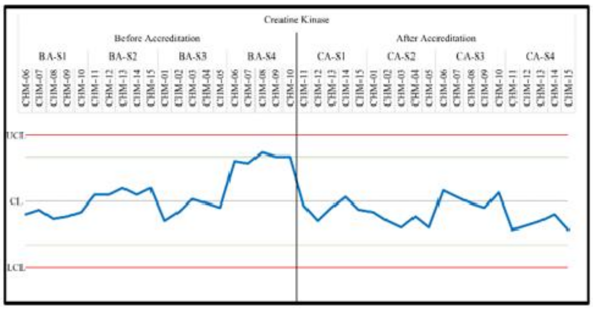


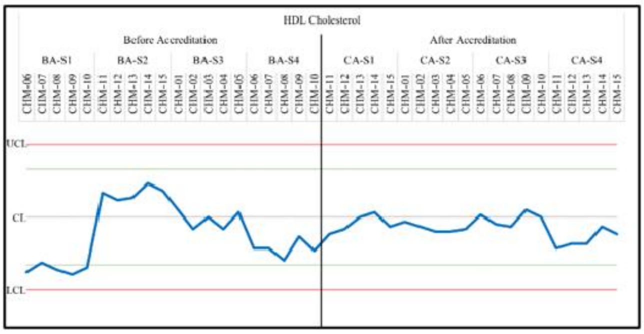


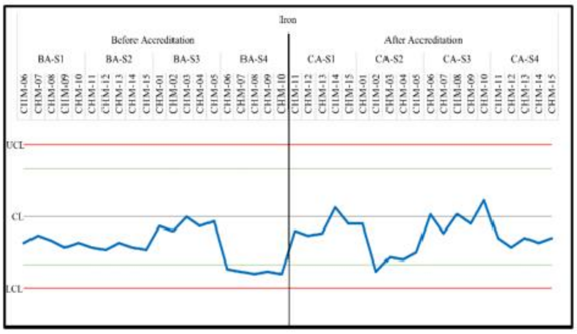

Calcium, ionized
Before Accreditation
After Accreditation
BA-S1
BA-S2
BA-S3
BA-S4
CA-S1
CA-S2
CA-S3
CA-S4
UCL
CL
LCL

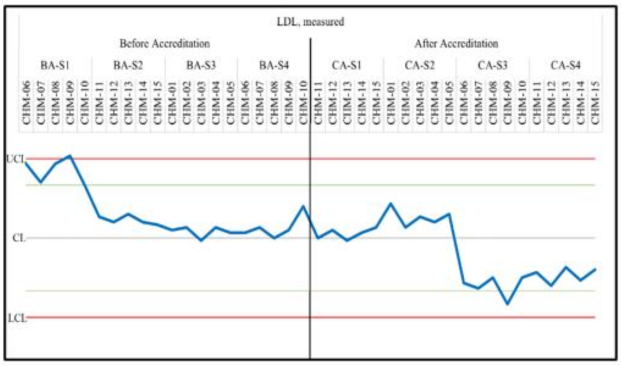

Calcium, serum
Before Accreditation
After Accreditation
BA-S1
BA-S2
BA-S3
BA-S4
CA-S1
CA-S2
CA-S3
CA-S4
UCL
CL
LCL

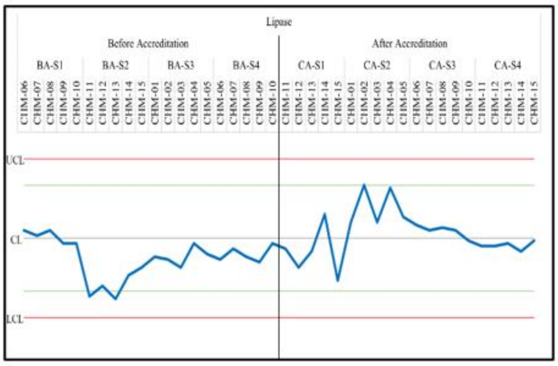

Chloride
Before Accreditation
After Accreditation
BA-S1
BA-S2
BA-S3
BA-S4
CA-S1
CA-S2
CA-S3
CA-S4
UCL
CL
LCL

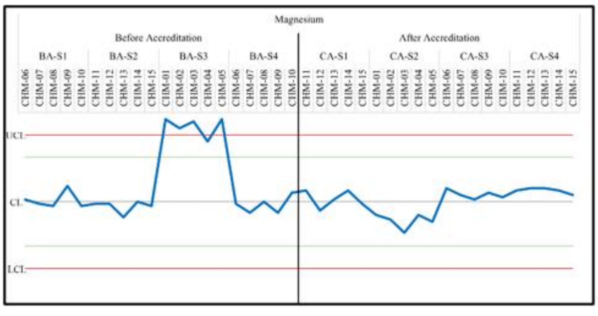

Creatine Kinase
Before Accreditation
After Accreditation
BA-S1
BA-S2
BA-S3
BA-S4
CA-S1
CA-S2
CA-S3
CA-S4
UCL
CL
LCL

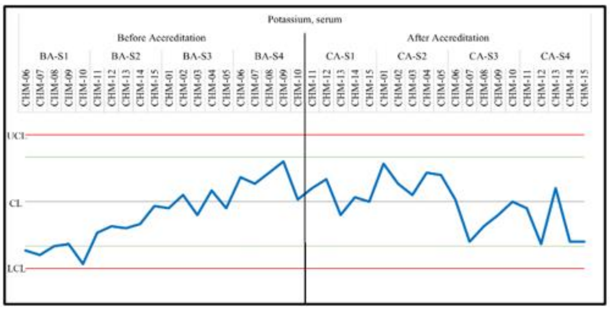

HDL Cholesterol
Before Accreditation
After Accreditation
BA-S1
BA-S2
BA-S3
BA-S4
CA-S1
CA-S2
CA-S3
CA-S4
UCL
CL
LCL

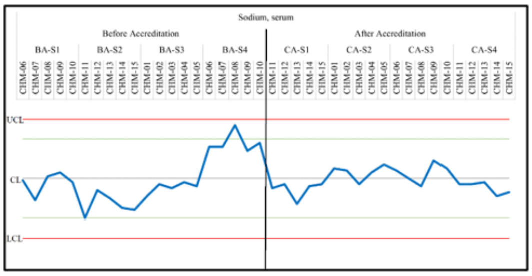

Iron
Before Accreditation
After Accreditation
BA-S1
BA-S2
BA-S3
BA-S4
CA-S1
CA-S2
CA-S3
CA-S4
UCL
CL
LCL

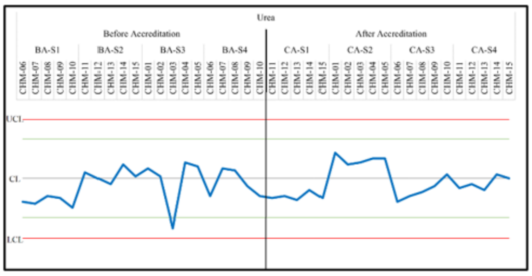

LDL, measured
Before Accreditation
After Accreditation
BA-S1
BA-S2
BA-S3
BA-S4
CA-S1
CA-S2
CA-S3
CA-S4
UCL
CL
LCL

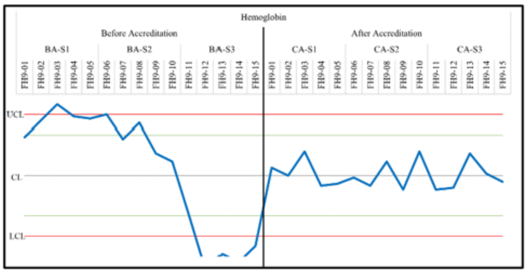

Lipase
Before Accreditation
After Accreditation
BA-S1
BA-S2
BA-S3
BA-S4
CA-S1
CA-S2
CA-S3
CA-S4
UCL
CL
LCL

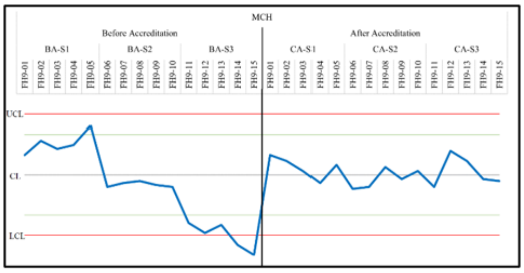

Magnesium
Before Accreditation
After Accreditation
BA-S1
BA-S2
BA-S3
BA-S4
CA-S1
CA-S2
CA-S3
CA-S4
UCL
CL
LCL

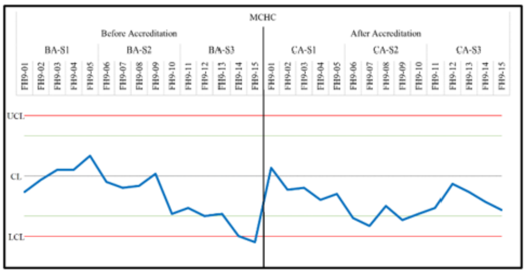

Potassium, serum
Before Accreditation
After Accreditation
BA-S1
BA-S2
BA-S3
BA-S4
CA-S1
CA-S2
CA-S3
CA-S4
UCL
CL
LCL

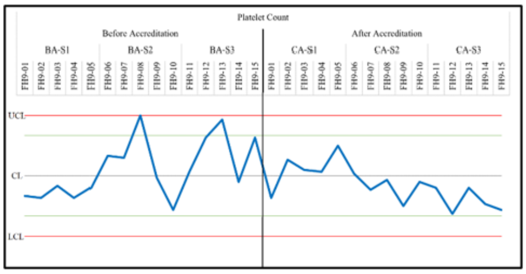

Sodium, serum
Before Accreditation
After Accreditation
UCL
CL
LCL

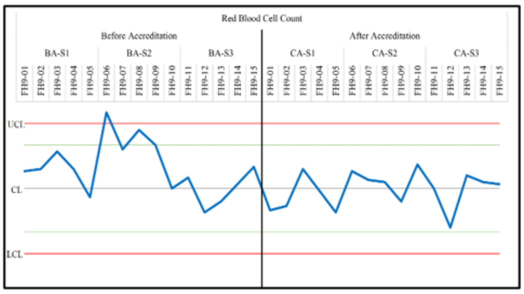

Urea
Before Accreditation
After Accreditation
UCL
CL
LCL

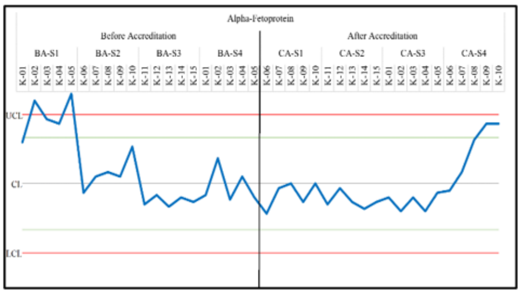

Hemoglobin
Before Accreditation
After Accreditation
UCL
CL
LCL

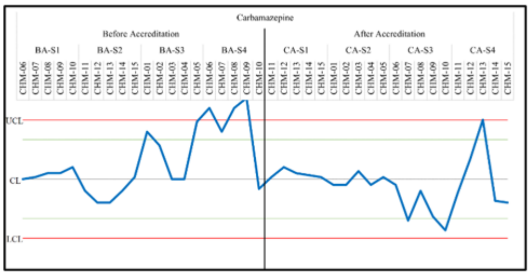

MCH
Before Accreditation
After Accreditation
UCL
CL
LCL

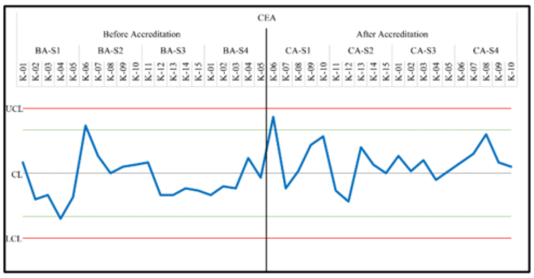

MCHC
Before Accreditation
After Accreditation
UCL
CL
LCL

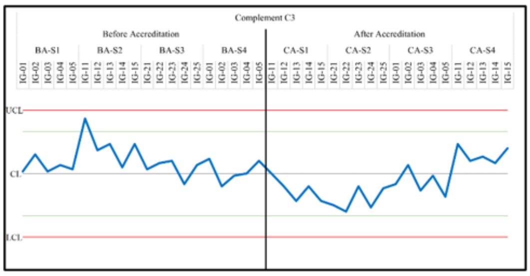

Platelet Count
Before Accreditation
After Accreditation
UCL
CL
LCL

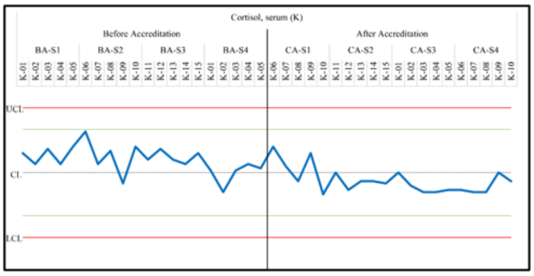

Red Blood Cell Count
Before Accreditation
After Accreditation
UCL
CL
LCL

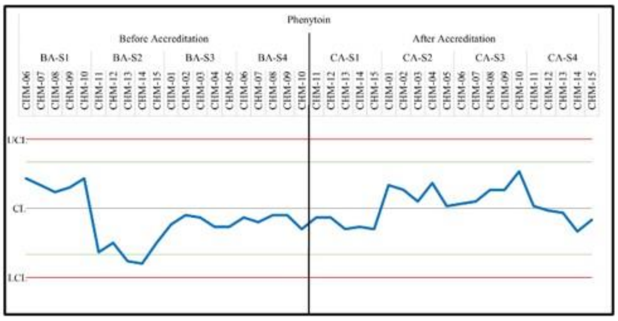

Alpha-Fetoprotein
Before Accreditation
After Accreditation
UCL
CL
LCL

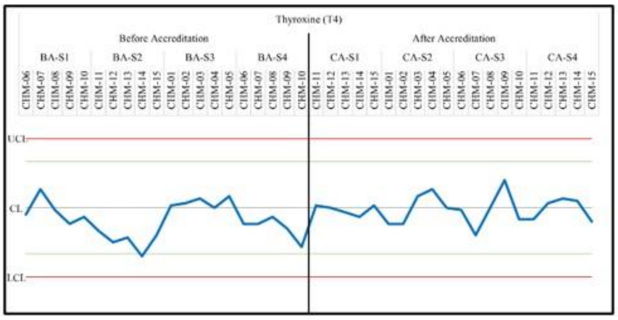

Carbamazepine
Before Accreditation
After Accreditation
UCL
CL
LCL

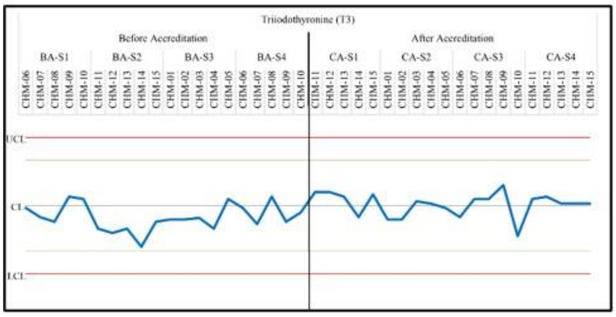

CEA
Before Accreditation
After Accreditation
UCL
CL
LCL

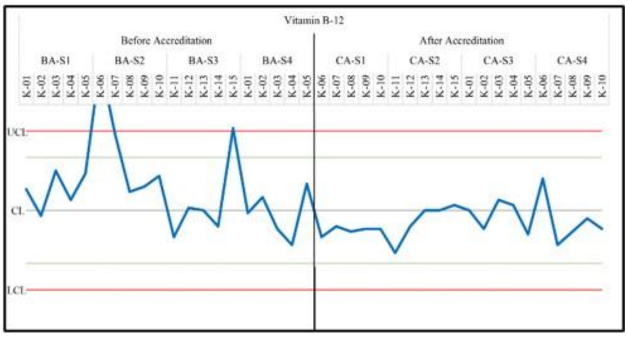

Complement C3
Before Accreditation
After Accreditation
UCL
CL
LCL


Cortisol, serum (K)
Before Accreditation
After Accreditation
UCL
CL
LCL









Correlation Analysis between Competency Assessment and PT SDI:
Pearson correlation coefficient is a vital method to measure the similarity of multiple data variables. Its value is between [−1,1]. If the correlation coefficient is between 0 to -1 it indicates the negative correlation. However, if the value lies between 0 to 1 it indicates positive correlation. Greater the absolute value of correlation coefficient indicates stronger relationship between variables (Zhu *et al.*, 2019). Pearson Correlation Analysis is performed between Competency Assessment score of each analyst and absolute SDI obtained in Proficiency Testing Result Evaluation in after-accreditation phase to check the relation among two variables. Table 1.5: Pearson Correlation for Competency Assessment score and SDI (After-Accreditation phase)

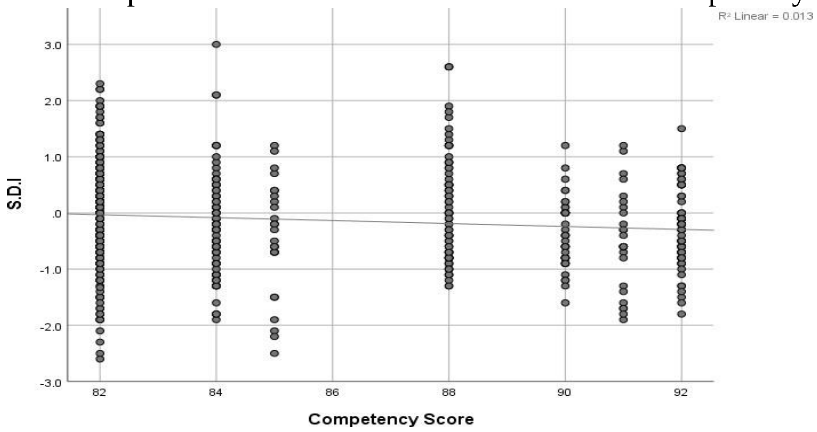
Correlations			
		Competency Score	**S.D.I**
Competency Score	Pearson Correlation	1	-0.112
	Sig. (2-tailed)		0.007
	N	575	575
S.D.I	Pearson Correlation	-0.112	1
	Sig. (2-tailed)	0.007	
	N	575	575

Table 1.5 demonstrates the correlation between SDI and Competency Score in after-accreditation phase. The correlation was measured using Absolute SDI. Pearson Correlation Coefficient is -0.112 which indicates the weak negative correlation between SDI and Competency Score. This suggest that as Competency Score increases, SDI tends to slightly decrease. Decrease in SDI indicates that performance is better for those analysts whose competency score is higher as compared to others. The p-value indicates the probability of detecting the correlation coefficient as extreme as the one calculated, assuming the null hypothesis that there is no correlation in the population. Here p-value 0.007 is less than conventional significance level of 0.05. Therefore, the correlation is statistically significant.

Scatter Plot between Competency Assessment and PT SDI:
A scatterplot is a plot of the data points in a set and plays an important role when reporting linear correlation. Scatter plot can reveal non-linear relationship which could be missed by Linear

correlation statistics (Sainani, 2016). Relationship between SDI (dependent variable) and Competency Assessment score (independent variable) is compared using Scatterplot.

Fig 4.31: Simple Scatter Plot with fit Line of SDI and Competency score



In this Figure, R2=0.013 denotes linear regression's coefficient of determination; it means that approximately 1.3% of the variability in the SDI score can be explained by the competency score in the linear regression model. Fit line indicates weak negative correlation. It is evident through visual representation that SDI for competency score $\geq$ 90 lies within $\pm$2SDI and no value exceeds Upper and Lower Control Limits

Conclusion:

This study investigated the impact of College of American Pathologists (CAP) accreditation on laboratory performance, using proficiency testing as a key performance indicator. Proficiency testing, originally designed for educational purposes, has gained significance through regulatory implementation. We analyzed proficiency testing evaluation reports of quantitative analytes using SPSS to identify important associations and trends. Data normality was assessed using the Shapiro–Wilk test, with most analytes found to be normally distributed. For non-normally distributed data, non-parametric tests, including the Wilcoxon Signed Ranks Test, were employed. Hypothesis testing involved comparing Standard Deviation Index (SDI) values before and after accreditation using paired sample t-tests and Wilcoxon Signed Ranks Tests. Results showed a significant reduction in SDI post-accreditation, indicating improved proficiency testing performance, as smaller SDI values reflect better accuracy. These findings are consistent with prior research by Peter et al. (2010) and Hoeltge et al. (2005), which also reported enhanced proficiency testing metrics following laboratory accreditation. Control charts created with Microsoft Excel visually confirmed improvements in performance, though six analytes showed non-significant mean differences. This suggests clinical significance despite statistical insignificance.

Exploring the relationship between proficiency testing performance and competency assessment scores revealed a weak negative correlation. This aligns with Mesfin et al. (2017), who highlighted the impact of personnel and equipment performance on analytical outcomes. Method validation's effect on proficiency testing performance was evident in the Blood Gases subdiscipline, where equipment replacement and validation led to noticeable improvements. However, correlation analysis and scatter plots indicated weak relationships, potentially due to limited post-accreditation data. In conclusion, our study supports the hypothesis that CAP accreditation positively impacts laboratory analytical performance, as evidenced by improved proficiency testing results. Competency assessment and method validation are key mediators in this process. The research underscores the value of CAP accreditation in enhancing laboratory performance and suggests avenues for future studies.

Future Research:
Sample Size and Generalizability: The study's focus on a limited number of departments and analytes may restrict the generalizability of findings. Future research should consider a larger sample size and a wider range of laboratories to enhance external validity. This study concentrated solely on quantitative analytes. Future research should examine both qualitative and quantitative analytes to identify potential differences in proficiency testing results. The study’s timeframe may have influenced the outcomes. Longitudinal studies with extended observation periods are recommended to assess the sustained effects of accreditation. Further investigation into other potential mediators, beyond method validation and competency assessment, should be conducted to gain a comprehensive understanding of factors influencing laboratory performance.

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