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Comparative Precision Analyses of Magnesium, Calcium, Phosphorus and Iron on Two Independently Operated Cobas c503 and Total Lab Automation c503 Chemistry Analyzers.

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Abstract
Quality and precision of analytical outcome became one of the most important issues for clinical laboratories in last few years, as more and more patients and Clinicians became aware of recent technologies and got access to internet information and newer discoveries. Current study described comparative precision analysis of sensitive ionic components, Calcium, Iron, Magnesium and Phosphorus on stand-alone automated chemistry analyzers Cobas c503 and total lab automation (TLA) c503 Cobas, operated by separate Lab technologists in 8 hours shifts, 24/7. Materials and Methods: Established protocol was followed for standardization of methods. Regression correlation analysis of thirty-five normal healthy individual-samples were analyzed on standalone Cobas c503 and TLA c503 (Roche Diagnostic, Basil) as per standard protocols prescribed in manufacturer sheets. Both instruments were operated by separated group of trained Lab technologists. Regression correlation data of health individuals precisions of Calcium was R2 = 0.8821, with precision of 88.21%. Similarly comparative precision analysis of Iron, magnesium and Phosphorus showed R2 of 0.9772, 0.9664 and 0.980, respectively, thus depicting precision of 97.72%, 96.64% and 98.00% accordingly. Current precision data and research clearly exhibited compatibility of two separately operating instruments, its precision and reproducibility, control kits, and efficiency of technologists. By performing such analyses, we restate our position that its now need of time for clinical laboratories to assess correctness, precision, attuned of multiple instruments, controls and even technical from time to time to ensure valued and quality assured services to the clinicians and patients.

Keywords: Precision, Standardization, Regression analysis

1. Introduction

During past two decades, standardization of techniques and equipment's, precision of results, quality assurances by internal and external controls in a multi-facet clinical laboratory, are few parameters to implement, maintain and sustain total quality management for better patients care and services. Quality and precision of analytical outcome

became one of the most important issues for clinical laboratories in last few years, as more and more patients and end-users (Clinicians) became aware of recent technologies and got access to internet information and newer discoveries.

It is a known fact that calibration, standardization of principles and techniques and reproducibility are the tools that clinician's wants from a clinical laboratory and lab professional's wants form in-vitro diagnostic (IVD) analytical analyzers [1-3]. It becomes highly significant when the lab posses multiple stand-alone and modular analytical systems, which are operational 24/7 and operated by various lab technologists. Importance of these components at large or even medium scale clinical laboratory is such that without having all these quality assurance capabilities, management, pathologists, lab professionals and lab scientist just don't want to go for the less [4-8]. Studies done by our research group on precision, reproducibility and compatibility (when individual instrument was operated by different lab technologists), calibration, and quality assurance studies documented the importance of these requirements to ensure quality pledged services to patients and end-users [1, 3, 4-8].

Current study described comparative precision analysis of sensitive ionic components, such as Calcium (Ca), Iron (Fe), magnesium (Mg) and Phosphorus (P) on two stand-alone automated chemistry analyzers Cobas c503 and total lab automation (TLA) c503, operated by separate Lab technologists in 8 hours shifts 24/7. Comparison was performed on samples obtained from thirty-five healthy individuals.

2. Materials and Methods

Blood samples were collected from thirty-five (n = 35) healthy individuals (M = 25, F = 10), centrifuged and plasma was used to determine Ca, Fe, Mg and P. Previously described protocol was followed for standardization [2]. Precinorm (PNU-PCCC1, Lot # 32420900) and Precipath (PPU-PCCC2, Lot # 32434500) controls of Iron, Magnesium, Calcium and Phosphorus (Roche Diagnostic, Basil) were used, and analyzed each on Cobas c503 and TLA c503, both operated by separated group of trained Lab technologists. All four analytes were determined by standard established methods as per documented protocols [9-12]. Reference ranges for PNU PCCC1 were; Magnesium = 1.57-1.85 mg/dl (Mean 1.71), Calcium = 8.18-9.62 mg/dl (mean 8.90), Phosphorus = 3.57-4.37 mg/dl (3.97) and Iron = 96-120 mg/dl (mean 108). Reference ranges for PPU PCCC2 were Magnesium = 2.95-3.47 mg/dl (Mean 3.21), Calcium = 12.60-15.00 mg/dl (mean 13.80), Phosphorus = 6.80-8.32 mg/dl (7.56) and Iron = 207-263 mg/dl (mean 235). The data was compared statistically by using SPSS ver 20.0 (USA), regression correlation analysis and considered significant when $P < 0.05$.

3. Results

Comparative precision analysis of four ionic components, Ca, Fe, Mg and P were performed on two stand-alone automated chemistry analyzers Cobas c503, and TLA c503 operated by separate groups of Lab technologists in 8 hours shift, 24/7. Comparison was performed by samples taken from 35 healthy individuals. Excellent regression correlation was noted in all comparative analyses when statistical evaluation was performed, relating performance of one analyzer, operated by group of lab technologists, with another similar analyzer, operated by a separate group of lab technologists. This shows precision of instruments, efficiency and reliability of various groups of technologists, their compatibility to operate and analytical skills as well. Regression correlation data of precisions of Ca was R2 = 0.8821, depicting precision of 88.21% (Y = 0.843 x + 1.6076) (Fig 1), whereas that of Fe was R2 = 0.9773, depicting precision of 97.73% (Y = 1.0455x -3.444) (Fig 2). Similarly precision comparison analyses of Mg and P showed R2 of 0.9664 (Y = 1.1449 x + - 0.2648) (Fig 3) and 0.9801 (Y = 0.9385x + 0.2112) (Fig 4) respectively, thus depicting precision of 97.73%, 96.64% and 98.01% accordingly.

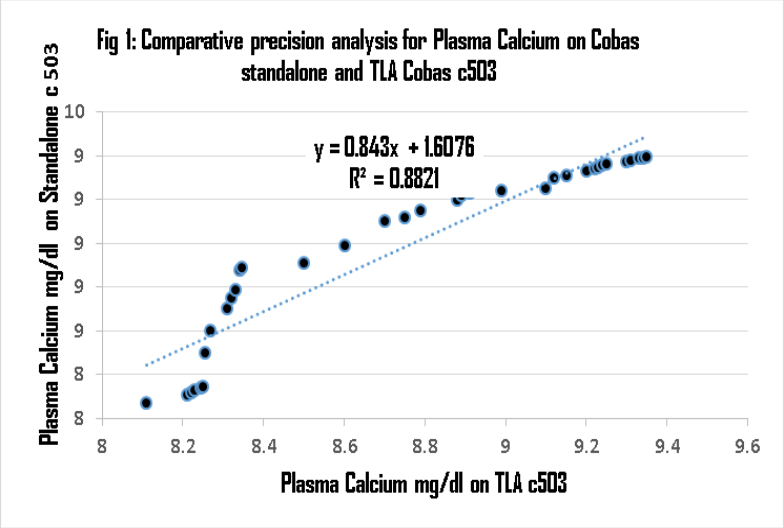


Fig 1: Comparative precision analysis for Plasma Calcium on Cobas standalone and TLA Cobas c503
y = 0.843x + 1.6076
R² = 0.8821
Plasma Calcium mg/dl on Standalone c 503
Plasma Calcium mg/dl on TLA c503

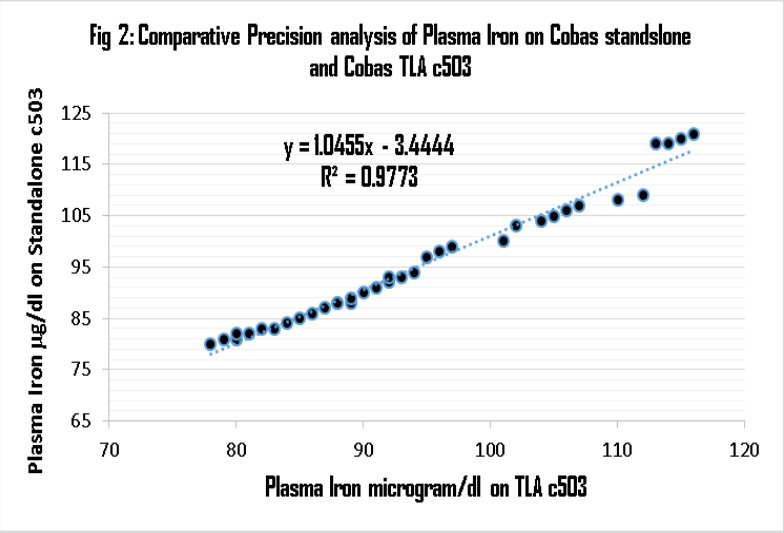


Fig 2: Comparative Precision analysis of Plasma Iron on Cobas standslone and Cobas TLA c503
y = 1.0455x - 3.4444
R² = 0.9773
Plasma Iron µg/dl on Standalone c503
Plasma Iron microgram/dl on TLA c503

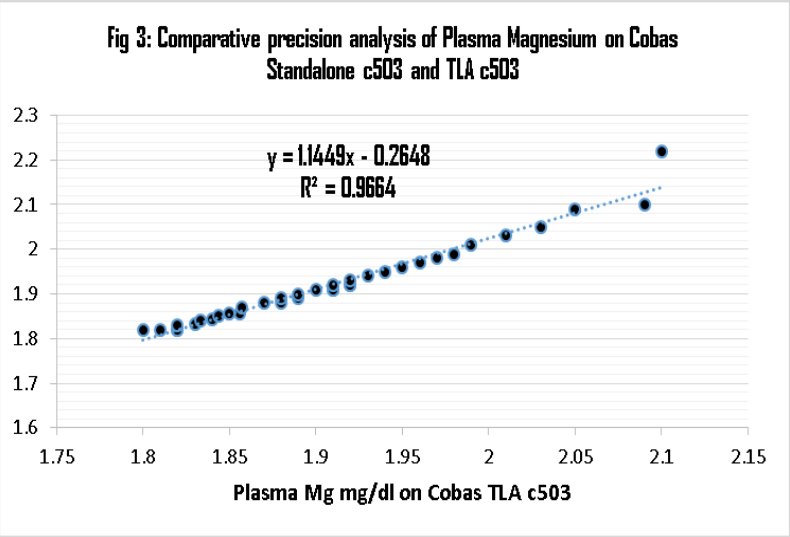
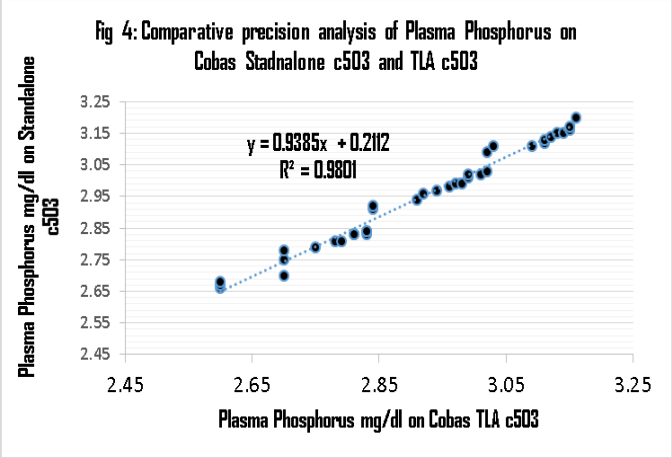


Fig 3: Comparative precision analysis of Plasma Magnesium on Cobas Standalone c503 and TLA c503
y = 1.1449x - 0.2648
R² = 0.9664
Plasma Mg mg/dl on Cobas TLA c503



4. Discussion

Instrument precision and reliability, staff accuracy and skills, reproducibility after multiple analyses are some of the attributes of a professionally performing clinical Laboratory [1-4; 13-15]. In our laboratory, which was established in 1974, uses multiple layers of instruments, standalone, modular, point of care and semiautomatic for routine chemistries, immunoassays, fluid and urine chemistry and related samples 24/7. Volume of our patients is around 800-900 per 24/7, 6500 analytes performed and reported through LRS, parametric tests volume 195,000 per month (2,340,000 per year, 2.34 million). To ensure better and sustainable customer/patients care, reliability, reproducibility, accuracy and precision of instruments, technical staff and available/applicable kits and reagents needs to be monitored and controlled [2, 13-15] In this regard our study documented comparative precision analysis of sensitive ionic components, such as Iron, Magnesium, Calcium and Phosphorus on two automated chemistry analyzers, standalone Cobas c503, and TLA c503, operated by separate Lab technologists in 8 hours shifts, 24/7. Regression correlation data of precisions of Ca was R2 = 0.8821, depicting precision of 88.21% (Y = 0.843 x + 1.6076) (Fig 1), whereas that of Fe was R2 = 0.9773, depicting precision of 97.73% (Y = 1.0455x -3.444) (Fig 2). Similarly precision comparison analyses of Mg and P showed R2 of 0.9664 (Y = 1.1449 x + - 0.2648) (Fig 3) and 0.9801 (Y = 0.9385x + 0.2112) (Fig 4) respectively, thus depicting precision of 97.73%, 96.64% and 98.01% accordingly.

Several previous studies mentioned precision, compatibility and standardization of instruments, analytical principles, staff skills and kits as the performance indicator of a clinical laboratory, regardless of specialty and size [1-3, 13-15]. As the world is getting faster and closer to each other, media and end-users (patients, clinicians) are becoming more and more conscious about lab reports and its reliability. Clinical laboratories around the world including Pakistan are mostly recognized by or follow international standards such as from CLSI, CAP, JCIA, AACC, IFCC, DGCK to run their analyzers to ensure reliability and precisions. Such compatibility, precision and standardization ensure value-added and quality assured services to the clinicians and patients and benefits the health care institute regarding competitive prices and services.

A recent study systematically compared the performance and comparability of two medical analytical instruments, the conventional wet chemistry analyzer (Cobas) and the dry slide technology (Vitros), across various clinical chemistry assays [16]. The evaluation focused on assessing imprecision, inaccuracy, recovery, and method comparison using patient serum samples. Obtained data indicated well to very good agreement for most clinical chemistry analytes. Study concluded to provide understanding and acknowledging method-specific variations that are crucial for accurate result interpretation in clinical laboratories.

5. Conclusion

Current research clearly displayed considerable compatibility, precision and reproducibility of instruments, control kits, and technologists when regression correlation analysis was performed on two standalone chemistry analyzers

c501 (Cobas, Roche, Basil), operated by two different groups of staff. By doing this we reiterated our stance and conviction that its now need of time for clinical laboratories to assess correctness, precision, attuned of multiple instruments, controls and even technical from time to time. By taking such initiatives, we shall be ensuring valued and quality assured services to the clinicians and patients that will benefits organization as well.

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