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Research Article

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Comparative Precision Analysis of Magnesium, Calcium, Phosphorus and Iron on Two Standalone, Separately Operated Cobas C501 Chemistry Analyzers

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Abstract *Background*: 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. *Aim:* Current study described comparative precision analysis of sensitive ionic components, Iron, Magnesium, Calcium and Phosphorus on two stand-alone automated chemistry analyzers Cobas c501, dedicated as A and B, operated by separate Lab technologists in a 8 hours shift. *Materials and Methods*: Established protocol was followed for standardization of methods. Regression correlation analysis of Precinorm (PNU-PCCC1) and Precipath (PPU-PCCC2) controls of Iron, Magnesium, Calcium and Phosphorus (Roche Diagnsotic, Basil) were done and analyzed 25 times each on cobas c501 A and c501 B, both operated by separated group of trained Lab technologists. *Results*: Regression correlation data of Precinorm PPU precisions of Mg was R2 = 0.972, with precision of 97.2%, Precipath was R2 = 0.978, precision of 97.8%. Precinorm of Calcium, Phosphors and Iron showed R2 of 0.987, 0.986 and 0.992, respectively where as Precipath of R2 = 0.986, 0.992 and 0.984, respectively, thus depicting precision of 98.7%, 98.6%, 99.2%, 98.6%, 99.2% and 98.4%, accordingly. *Conclusion:* Current 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

Introduction

During past two decades, standardization of techniques and equipments, 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, 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 Iron, Magnesium, Calcium and Phosphorus on two stand-alone automated chemistry analyzers Cobas c501, dedicated as A and B, operated by separate Lab technologists in a 8 hours shift. Comparison was performed on both normal (Precinorm-PNU) and pathological (Precipath-PPU) controls.

Materials and Methods

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 Diagnsotic, Basil) were used, and analyzed 25 times each on cobas c501 A and c501 B, 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 $P < 0.05$.

Results

Comparative precision analysis of four ionic components, Magnesium, calcium, Phosphorus and Iron were performed on two stand-alone automated chemistry analyzers Cobas c501, dedicated as A and B, operated by separate groups of Lab technologists in a 8 hours shift, 24/7 Comparison was performed by both normal (Precinorm-PNU) and pathological (Precipath-PPU) controls. 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 Precinorm PPU precisions of Mg was $R^2 = 0.972$, depicting precision of 97.2% ($Y = 0.986 x + 0.027$) (Fig 1), whereas that of Precipath was R2 = 0.978, depicting precision of 97.8% (Fig 2). Similarly Precinorm of Calcium, Phosphors and Iron showed R^2 of 0.987 (Fig 3), 0.986 (Fig 5) and 0.992 (Fig 7), respectively where as Precipath of $R^2 = 0.986$ (Fig 4), 0.992 (Fig 6) and 0.984 (Fig 8), respectively, thus depicting precision of 98.7%, 98.6%, 99.2%, 98.6%, 99.2% and 98.4%, accordingly.

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, tests profile volume 87,000-96,000 per month (1,044,000 per year) and parametric test volume per year 2.7 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 stand-alone automated chemistry analyzers Cobas c501, dedicated as A and B, operated by separate Lab technologists in a 8 hours shift. Comparison was performed on both normal (Precinorm-PNU) and pathological (Precipath-PPU) controls. Regression correlation data of Precinorm PPU precisions of Mg depicted precision of 97.2% whereas that of Precipath, 97.8%. Similarly Precinorm and Precipath of Calcium, Phosphors and Iron showed precision of 98.7%, 98.6%, 99.2%, 98.6%, 99.2% and 98.4%, 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 ensures value-added and quality assured services to the clinicians and patients and benefits the health care institute regarding competitive prices and services.

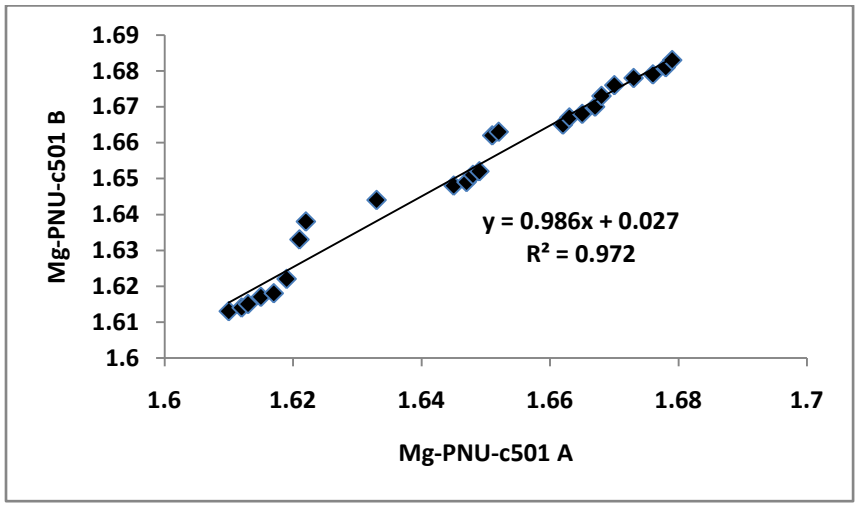

Figure 1: Comparative Precision analysis of Mg (Precinorm-PNU) control on Cobas c501 A and Cobas c501 B

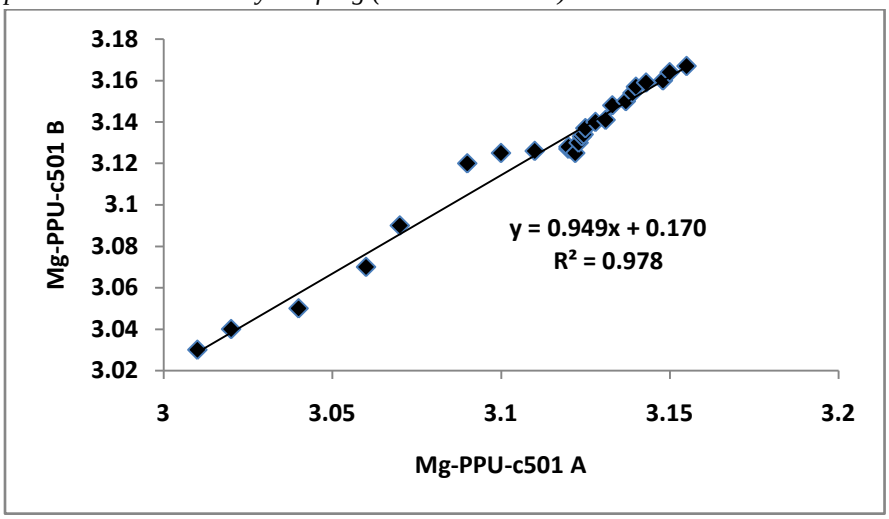

Figure 2: Comparative precision analysis of Mg (Precipath-PPU) control on Cobas c501 A and Cobas c501 B

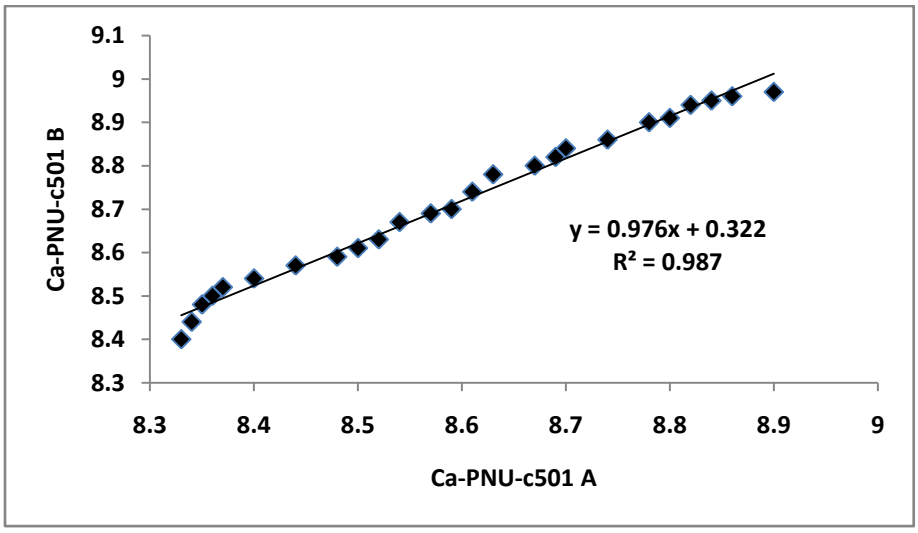

Figure 3: Comparative Precision analysis of Ca (Precinorm-PNU) on Cobas c501A and Cobas c501B

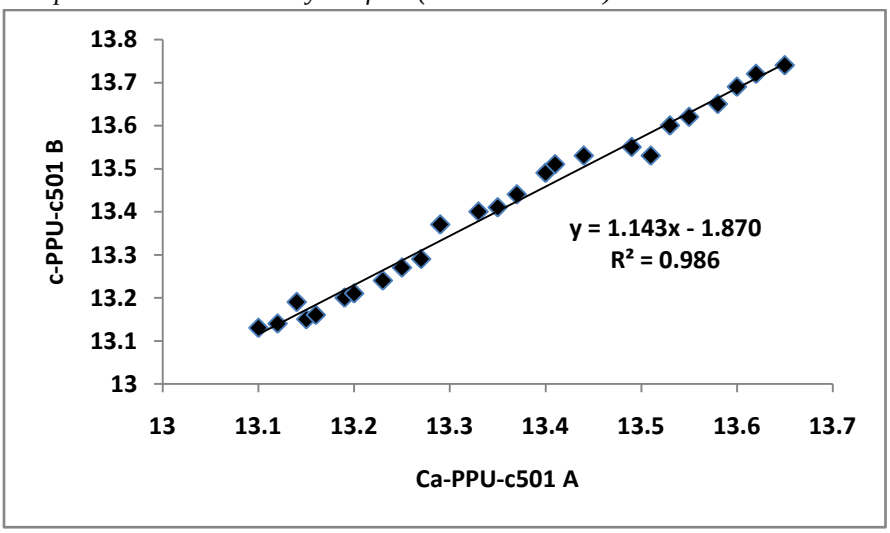

Figure 4: Comparative Precision analysis of Ca (Precipath-PPU) on Cobas c501 A and Cobas c501 B

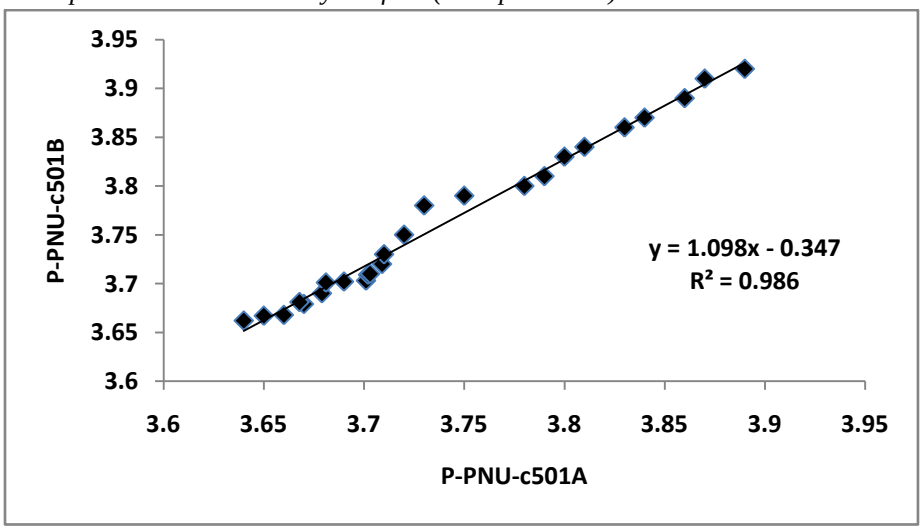

Figure 5: Comparative precision analysis of Phopshorus (Precinorm-PNU) on Cobas c501 A and Cobas c501B

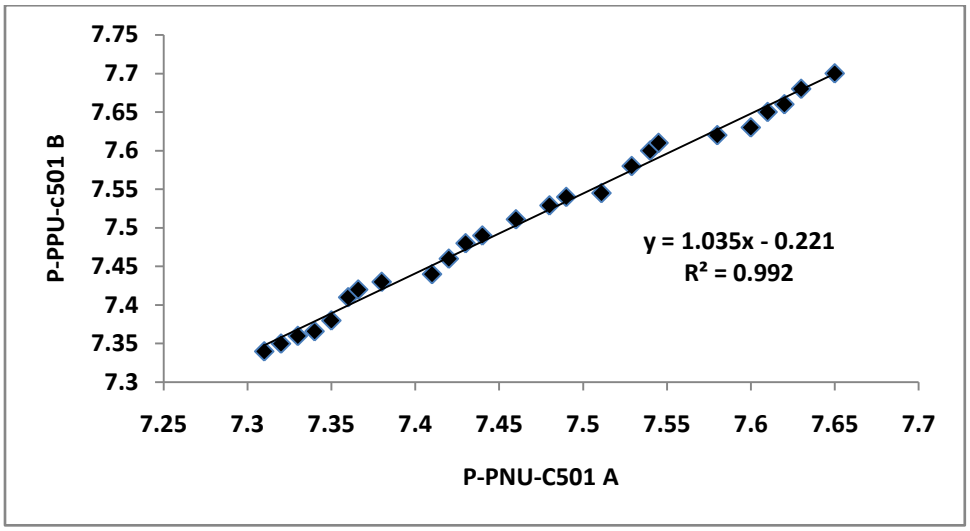

Figure 6: Comparative Precision analysis of Phosphorus (Precipath-PPU) on Cobas c501 A and c501B

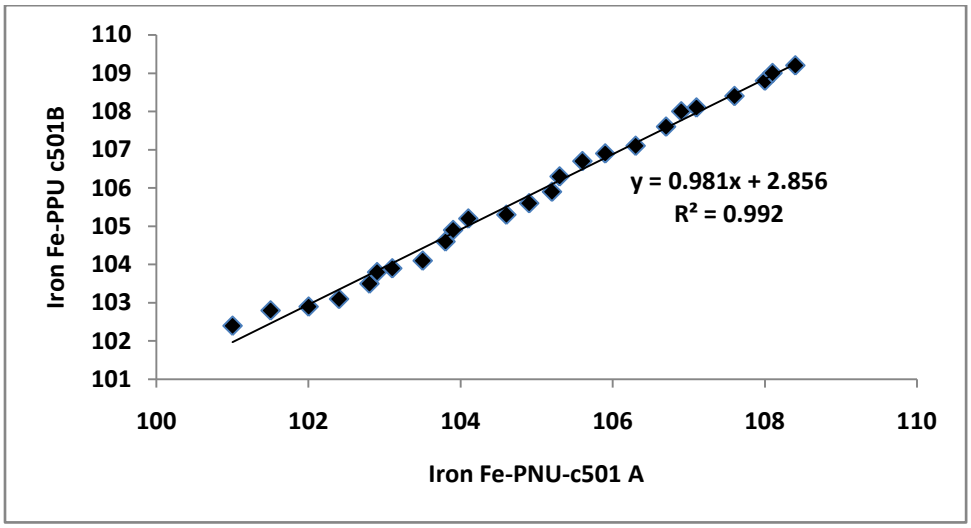

Figure 7: Comparative precision analysis of Iron (Precinorm-PNU) on Cobas c501 A and c501 B

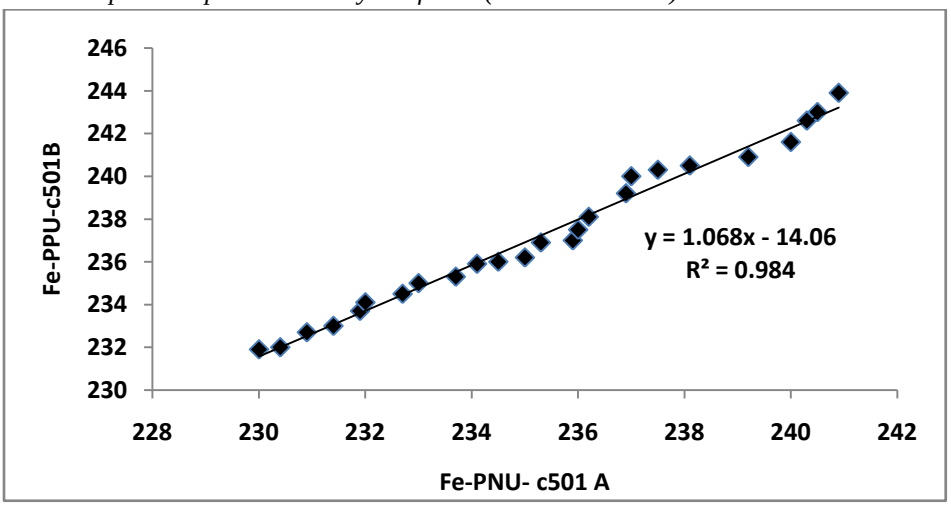

Figure 8: Comparative Precision analysis of Iron (Precipath-PPU) on Cobas c501A and c501B

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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