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Comparative precision, quality checks, and regression analyses of plasma electrolytes on Nova Biomedical CRT standalone electrolyte analyzer and Cobas c503 TLA, operated by different sets of lab technologists

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Abstract
Regarding clinical laboratories, results and reports, and all analyzed parameters must accurate, precise, quality controlled and standardized. Results might get deviated due to systemic, and/or random error, pre-analytical, analytical or post analytical errors. In this context, current study described the precision and accuracy of electrolytes, Chloride Cl, Sodium Na, Potassium K, bicarbonate HCO_3 on two separate analyzer and techniques, NOVA biomedical CRT electrolyte analyzer (Massachusetts, USA) and Cobas c503 TLA (Basil, Switzerland) operated by different sets of laboratory technologists. Percent precision and linear regression were analyzed to be Chloride 87.4%, Sodium 97.62%, Potassium 97.36% and bicarbonate 98.49%. All results were assessed via Regression correlation analysis R2 calculating Y and X intercepts to acquire R values representing present association and linearity. Regression analysis of all four electrolytes exhibited excellent correlation with each other manifesting considerable precision and accuracy of analytical processes, instruments and technologists.

Keywords: Precisions, accuracy, regression, quality control, electrolytes

1. Introduction

It has been recently documented that clinical laboratories all around the world performs around 7 billion per year, the reports of which is directly related to clinicians decision, patient treatments, and outcome [1]. In this scenario, results and reports, all analyzed parameters must accurate, precise, quality controlled and standardized. Results might get deviated due to systemic, and/or random error, pre-analytical, analytical or post analytical errors etc [2,3]. Moreover, large scale clinical laboratories spent considerable amount on standardization of analytical processes, however, error does occur due to deviation from prescribed processes and protocols. It was estimated that 32% of the revenue goes to the cost of quality (COQ) [4,5]) and even then having inaccurate, non-standardized results ensued in bad reputation, incorrect clinical decisions, and sometimes costly legal issues.

Quality controls, in addition to aforementioned necessities, is required to assess daily performance of all analytical instruments, including mechanics, procedures, dry and wet chemistries, immunology protocols, integration, sample

analysis and results outcome. As per recently published article [6] reiterated the two common technologies of quality control used in clinical labs worldwide as Accuracy: which refers to the proximity of a result to the definite value (True value). It is generally measured by direct comparison to a reference by using quality control serum, with an accurate value assigned to it by the manufacturer [7]. Precision: It refers to the reproducibility or closeness of values to each other [7]. Ideally a laboratory should be trying for both good accuracy and precision.

Current study described the precision and accuracy of electrolytes, Chloride Cl, Sodium Na, Potassium K, bicarbonate HCO_3 on two separate analyzer and techniques, NOVA biomedical CRT electrolyte analyzer (Massachusetts, USA) and Cobas c503 TLA (Basil, Switzerland) operated by different sets of laboratory technologists.

2. Material and Methods

Precision and accuracy of electrolytes, Chloride Cl, Sodium Na, Potassium K, bicarbonate HCO_3 on two separate analyzer and techniques, NOVA biomedical CRT electrolyte analyzer (Massachusetts, USA) and Cobas c503 TLA (Basil, Switzerland) operated by different sets of laboratory technologist. Thirty samples from normal, healthy individuals were analyzed on both instrument, twice each sample with controls, Precinorm and Precipath, divided into fifteen each into morning and evening shifts. Where needed, individual samples were analyzed multiple times (3 maximum) and mean was taken as final result. Normal reference values of electrolytes are Sodium: 136 to 144 mmol/L, Potassium: 3.7 to 5.1 mmol/L, Chloride: 97 to 105 mmol/L, Bicarbonate: 22 to 30 mmol/L. Results are analyzed via Regression correlation analysis R2 calculating Y and X intercepts to acquire R values representing present association and linearity. Earlier studies by our department and its references were taken as protocols [8,9,10]

3. Results

Results are summarized in Fig 1-4. Comparative precision data analyzed in current study showed precision and accuracy of electrolytes, Chloride Cl, Sodium Na, Potassium K, bicarbonate HCO_3, when run of on two separate analyzer and techniques, NOVA biomedical CRT electrolyte analyzer (Massachusetts, USA) and Cobas c503 TLA (Basil, Switzerland) operated by different sets of laboratory technologists. Chloride regression was Y = 0.9662x + 4.575 with R^2 0.874 (87.4 %), Sodium Y = 1.1963x -26.795 with R^2 0.9762 (97.62%), Potassium Y = 1.5987x - 2.0971 with R^2 0.9736 (97.36%) and Bicarbonate Y = 0.9964x + 1.3461 with R^2 0.9849 (98.49%). Regression analysis of all four electrolytes exhibited excellent correlation with each other manifesting considerable precision and accuracy of analytical processes, instruments and technologists. Percent precision and linear regression were Chloride 87.4%, Sodium 97.62%, Potassium 97.36% and bicarbonate 98.49%.

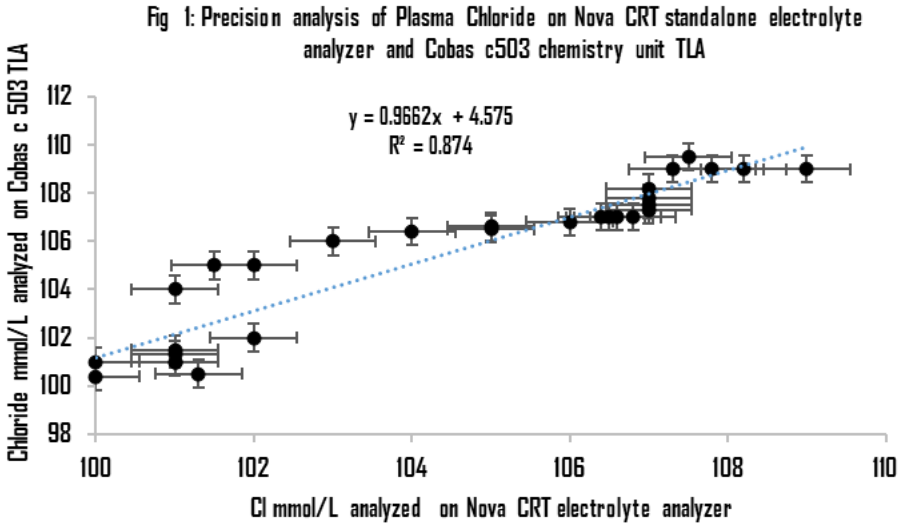


Fig 2: Precision analysis of Plasma Sodium on Nova CRT standaalone electrolyte analyzer and Cobas c503 TLA

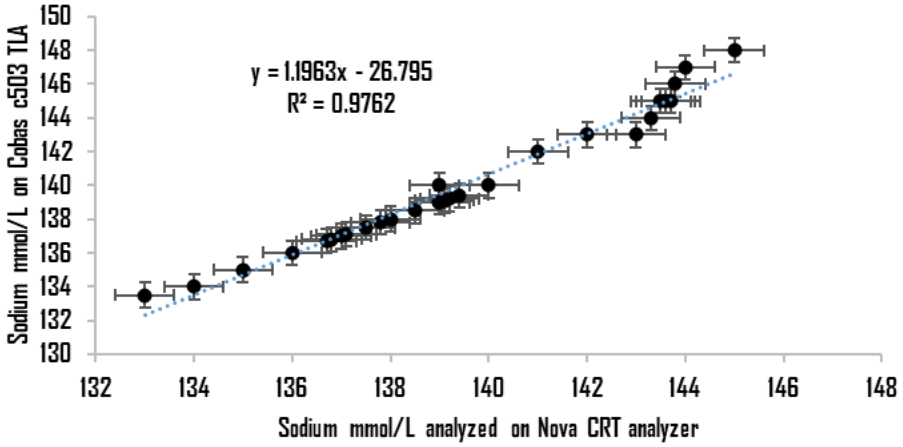


Fig 3: Precision analysis of Plasma Potassium on Nova CRT standalone analyzer and Cobas C503 TLA

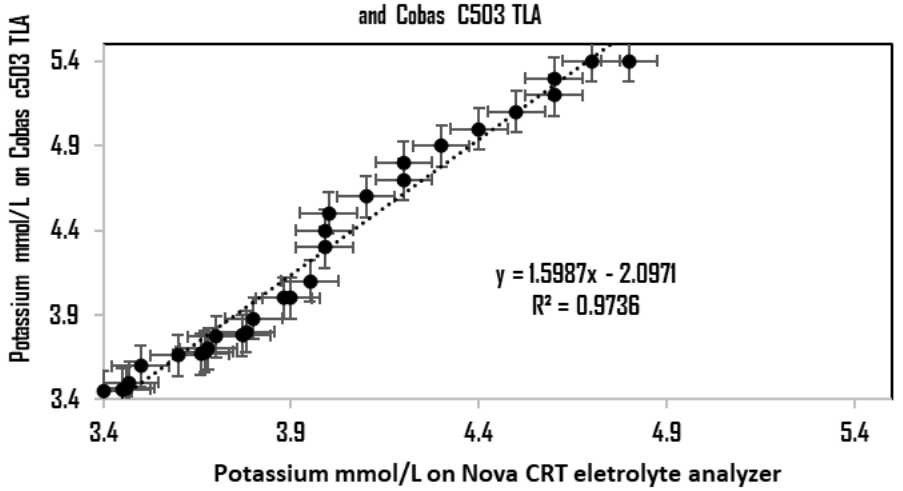
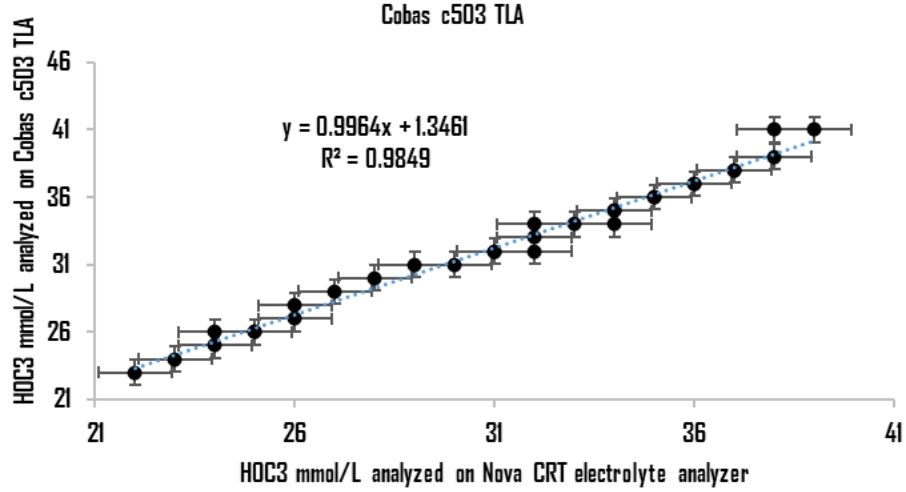


Fig 4: Precision analysis of Plasma HCO3 on Nova CRT electrolyte analyzer and Cobas c503 TLA



4. Discussion

Laboratory results and reports are critically related to prompt decision by clinicians and timely treatment of patients. Without specified turn-around time and quality controlled analysis, with undisputable precision and accuracy, any report or result from a clinical laboratory becomes useless unless provide with mentioned attributes. With quality control procedures, of which periodic precision and accuracy analyses is an integral part; end users, clinicians, patients becomes certain about credibility of lab investigation, and develops confidence in lab reports and services.

Quality controls, precision and accuracy assessment methods has the ability to evaluate and sustain the standardized processes of lab investigation. Moreover, precision and accuracy assessment can directly and indirectly check errors, mostly that of analytical phase and its components. Its has been suggested that reliability of lab reports via strictly checked steps regularly, always ensured outcome [1,6].

Regression analysis and precision and accuracy evaluation are some of the easy to handle, user friendly and productive. Our earlier studies regarding comparative precision and regression analyses of Ferritin with inflammatory biomarkers (PCT, IL-6, D-Dimer, LDH, CRP) from SARS-Covid 19 patients, Urinary micro-albumin analysis with Precision testing on two separately operated Cobas chemistry analyzers c501, quality check, comparative precision and standardization of liver function test (LFTs) parameters on two identical standalone Cobas c501 analyzers, organized 24/7 and operated by different sets of lab technologists, comparative precision analysis of Urinary microalbumin on two Cobas c501 chemistry analyzers, separately operated in different shifts and comparative Performance and Precision evaluation of Thyroid Hormones on ECL Cobas e411 during two different shifts, manifested appreciable correlation, accuracy and precision [2,3,8-10]. In presented study, regression analysis of all four electrolytes exhibited exceptional correlation with each other demonstrating considerable precision and accuracy of analytical processes, instruments and technologists. Percent precision and linear regression were for Chloride 87.4%, Sodium 97.62%, Potassium 97.36% and bicarbonate 98.49%. Such accuracy and precision, regarding instrumentation, analytical methods, techniques, technologist skills shall always ensures better outcome that benefits patients and decision making clinicians. Furthermore, it guarantees sustainability of quality assured services and credibility of clinical laboratories.

5. Conclusion:

Current study described the precision and accuracy of electrolytes, Chloride Cl, Sodium Na, Potassium K, bicarbonate HCO_3 on two separate analyzer and techniques, NOVA biomedical CRT electrolyte analyzer (Massachusetts, USA) and Cobas c503 TLA (Basil, Switzerland) operated by different sets of laboratory technologists. Regression analysis of all four electrolytes exhibited excellent correlation with each other manifesting considerable precision and accuracy of analytical processes, instruments and technologists. Percent precision and linear regression were Chloride 87.4%, Sodium 97.62%, Potassium 97.36% and bicarbonate 98.49%.

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