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Research Article

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Comparative precision analysis of six enzymatic parameters from both normal and diseased individuals on two separate standalone Cobas c501 and TLA modular CCM Cobas c503 instruments

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Abstract Analytical precisions, accuracy and standardization are now mandatory requirements for a clinical laboratory for sustainable patient care and good standing. Present study described comparative precision analysis of six enzymatic parameters from both normal and diseased individuals on two separate standalone Cobas c501 and TLA modular CCM Cobas c503 instruments. Blood was collected from fifty (n = 50), healthy individuals, as well as fifty (n = 50) from confirmed cases of hepatic, muscular and cardiac patients, twenty five each from either gender (males or female). Plasma was separated, aliquot were made and analyzed on both instruments, standalone Cobas c501 and TLA Cobas c503 simultaneously for ALT, AST, ALP, LDH, CPK and □GT. Mann-Whitney U statistical test was used for comparative examination which manifested markedly non-significance in all enzymatic parameters, both from normal, healthy ($P < 0.09$ to $P < 0.85$) and diseased ($P < 0.12$ to $P < 0.96$) individuals. Data suggests very strong precision and analytical accuracy of both instruments, technically, chemically, methodology and workstation continual improvement.

Keywords Precision, enzymes, Accuracy, standalone, total lab automation.
Short Title: Comparative precision analysis of six enzymatic parameters

1. Introduction

Precision of analytical determination, mainly in clinical setups of laboratory services, is as significant as medical care of patients. Any deviations from required and prescribed analytical outcome may result in incorrect medications, treatments and management, sometimes causing fatality. In last two decades, importance was given to analytical precisions, standardizations, quality assurance and accuracy of clinical laboratory instruments, equipment, methods and quality control materials to ensure correct and meticulous results and reports. International organizations and societies like IFCC, AACC, WHO, JCIA, ISO, ISO 15189, took great measures to impart, deliver, familiarize, and ensure standardization of analytical processes and the instruments that perform such work, for making treatments, management and care of patients, better and sustainable across the board.

Accurate diagnosis of an intended blood parameter(s), such as urea, creatinine, electrolytes, liver function test profile, hepatic and muscle enzymes etc as well urinary components e.g sugar, protein, albumin, oxalate, citrate and urinary micro-albumin is very important in clinical decision making and correct treatment by physicians [1]. Several special chemistry profiled parameters such as Troponin I, pro-BNP, and tumor markers also needed to be assesses

urgently and with accuracy to ensure proper diagnosis and long term prognosis [2-5]. Procurement of new instruments, replacements with advanced versions, addition or replacement of older methods with newer, more technically advanced ones, are some of the routine improvements that are done everywhere in the world either in a standalone clinical lab or those associated with a hospital. However, before making these advancements, replacements, changes of methods and instruments live (means accessing for direct patient care), its exactitude, standardization, quality assurance, precision needs to be assessed for sustainable accuracy and outcome maintainability [1-5]

Current study described comparative precision analysis of some routine chemistry enzymatic parameters, such as alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), lactate dehydrogenase (LDH), creatinine phosphokinase (CPK) and gamma glutamyl transpeptidase (□GT) on our newly acquired total lab automation system (TLA, Cobas CCM series) Cobas c503 in comparison with existing standalone Cobas c501 chemistry analyzer.

2. Material and Methods

Blood was collected from fifty (n = 50), healthy individuals, as well as fifty (n = 50) from confirmed cases of hepatic, muscular and cardiac patients, twenty five each from either gender (males or and female). Plasma was separated, aliquot were made and analyzed on both instruments, standalone Cobas c501 and TLA Cobas c503 simultaneously for ALT, AST, ALP, LDH, CPK and gGT. Analytical methods were standard as per protocols used earlier [4-6]. Analytical data from both instruments were compared with each other using Mann-Whitney U test. The Mann-Whitney U test is a statistical test that allows two groups or conditions or treatments to be compared without making the assumption that values are normally distributed. Its null hypothesis asserts that the medians of the two samples are identical. P value was taken <0.05 as standard, with less than 0.05 outcome shall be taken as significant. Results are summarized as mean ± Standard error of means.

3. Results

Comparative precision analysis of parametric data of six plasma enzymes from fifty healthy individuals and fifty from cardiac, hepatic and muscular disease patients of either gender was performed using Mann-Whitney U statistical test (Table 1).

Table 1: Comparative precision data analysis of six enzymatic parameters from both normal and diseased individuals on two separate standalone Cobas c501 and TLA Cobas c503 instruments

Parameters	Mean ± SE Cobas c501	Mean ± SE Cobas C 503	P value (P< 0.05) C501 vs C503	Z score	U score
Normal values					
ALT IU/L	29.72 ± 0.798	30.5 ± 0.637	P< 0.4777	-0.7066	1147
AST IU/L	26.60 ± 0.712	28.2 ± 0.675	P< 0.1585	-1.4063	1554
ALP IU/L	87.64 ± 0.89	85.66 0.826	P< 0.2670	1.1064	1089
LDH IU/L	126.7± 0.891	129.24 ± 0.795	P< 0.0929	-1.6820	1005
CPK IU/L	109.58 ±1.405	109.78 ±1.09	P< 0.8572	0.1826	1223
γGT IU/L	24.64 ± 0.234	25.66 ± 0.274	P< 0.6965	0.3896	1193
High values					
ALT IU/L	58.26 ±0.691	55.22 ± 0.684	P< 0.9681	-0.0413	1243
AST IU/L	56.04 ±1.55	62.94 ± 0.897	P< 0.4354	-0.7790	1136
ALP IU/L	170.15 ±5.35	161.10 ± 4.199	P< 0.1970	1.2925	1062
LDH IU/L	189.32 ±1.42	190.24 ±1.61	P< 0.1235	-1.540	1026
CPK IU/L	185.54 ±4.84	183.24 ±4.81	P< 0.3503	-0.9306	1114
γGT IU/L	41.92 ± 0.49	41.82 ±0.80	P< 0.6672	-0.4274	1187

Results are expressed as Mean ± SE, data is significant when P < 0.05

Analysis was done on two separate chemistry analyzers, standalone Cobas c501 and TLA Cobas c503 (Table 1). Comparative examination manifested to be markedly non-significant in all enzymatic parameters, both from normal,

healthy and diseased individuals, suggesting very strong precision and analytical accuracy of both instruments, technically, chemically, methodology and workstation. In group of enzymes from normal individuals non significance ranges from P< 0.09 to P < 0.85 whereas in diseased group from P < 0.12 to P < 0.96 (Table 1). Technical and analytical precision is thus very significant factor in ensuring sustainable accuracy, patients care and trust of end-users and clinicians.

4. Discussion

What transpired in recent years is the significant urge in requirements of urgent testing, with accurate results, precise, standardized, that can help, and support quick medical decision and prompt patient care [1, 2, 3, 6]. In today's world of health care industry, space limitation, qualified staff, financial constraints, procurement of latest technologies and/or kits, chemicals are some of the components, either one of it or all, that can induce pressure to have further enhanced and robust analytical systems that has the ability to perform with precision and accuracy for better patient care and trust [1, 3, 4, 7]. Regardless of the financial cost, it has been advocated many times that the aim should be a robust analytical testing system for patients care with efficient turnaround time (TAT), minimal blood or sample volume, readily accessible results and desirable outcome. Moreover with more efficient precision and analytical performance, maintenance of high tech instruments is also now becoming essential and mandatory. To have periodic preventative maintenance (PPM) system, is always beneficial for long term sustainable and standardized laboratory services.

Our current study performed comparative precision analysis of enzymatic data of healthy and diseased individuals using statistical analysis, which has been performed on two different instrument, a standalone Cobas c501 and a TLA modular Cobas c503. Mann-Whitney U method used that provided markedly non-significant comparison analyses, manifesting strongly related-precision and accuracy of two different instruments, suggesting standard methods, fastidious performance, skilled staff, accurate collection techniques and robust support system. In a recent study published that covers the assessment of seventy-six application of Cobas instruments at five different sites all around Europe depicted Pearson correlation of 0.998 R2, which means 99.8% accuracy. The study also reported the efficiency of integrated systems, that we also have, and coefficient of variations of less than 1% for ion selective electrodes assays, less than 2% for clinical chemistry assays, and less than 2.5% for immunoassays [1]. Coefficient of variations for Intermediate was noted to be most less than 2% for ISE assays, less than 2% for clinical chemistry assays and less than 2.5% for immunoassays. Our data, where Mann-Whitney U test was used for comparative precision, all U scores came out of around 1000^{th} means distribution of ranks is similar in both groups. Non significance of results of all enzymatic determination depicts strong precision in both standalone c501 and TLA c503 instruments, which is appreciable and provides sustainable accuracy, meticulous results for better and accurate clinical decisions.

5. Conclusion

Our presented study describe comparative precision data analysis of six enzymatic parameters from both normal and diseased individuals on two separate standalone Cobas c501 and TLA Cobas c503 instruments. Results showed non-significant difference in values of enzymatic parameters from P< 0.09 to P < 0.85 in normal individuals and from P < 0.12 to P < 0.96 in diseased individuals where we have selected P< 0.05 as significant. Data depicts significant precision, accuracy, standardization of analytical skills, methods, kits and support services in our department and installed instruments. Such efforts and quality assured system benefits prompt clinical decisions, timely treatments and long term patients trust.

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