Comparative precision analysis of urinary micro-albumin of female diabetic patients with underlying clinical conditions on Standalone Cobas c501 and CCM Cobas Total Lab Automation c503

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Abstract Elevated levels of urinary micro-albumin indicates proceeding cardiovascular and renal anomalies and should be treated immediately. Timely reporting of such an important biomarker, with precision and accuracy must and should be a priority of any clinical laboratory. Aim of present study is to analyze precision and accuracy of newly installed total lab automation system CCM c503 analyzer with existing standalone Cobas c501 and vice versa using urinary micro-albumin as test material. Samples from diagnosed female patients of hypertension (n = 35), renal disease (n = 40) and diabetes (n = 40) were taken and simultaneously analyzed on both instruments. Data exhibited regression correlation R^2 of 0.97, 0.980, 0.985, respectively with manifested precision accuracy of 97%, 98% and 98.5% in three categories of micro-albumins analyses. Results suggests significant accuracy and standardization of method, instrument, skills of staff, technically well maintained instrument and analytical capabilities of both c501 and TLA c503 systems.

Keywords Precision, Accuracy, total lab automation, urinary micro-albumin
Short Title: Precision analysis of urinary micro-albumin

1. Introduction

Increase concentration of urinary micro-albumin not only indicates uncontrolled diabetic condition but also depicts a proceeding cardiovascular and renal complications. Even a minimal incremental increase in urinary micro-albumin can cause a cascade reaction leading to cardiovascular anomalies, if not treated on time [1]. A study conducted earlier reported that a 2-fold increase in urinary micro-albumin can induce an increased risk of 1.29 and 1.12-times for cardiovascular mortality and non-cardiovascular mortality, respectively [2, 3]. Moreover, increase or abnormality in micro-albumin levels has been reported not only from diseased population of cardiovascular, diabetic, hypertensive, and coronary artery diseases but also from general population, which is a matter of grave concern [1]. Furthermore, direct association has also been reported between urinary micro-albumin and metabolic syndrome, such that prevalence of micro-albuminuria is higher in population suffering from metabolic syndrome [4]. In this regard, accurate analytical determination of urinary micro-albumin is of significant importance to provide actual figurative information to clinical decision maker. Earlier studies performed in our laboratory regarding precision analysis and comparative determination of inter and intra-instrumental, methods, staff performance depicted appreciable outcome, provided that standardization, quality control parameters, quality assurance protocols

are in place and implemented with due diligence and strictness [5, 6]. A year ago we have procured and installed total laboratory automation CCM system of Cobas (Roche, Basil) series inclusive of c503, e801. To ensure intra-instrumental precision we have performed simultaneous precision analysis of urinary micro-albumin samples from diseases population of female group, categorized as hypertensive, renal problems and diabetic and compare the data using Pearson regression R2 correlation calculation and chart. Present study details the analysis and precision outcome of this project.

2. Materials and Methods

Urinary samples were collected from carefully selected female patients with confirmed cases of hypertension (n = 35), renal disease (n = 40) and diabetic (n = 40). Urinary micro-albumin was analyzed simultaneously on standalone Cobas c501 and Total lab automation CCM system Cobas c503 with existing standard method described earlier [5]. Pearson's regression correlation statistical analysis was performed to get R2 and percentage precision compliance. Results are expressed as mg/g of creatinine.

3. Results

Comparative precision analysis of estimation of urinary micro-albumin came out successfully with Pearson's regression correlation R2 of 0.97, 0.980, 0.985, respectively for samples collected from three categories of female patients, hypertensive (Fig 1), renal (Fig 2) and diabetic (Fig 3). Regression data manifested precision accuracy of 97%, 98% and 98.5% in three categories of micro-albumins analyses, suggesting excellent accuracy and standardization of method, instrument, skills of staff, maintenance of instrument and analytical capabilities of both c501 and TLA c503 systems.
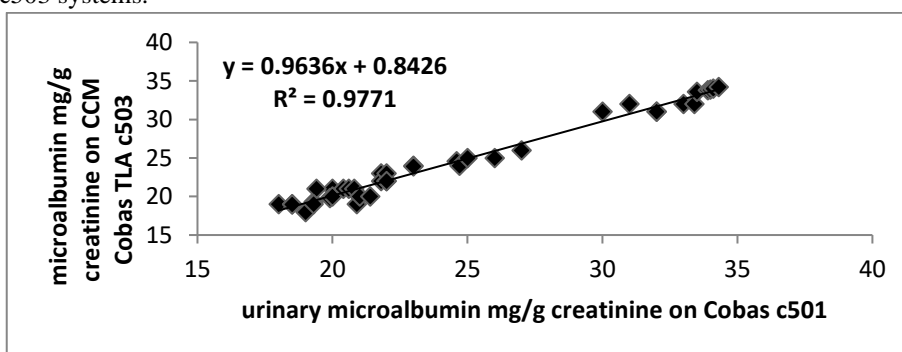

Figure 1: Comparative precision analysis of urinary microalbumin of Female Hypertensive patients (n = 35) on Standalone c501 and Cobas CCM TLA c503
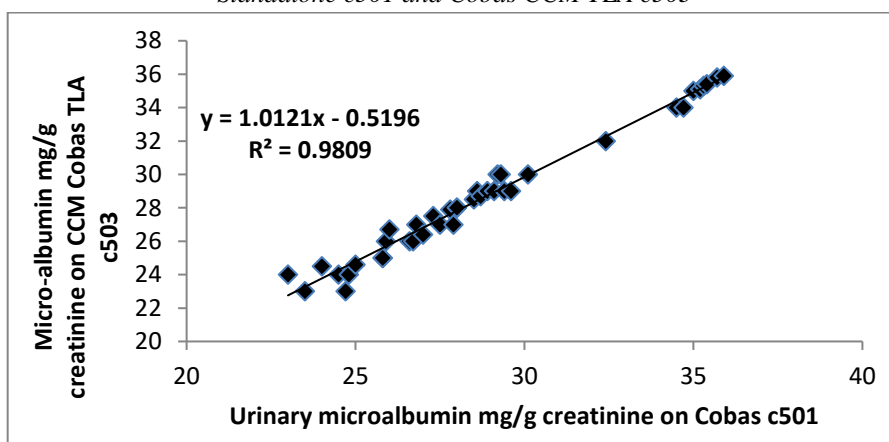

Figure 2: Comparative precision analysis of urinary microalbumin of female renal disease patients (n = 40) on Standalone Cobas c501 and CCM Cobas TLA c503
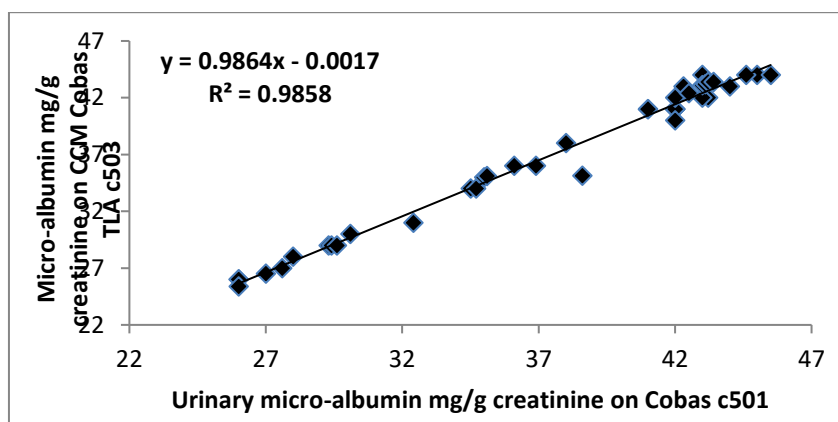
$y = 0.9864x - 0.0017$
$R^2 = 0.9858$

Figure 3: Comparative precision analysis of urinary microalbumin of female diabetic patients (n = 40) on standalone cobas c501 and CCM Cobas TLA c503

4. Discussion

Analytical precisions, standardization, accuracy, quality control and assurances inclusive of instrument maintenance and staff training are few mandatory component that envisage better patient care and timely reports. One of the requirement of such quality assured and trust worthy services is staff training, continual improvement and quality checks/audits periodically and as and when required. A recent article underlines modules, methods and categories of clinical lab trainings at certificate, undergraduate and postgraduate levels [7]. Cost, efficiency, mergers, modular system, automation, highly advanced analytical systems are few major changes that we have witnessed in last decades and that immensely impacted clinical lab staff sustainability, proficiency and suitability. Majors have been taken and suggestion have been forwarded by international organizations such as WHO, IFCC, AACC, CAP and related to safeguard short, and long term training regiments, on-spot, vocational, online and distant learning facilities to ensure continual quality improvement in patient care services by clinical laboratories.

Precision analysis, accuracy and standardization checks, periodic preventive maintenance (PPM) are integral components that mid-level and senior level clinical lab staff must know and practice. Our current study was part of such continual improvement strategy to have comparative precision check and availability of accurately-driven analytical instruments for justifiable and maintainable services. We have taken urinary micro-albumin as a parameter to be assessed on our old standalone c501 chemistry analyzer system and newly installed total lab automation Cobas CCM c503 analyzer. Results were promising as samples from all three categories of patients, Hypertensive, renal disease and diabetic showed excellent precision with R2 of 0.97, 0.980, 0.985, respectively, depicting percent compatibility of both instrument to each other at 97%, 98% and 98.5%. Our earlier studies reported similar pattern of precision regarding urinary micro-albumin where it was analyzed on two separately operated but similar chemistry analyzer Cobas c501 working in different shifts [6]. Outcome of our study clearly exhibited accuracy, precision of a well maintained older version of Cobas c501 analyzer, which is a standalone components, in compatibility with a newly acquired, high tech, modular total laboratory automation system CCM of Cobas c503.

5. Conclusion

Present study detailed precision analysis of urinary micro-albumin from female patients of hypertension, renal disease and diabetes on a standalone c501 and TLA CCM Cobas c503 chemistry analyzers. Person's correlation analyses exhibited R2 of 0.97, 0.980, 0.985, respectively, depicting excellent percent compatibility of 97%, 98% and 98.5%.

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