

Comparative precision analysis of Precision-controls on automated chemistry analyzers

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Abstract

Background: Automated diagnostic equipments took over manual testing in last three decades, that allowed enhanced reproducibility, precision and accurateness of results; in addition to 24/7 availability of major lab testing profiles. **Aim:** In this regard, present study described comparative equipments' precision assessment of conventional chemistry analyzer, Hitachi 912 with Cobas c501 on parametric panels of Preci-controls, both normal (PNU) and pathological (PPU). **Materials and Methods:** Comparative performance assessment of instruments, the conventional automated Hitachi chemistry analyzer 912 and Cobas c501 (Roche Diagnostics, Basel), was done through analysis of either PNU or PPU, 30 times each on either instruments. For precision, samples for five parameters, creatinine, urea, sugar, total protein and calcium from both PNU and PPU were analyzed by standard methods during January 2015 to Feb 2015. **Results:** Comparative analysis showed excellent precision correlations among all five parameters on both instruments with R^2 regression ranging from 0.990 to 0.999 for PNU and 0.993 to 0.997 for PPU depicting the precision and reliability of methods, standardization and system equivalency. **Conclusion:** Regression analysis exhibited near-equivalent data ranging from 84.3% to 99.8%, thus ensuring that standardization and proper calibration of both instruments is upto the mark for routine chemistry analysis of referred parameters. **Key Words:** Chemistry analyzers, TAT, automation, Cobas 6000c 501, Hitachi 912, analytical performance, precision analysis

1. Introduction

In last three decades, automated diagnostic equipments took over manual testing, especially in independent large scale clinical laboratories and/or tertiary care hospitals, where faster TAT is a necessity to cater higher patient's volume and wide variety of medical/surgical specialties [1-4]. Moreover, it also allowed enhanced reproducibility, precision and accurateness of results; in addition to 24/7 availability of major lab testing profiles [5-9]. In this context, in recent years, both in developing and developed countries, clinical laboratories, either in independent capacity or as part of hospital care, required to have the tests performed according to standardized protocols with appreciable turnaround time 'TAT' [1-3,10-12]. Traditionally, shifting tests profiles or even parametric tests from one automation-system (or semi automation, where applicable) to another automated-arrangement requires the comparative analytical evaluation of analyzers,

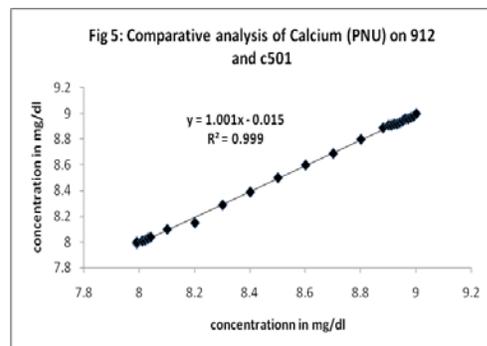
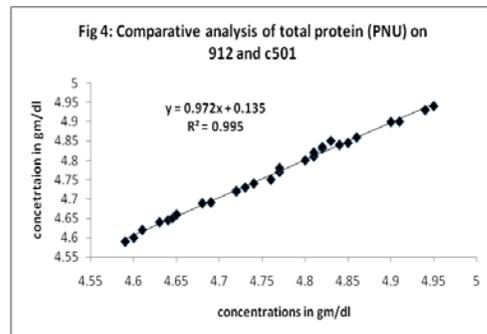
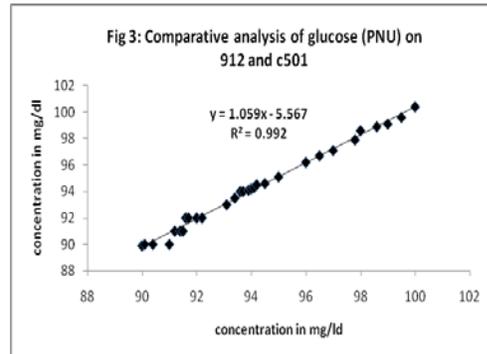
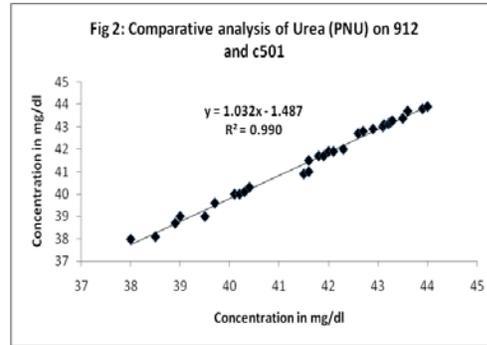
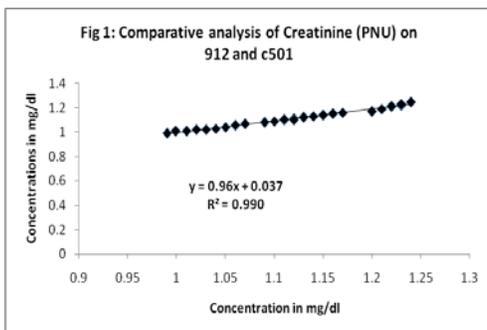
methods, calibration and precision testing of controls, both normal (preci-normal = PNU) and pathological (preci-Path = PPU), before introduction of the equipment into the clinical lab system [10,11,13,14]. Moreover, even if automated system is already available within the lab, addition or replacement with advanced version or as a backup, or adding of new precision-controls, also requires that its multi-channels, variability, testing profiles, international analytical methodological standards, in addition to reproducibility, accuracy and precision be also assessed before placing it into routine use [1,2,4,9,11,15]. Thus the present study reports comparative equipments' precision assessment of conventional chemistry analyzer, Hitachi 912 with Cobas c501 on parametric panels of Preci-controls, both normal (PNU) and pathological (PPNU). The parameters tested for analytical precisions were Creatinine, Urea, glucose, total protein and calcium.

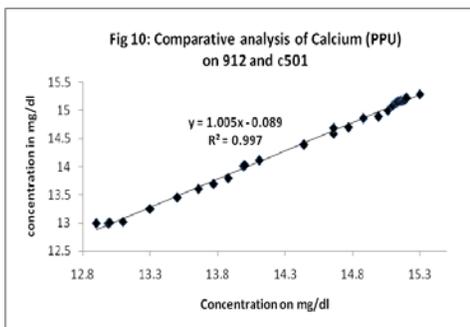
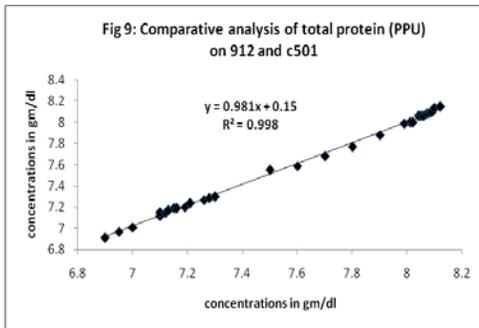
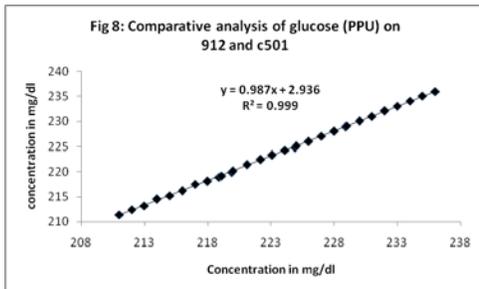
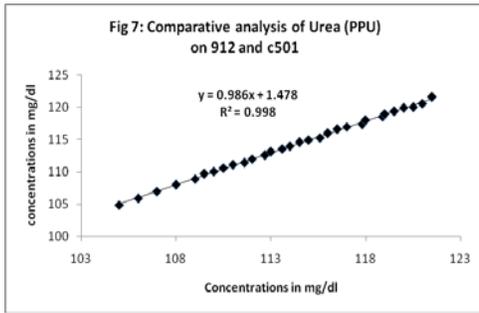
2. Materials and Methods

Samples from both PNU and PPU were used in present study during January 2015 to Feb 2015. Comparative performance assessment of instruments, the conventional automated Hitachi chemistry analyzer 912 and Cobas c501 (Roche Diagnostics, Basel), was done through analysis of five parameters, creatinine, urea, sugar, total protein and calcium. Either PNU or PPU were run (analyzed) 30 times each on Hitachi 912 and Cobas c501. Urea was analyzed by UV-urease assay [16], whereas Creatinine by Jeff's rate-blanked and compensated method [17]. Glucose, was assessed by Gluco-quant-hexokinase [18], whereas total protein by Biuret method [19] and calcium by Ca-Gen 2 [20] methods, respectively. Manufacturers' instructions were used for standardization, calibration, controls, dilutions and additions of reagents and resulting analytical determinants, complexes and end-products. The PNU ranges of parameters are, creatinine = 0.97-1.39 mg/dl; urea = 34.4-46.4 mg/dl, sugar = 86-116 mg/dl; total protein = 4.48-5.68 gm/dl and calcium = 7.60-9.64 mg/dl, whereas PPU ranges are creatinine = 3.60-5.16 mg/dl; urea = 103-139 mg/dl, sugar = 200-272 mg/dl; total protein = 6.86-8.72 gm/dl and calcium = 12.10-15.70 mg/dl. All steps were performed automatically through modular/Hitachi programs provided with the instruments (Roche, Basel). Data analysis, comparative studies and regression correlation of respective conventional Hitachi 912 and Cobas c501 systems were performed for precision and accuracy and through SPSS (ver 10, USA) for statistical analysis.

3. Results

Comparative precision performance assessment of five parameters, creatinine, urea, glucose, total protein and calcium from Preci-control-normal and Preci-control Pathological, was carried out on two instruments, the conventional chemistry analyzer Hitachi 912 and Cobas 6000 stand-alone c501. Standardized methodology and protocols were used on both systems as per kit inserts or/and manufacturer’s manual and procedural instructions. Both PNU and PPU samples were run (analyzed) thirty times on either of the instruments. The mean analyzed values of PNU parameters on 912 and c501, respectively, were; creatinine = 1.105 & 1.110 mg/dl; urea 41.61 & 41.47 mg/dl; glucose = 94.22 & 94.11 mg/dl; total protein = 4.75 & 4.77 gm/dl and calcium = 8.61 & 8.59 mg/dl. Similarly the mean analyzed values of PPU parameters on 912 and c501, respectively, were; creatinine = 4.011 & 4.018 mg/dl; urea = 114.3 & 114.10 mg/dl; glucose = 223.46 & 223.61 mg/dl; total protein = 7.56 & 7.65 gm/dl and calcium = 14.39 & 14.40 mg/dl. Comparative analysis showed excellent precision correlations among all five parameters on both instruments with R^2 regression ranging from 0.990 to 0.999 for PNU and 0.993 to 0.997 for PPU depicting the precision and reliability of methods, standardization and system equivalency. Correlation results showed regression and y intercept for PNU parameters as creatinine = $y = 0.96x + 0.037$, R^2 0.990 (Fig 1), urea = $y = 1.032x - 1.487$, R^2 0.990 (Fig 2), glucose = $y = 1.059x - 5.567$, R^2 0.992 (Fig 3), total protein = $y = 0.972x + 0.135$, R^2 0.995 (Fig 4) and calcium = $y = 1.001x - 0.015$, R^2 0.999 (Fig 5). Similarly PPU parametric correlation data showed significant regression and y intercept for creatinine = $y = 0.992x + 0.024$, R^2 0.993 (Fig 6), urea = $y = 0.986x + 1.478$, R^2 0.998 (Fig 7), glucose = $y = 0.987x + 2.936$, R^2 0.999 (Fig 8), total protein = $y = 0.981x + 0.15$, R^2 0.998 (Fig 9) and calcium = $y = 1.005x - 0.089$, R^2 0.997 (Fig 10).





4. Discussion

Previous researches regarding precision and analytical performance evaluation, technology comparison and instrument validation shows significant information's [4,6,8,9,12]. Those studies includes work-flow performance of special chemistry

tests such as CEA, PSA, AFP, folate, B12 T4, TSH, FT4 on Architect ci800, analytical evaluation of routine chemistry parameters such as glucose, Creatinine, uric acid, cholesterol, triglyceride, calcium ALT etc on Olympus AU 2700-plus, calibration verification for Olympus and Hitachi analyzers using single chemical analyte (albumin) through currently approaches of CAP and assessment of consolidation of procedure performance for Cobas 6000 compared with Beckman Coulter AU640 using 30 analytes comprising all ranges of metabolic enzymes, trace elements and proteins [6,9-11]. Even inter-laboratory evaluation of equipments were studied in labs of tertiary care hospital, such as Cobas integra 400, evaluation of multiple critical care analyzers with NOVA stats and Dimensions RxL systems, comparison of biochemistry analyzers Olympus AU2700 and AU 640 according to accreditation of status vs ISO 15189 and policy making regarding new approaches to automation through modular system [4,8,15].

Ours is a tertiary care laboratory, processing 800 patients on daily basis 24/7 with panels or individual parameters of 160 types of tests. We are attached to one of the largest tertiary care hospital of the country catering 3000 patients on daily basis. Our analyzers, Hitachi 912 and Cobas c501 are both random access instruments for clinical chemistry analytes, including urea, Creatinine, electrolytes, liver and cardiac function tests, serum proteins, enzymes, with available options of analysis through spectrophotometry, turbidometry, UV/kinetics, chromogen end product and indirect potentiometry in many samples such as plasmas, serum, urine, cerebrospinal, synovial and pleural fluids. It is known that analytical precision evaluation of analyzers or analytes (controls, samples, calibrators) can be done through determination of within run and between-run imprecision, inaccuracy evaluations and comparison of methods, where applicable [11].

Our presented study evaluated analytical precision of five parameters from normal and pathological controls, known as Preci-normal (PNU) and Preci-Path (PPU). The parameters were creatinine, urea, glucose, total protein and calcium, analyzed on both Hitachi 912 and modular cobas c501. Results showed correlated precision and standardized methodology by conventional and modular systems, which is exhibited through regression analysis data of 0.990 to 0.999 in case of PNU parameters and 0.993 to 0.999 in case of PPU. The mean values of all analytes also exhibited comparative near-equivalent results on both equipments.

Our comparative performance evaluation analysis exhibited similar pattern of precision, accuracy and workflow coordination between both 912 and c501 analyzers as reported in earlier studies [1-3, 10-12]. Additionally, all methods, principles and protocols found to be at equivalency and standardized levels to each other as evident by correlation of 93% to 99.0% in precision run of normal and pathological controls. Furthermore, analytical steps and reagent specifications that were available on conventional system 912 were also found compatible on modular system c501 as well. It is a known fact that calibration assessment, precision analysis and verification are one of the significant protocols to evaluate equipments' or methods' comparative performance. A study carried out with albumin as a component, to verify calibration status of two analyzers, Hitachi and Olympus through CAP protocols [9]. The conclusion drawn from that multi-centered study reiterates the confirmation that

64.5% of the participating labs passed the evaluation for both instruments. Previously, within equipment precision was examined in 14 laboratories in Australia, Europe and USA regarding Cobas 8000 modular system with a wide spectrum of routine and immuno chemistry parameters [12]. More recently several studies were reported regarding analytical performance evaluation of chemistry analyzers using quality control materials [1], accuracy of creatinine-analyzing point-of-care devices [7] and Nova StatSensor analyzer [5], that advocated and supported our study and protocols of analytical precision evaluations.

5. Conclusion

In conclusion, the present study described the comparative analytical performance of two instruments, one being the conventional Hitachi chemistry analyzer 912 and other being the modular version Cobas 6000, using six routine chemistry parameters. Regression analysis exhibited near-equivalent data ranging from 84.3% to 99.8%, thus ensuring that standardization and proper calibration of both instruments is upto the mark for routine chemistry analysis of referred parameters.

6. References

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