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CALIBRATION VERIFICATION FOR OLYMPUS AU 480 AND MERIL AUTOQUANT AQ 400i AUTOMATIC BIOCHEMISTRY AUTO ANALYSER USING SEVEN ANALYTES.

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ABSTRACT

Background: Routine diagnostic laboratories are confronted with an ever-increasing workflow with limited resources. Automation has provided some solutions to these challenges, particularly with high throughput analysers such as the Meril AutoQuant AQ 400i. **Objective:** The objective of this study was to perform the analytical evaluation of the clinical chemistry analyser Meril AutoQuant AQ 400i, according to the guidelines of the European Committee of Clinical Laboratory Standards (ECCLS). **Study design:** The evaluation study determines within-run and between-run imprecision, inaccuracy in comparison with Olympus AU 480. The tested analytes were: glucose, albumin, creatinine, calcium, cholesterol, alkaline phosphatase and lactate dehydrogenase. **Results:** The result shows that both imprecision (CV%) and inaccuracy (Bias, B%) were < 5% in all parameters of both normal (Level 1) and pathological (Level 2) controls except for alkaline phosphatise (AlkP), where the CV% is slightly higher than 5% (5.37) in normal control (Level 1). Regression analysis studies reveal that the both Bias, (B%) and CV% are maintaining a mathematical relationship ($R^2 = 1.0$) either in positive or negative directions depending on nature of test parameters. **Conclusion:** The study describes the analytical performance of Meril AutoQuant AQ 400i, using seven routine chemistry parameters. Meril AutoQuant AQ 400i auto analyser shows acceptable precision and accuracy for majority of analytes. This evaluates the auto analyser as able to perform rapid and precise tests suitable for a fully automateanalytical procedure. Regression analysis also exhibits near equivalent data ranging from 0.9 to 1.1.

KEYWORDS: Chemistry analyser, Analytical performance, Precision analysis, Regression analysis, Analytical evaluation.

INTRODUCTION

In last four decades, automated chemistry analysers took over methods, calibration and precision testing of controls (both normal and pathological), before introduction of the equipment in to the medium or large scale medical testing laboratories and tertiary care hospitals, where faster turn-around-time (TAT) is a necessary to cater to higher patients' volume and wide variety of medical or surgical specialities in lowest possible cost.[1] Be automated systems already available within the laboratory, addition or replacement with other version or as a backup, or adding of new precision, all requires multi-channels, variability, testing chemistry menu, international analytical methodological standards; in addition to reproducibility, accuracy and precision must also be assessed before placing it into routine use.[1]

In this study, we aimed to assess the analytical performance of seven analytes (parameters) determined on AutoQuant AQ 400i auto analyser (Meril Diagnostics, India). For these analytes, a comparison with the Olympus AU 480 auto analyser (Beckman Coulter, Tokyo, Japan) was also done. This evaluation was performed according to the guidelines of European Committee for Clinical Laboratory Standards (ECCLS).

MATERIALS AND METHODS

Samples from both normal and pathological controls (BioRad, USA) were used in present study during August 2017 to September 2017. Also, calibration was done by the commercial calibrators (Cfas, Roche Diagnostics). Comparative performance assessment of instrument was done through analysis of seven analytes. Both normal and pathological controls were run (analysed) 30 times each on Olympus AU 480 and AutoQuant AQ 400i auto analysers. Manufacturers' instructions were used for standardization , calibration, controls, dilutions and addition of reagents and resulting

analytical determinants, complexes and end products. Methods and reagents used for this validation are presented in Table 1.

Table 1: Methods and reagent used in the evaluation of AutoQuant AQ 400i auto analyser.

Analyte	Unit	Method	Linearity (Low)	Linearity (High)	Manufacturer
Glucose	mg/dl	Glucose Oxidase Peroxidase	05	500	Meril Diagnostics
Albumin	gm/dl	Bromo Cresol Green (BCG) Dye binding	0.1	6.0	Meril Diagnostics
Creatinine	mg/dl	Jaffe Kinetic	0.2	30	Meril Diagnostics
Calcium	mg/dl	Arsenazo III Chromogene	0.2	15	Meril Diagnostics
Cholesterol	mg/dl	CHOD-PAP	05	750	Meril Diagnostics
Alkaline Phosphatase (AlkP)	U/L	IFCC, pNPP with AMP buffer, 37°C	100	1200	Meril Diagnostics
Lactate dehydrogenase (LDH)	U/L	IFCC, Pyruvate to Lactate, 37°C	05	2000	Meril Diagnostics

CHOD – Cholesterol Oxidase, pNPP – para nitrophenyl phosphate, AMP – 2 amino 2- methyl-1- propanol.

Analytical evaluation of analyser included the determination of within-run and between-run impression, inaccuracy and methods comparison. Within-run and between-run impression were used to determine the extent of random error and accuracy was used to direct the extent of systematic error affecting the measurement.[2]

Between-run imprecision was determined measuring the concentration of analytes in the control sera of different concentration ranges (BioRad Level 1, Lot No. 26411 and Level 2, Lot No. 26412; Expiry date: January 31, 2019) in triplicate during the period of 30 days. Impression was expressed in mean and the coefficient of variation (CV%). Within-run impression was determined in triplicate on 30 consecutive measurement of different analyte concentrations in control sera (both level 1 and level 2) and also expressed as a coefficient of variation (CV%).

Inaccuracy of measurement of control samples was shown as bias (B%), percentage of deviation of the analytes mean value from the control sera declared mean value. To calculate the bias, measured values from day-to-day impression were used.

Obtained values for precision and bias were assessed by comparing within the specifications derived from biological variation.[3]

Data analysis, calculation of mean, coefficient of variation (CV%) and bias (B%), comparative studies were performed for precision and accuracy and through SPSS (Ver.12, USA) for statistical analysis. The level of significance was set at $p<0.01$.

RESULTS

The desirable specifications for impression and bias, derived from biological variation are expressed in Table 2.

Table 2: Desirable specifications for imprecision and bias derived from intra- and inter-individual biological variation for the tested analytes, day-to-day, within-run imprecision and inaccuracy.

Analyte	Declared Level 1	Declared Level 2	Unit	Level 1 CV%	Level 1 Mean	Level 1 Bias (B%)	Level 2 CV%	Level 2 Mean	Level 2 Bias (B%)	Desirable I (%)
Glucose	90	275	mg/dl	2.5	92	2.22	2.7	280	1.8	2.8
Albumin	3.8	2.49	gm/dl	2.2	3.89	2.36	1.7	2.52	1.2	2.1
Creatinine	2.26	5.36	mg/dl	2.8	2.32	2.65	2.9	5.45	1.67	2.9
Calcium	9.4	12.0	mg/dl	1.82	9.5	1.06	1.13	12.3	2.66	1.1
Cholesterol	246	101	mg/dl	2.54	255	3.65	1.36	102	1.58	2.8
Alkaline Phosphatase (AlkP)	103	390	U/L	5.37	108	4.85	3.84	406	4.1	3.9
Lactate dehydrogenase (LDH)	171	362	U/L	4.83	178	4.09	3.65	378	4.41	4.8

The seven parameters like glucose, albumin, creatinine, calcium, cholesterol, alkaline phosphatise (AlkP) and lactate dehydrogenase (LDH) were selected for evaluation of both imprecision and inaccuracy studies of the 400 throughput auto analyzer based on two different properties of measurement principles like "End Point" and "Kinetic" reactions.

The result shows that both imprecision (CV%) and inaccuracy (Bias, B%) were < 5% in all seven parameters of both normal (Level 1) and pathological (Level 2) controls excepting in case of AlkP parameters the CV% were slightly higher than 5% (5.37) in normal control (Level 1) represented in Table 2.

Imprecision studies of both controls furthermore evaluated and all test results reveals that the CV% of individual test parameters maintain the guidelines very precisely as per desired criteria limits in comparison with both biological variations and inter variations protocols.

Inaccuracy studies (Bias, B%) of pathological controls (Level 2) reveals that individual Bias, B% of glucose, albumin, creatinine, cholesterol were very precise in target value (< 2 %) in comparing to desirable limits represented in summary Table 2. The Bias (B%) of lactate dehydrogenase (LDH) was higher (> 4%) but maintain guideline as per desirable limits (4.8%).

Regression analysis studies reveals that the both Bias, (B%) and CV% maintaining a mathematical relationships (R^2 = 1.0) either in positive or negative directions depending on nature of test parameters represented in the figure1 to figure 7, respectively.

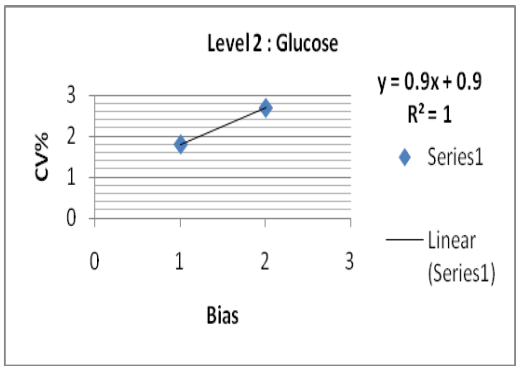


Figure 1.

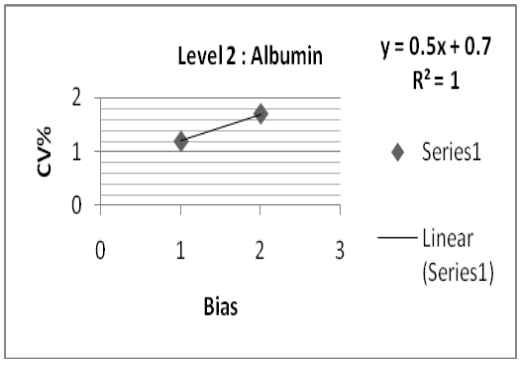


Figure 2.

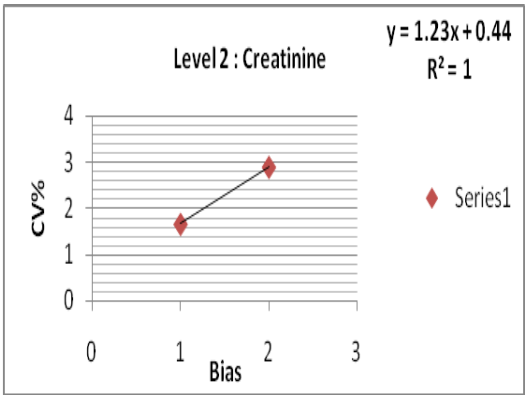


Figure 3.

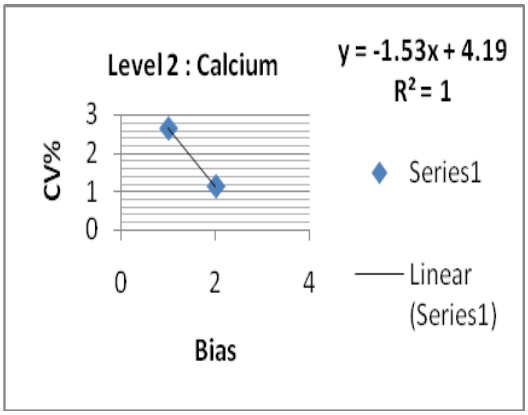
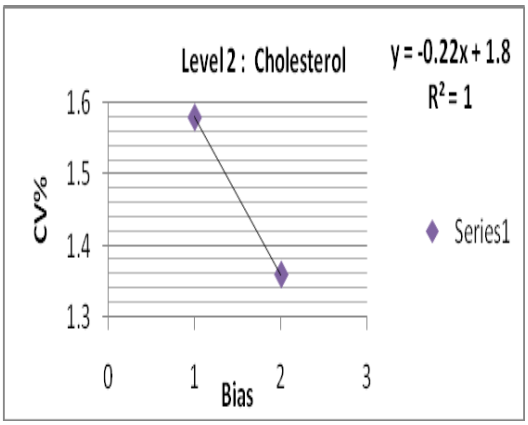


Figure 4.



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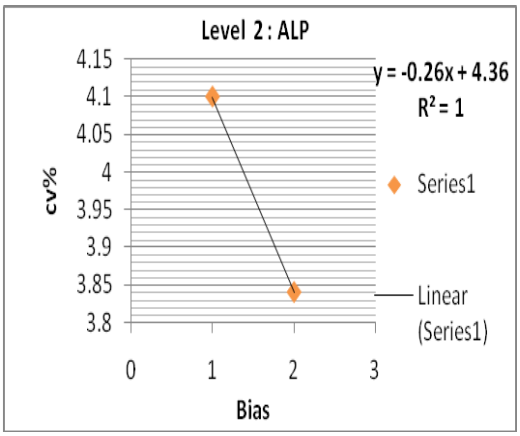

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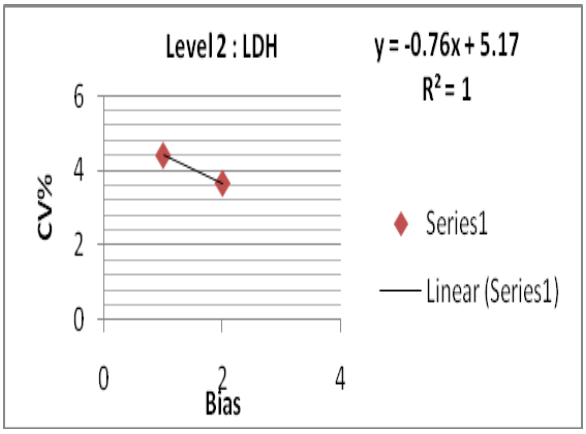

Figure 7.

Linearity studies of glucose (figure 8 and figure 9) and creatinine (figure 10 and figure 11) were undertaken in both Meril AutoQuant AQ 400i and Olympus AU480 auto analyzers and result shows that the pattern of responses i.e., slope were similar (R^2 = 0.999) in both the instruments excepting minor differences of intercepts were noted 0.998 x in Meril AutoQuant AQ 400i and 1.0 x in Olympus AU480.

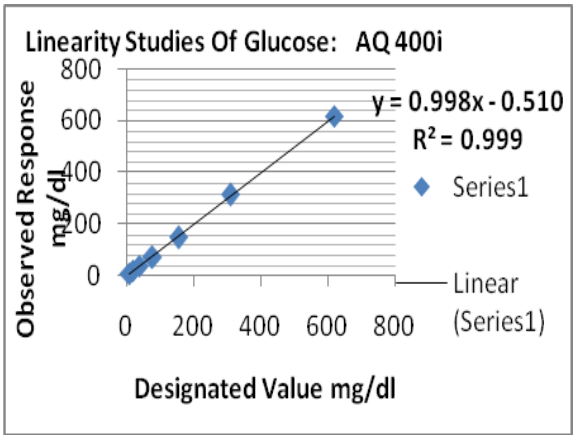

Figure 8.

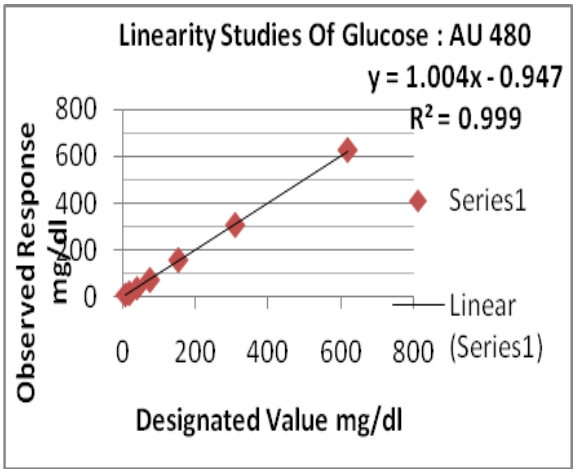

Figure 9.

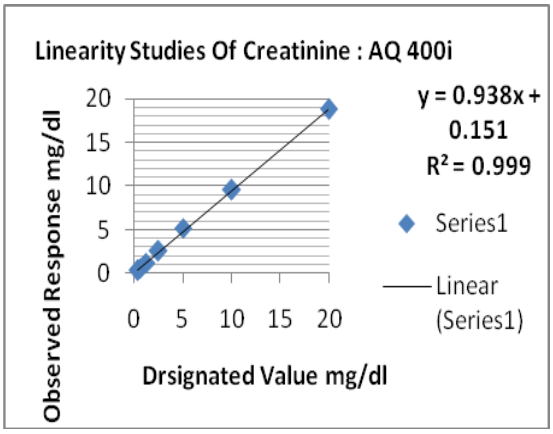

Figure 10.

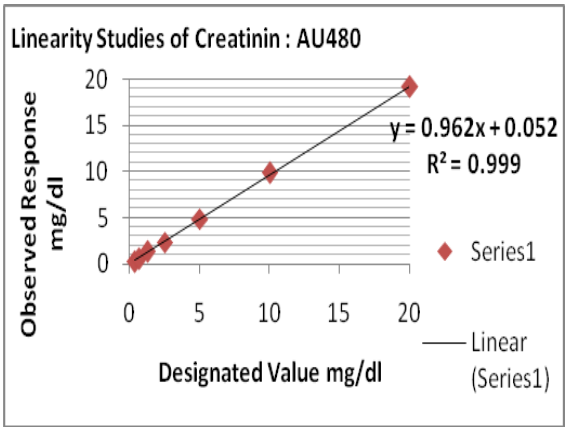

Figure 11.

Harmonization studies reveals that the data points of both glucose and creatinine are very close to each other along the regression lines with a maximum deviations of 6 in case of glucose and 0.4 in case of creatinine respectively as the average values increases. Regression line trends are towards a negative directions in both case depicted in figure 12 and figure 13.

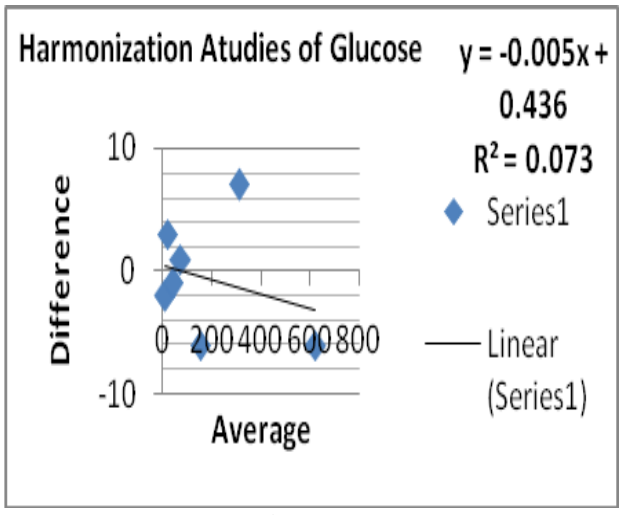

Figure 12.

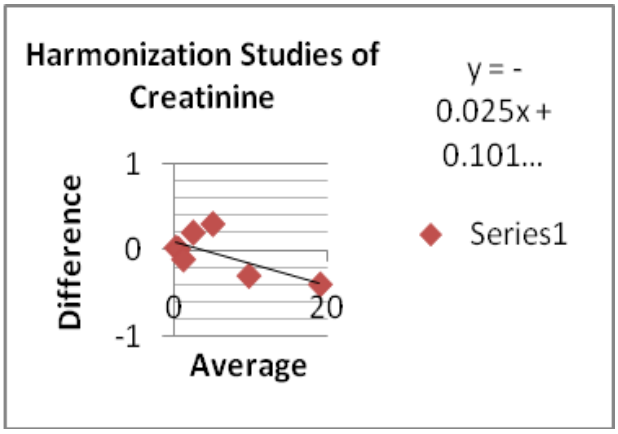

Figure 13.

DISCUSSION

Previous studies regarding precision and analytical performance evaluation, technology comparison and instrument validation shows significant information's[1]. The results of analytical validation showed acceptable coefficients of variation for day-to-day impression, within-run impression as well as a satisfactory degree of accuracy. For setting the criteria for acceptable imprecision and inaccuracy, we considered the biological variations of analytes[3]. Depending on the measurement procedure, measuring instruments and compliance with a reference or definitive method, we can assess whether the new method or analyser is suitable for routine use and whether they are of satisfactory accuracy.[2]

Ours is a tertiary care laboratory, which is attached to one of the tertiary care hospitals, processing about 600 patients' samples on daily basis & days a week, with panels or individual parameters of 36 types of tests in routine clinical biochemistry. Our analysers Olympus AU 480 and Meril AutoQuant AQ 400i are both random access instruments for clinical biochemistry analytes, including glucose, enzymes, liver, renal, cardiac, pancreatic function tests with available option of analysis through spectrophotometery, turbidometry, UV kinetics and chromogen end products in many samples such as serum, plasma, urine, cerebrospinal, pleural and synovial fluids. As per standard protocol, the analytical precision evaluation of analysers or analytes (controls, samples, calibrators) can be done through determination of within-run and between-run impression, inaccuracy evaluations and comparison of methods, where applicable.[4] The comparison of clinical biochemistry analysers Olympus AU 480 and Meril AutoQuant AQ 400i according of status vs ISO 15189:2012 and policy making regarding new approaches to automation through system.[5]

The reason for not fulfilling the desirable criteria for alkaline phosphatise (AlkP) and lactate dehydrogenase (LDH) is the high biological variation, as well as the lack of analytical method capable to follow that variation with the results that are precise and accurate enough. However, laboratories must be aware of the limitation and ensure smaller measurement of uncertainty using quality control tools (participation in proficiency testing / external quality assessment programme of pre analytical / pre examination and post analytical / post examination phase).[6]

Correlation analysis yielded high correlation coefficients proving correlation for all the tested parameters.

CONCLUSION

In conclusion, the present study described the comparative analytical performance of two instruments, on being the conventional Olympus AU 480 and other being the Meril AutoQuant AQ 400i, using seven routine chemistry parameters. Meril AutoQuant AQ 400i auto analyser shows acceptable precision and accuracy for majority of analytes. In this study, evaluated Meril AutoQuant AQ 400i auto analyser are rapid and precise tests suitable for a fully automated analytical procedure. Method comparisons with established assays showed excellent agreement. Regression analysis exhibit near equivalent data ensuring that standardisation and proper calibration of both instruments is up to the mark for routine chemistry analysis of referred parameters. The Meril AutoQuant AQ 400i is a useful tool for the concurrent analysis of different serum / plasma tests with the potential to provide significant improvement in laboratory performance through workstation consolidation.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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