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Original Article

Biochemistry Section

Comparison of Analytical Performance of Dry Chemistry Analysers Vitros 5600 and Vitros 250: A Cross-sectional Study

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ABSTRACT

Introduction: Maintaining the reliability of clinical laboratory results is essential for accurate diagnosis and monitoring treatment outcomes. Due to poor awareness regarding the statistical evaluation of Internal Quality Control (IQC) results from two analysers, most laboratories in tertiary care centres do not conduct comparative studies, which may lead to erroneous results.

Aim: To compare the performance of two analysers Vitros 5600 and Vitros 250 (which utilise the same techniques and methods of estimation), within the same clinical chemistry laboratory, rather than relying solely on daily monitoring of each analyser. Additionally, it emphasises the importance of periodic statistical analysis of Bio-Rad Independent Quality Control (IQC) samples.

Materials and Methods: An analytical cross-sectional study was conducted at the Division of Biochemistry, Malabar Cancer Centre, Kannur, Kerala, India from July 2022 to October 2022. Two levels of IQC samples were run daily on the Vitros 5600 (reference equipment) and Vitros 250 (test equipment), both of which are integrated dry chemistry fully automated analyser using the same batch of reagents. After each run, the acceptability of the control values was verified against the laboratory control limits according to Westgard multiple rules. If results from an analyser fell outside the acceptable range, the analyser was calibrated and the IQC procedure was performed again. Acceptable values were recorded for comparison.

Results: The superiority of the reference analyser in terms of analytical performance was evidenced by consistently lower Coefficient of Variation (CV%) values across multiple analytes. However, a negative correlation was observed for phosphorus at level two in Analyser 2, indicating potential systematic bias in measurements for this specific analyte. Phosphorus at Level 1 showed a correlation coefficient of 0.576 (p-value=0.008), while phosphorus at Level 2 had a correlation coefficient of -0.758 (p-value <0.0001). Bland-Altman analysis indicated minimal mean differences between the analysers.

Conclusion: The Vitros 5600 (reference equipment) performed well, with minimal deviations in results, underscoring its potential for accurate clinical testing. The present study highlights the importance of periodic statistical analysis to compare the performance of two analysers in a clinical chemistry laboratory, rather than relying solely on daily quality checks.

Keywords: Accuracy, Analytical chemistry technique, Clinical laboratory services, Precision, Quality control

INTRODUCTION

In medical diagnosis, biochemistry laboratories handle various sample types using different instruments and these tools perform specific tests with accuracy. A robust quality system is crucial for cost-effectiveness and safety [1]. For medical laboratories, the International Organisation for Standardisation (ISO) 15189 standard plays a pivotal role, serving as an essential framework for establishing requirements related to proficiency and excellence in the field of biochemistry [2].

Across all laboratory establishments, the meticulous implementation of both IQC and active participation in External Quality Assurance Schemes (EQAS) remains of paramount importance [3]. Particularly for laboratories that adhere to international accreditation standards, the use of two or more distinct analysers or procedural approaches for diagnostic assessments necessitates the formulation of a structured framework for the comparative evaluation of resultant outcomes [4]. This strategic pursuit aims to harmonise and standardise the diverse analytical pathways, leading to cohesive and reliable diagnostic conclusions in accordance with the high standards established by international guidelines [4].

Ensuring optimal laboratory performance involves intricate processes, numerous procedural steps and the involvement of multiple personnel. Clinical biochemistry, a vital aspect of laboratory medicine and clinical practice, entails analysing compounds in body fluids, particularly blood, to facilitate disease diagnosis, prevention and treatment [5].

Analytical precision and accuracy are pivotal indicators of quality performance [6]. Precision is quantified through the iterative replication of test executions, serving as a metric for the analytical method's capacity to yield consistent results. In parallel, accuracy assumes significance as it gauges the proximity of the measured value to the true value, thereby elucidating the veracity of the measurement [7]. Every biochemical method must meet acceptable standards of precision and accuracy for its test parameters [8,9]. Controlling factors such as preanalytical and analytical errors is vital for accurate results [10].

Laboratories with high testing volumes typically employ fully automatic multiple analysers to optimise time and deliver results promptly [11]. However, the test results obtained from the automatic analysers should be monitored and compared with results from other analysers to ensure the delivery of quality results. Two or more instruments with the same capacity, potency, brand, model and manufacturer do not necessarily exhibit similar performance [12]. Therefore, documentary evidence, supported by appropriate statistical analyses, is essential to demonstrate equivalence among all tested instruments based on the obtained results [13].

It is important to harmonise equipment to ensure that various instruments can produce similar laboratory results, establishing a standard for laboratory excellence atleast twice a year. Due to poor awareness of the statistical evaluation of IQC results from two analysers, most laboratories in tertiary care centres are not

conducting comparative studies and thus the results are not free from errors. The present study aimed to assess the quality performance of two fully automatic analysers by analysing biochemical parameter test results using internal quality materials for comparison and to emphasise the importance of periodic statistical analysis of Bio-Rad IQC samples.

MATERIALS AND METHODS

An analytical cross-sectional study was conducted at the Division of Biochemistry, Malabar Cancer Centre, Kannur, Kerala, India from July 2022 to October 2022. The study was approved by the Institutional Research Board. Since no patient samples were involved, IEC approval was not required. The study was carried out in accordance with the procedures established by the Institutional Research Committee.

Study Procedure

The Bio-Rad IQC samples, specifically two levels known as Lyphochek® Assayed Chemistry Control Levels 1 and 2 (ACC1 and ACC2), were used as the control samples. Both levels of QC were run daily on the Vitros 5600 integrated Dry Chemistry fully automated analyser (which served as the reference equipment) and the Vitros 250 Dry Chemistry fully automated analyser using the same batch of reagents. Testing was conducted for a total of 16 different parameters during the study period. The parameters analysed included albumin, total protein, Serum Glutamate-Oxaloacetate Transaminase (SGOT) or Aspartate Aminotransferase (AST), Serum Glutamate Pyruvate Transaminase (SGPT) or Alanine Aminotransferase (ALT), Alkaline Phosphatase (ALP), total bilirubin, glucose, urea, creatinine, uric acid, sodium, potassium, phosphorus and magnesium, as per the manufacturer's protocol.

Albumin was detected using the Bromcresol green method [14]. Total protein detection was based on the Biuret reaction [14]. The SGOT assay involved a reaction in which the amino group of L-aspartate is transferred to α-ketoglutarate in the presence of Pyridoxal-5-phosphate (P-5-P), producing glutamate and oxaloacetate. The oxaloacetate formed during the deamination of L-aspartate is converted to pyruvate and carbon dioxide by oxaloacetate decarboxylase. Pyruvate is then oxidised to acetyl phosphate and hydrogen peroxide by pyruvate oxidase. The final step of the reaction involves the peroxidase-catalysed oxidation of a leuco dye to produce a coloured dye. The rate of oxidation of the leuco dye is monitored by reflectance spectrophotometry [14].

In the sample, ALP catalyses the hydrolysis of p-nitrophenyl phosphate to p-nitrophenol at alkaline pH [15]. Total bilirubin analysis is based on a modification of the classic diazo reaction and indirect bilirubin levels are detected following the kit protocol provided by the manufacturer. Glucose concentration is measured using the glucose peroxidase method, urea by the urease method and creatinine by the creatininase method [15]. Sodium, potassium, uric acid, magnesium, phosphorus and LDH levels were detected according to the manufacturer's kit protocol [Table/Fig-1] [14,15].

S. No.	Parameters	Method of estimation	Cut-off range	Reference no.
1	Glucose	Colorimetric- glucose oxidase peroxidase	80-120	[15]
2	Urea	Endpoint/colorimetric-urease	15-35	[14]
3	Creatinine	Two pint rate-Creatinine Aminohydrolase	0.7-1.2	[15]
4	Uric acid	Colorimetric-uricase peroxidase	2.5-6.2	[14]
5	Total bilirubin	Colorimetric-dual wavelength-Reflectance spectrophotometry	0.2-1.3	[15]
6	AST	Multipoint rate with p-5-p (pyridoxal 5 phosphate)	14-36	[14]
7	ALT	Multipoint rate/UV with p-5-p (pyridoxal 5 phosphate)	<35	[14]
8	ALP	Multipoint rate- p-nitrophenyl phosphate AMP buffer	38-126	[15]
9	Total protein	Colorimetric biuret method	6.3-8.2	[14]
10	Albumin	Colorimetric-bromo-cresol green	3.5-5	[14]
11	Calcium	Colorimetric- Arsenazo	8.4-10.2	[14]
12	Phosphorus	Colorimetric- Phosphomolybdate formation	2.5-4.5	[14]
13	Magnesium	Colorimetric- Forzman dye	1.6-2.3	[14]
14	Sodium	Direct ISE-potentiometric	137-145	[14]
15	Potassium	Direct ISE-potentiometric	3.5-5.1	[14]

[Table/Fig-1]: Parameters, method of estimation and cut-off range [14,15].

The IQC samples for both levels were treated alongside the patient samples in both reference and test equipment. After each run, the acceptability of the control values was verified against the laboratory control limits as per Westgard's multiple rules. If the results from an analyser were outside the acceptable range, the analyser was calibrated and the IQC procedure was performed again. Acceptable values were then entered into the sheet for comparison [16].

STATISTICAL ANALYSIS

Data were entered into Microsoft Excel 2013 and analysed using the Statistical Package for the Social Sciences (SPSS) software program, version 20.0. The data were expressed as n (%), Mean±SD, 95% CI, etc. The data were subjected to Bland-Altman plots and Spearman's correlation analysis was performed. The average measured bias percentage was calculated to determine the acceptability of the analysers. Bland-Altman plot analysis was conducted to assess the measures of agreement between two different methods of estimating biochemical parameters. Before performing the Bland-Altman analysis, the authors tested the mean difference between the two measurements. If the mean difference was statistically significant, there was no need to measure the level of agreement.

RESULTS

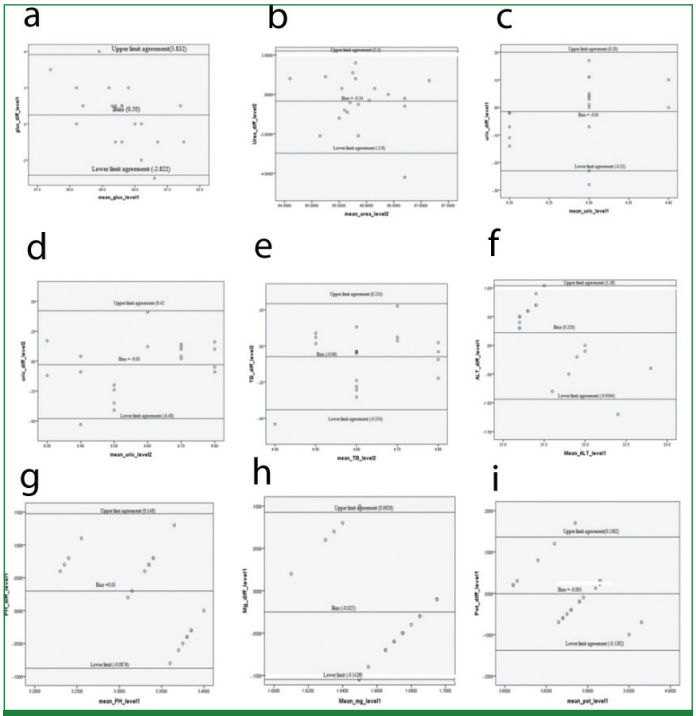
A comparison of biochemical parameters between the reference analyser (Analyser 1) and the test analyser (Analyser 2) revealed variations in the Coefficient of Variation (CV%) across several analytes. Analyser 1 consistently exhibited lower CV% values, indicating greater consistency compared to Analyser 2 for many parameters. Specifically, for glucose at both levels, Analyser 1 showed CV% values of 1.06 and 1.86, respectively, which were better than those of Analyser 2. Similar trends were also observed for urea (0.97 for Analyser 1 and 1.1 for Analyser 2), creatinine, ALP and total bilirubin at Level 2. At Level 1, BuBc, AST and ALT all showed lower CV% values in Analyser 1 compared to Analyser 2. Additionally, Analyser 1 consistently produced lower CV% values for total protein, albumin, calcium and phosphorus at Level 1. Furthermore, magnesium, sodium and potassium also supported the notion that Analyser 1 demonstrated greater consistency compared to Analyser 2 [Table/Fig-2,3].

Correlation analysis between the analysers for glucose at Level 2 exhibited a correlation coefficient (r) of 0.66 (p=0.002) and a regression equation of Y=158.8+0.417 X (where Y represents measurements in Analyser 1 and X represents measurements in Analyser 2). BuBc at Level 1 showed a correlation coefficient of 0.534 (p=0.015) with a regression equation of Y=0.532+0.245 X. ALT at Level 1 had a correlation coefficient of 0.523 (p=0.018) with a regression equation of Y=16.5+0.242 X. ALP at Level 2 exhibited a correlation coefficient of 0.5 (p=0.05) with a regression equation of Y=129.02+0.461 X. Phosphorus at Level 1 showed a correlation coefficient of 0.576 (p=0.008) with a regression equation of Y=2.268+0.325 X, while phosphorus at Level 2 had a correlation coefficient of -0.758 (p<0.0001) with a regression equation of Y=12.5-0.795 X. In summary, a significant positive correlation

Variables			Mean	SD	CV%	Skewness	Kurtosis	Correlation coefficient	p-value
Glucose	Level-1	Analyser 1	89.8	0.95	1.06	0.44	0.25	0.24	0.308
		Analyser 2	89.3	1.66	1.86	-0.15	-0.52		
	Level-2	Analyser 1	267.2	3.9	1.46	-1.04	0.46	0.66	0.002*
		Analyser 2	259.9	6.3	2.42	-0.76	-0.76		
Urea	Level-1	Analyser 1	34.1	0.57	1.7	-1.28	1.34	0.045	0.85
		Analyser 2	34.6	0.39	1.1	-0.11	-1.47		
	Level-2	Analyser 1	85.7	0.83	0.97	0.03	-0.20	-0.104	0.663
		Analyser 2	86.07	0.97	1.1	0.73	2.36		
Creatinine	Level-1	Analyser 1	1.7	0.03	1.8	-0.01	0.45	0.112	0.638
		Analyser 2	1.8	0.05	2.8	0.44	1.30		
	Level-2	Analyser 1	5.04	0.05	0.99	-0.02	-0.93	0.297	0.204
		Analyser 2	5.21	0.08	1.5	-0.09	-1.15		
Uric acid	Level-1	Analyser 1	4.3	0.09	2.09	-0.12	-1.54	0.073	0.76
		Analyser 2	4.3	0.07	1.63	0.29	-0.73		
	Level-2	Analyser 1	8.6	0.22	2.6	-0.26	-1.61	0.327	0.159
		Analyser 2	8.6	0.16	1.9	-0.87	0.27		
Total bilirubin	Level-1	Analyser 1	1.04	0.05	4.8	-0.40	-1.38	0.265	0.258
		Analyser 2	0.98	0.07	7.1	0.18	-0.55		
	Level-2	Analyser 1	4.6	0.06	3.5	-0.72	1.36	0.396	0.084
		Analyser 2	4.7	0.11	2.3	0.33	-0.47		
Indirect bilirubin	Level-1	Analyser 1	0.68	0.02	2.9	-0.83	-0.27	0.534	0.015*
		Analyser 2	0.59	0.04	6.8	-2.12	2.78		
	Level-2	Analyser 1	3.6	0.24	6.7	0.64	-1.36	0.327	0.159
		Analyser 2	3.4	0.1	2.9	-0.11	0.05		
AST	Level-1	Analyser 1	44.6	0.71	1.6	-0.56	-0.83	0.319	0.171
		Analyser 2	43.9	0.83	1.9	-0.53	0.16		
	Level-2	Analyser 1	197.1	3.7	1.9	0.30	0.02	0.321	0.168
		Analyser 2	192.2	5.7	2.9	0.33	-0.67		
ALT	Level-1	Analyser 1	21.7	0.32	1.5	1.19	2.62	0.523	0.018*
		Analyser 2	21.5	0.69	3.2	1.28	0.54		
	Level-2	Analyser 1	74.5	1	1.3	0	0.69	-0.272	0.246
		Analyser 2	72.8	1.4	1.9	0.60	-0.42		
ALKP	Level-1	Analyser 1	52.1	1.1	2.1	0.68	-0.08	-0.215	0.364
		Analyser 2	57.2	1.1	1.9	0.16	-0.63		
	Level-2	Analyser 1	254.2	4.2	1.65	-0.13	-0.67	0.5	0.025*
		Analyser 2	271.9	4.6	1.69	0.16	-0.62		
Total protein	Level-1	Analyser 1	4.9	0.17	3.5	1.27	3.80	0	0.999
		Analyser 2	5.4	0.2	3.7	-0.12	-1.78		
	Level-2	Analyser 1	3.5	0.14	4	1.88	2.46	0.372	0.106
		Analyser 2	3.8	0.21	5.5	-0.17	-1.75		
Albumin	Level-1	Analyser 1	4.7	0.07	1.5	0.64	0.38	-0.031	0.897
		Analyser 2	4.5	0.11	2.4	-1.90	4.10		
	Level-2	Analyser 1	2.7	0.04	1.48	0.12	-0.05	-0.276	0.238
		Analyser 2	2.7	0.07	2.59	-0.54	0.82		
Calcium	Level-1	Analyser 1	8.4	0.14	1.7	0.31	-0.89	0.056	0.815
		Analyser 2	8.2	0.25	3.04	0.91	-0.65		
	Level-2	Analyser 1	11.6	0.15	1.3	0.29	-1.62	0.081	0.735
		Analyser 2	11.4	0.22	1.9	0.84	-0.51		
Phosphorus	Level-1	Analyser 1	3.35	0.04	1.19	-0.44	0.02	0.576	0.008*
		Analyser 2	3.32	0.08	2.41	-0.37	-1.13		
	Level-2	Analyser 1	6.9	0.15	2.2	1.20	0.42	-0.758	0.0001*
		Analyser 2	7.06	0.14	1.9	-1.27	1.21		
Magnesium	Level-1	Analyser 1	1.7	0.03	1.8	-0.18	-0.76	-0.312	0.181
		Analyser 2	1.7	0.04	2.4	-1.25	-0.50		
	Level-2	Analyser 1	4.81	0.05	1.04	0.30	0.94	0.278	0.236
		Analyser 2	4.5	0.07	1.6	0.15	-0.88		

Sodium	Level-1	Analyser 1	140.3	1.15	0.82	0.41	0.13	0.399	0.081
		Analyser 2	143.2	2.3	1.61	0.40	0.01		
	Level-2	Analyser 1	124	0.97	0.8	-0.61	-0.03	0.334	0.151
		Analyser 2	125.1	1.6	1.3	-0.28	0.22		
Potassium	Level-1	Analyser 1	3.9	0.04	1.03	0.35	-0.86	0.207	0.381
		Analyser 2	3.9	0.06	1.5	0.12	-0.21		
	Level-2	Analyser 1	5.9	0.07	1.19	-0.08	1.42	0.185	0.436
		Analyser 2	6.02	0.07	1.16	-0.29	-0.73		

[Table/Fig-2]: Descriptive statistics, skewness, kurtosis and Spearman's correlation between two measurement methods.



[Table/Fig-3]: Correlation between analyser 1 (Reference) and analyser 2 (test). Descriptive statistics, skewness, kurtosis and correlation between two measurement methods. Agreement between analyser 1 (Reference) and analyser 2 (Test).
a) IQC material glucose test, Level-1: p-value: 0.204, not statistically significant, there is no difference in the performance of analyser 1 and 2; b) IQC material urea test, Level-2: p-value: 0.273, not statistically significant, there is no difference in the performance of analyser 1 and 2; c) IQC material uric acid test, Level-1: p-value: 0.557, not statistically significant, there is no difference in the performance of analyser 1 and 2; d) IQC material uric acid test, Level-2: p-value: 0.523, not statistically significant, there is no difference in the performance of analyser 1 and 2; e) IQC material total bilirubin test, Level-2: p-value: 0.086, not statistically significant, there is no difference in the performance of analyser 1 and 2; f) IQC material ALT test, Level-1: p-value: 0.110, not statistically significant, there is no difference in the performance of analyser 1 and 2; g) IQC material phosphorus test, Level-1: p-value: 0.074, not statistically significant, there is no difference in the performance of analyser 1 and 2; h) IQC material magnesium test, Level-1: p-value: 0.086, not statistically significant, there is no difference in the performance of analyser 1 and 2; i) IQC material potassium test, Level-1: p-value: 0.948, not statistically significant, there is no difference in the performance of analyser 1 and 2.

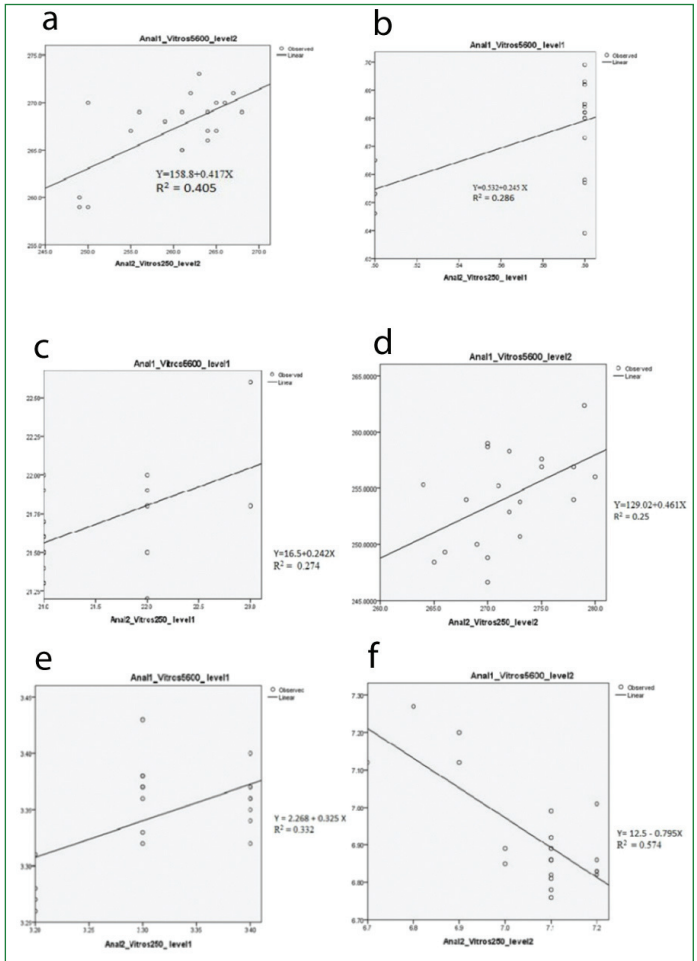
was found between the measurements obtained from Analyser 1 (Reference) and Analyser 2 (Test) using two levels of IQC materials for many parameters [Table/Fig-2,3].

Bland-Altman analysis of agreement was used to compare the performance of Analyser 1 and Analyser 2. It was found that the mean difference was minimal for potassium at Level 1 (mean difference of 0.001), with Limits of Agreement (LOA) between -0.138 and 0.136. Glucose exhibited the highest mean difference in Level 1 IQC samples [Table/Fig-4,5].

The mean difference is statistically significant for the variables Glucose Level-2 measurements, urea Level-1, Creatine level1 and Level-2, Total Bilirubin Level-1, BuBc Level-1 and Level-2, AST level1 and Level-2, ALT Level-2, ALKP Level-1 and amp; Level-2, Total protein level 1 and amp; Level-2, Albumin Level-1 and amp; Level-2, Calcium Level-1 and Level-2, Phosphorus Level-2, Magnesium Level-2, Sodium Level-1 and Level-2 and Potassium Level-2 measurements. Thus these variables were not considered for Bland-Altman Analysis.

Parameters	Difference	Mean	Limits of agreement	
			Lower limit	Upper limit
Glucose	Analyser 1_level1 -Analyser 2 Level-1	0.5	-2.822	3.832
Urea	Analyser 1_level2 -Analyser 2 Level-2	-0.34	-2.9	2.3
Uric acid	Analyser 1_level1 -Analyser 2 Level-1	-0.01	-0.23	0.2
	Analyser 1_level2 -Analyser 2 Level-2	-0.03	-0.48	0.42
Total bilirubin	Analyser 1_level2 -Analyser 2 Level-2	-0.06	-0.35	0.23
ALT	Analyser 1_level1 -Analyser 2 Level-1	0.22	-0.93	1.38
Phosphorus	Analyser 1_level1 -Analyser 2 Level-1	0.026	-0.09	0.148
Magnesium	Analyser 1_level1 -Analyser 2 Level-1	-0.025	-0.14	0.09
Potassium	Analyser 1_level1 -Analyser 2 Level-1	-0.001	-0.138	0.136

[Table/Fig-4]: Bland-Altman analysis of level of agreement.



[Table/Fig-5]: Correlation between reference and test analyser. Bland-Altman analysis of level of agreement. Correlation between analyser 1 (Reference) and analyser 2 (Test). a) Correlation between analyser 1 (Reference) and analyser 2 (Test): IQC Level-1 for glucose; b) Correlation between analyser 1 (Reference) and analyser 2 (Test): IQC Level-1 for BuBc (conjugated and unconjugated bilirubin); c) Correlation between analyser 1 (Reference) and analyser 2 (Test): IQC Level-1 for ALT; d) Correlation between analyser 1 (Reference) and analyser 2 (Test): IQC Level-2 for ALP; e) Correlation between analyser 1 (Reference) and analyser 2 (Test): IQC Level-1 for phosphorus; f) Correlation between analyser 1 (Reference) and analyser 2 (Test): IQC Level-2 for phosphorus.

The positive correlation coefficients observed for several parameters, including glucose, BuBc, ALT and phosphorus, suggest a strong linear relationship between the results of the two analysers. This implies that when Analyser 1 produced higher values, Analyser 2 consistently yielded higher measurements and vice versa, supporting the notion of concordance between the two instruments. However, it is worth noting that Analyser 2 exhibited a negative correlation for phosphorus at Level 2, indicating a systematic bias or deviation in measurements.

DISCUSSION

The comparison between two automated analysers, referred to as Analyser 1 (the reference analyser) and Analyser 2 (the test analyser), using biochemical parameters of IQC materials revealed variations in means across several analytes. Analyser 1, which is participating in the EQAS program, consistently exhibited lower CV% values than Analyser 2. This suggests that Analyser 1 demonstrated greater consistency in its measurements.

In recent years, the commercialisation and adoption of automated laboratory instruments have witnessed a significant transformation in the landscape of clinical diagnostics. The integration of automated systems, characterised by their standardisation and precision, into laboratory workflows has gained paramount importance [17]. This integration, coupled with stringent quality control protocols and the expertise of highly trained personnel, has led to significant advancements. This evolution has greatly facilitated physicians in making prompt and accurate diagnostic decisions [18]. A recent study has documented the substantial impact of automation combined with artificial intelligence in clinical laboratories on improving diagnostic accuracy, streamlining workflows and enhancing overall patient care [19].

The CV% is a crucial metric in clinical laboratory analyses, representing the precision and reliability of measurement methods [20]. Low CV% values signify enhanced accuracy and precision [21]. Such values imply minimal variability between measurements, which is essential for clinical decision-making. In healthcare, low CV% values are vital for accurate diagnosis, treatment monitoring and establishing reliable reference intervals [22]. These values form the cornerstone of dependable laboratory results, fostering confidence in clinical practice and improving patient care [23]. However, individual performance was also good in terms of the CV% for known values of IQC materials at different levels. Elevated CV% values in urea, creatinine, bilirubin, AST and ALT measurements may hinder the precision required for the timely detection of changes in bodily functions. Fluctuations in CV% for electrolytes and nutritional markers can lead to misinterpretation of patients' overall health and nutritional status, impacting appropriate dietary recommendations and treatment strategies. Therefore, minimising CV% values for these analytes is imperative to ensure accurate and reliable clinical decisions, ultimately improving patient care [24].

The Bland-Altman analysis provides valuable insights into the agreement between Analyser 1 and Analyser 2 regarding their performance. A minimal mean difference of 0.001 for potassium at Level-1 IQC materials, along with narrow Limits of Agreement (LOA) between -0.138 and 0.136, indicates a high degree of concordance between the two analysers for this parameter, suggesting consistent and accurate measurements. However, the notably higher mean difference observed for glucose in Level-1 IQC samples indicates a greater discrepancy in measurements between the two instruments for this specific analyte, potentially requiring further investigation or calibration to enhance agreement and ensure the accuracy of glucose assessments in clinical practice.

In every laboratory, it is of outstanding importance to ensure the quality control (IQC) measures are in place, as well as to participate in EQAS [25]. It is important to compare two dry chemistry automated analysers that are based on the same principles, techniques and methods for analysis. Ensuring the comparability of analytical systems minimises bias and ensures the best patient care. The study found that both systems performed well with minimal deviation in the results; however, the performance reference analyser was particularly accurate across various IQC levels for multiple parameters.

Limitation(s)

The study did not calculate the total bias using the EQAS data or the average measured bias for each parameter.

CONCLUSION(S)

The study found that both Analyser 1 and Analyser 2 performed well, with minimal deviations in results, highlighting their potential for accurate clinical testing. In particular, the reference analyser exhibited exceptional accuracy across various IQC levels, further emphasising its suitability for precise and reliable patient diagnostics. Ultimately, this study contributes to ongoing efforts to enhance the quality of clinical laboratory testing and, by extension, improve patient care.

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