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Error detection and effectiveness of external quality control program for urine chemistry in comparison with serum chemistry parameters.

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Abstract
Introduction
In today's medical diagnostics, clinical laboratory testing is essential, and doctors mostly depend on reliable test results. Labs must maintain quality in all processes and adhere to professional standards in order to guarantee dependability. Programs for External Quality Assessment (EQA) and Internal Quality Control (IQC) are regularly carried out to evaluate and improve analytical quality, guaranteeing the precision and consistency of lab results. (1)
A key component of laboratory quality assurance is External Quality Assessment (EQA). Participating laboratories can use EQA as a guide to compare their results with those of other laboratories. (2)
Objectives
To determine effectiveness of urine chemistry External quality control program in comparison with serum chemistry external quality control program by using Z-score, BIAS.
Methods
Monthly reports containing Z score and BIAS received from BIORAD EQAS program of Serum and Urine chemistry parameters are compared in Clinical Biochemistry section of Father Muller Medical College Hospital.
Results
By comparing Z-SCORE and BIAS % of URINE EQAS and SERUM EQAS. It shows non-significant differences in parameters like calcium, glucose, phosphorus, Magnesium, total protein, urea, uric acid, which implies that the test accuracy of calcium, glucose, phosphorus, Total protein, magnesium, urea, uric acid of Urine EQAS and Serum EQAS are same.
Conclusions
There is no significant difference between serum and urine chemistry parameters in EQAS. Therefore, EQAS for routine urine parameters like calcium, glucose, phosphorus, total protein, magnesium, urea, uric acid does not add to accuracy of the parameters.

Keywords: 1. External Quality Assessment scheme (EQAS)
1. Internal Quality Control [IQC]
2. External Quality Assessment (EQA)

1. Introduction

In today's medical diagnostics, clinical laboratory testing is essential, and doctors mostly depend on reliable test results. Labs must maintain quality in all processes and adhere to professional standards in order to guarantee dependability. Programs for External Quality Assessment (EQA) and Internal Quality Control (IQC) are regularly carried out to evaluate and improve analytical quality, guaranteeing the precision and consistency of lab results. (1)
A key component of laboratory quality assurance is External Quality Assessment (EQA). Participating laboratories can use EQA as a guide to compare their results with those of other laboratories. (2)
In the 1940s, the scope of EQA in laboratories changed. EQA programs are now a crucial part of the requirements for laboratory accreditation. Monitoring lab performance, identifying subpar performance, detecting analytical errors, and taking corrective action are

all-important EQA goals. A laboratory's performance is evaluated by participation in EQA. As a result, accreditation requires the review of EQA reports. (3)

2.Material and Methods

2.1 Source of Data

This study was done at the Central Clinical Laboratory of Father Muller Medical College Hospital (FMMCH), Mangalore. External Quality Control data were used for this study, External Quality Assessment Scheme (EQAS) reports were obtained from BIORAD Website.

2.2 Sample Size

Since it is a time bound study there is no sample size. All the data received in a period of four year of study (Jan 2021-Dec 2024) were collected. Parameters like Glucose, urea, uric acid, Total protein, phosphorus, magnesium, and calcium were selected from urine and serum. Maximum of 48 values were collected for each parameter.

2.3 Study Design

It is a Time bound study from January 2021- December 2024

2.4 Method of Data Collection and Analysis

Reports were collected from BIORAD EQAS program. Monthly reports received from BIORAD EQAS program of Serum and Urine chemistry parameters were used. Z score and BIAS % of parameters like calcium, glucose, phosphorus, magnesium, total protein, urea, and uric acid were collected from BIORAD EQAS program.

2.5 Statistical analysis

Collected data of Z score and BIAS % of urine EQAS and Serum EQAS were compared by using Wilcoxon signed rank rest. P value obtained is used to find the correlation between Z score and % BIAS of Urine EQAS and Serum EQAS. The compared data are classified as highly significant, significant and non-significant.

Interpretation of Intraclass Correlation Coefficient	
< 0.40	Poor agreement
.4 -- .75	Fair agreement
.75 -- .85	Good agreement
> 0.85	Excellent agreement

Table 2.1 Interpretation of Intraclass Correlation Coefficient.

3.Results

This study evaluates the effectiveness of an External Quality Assessment Scheme (EQAS) for urine chemistry in comparison to serum chemistry, focusing on the necessity of separate EQAS programs for these matrices. Using the Wilcoxon signed-rank test, we compared Z-scores and bias percentages (% bias) for urine and serum parameters, including calcium, glucose, phosphorus, total protein, magnesium, urea, and uric acid. Results showed in Table 3.1 shows there is no significant differences between the Z-scores and % bias of urine and serum EQAS samples, suggesting a high degree of resemblance.

Table 3.1 Wilcoxon Test P value.

	PARAMETER	EQAS		N	Mean	Wilcoxon test p value	Significance
	CALCIUM	BIAS %	URINE	17	-0.34	0.61	NS
			SERUM	17	0.03		
		Z SCORE	URINE	17	-0.01	0.81	NS
			SERUM	17	0.05		
	GLUCOSE	BIAS %	URINE	28	-0.68	0.09	NS
			SERUM	28	0.13		
		Z SCORE	URINE	28	-0.21	0.13	NS
			SERUM	28	0.04		
	PHOSPHORUS	BIAS %	URINE	30	-0.82	0.06	NS
			SERUM	30	-0.17		
		Z SCORE	URINE	30	-0.24	0.08	NS
			SERUM	30	-0.03		
	TOTAL PROTEIN	BIAS %	URINE	32	2.97	0.22	NS
			SERUM	32	1.01		
		Z SCORE	URINE	32	0.20	0.23	NS
			SERUM	32	0.49		
	MAGNESIUM	BIAS %	URINE	22	-0.15	0.59	NS
			SERUM	22	0.45		
		Z SCORE	URINE	22	-0.08	0.54	NS
			SERUM	22	0.20		

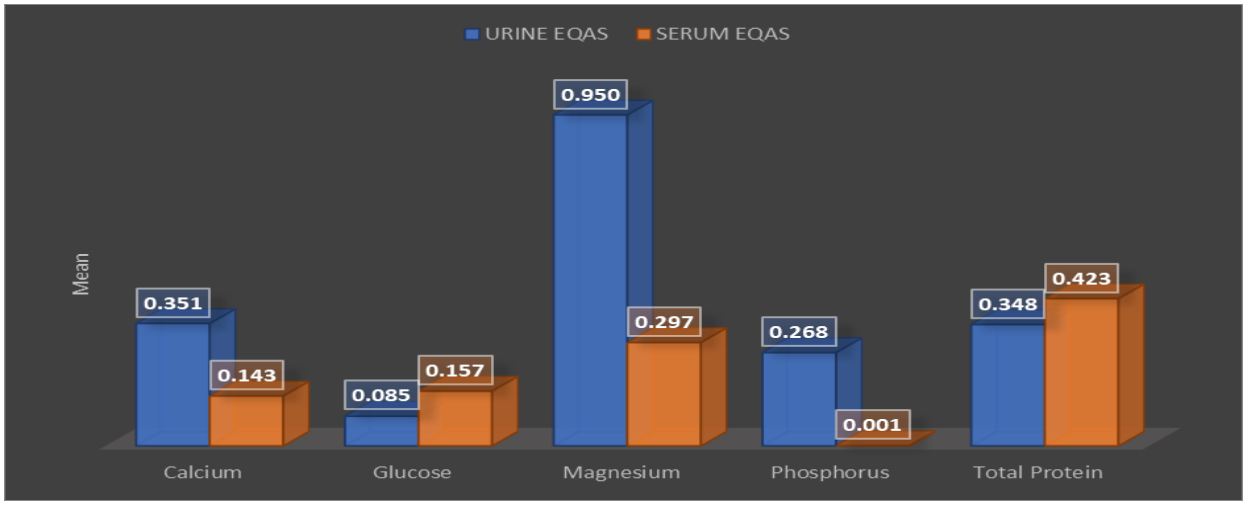

Figure 3.1 Z-Score and BIAS% Comparison.

Figure 3.1 Z-Score and BIAS% shows that, By comparing Z SCORE and BIAS % of Urine and Serum EQAS by Wilcoxon signed rank test, Result obtained after the running of EQAS sample shows non-significant differences, Implies the resemblance of EQAS samples for Urine and Serum for parameters like Calcium, glucose, phosphorus, total protein, Magnesium, urea, uric acid. This Resemblance shows that there is no need of a separate EQAS program for urine and Serum parameters where it shows no significant differences in Z-score and BIAS% of EQAS samples.

4. Discussion

According to this study, urine assays that are conducted under the same assay conditions as serum assays do not require a separate EQA program. Urine EQA can be avoided for these assays and costs can be reduced because there is an EQA program accessible for serum testing.

This study examined the Z-Score and BIAS% of serum and urine to determine the use of the urine EQA program for the following assays: calcium, glucose, phosphorus, magnesium, total protein, urea, and uric acid. The number of assays chosen for the study is one of its limitations.

This study can be expanded to obtain more EQA data by extending the time and incorporating all urine assays conducted with a serum-based calibrator for calibration.

5. Conclusion

Since no discernible variations in quality control methods were found, the results suggest that distinct EQAS programs for urine and serum may be unnecessary for some metrics. Currently, laboratories run separate EQAS programs for serum and urine, which raises quality control costs without showing any further benefits. The efficacy of a unified EQAS approach, in which remedial measures for serum outliers are adequate for urine under the same test settings, is supported by this study. By lowering expenses and increasing productivity, a unified EQAS software could eventually make quality control measures more accessible to labs.

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