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Evaluation of the External Quality Assessment Scheme as a Performance Tool in Clinical Biochemistry Laboratory in Tertiary Care Centre

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ABSTRACT

Background: Implementing both Internal Quality Control (IQC) and External Quality Assessment Schemes (EQAS) is necessary to ensure the quality of the reports released by the Clinical Laboratories. EQAS helps us assess our laboratory's performance by comparing it to that of peer laboratories, providing insights into our quality standards and identifying areas for improvement. The objectives were to interpret the results of the Biochemical parameters of the external quality assessment scheme and to analyse the performance of the laboratory by using indicators of the external quality assessment scheme.

Methods: This retrospective observational study was conducted in a Clinical Biochemistry Laboratory at a Tertiary Care Centre with clearance from the Institutional Ethics Committee. Two analysers were involved: the VITROS 250 and the VITROS ECI hormone analyser. In 2022, 31 biochemistry parameters were registered under the EQAS program by Randox (RIQAS). Results for each parameter were compared to the mean to generate performance statistics, including SDI, Target Score, and %Deviation. The analysis, covering RIQAS reports from 2022 and 2023, utilized Windows 10, MS Excel, and SPSS version 20 to calculate yearly averages and assess performance based on monthly target scores and deviations.

Results: Iron (target score:48.82) and Lactate (SDI:3.0) were outliers in the year 2022, whereas in 2023, Aspartate transaminase (AST) (SDI:2.57) and Lactate dehydrogenase (LDH) (SDI:2.45) were the outliers.

Conclusion: Two years of EQAS experience in our laboratory demonstrated satisfactory results, reinforcing confidence in the quality of patient reports. This study also helped identify potential risks and develop strategies to address them.

Key-words: Biochemistry laboratory, External quality control, Performance tool, Randox, Tertiary care hospital

INTRODUCTION

Clinical laboratories play a major role in the diagnosis and patient care in any hospital setting [1].

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The laboratory is the backbone of any healthcare setup. 60-70% of the decisions in the medical field are dependent mostly on laboratory reports. The quality of the reports generated in a laboratory should be maintained to have patient doctors' trust. The quality of the reports can be maintained by performing IQC and EQAS. Errors during the analytical phase are due to errors in the processing of the patient sample, so it is important to maintain quality by doing IQC daily [2-4].

IQC maintains precision and accuracy inside the laboratory, it helps us to know how well we maintain the

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quality in the laboratory whereas EQAS helps us to know where our laboratory stands in terms of quality in comparison with the peer group [5,6].

With the introduction of many accreditation programs, EQAS is also becoming the need of the hour to know the performance of the laboratory. The National Accreditation Board for Testing and Calibration Laboratories (NABL) mandates the participation of laboratories in the EQAS program for accreditation [7].

EQAS is a process in which participating laboratory is registered under the EQAS program suited to their specific testing needs. Such programs are typically managed by third-party organizations or accreditation bodies. The providers provide 12 cycles based on the 12 months of the year, each cycle for each month. Every month one vial of anonymized sample of quality control (QC) material is sent by the EQAS provider to participating laboratories. These samples are intended to assess the accuracy and dependability of the laboratory's testing methods. The participating laboratory has to analyse this sample like a routine procedure and results are recorded and then uploaded into the provider's software within a specified time. The EQAS provider evaluates the results by comparing each laboratory's data with results from peer laboratories using the same methods and equipment, as well as with established benchmarks to ensure accuracy and consistency. Once the results are sent back, the participating laboratory must interpret the data and if there is any outlier then proper corrective action to be taken.

Thus, EQAS are systematic evaluations of a laboratory's performance compared to established standards or the performance of peer laboratories [6]. It is used to assess the accuracy and reliability of laboratory test results and to identify areas for improvement. They help laboratories to benchmark performance, help in comparing results with other laboratories, so that we can detect errors and deviations from the expected value. EQAS supports the laboratories in meeting high-quality standards and regulations, ensuring consistency and reliability of their performance.

The Biochemistry laboratory of our tertiary care hospital also has been enrolled in the EQAS program since 2022. To reflect and offer reassurance of the quality of our Biochemistry laboratory reports, we took a step aiming at interpreting the results of the Biochemical parameters of the external quality assessment scheme. We also aimed to analyze the performance of the laboratory by using indicators of an external quality assessment scheme.

MATERIALS AND METHODS

Place of the study- This was a retrospective observational study, conducted in a clinical Biochemistry laboratory in Kanachur Institute of Medical Sciences, Mangalore, Karnataka.

Our Biochemistry laboratory having 2 instruments VITROS 250 for routine parameters and a Hormone analyzer VITROS ECI, was registered in the EQAS program provided by Randox Laboratories Ltd (RIQAS) in the year 2022. Each year laboratory was provided with 12 EQAS samples for one year. A total of 31 parameters under the Biochemistry department were registered under RIQAS. Each month, on a designated date, usually in the last week of the month, one vial of EQAS for that particular month was run like an unknown patient sample, and results were documented. After checking the lot number, generation number, and all specific details of each Biochemistry parameter, values were uploaded to the website on the same day.

Inclusion criteria- All the biochemical parameters which were registered under the EQAS program were included.

Exclusion criteria- Parameters which were not registered under the EQAS program were excluded from the study.

Methodology- Our RIQAS results were evaluated by comparing them to a mean for comparison, which was based on consensus.

RIQAS Protocol- All participants of RIQAS were registered on each programme according to their chosen parameter, method, instrument, unit, measuring temperature (wherever appropriate), and Ortho slide generation number (where VITROS Machine was used). For a given sample and parameter, our results returned were compared to a mean for comparison to generate performance statistics. The mean for comparison was given based on the Instrument, the Method, or the All Methods group of results, depending on the number of results. On the top left of each parameter report page, the text section summarises the parameter and our chosen unit of result submission, Calculated statistics for the current sample, presented in our chosen unit, our result, our selected mean for comparison, our performance scores: SDI, Target Score and % Deviation,

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along with Running Means, Acceptable limits of performance. Our performance was reviewed on the summary page presented at the back of each report. The report showed our performance scores and means for comparison for each registered parameter. Performance scores, which fall outside the acceptable criteria, were presented in underlined, bold text. When a result fell outside all 3 acceptable criteria, a red triangle was shown in the "Performance" column. Results were obtained after a week from the website and were saved. The performance of the laboratory was assessed by the quality indicators provided by the RIQAS in the result sheet. Data from two years 2022 and 2023 was collected and performance was analyzed by using the following indicators.

Criteria for acceptable performance were

- Target score greater than 50.
- Standard deviation index (SDI) less than±2.
- Percentage deviation within acceptable limits.

When our result fell outside all three criteria (outlier), a red triangle was shown beside the parameter on the summary page of the routine report, as an overall indication of poor performance.

Calculating the Target Score (TS)- The Target Scoring system was developed to provide a simple interpretation of the laboratory's performance. The system presented the performance of results for each RIQAS sample and showed how the laboratory's performance varies with time. To calculate the Target Score, the laboratory result was calculated as a percentage deviation (V) from the Mean for Comparison. This deviation was then compared to a Target Deviation for Performance Assessment to calculate the Target Score.

The participant's Target Score was calculated as follows:

$$V = \frac{\text{(Participant's result - Mean for Comparison) x 100}}{\text{Mean for Comparison}}$$

Target Scores were in the range from 10 to 120 and were interpreted as follows

less than 40= Unacceptable
41–50= Need for improvement
51–70= Acceptable
71–100= Good
101–120= Excellent

Calculation of SDI- The Standard Deviation Index is a measurement of how far the reported result is from the consensus mean relative to the Standard Deviation for Performance Assessment, and was calculated as follows:

$$\text{SDI} = \frac{\text{Participant's result – Mean for comparison}}{\text{SDP Adjusted}}$$

Calculation of Percentage Deviation Score (% Dev)

$$\text{Deviation (\%)} = \frac{\text{Participant's result - Mean for comparison x 100}}{\text{Mean for comparison}}$$

Statistical Analysis- Analysis was done by using Windows 10, MS Excel and SPSS version 20. Yearly average was calculated using monthly target score, SDI and % Dev for all the study parameters.

Ethics committee approval- Institutional Ethics Committee clearance (KIMS/IEC/FCOO4/2024-EC/NEW/INST/2023/3522) was obtained before starting the study. Our study procedures adhered to the ethical committee regulations.

RESULTS

Table 1 shows the average SDI, TS and % Dev of all 31 parameters for the study period of years 2022 and 2023.

In the year 2022, there were two outliers, Iron and Lactate. AST and LDH were the outliers in the year 2023.

Table 1: Average SDI, Target score and % Deviation for the parameters for the study period 2022 and 2023

Parameters	Average SDI		Average TS		Average % dev	
	2022	2023	2022	2023	2022	2023
Albumin	0.34	-0.06	99.55	100.18	-2.60	-0.34
Alkaline phosphatase	0.20	0.87	110.30	97.91	3.71	10.21
Alanine transaminase (ALT)	0.37	1.15	104.18	95.91	3.69	13.13

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Amylase	0.42	1.29	96.30	100.20	5.85	13.29
Aspartate transaminase (AST)	0.28	2.57	110.36	88.73	0.99	23.17
Conjugated Bilirubin	0.87	-0.41	0.00	0.00	-25.96	-13.06
Unconjugated Bilirubin	0.69	0.29	82.00	90.00	-4.45	3.46
Total Bilirubin	0.43	-0.11	85.36	85.18	-7.54	-1.47
Calcium	0.52	0.73	104.27	84.73	-0.74	3.94
Chloride	0.33	0.43	110.00	97.73	0.12	1.19
Cholesterol	0.33	0.33	103.09	92.09	1.16	1.76
Creatinine	0.35	1.01	106.82	72.09	2.83	7.66
Glucose	0.56	-0.03	91.50	96.36	-2.27	-0.20
HDL Cholesterol	0.46	-1.35	77.82	61.45	-10.63	-16.99
Iron	1.60	-1.45	48.82	63.00	4.19	-9.92
Lactate	3.00	0.75	0.00	75.18	15.57	4.50
Lactate dehydrogenase (LDH)	0.33	2.45	106.80	82.18	1.63	18.96
Magnesium	0.92	1.53	0.00	62.91	0.11	10.11
Phosphate	0.58	0.61	93.20	89.64	1.35	3.42
Potassium	0.37	0.33	91.55	103.18	2.49	1.11
Total protein	0.35	0.82	100.36	82.55	2.48	5.97
Sodium	0.43	0.19	96.91	84.82	0.64	0.41
Free T3	0.30	-0.13	105.36	107.60	-4.07	-1.27
Total T3	0.25	0.36	110.64	108.10	4.41	5.37
Free T4	0.32	0.04	109.00	98.50	-2.13	-1.04
Total T4	0.63	0.24	94.45	92.80	6.14	3.95
Total iron binding capacity (TIBC)	0.38	0.65	109.00	85.00	0.48	6.70
Triglyceride	0.24	0.15	111.36	111.82	-2.98	1.27
Thyroid-stimulating hormone (TSH)	0.45	-0.30	100.27	111.70	-3.72	-4.21
Urea	0.42	0.39	103.73	87.55	-0.75	2.95
Uric acid	0.41	0.24	107.64	115.91	-0.67	1.45

Fig 1 shows that the SDI of lactate, one of the outliers of 2022 was 3.0, whereas the SDI of another outlier of 2022, iron was 1.6. Outlier of 2023, LDH had an SDI of 2.45.

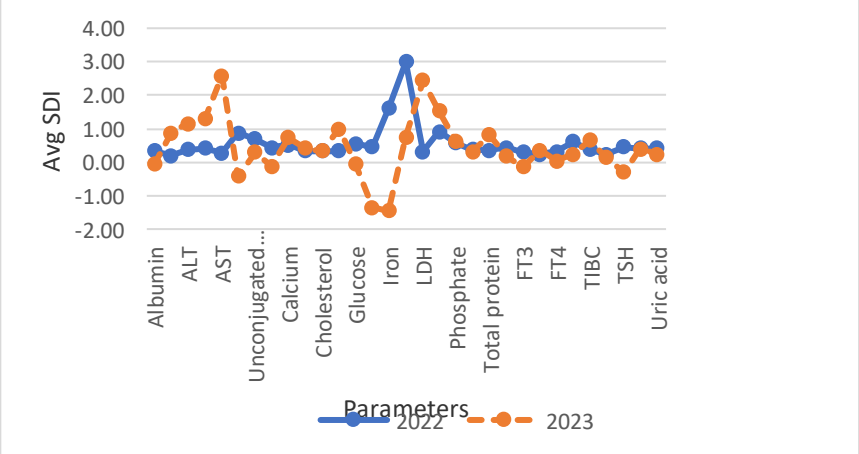

Fig 1: Graph showing Average SDI of the parameters for the study period 2022 and 2023.

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The target score of iron in the year 2022 was 48.82 as shown in Fig. 2.

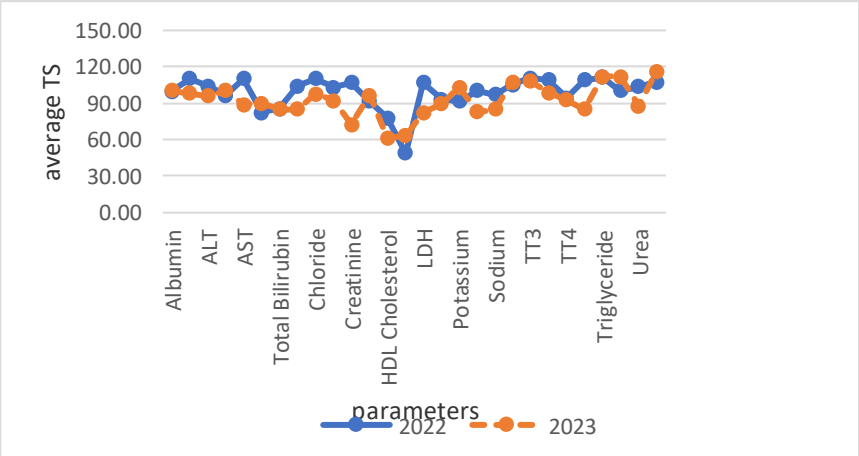

Fig 2: Graph showing Average Target score of the parameters for the study period 2022 and 2023.

Fig. 3 shows the outlier AST with % Dev of 23.17. Conjugated bilirubin had % Dev of –25.96 in 2022. HDL cholesterol demonstrated % Dev of -10.63 and -16.99 in 2022 and 2023 respectively.

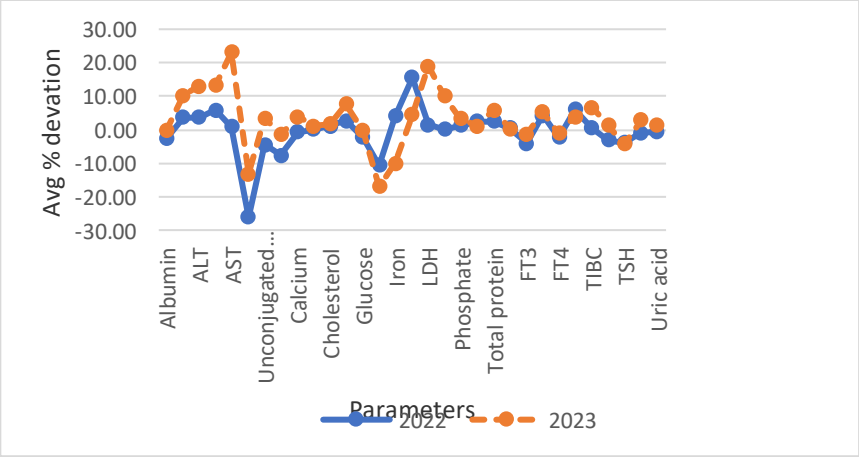

Fig 3: Graph showing Average % Deviation of the parameters for the study period 2022 and 2023.

DISCUSSION

In the present study, the EQAS report for the years 2022 and 2023 was included. Our Clinical Biochemistry laboratory has been enrolled in the EQAS program by Randox Laboratories Ltd and 31 biochemical parameters are included in the program. The overall performance of our Clinical Biochemistry laboratory with two sets of EQAS materials having 12 samples each for each year (2022 and 2023) is acceptable with a minimum number of tests being outliers. In the year 2022, iron and lactate among 31 parameters were the outliers in our laboratory, whereas in 2023, AST and LDH were the outliers. The acceptance of the EQAS report by the provider is based on TS, SDI and per cent deviation score (% Dev). SDI is a better index of expressing the EQAS report concerning its ability to reflect the efficacy of the quality control procedures of the participants [7]. % Dev assesses concentration-related biases, while the TS provides a numerical performance index for a quick evaluation [8]. In an earlier retrospective Six Sigma analysis study finding, an ideal performance concerning certain biochemical parameters such as chloride, creatine kinase and magnesium was observed [9].

EQAS report given by the EQA providers after the values are uploaded, is an important feedback tool for the participating laboratory [10]. In the RIQAS program, the participant Laboratories receive detailed reports of each parameter including target mean, target score, SDI, and Coefficient of variation in the Excel sheet. This is followed by a summary report with graphs and charts. Once the summary report is obtained, a thorough

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evaluation of the report is done to find the outliers. Root cause analysis is done and corrective action and preventive actions are taken and documented. At this juncture, we suggest that it would be better if EQAS providers gave some suggestions regarding dealing with frequent outliers. Earlier authors have recommended that EQAS providers present results in a clear, non-statistical manner that is easily understandable for all participants [11].

Different laboratories measure a single analyte using various methods, and EQAS evaluates these results to determine the target mean [11]. Different methods and different instruments are compared and peer group evaluation is done. Laboratory results are evaluated by comparing them to a mean for comparison [2]. All participants are registered in EQAS based on their analyte method, instrument, unit temperature and slide generation number. Participant laboratories can take up following measures to improve the quality-narrow range in IQC, increasing the frequency of calibration, periodic checking and instrument verification, and observing EQAS result for trends and bias [12].

In our clinical laboratory, generation number mismatch was identified as the cause for 2 outliers in 2022, as the EQAS program was newly implemented and it was a transcriptional error by our technical staff. Electrical fluctuation of the instrument was identified in the year 2023 which led to 2 outliers. Temperature calibration was needed for conjugated Bilirubin in 2022. Common causes of errors in EQAS are identified as transcriptional errors, method errors, instrument maintenance and calibration, reagent stability, temperature maintenance, pipette calibration and environmental conditions [13-15]. Technical errors like reconstitution errors, and using expired QC. Errors by EQAS providers like QC material error, incorrect volume, and inappropriate target value [16-18].

The RIQAS reports with outliers received by the service providers helped our clinical laboratory. We educated the technicians to do temperature calibration in a better way. The technicians of our laboratory were also taught the importance of doing root cause analysis to prevent future errors. As part of root cause analysis, checking IQC, and temperature logs were taught to the technicians and was practiced in our laboratory regularly. Environmental factors like humidity and the high temperature of this geographical area might also cause EQAS failure for some analytes [19]. In our laboratory, measures were taken to check humidity and temperature and the proper use of humidity packs in the instrument. These measures helped us in reducing errors in subsequent years. Thus, the educational role of EQA, especially in emerging measurement areas, should not be underestimated, as EQA programs generally lead to continuous improvement over time [20].

Certain recommendations for participant laboratories of EQAS were made by the earlier authors [21]:

- Assess peer group dispersion to identify the most precise group.
- Analyze error types to determine if they are clerical, procedural, methodological, due to personnel, or unexplained.
- Implement corrective actions and evaluate their effectiveness using subsequent EQAS reports.

In this regard, further advancement of the existing EQAS program can be achieved through the use of commutable materials, value assignment with higher-order references, common data analysis, performance specifications, and harmonized method classification, which will be realized through coordinated efforts among EQAS programs adopting common practices and thoroughly reviewing results from various programs [22].

CONCLUSIONS

Enrolling a laboratory in an EQAS program provides assurance that test results are accurate and dependable, which is crucial for effective diagnosis and treatment. Laboratories can uphold high standards of quality maintain consistent performance and help in accreditation. It can also serve as an educational tool in training technical staff in identifying early warning signs, and deviations and in taking corrective steps.

Two years of EQAS experience in our laboratory showed satisfactory results. EQAS gives confidence in patient report quality. This study helped us in identifying the risks and finding out methods to overcome them. Ultimately, being part of an EQAS program enhances trust in the laboratory's results by demonstrating a commitment to accuracy and quality. Our tertiary care hospital Biochemistry laboratory will continue with the EQAS programme to ensure the quality of the test reports.

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