

# EQAS: Experience, Challenges and Trouble Shooting as a Participating Laboratory in Public Sector

Shahla Shafique<sup>1</sup>, M Sinha<sup>2</sup>, A Das<sup>3</sup>

Senior Resident, Department of Biochemistry, Janakpuri Super Speciality Hospital, Janakpuri, New Delhi, India

**Abstract:** ***Introduction:** Quality assurance (QA) is an indispensable part of medical laboratory processes for systemic monitoring of operation in clinical laboratory. It consists of internal quality control (IQC) and external quality assessment scheme (EQAS). Quality assurance includes all the three phases of laboratory system that is pre analytical, analytical and post analytical. It takes into consideration the overall program related to a laboratory and thus ensures that the final report/result released by the laboratory are correct. Quality control is a process through which a laboratory ensures that, its products quality is maintained or improved and manufacturing errors are reduced or eliminated. Quality control refers to the measures that must be included during each test run to verify that the test is working properly. Quality control emphasis statistical and non-statistical procedures and is able to detect the problem early enough to prevent their consequences. **Objective:** Data was collected from EQAS samples received from January 2016 to April 2018 at the Clinical Biochemistry Laboratory of Janakpuri Super speciality Hospital (An autonomous organization under Delhi government), New Delhi, India for the study. The main purpose of EQA, beside monitoring and documenting the analytical quality is to identify poor performance to detect analytical errors, and to take corrective actions for the same. **Methods:** Four lyophilized samples received on quarterly basis that were stored at required optimum temperature, reconstituted and analyzed as per instruction and guidelines provided by the EQAS organizing body. Every month an unknown/blind sample provided by Christian Medical College, Vellore is reconstituted as per instruction on schedule date, analyzed for the number of parameters for which our laboratory is participating. The results obtained for every particular parameter is uploaded on the official website of CMC, Vellore on or before the schedule date as per the protocol. Our performance score was downloaded after completion of each month. The tests were performed on the fully automated biochemistry analyzer ErbaTransasia XL 1000. **Results:** On analyzing, the monthly VIS of all the selected parameters for the study year 2016 - 2018 the laboratory's performance was found to be very good as (VIS < 200) in 14.6 % of the total selected parameters for the year 2016 and 8.2 % in all the selected parameters for the year 2017 respectively. The performance in terms of VIS for the year 2018 was found to be equally good as VIS (< 100) in 95.1 % in all the selected parameters. **Conclusion:** The overall performance of laboratory as far as OMVIS is considered for the study year 2016, 2017 and 2018 is found to be very good with 90.3% of the value falling below 100 in the year 2017, and 95.1% of the value falling below 100 for the year 2018 (till May). However, the values of calcium, phosphorus, sodium and potassium crossed >200 in the month of February, March and July in the year 2017, the possible reason being quality of water supply in the institute.*

**Keywords:** Quality assurance (QA), Internal quality control (IQC), External quality assessment scheme (EQAS)

## 1. Introduction

Quality assurance (QA) is an indispensable part of medical laboratory processes for systemic monitoring of operation in clinical laboratory. It consists of internal quality control (IQC) and external quality assessment scheme (EQAS). Quality assurance includes all the three phases of laboratory system that is pre analytical, analytical and post analytical. It takes into consideration the overall program related to a laboratory and thus ensures that the final report/result released by the laboratory are correct. Quality control is a process through which a laboratory ensures that, its products quality is maintained or improved and manufacturing errors are reduced or eliminated. Quality control refers to the measures that must be included during each test run to verify that the test is working properly. Quality control emphasis statistical and non-statistical procedures and is able to detect the problem early enough to prevent their consequences. In laboratory, quality Control is put into practice because it helps to study the sources of variation and procedure use to recognize and minimize them. The main emphasis of quality control (QC), which is apart of internal quality control program (IQC) is to monitor the precision and accuracy of the performances of analytical methods. The day-to day, in house internal quality program

is for maintenance of consistency and precision. Whereas External Quality Control programs (EQC) is designed and aimed to provide a comparability of results between all the laboratories using the same method. External quality assurance (EQA) is a system for objectively checking the laboratory's performance using an external agency or facility. EQA is done for periodic and retrospective monitoring of the laboratory results through a third party to prevent bias in their system and methods. The underlying objective of External quality assessment (EQA) is to provide a measure where an individual laboratory can maintain its quality through regular practice of internal quality control procedures that helps to provide "state of the art" for all laboratory test and procedures, to obtain consensus values when true values are unknown, to investigate factors in performance (methods, staff etc.) and last but not the least to act as an educational stimulus to improvement performance. The main aim of quality control in the settings of a clinical laboratory refers to all the procedures that are designed to monitor the routine performance of the testing processes in order to detect any possible errors, reduce them if any and to correct the deficiencies before the test results are reported (1). Results from laboratory that do not maintain quality control, which includes internal quality control (IQC) and external quality assessment (EQA) cannot be relied upon.

So, to maintain a good standard of accuracy, a laboratory should monitor its own performance continuously with the help of IQC and EQAS.

External quality assessment scheme (EQAS) is a significant tool for proper functioning of a laboratory. Under this scheme a QC sample of unknown value are periodically send to the participating laboratories and to prevent bias they are required to analyze it along with the routine samples. Results obtained are required to be uploaded on the official website of the organizers. The collected results are published to all the concern laboratories so that each participant can see how the results compare with those of the other laboratories in the scheme. The statistical parameter like the variance index score (VIS), which is recommended by WHO is made use of for external quality assessment scheme. They also make use of coefficient of variation (CV %). This has been recommended by world health organization (WHO) as the ideal precision, based on the performance by many Indian Laboratories in WHO and by Delhi government health scheme (DGHS).

The main purpose of EQA, beside monitoring and documenting the analytical quality is to identify poor performance to detect analytical errors, and to take corrective actions for the same. Participation in EQA gives an evaluation of the performance of the individual laboratory and of the different methods and instruments (2,3).

Data was collected from EQAS samples received from January 2016 to April 2018 at the Clinical Biochemistry Laboratory of Janakpuri Superspeciality Hospital (An autonomous organization under Delhi government), New Delhi, India for the study. Four lyophilized samples received on quarterly basis that were stored at required optimum temperature, reconstituted and analyzed as per instruction and guidelines provided by the EQAS organizing body. Every month an unknown/blind sample provided by Christian Medical College, Vellore is reconstituted as per instruction on schedule date, analyzed for the number of parameters for which our laboratory is participating. The results obtained for every particular parameter is uploaded on the official website of CMC, Vellore on or before the schedule date as per the protocol. Our performance score was downloaded after completion of each month. The tests were performed on the fully automated biochemistry analyzer ErbaTransasia XL 1000.

Seventeen parameters from our laboratory were chosen for assessment in EQAS program. Starting from blood glucose, total cholesterol, triglyceride, high density lipoprotein (HDL), total bilirubin, total protein, albumin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), urea, creatinine, uric acid, calcium, phosphorus, sodium and potassium. Performance was analyzed in terms of the VIS (variation index score) and SDI from each month from the period of January 2016 to April 2018.

## 2. About VIS / SDI

To assess the performance of the laboratories, we employ the statistical parameter VIS, which is recommended by WHO. To calculate the VIS the term desired CV is used which is similar to CCV (chosen coefficient of variation). The desired CV is derived from the performance of the participants over the last two years in this program. The desired %CVs for the various analytes are listed below.

The following example explains the calculation of VIS for a lab for a particular analyte in our EQAS [e.g. Glucose].

$$\begin{aligned} \text{Designated Value [DV]} &= 120 \text{ mg\%} \\ \text{Participant's result} &= 95 \text{ mg\%} \\ \text{\% variation [\%V]} &= \frac{\text{Difference between participant's Result and designated value}}{\text{Designated value}} \times 100 \\ &= \frac{120-95}{120} \times 100 = \frac{25}{120} \times 100 \\ &= 20.8 \\ \text{Variance Index} &= \frac{\%V}{\text{Desired CV}} \times 100 = \frac{20.8}{7} \times 100 \\ &= 297 \end{aligned}$$

When VI is less than 400, it is designated as VIS. Therefore VIS = 297.

### Significance of VIS

If your VIS is

< 100	-----	Very Good
100 - 150	-----	Good
150 - 200	-----	Satisfactory
> 200	-----	Not Acceptable

If the VIS is >200 on two or more occasions for the same analyte, then check your standardization procedures.

### Standard Deviation Index (SDI)

The standard deviation index is a measurement of bias (how close your value is to the target value). The following formula is used to calculate the SDI:

$$\text{Standard Deviation Index [SDI]} = \frac{\text{Your result} - \text{Mean for Comparison}}{\text{SD of Mean for Comparison Group}}$$

The VIS values in a month is termed OMVIS.

### Interpreting the SDI

The target SDI is 0.0, which indicates there is no difference between the laboratory mean and the designated value (DV). A SDI  $\pm 1$  indicates a possible problem with the test.

The SDI expresses bias as increments of the standard deviation. A SDI of -1.8 indicates a negative bias of 1.8 standard deviations from the method mean (DV).

Bias increases or decreases the percentage of patients outside the defined reference limit. For example, a positive bias decreases the percentage of patients normally outside the lower limit and increases the percentage of patients normally outside the upper reference limit. This creates an increase in false positive test results. Negative bias has an opposite effect and decreases true positives and creates false negatives.

Use the following guidelines to interpret the SDI

SDI Value	Interpretation
0	Perfect comparison with consensus group
<=1.25	Acceptable
1.25 - 1.49	Acceptable to marginal performance. Some investigation of the test system may be required.
1.5 - 1.99	Marginal performance.
2.0 - 3.0	Warning Signal . Investigation of the test system is recommended
>3.0	Unacceptable performance. Action Signal.

### 3. Results

On analyzing, the monthly VIS of all the selected parameters for the study year 2016 - 2018 the laboratory's performance was found to be very good as (VIS < 200) in 14.6 % of the total selected parameters for the year 2016 and 8.2 % in all the selected parameters for the year 2017 respectively. The performance in terms of VIS for the year 2018 was found to be equally good as VIS (< 100) in 95.1 % in all the selected parameters. The performance of parameters like glucose, cholesterol, urea and uric acid were also found to be very good (VIS < 100) in the year 2017 and equally good in the year 2018.

VIS	2016	2017	2018
Excellent (< 50)	30.3	32.1	35.6
Very good (50 - 100)	49.8	58.2	59.5
Good (101 - 150)	5.3	1.5	1.2
Satisfactory (151- 200)	14.6	8.2	3.7

The overall performance of the our laboratory if we speak in terms of OMVIS (overall mean of VIS ) for the year 2016, 2017 and 2018 was found to be good with most of the values falling below <100 score category. 80.1% of the value falling below <100 in the year 2016 ever since we started participating in the EQAS program. However, VIS for calcium, phosphorus, sodium and potassium did cross ( more than) > 150 in few months. The possible reason being inconsistency in maintaining the pH of the supply water where the TDS was found to be very high.

A part from this the standard deviation index (SDI) of each variety of sample was calculated on a monthly basis of each year. Majority of the parameter 's results were found to be in the range of good in all the respective study years.

### 4. Discussion

The value of participating in EQAS for the laboratory depends on proper evaluation and interpretation of the EQA result. Key factors for interpreting EQA results are knowledge of the EQA material used, the process used for target value assignment, the number of replicate measurement of the EQA sample, the range chosen for acceptable values around the target (acceptance limits), and the impact of between lot variations in reagents used in measurement procedures (4-6).

External Quality Assessment (EQA) program is a valuable tool to periodically assess analytical performance of a laboratory and achieve added confidence in reporting patient

test results. Results are objectively compared to other laboratories participating in the EQAS program.

VIS of various biochemical parameters indicates the deviations from the target or expected value. In case of significant deviation a laboratory has to take corrective measures and do trouble-shooting right from the start from sample receipt till the results are analyzed.

The overall performance of laboratory as far as OMVIS is considered for the study year 2016, 2017 and 2018 is found to be very good with 90.3% of the value falling below 100 in the year 2017, and 95.1% of the value falling below 100 for the year 2018 (till May). However, the values of calcium, phosphorus, sodium and potassium crossed >200 in the month of February, March and July in the year 2017, the possible reason being quality of water supply in the institute.

To eradicate this problem a Reverse osmosis system (RO system) was installed in the month of September 2017 and connected with the deionized plant before supplying water to the respective equipment. The quality of water is being maintained since then through daily monitoring of total dissolved solids (TDS) and regular service of the RO system.

Apart from this the value of creatinine was found to be not in par with the expected result with VIS > 200 in the month of March and June 2017, the stability of the reagent was a major concern, we changed our method of sample analysis from Jaffes's kinetic method to enzymatic method (creatinase kinase, DGKC) and found our results to be closer to the target value. Temperature also has a major role and influences most of the test results.

A study survey reports that systematic differences in the calibration of plasma creatinine assays account for 85% of the observed 5 differences between laboratories. (7).

Stability of reagent on board has also been a major concern for our laboratory as ours being a medium size laboratory. We observed that the quality and stability of reagents with a bigger pack size (6 x 44 ml / 3 x 22 ml) deteriorated much before than what was mentioned in their respective kit insert. To overcome this problem we changed our pack size from large pack size (6 x 44 ml/ 3 x 22 ml) to the smaller pack size (5.2 x11 ml / 2 x 4 ml). Even since then we encounter less problem with on board stability of the reagent.

Pre analytical variables account for most of laboratory errors and there are many factors that affect and contribute to the results of a patient (8).For some of the routine biochemical laboratory tests, results can be altered by the choice of blood collection tube that are used and the storage conditions in the laboratory (9,10,11).

One such condition that we encountered is the quality of the vacutainers being used at phlebotomy. The quality of gel being used in the plain vacutainers for biochemical analysis was highly questionable, it gave erroneous results the possible reason being inter mixing of the gel present in the respective vacutainer with that of the patient

sample. Proficiency studies demonstrate that although between laboratory coefficients of variation (CVs) of < 3 % are achievable within methods group, overall between laboratory agreement across methods is much poorer (12, 13). Systemic variation between laboratories of 0.2 to 0.4 mg/dl is common (14).

EQAS program provides an opportunity to the participating organizations to compare activities and modify their own practices based on what they learn (15, 16).

EQAS helps to assess the overall performance of laboratory. It establishes inter-laboratory comparison and also serves as an early warning system for problems, also helps in identifying systematic kit problems. Provides objective evidence of laboratory quality, indicates areas towards which efforts need to be directed for improvement of quality of results also helps in identifying training needs.

For medical laboratories, EQAS have been found useful, in that it initiates a "peer-review" process towards solving technical and methodological problems to improve the quality of service for each individual laboratory as well as to achieve comparability of results among different laboratories. (17).

## 5. Conclusion

EQAS is considered an important tool that develops confidence and faith in generating a reliable laboratory report. It also helps in maintaining the quality and standard of the laboratory so that it is at par with other laboratory participating in EQA.

Quality is a continuous process and there is always a scope for improvement. Reliable results produced by a laboratory generates confidence and help in decision making capacity of the clinicians. The consequences of poor quality management system can prove fatal. It may lead to inappropriate action that might lead to over treatment, over investigation, mistreatment, lack of treatment or inadequate investigation. Quality is ensured through a well defined quality system which is a part of over all quality management that aims at ensuring consistency, reproducibility, traceability and efficiency of the product. A trust worthy result can be obtained through daily monitoring, surveillance and guidance. All laboratory personal involved should perform their duty as per their job responsibility assigned to them because it is a proven fact that quality system is as good as the staff who actually work for it. To maintain quality it must be ensured that all equipments are in their best functional capacity, good quality of reagents and controls being used. Regular update of all laboratory staff, involved from pre analytical, analytical to post analytical phase. Quality cannot be achieved by an individual, rather it is a combined approach of all involved. Each individual should perform their work with complete responsibility and reliability and hence help in generating a reliable test result.

The key objective of EQA is continuous quality improvement within a laboratory medicine and EQA providers should therefore include quality improvement of scheme design as an essential requirement of the service. It

is hoped that accreditation of EQA Schemes should facilitate this improvement.

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