Estimating HbA1c External Quality Assurance Scheme (EQAS) Findings in Princess Iman Center; a Stepwise in Quality Improvement Plan

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I. Introduction

Laboratory is simultaneously the most, and the least used resource of the healthcare system, laboratory tests provide information which help doctors to provide better and more effective care for their patients. It's often cited that laboratory results are an integral part of every medical decision.

The daily routine basis in clinical laboratories that maintain a good control over all the result in a single laboratory are known as internal quality control (IQC), which is one of the most important impacts on laboratory testing; it ensures both precision and accuracy of patient sample results. The integrity of quality control samples is important to both management of overall quality as well as to meeting requirements of proficiency testing.

The role of External Quality Assessments (EQA) in ensuring good laboratory practice is recognized at national and international level, EQA schemes are the main tools for measuring the quality of laboratory results, for maintaining confidence in all tests and for implementing the standards of quality assurance [1].

How it is works, External Quality Assessment (EQA) / Proficiency Testing (PT) allows for a comparison of a laboratory's testing procedures to other laboratories across the world. Comparisons can be made to a peer group of laboratories or to a reference laboratory.

EQAS measures a laboratory's accuracy using 'blind' samples that are analyzed as if they were patient samples. Results are returned to the scheme organizer for statistical analysis. Laboratories receive a report comparing their individual performance against other participants in the programme [2].

II. Objective:

The object of this study is to evaluate the performance of clinical chemistry laboratory targeting HbA1c test using the indicators (Standard Deviation Index SDI) used by EQAS body.

III. Materials and Methods:

This study was conducted for HbA1c test in clinical chemistry department at Princess Iman Center in King Hussein Medical City, during the period of December 2016 until November 2020. A period of 4 periodically cycles. Each cycle completion in one year consist of 12 samples, one sample was ran every month. The EQAS samples were lyophilized samples provided from BIO-RAD. The analyzer were the tests been done was Cobas c501 from Roche Diagnostic system.

The results were uploaded on the EQAS website (BIO-RAD QC NET) on scheduled dates and the final reports were downloaded after the completion of each cycle (12 samples).

Performance indication was analyzed in terms of the (Standard Deviation Index SDI/Z-score, Range and Mean) and (Variance index score VIS) at the end of each cycle for all of 12 samples.

Standard Deviation Index (SDI): it is calculated as:

$$SDI = \frac{\text{differences between lab value and target value}}{\text{SD of mean for comparison group}}$$

And interpreted as
0.0 = 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 test system is recommended)

Variance Index Score (VIS): it is calculated as:

$$\%\,Variation = \frac{\text{differences between participant's result and group mean}}{\text{group mean}} \times 100$$

$$Variance\ Indedx\ Score\ (VIS) = \frac{\%\text{Variance}}{\text{Desired CV}} \times 100$$

The VIS interpreted as,

$$< 100 - very\ good$$
$$100 - 150\ good;$$
$$150 - 200\ \ satisfactory$$
$$> 200 - not\ acceptable$$

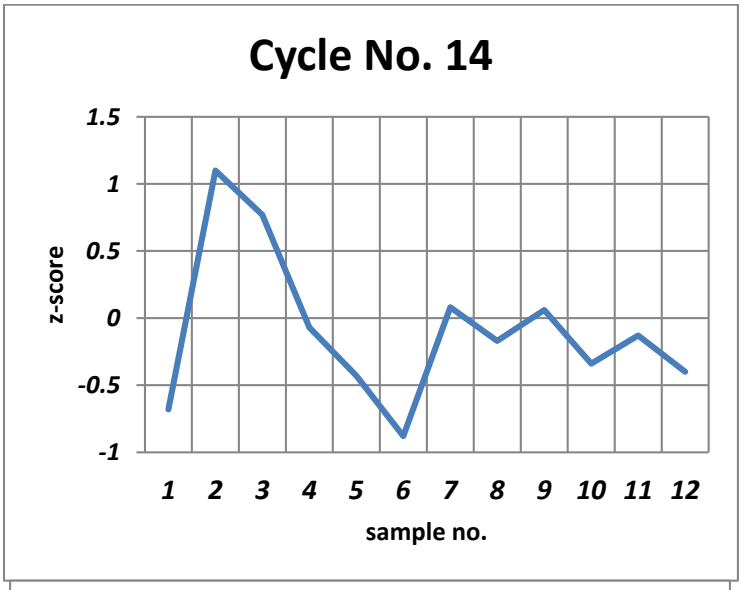
IV. Results:

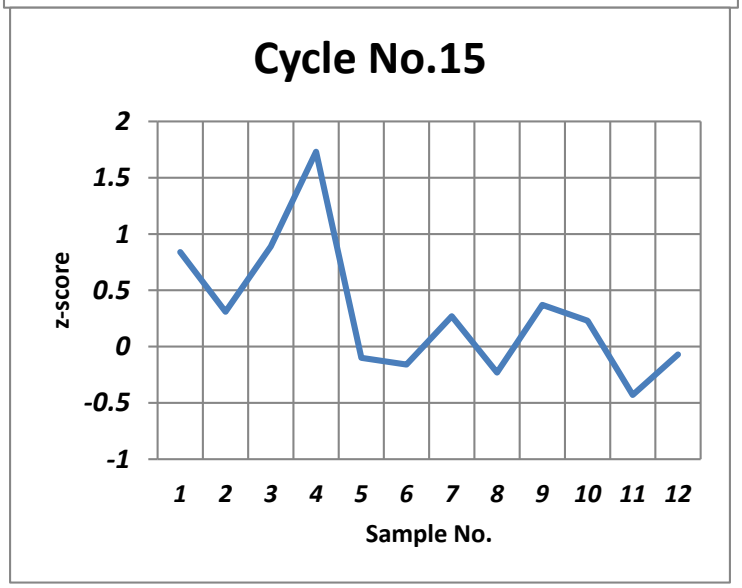
Based on the results assorted from (BIO-RAD QC NET) web site and according to the indicators we specify which is the Standard Deviation Index (SDI) for every sample in each cycle, the mean SDI for cycle 14 was (0.425) <1.25 = acceptable, for cycle 15 was (0.469) <1.25 = acceptable, for cycle 16 was (0.439) <1.25 = acceptable and for cycle 17 was (0,456) <1.25 = acceptable.

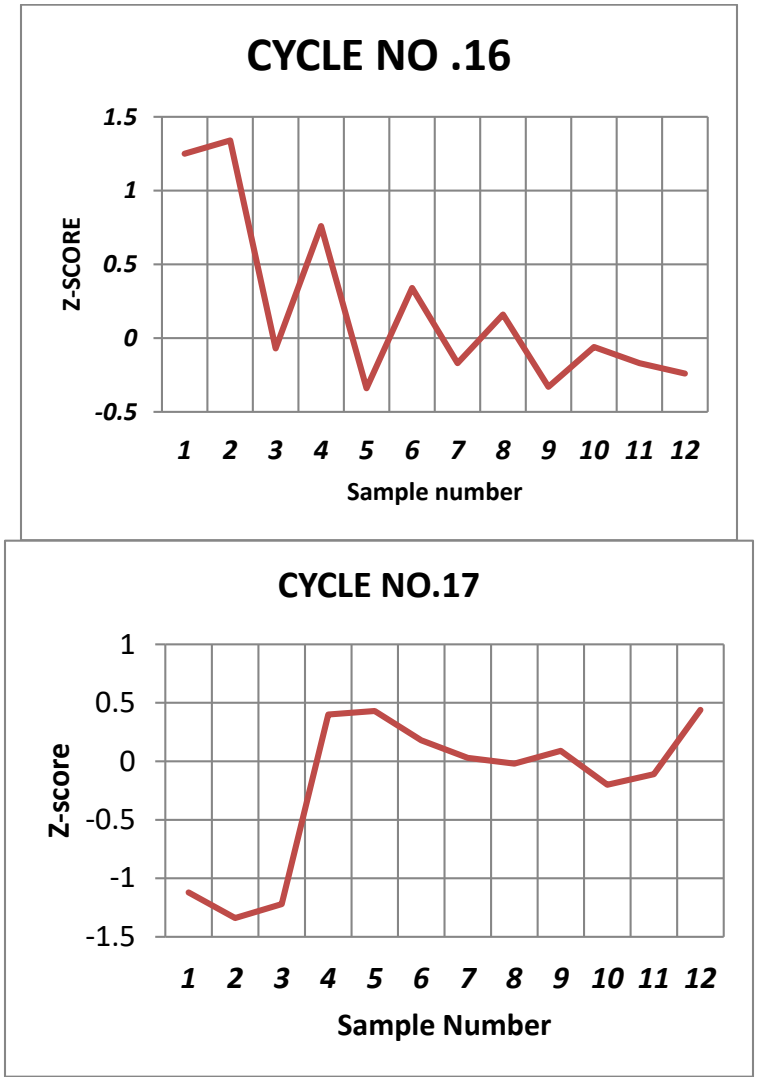
The second indicator which is Variance index score (VIS) value for every sample in each cycle and similarly the overall mean of VIS (OMVIS) for cycle 14 was (42.6) < 100 very good, cycle 15 was (46.9) < 100 very good, cycle 16 (55.5) < 100 very good and cycle 17 (43.5) < 100 very good.

SDI (Z-Score) and VIS for the four EQAS cycles from 12/2016-11/2020

Cycle number	Range of SDI	Mean SDI	Variance Index Score VIS
14	**-0.88 to 1.10**	**0.425**	**42.6**
15	**-0.43 to 1.73**	**0.469**	**46.9**
16	**-0.33 to 1.34**	**0.439**	**55.50**
17	**-1.34 to 0.44**	**0.456**	**43.5**







V. Discussion:

EQAS is an important tool to monitor and maintain the laboratory performance output. It is obviously acceptable to have a very close result along this period of cycles because of the test was done to only one analyte (HbA1c), but this is not considered as failure but much stability and consistency in daily and monthly good laboratory practices, following scheduled instrument maintenance.

The SDI and VIS results we get for every month in each cycle were very close to the accepted group of results and they don't need any corrective action. The overall performance of our lab for the study period in terms of mean Z-Score of the HbA1c test for all cycles are acceptable, as far as the OMVIS with an excellent score.

The EQAS program is valuable management tool destined to improve the efficiency and services of a laboratory in particular lab and a hospital in general. The program provides an opportunity to the participating organizations to compare activities and modify their own practices based on what they learn [3][4].

EQAS evaluate the performance of procedure, equipment, materials, personnel and suggests areas for improvement. 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 [5].

VI. Conclusion:

The benefit of applying the EQAS program is to provide reliable information that allows laboratories to assess and monitor the quality status of internal procedures and processes, suitability of the diagnostic systems, accountability and competence of the staff. In addition it provides important role in improving the efficiency of a laboratory service.

We believe that global participation in such an EQAS program will definitely improve the quality of a hospital service because no health care facility can be totally self-sufficient and there is always an inclination for improvement and development in a system [6].

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