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The importance of the Internal Quality Controls in medical laboratories to ensure high quality results

Lhajjam, H[1*]; Azzouzi, H[2]; Sefiani, N[2]; Elmrabet, H[2]; Ihendyane, N[3]

1 Ph.D. Candidate, Faculty of Science and Techniques Tangier, Abdelmalek Essaadi University, Morocco
2 Ph.D. Professor, Faculty of Science and Techniques Tangier, Abdelmalek Essaadi University, Morocco
3 N., Medical Biology Analysis Laboratory Tangier, Morocco.

ABSTRACT

Objective: Internal quality control plays a crucial role in the quality assurance of biological laboratories, ensuring both the monitoring of equipment performance and the reliability of test results. However, the adoption and acceptability strategies for these controls vary from laboratory to laboratory. Improved quality of results based on the standardizing of the internal quality control material selection, target and range assignments, and statistical rules used, validation and troubleshooting methods. The formation of networked laboratories presents additional challenges to internal quality control systems, as robust cross-site programs are required to ensure comparability of results. In this paper, we aim to redefine the foundations of key internal quality control theory, and outline a strategy to simplify the problem detection. We will also attempt to define a set of recommendations to bring internal quality control laboratory practice to the required standard, to ensure high quality laboratory results and thus patient safety.

METHODS: This study focuses on gathering essential laboratory quality controls, and give clear overview for it. It explains the differences between: Quality control, Quality assurance, Accreditation and certification, Different kinds of laboratory tests quality controls, Standard operating procedures.

FINDINGS: To set up an efficient quality system in a medical biology laboratory requires a long implementation phase that includes: Proper training, Planning, Documentation, Organization. This cannot be accomplished without a clear communication. This method may potentially be harmful to the patients if it impedes the results communication owing to misleading IQC rejections. Furthermore, it encourages the laboratories to broaden the coefficients of the variation (CVs) of the control chart follow-up by employing Westgard guidelines for CVs that do not correctly mirror the real dispersion of IQC values. The Sigma index appears to be the solutions as it entails determining the numbers of controls needed, their frequency, and the Westgard rules to be used depending on the performance of each technique and the clinical criteria connected with each parameter.

CONCLUSION: The Sigma index is the most efficient method that involves calculating the number of controls required, and their frequency, while Westgard rules are based on the performance of each technique and their clinical criteria associated. Overall, the quality application must prioritize patient benefit while remaining realistic, practical, and effective. It is critical not to fall into the trap of over-quality, which can be costly, and demotivating and to never lose the sight of what is essential and most important: patient service.

Key words: Quality Control; Medical Laboratory Analysis; Westgard rules; Biology laboratories; Coefficient of variation; Sigma capability index.;

INTRODUCTION

Accurate diagnoses and treatment choices depend on the validity of the data from laboratory testing and analysis. In order to avoid misdiagnosis, ineffective treatment, and inaccurate health reports, it is crucial to ensure the quality and the precision of laboratory data [1, 2]. In order to guarantee that the analytical procedures are exact, accurate, and consistent, internal quality control, or IQC, is an essential part of the laboratory's quality management system [3]. The significance of internal quality control in laboratories is covered in this review article, along with its guiding principles, procedures, and advantages [4, 5]. Internal Quality Control (IQC) is a quality management system that checks the analytical procedures carried out by a lab to guarantee the correctness, the precision, and dependability of lab findings [6].

IQC entails keeping an eye on and recording all analytical procedures carried out in the lab, such as reagent preparation, equipment calibration, and data recording [7]. IQC allows laboratories to detect mistakes and variances in the analytical procedures, accurate and reliable results of the laboratory [8, 9].

The foundation of Internal Quality Control (IQC) is a process of ongoing observation and documenting of the analytical procedures used in laboratories [10]. The IQC procedure include keeping an eye on the analytical techniques' precision and accuracy, as well as the performance of the instruments and reagents [11, 12].

The establishment of Quality Control (QC) measures, which are the samples or materials used to monitor the correctness and precision of the analytical procedures, must also be a part of the IQC process [13, 14].

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The IQC principles guarantee that the laboratory's analytical procedures are exact, accurate, and consistent, avoiding mistakes from showing up in the findings of the laboratory [15].

Establishing Quality Control (QC) measurements, keeping tabs on the analytical procedures, and recording the outcomes are all phases in the Internal Quality Control (IQC) process [16, 17]. The selection of relevant samples or materials to check the accuracy and precision of the analytical procedures is part of the process of establishing QC measures [18]. Analysing the QC metrics alongside the patient samples as part of the analytical process monitoring ensures that the findings are consistent and fall within the laboratory's permitted range[19]. Recording the outcomes of the QC measures and the laboratory's remedial steps when the outcomes are outside of the permitted range are included in the documentation of the findings [20, 21]. Improved accuracy, precision, and consistency of laboratory findings are just a few advantages that the laboratory and its patients can gain through the application of internal quality control (IQC)[22]. IQC lessens the possibility of mistakes and discrepancies in laboratory findings by ensuring that the laboratory's analytical methods are functioning within the acceptable range [23]. A laboratory's entire quality management system may be improved by executing corrective actions and identifying areas for improvement through the use of IQC [24].

A key element of the laboratory's quality management system, internal quality control ensures the consistency, correctness, and reliability of laboratory results. The foundation of IQC is the ongoing observation and documentation of the laboratory's analytical procedures, which includes establishing Quality Control measures, overseeing the procedures, and recording the outcomes [25]. Improved accuracy, precision, and consistency of laboratory findings, a decreased risk of mistakes and variability in laboratory results, and the identification of areas for development are just a few advantages of implementing IQC[26]. In order to improve the quality of patient care and the results of scientific research, laboratories must employ IQC methods to make sure that their analytical techniques are precise and consistent [27].

Objective and scope of this article

To guarantee the accuracy and dependability of laboratory test findings, quality controls in laboratories are essential. Quality control procedures assist to confirm the correctness of test results, find and fix problems, and make sure tools and equipment are working properly [28]. This review article's main goal is to give readers an overview of laboratory quality controls.

The main ideas and definitions of quality controls will be covered in this article, along with the differences between quality control and quality assurance, accreditation and certification, different kinds of laboratory tests and quality controls, and standard operating procedures [29].

Quality control key terms and concept

Quality assurance vs quality control

In laboratory testing, quality control (QC) and quality assurance (QA) are two essential concepts. The system of regular checks and procedures used to guarantee the accuracy and dependability of laboratory results is known as quality control (QC). It entails a number of actions, including as routinely checking reagents and samples, validating procedures, and calibrating instruments[30, 31].

On the other hand, QA refers to a more extensive set of guidelines, protocols, and practices that guarantee the accuracy and dependability of laboratory results. It consists of QC in addition to safeguards for the staff's competence, suitable record-keeping, and continual assessment of the laboratory's overall performance[32-34].

Accreditation and certification

Two essential procedures—accreditation and certification—ensure that testing facilities adhere to a set of standards and specifications. According to ISO (15189), accreditation is a formal declaration made by an accrediting organization that a laboratory satisfies specific requirements for testing proficiency and quality. The process of confirming, on the other hand, that a laboratory satisfies certain standards for a particular type of testing or service is known as certification[35, 36].

In order to give external confirmation of a laboratory's quality and competence, accreditation and certification are crucial. They also give clients and other stakeholders the reassurance that the laboratory is conducting tests in accordance with accepted industry standards[37].

Lab testing and quality assurance measures

Diagnostic, screening, and monitoring tests are the three broad categories into which laboratory tests can be divided. While screening tests are designed to identify the existence of a certain ailment in a population, diagnostic tests are used to confirm or rule out a specific diagnosis. Monitoring tests are used to monitor a condition's development or therapy [38].

Different quality controls are needed for various kinds of laboratory testing. For instance, because the findings of diagnostic tests are frequently used to inform treatment decisions, more stringent QC techniques may be necessary for diagnostic testing than for screening tests [39, 40].

Standardized practices and procedures

Are written instructions that specify how certain laboratory tasks need to be carried out. Because they give laboratory employees specific instructions and rules to follow, SOPs (Standard Operating Protocols) are a crucial component of laboratory quality management [41]. SOPs can aid in standardizing lab procedures, minimizing mistakes, and guaranteeing that testing is carried out regularly and properly [42]. SOPs have to be created in accordance with industry standards, legal regulations, and the unique requirements and conditions of the laboratory. To make sure they stay current and pertinent, they should be examined and updated frequently [43].

In conclusion, achieving accurate and dependable testing requires an awareness of fundamental concepts and terminologies in laboratory quality control. Important elements of laboratory quality management include quality control and assurance,

accreditation and certification, different kinds of laboratory testing, and standard operating procedures. Following these guidelines can assist to guarantee accurate, dependable, and consistent laboratory findings, which can eventually enhance patient outcomes [44].

The importance of the IQC:

Why introduce internal quality controls in laboratories?

The implementation of laboratory controls is essential to guarantee the quality and reliability of the results obtained. Controls are used to detect and correct errors or variations in the analytical process, whether related to instruments, reagents or the operator [45]. The controls also ensure the traceability of results and verify that the laboratory's performance is in accordance with established norms and standards. Finally, the controls allow us to guarantee the safety of the personnel by presenting the risks of contamination and by ensuring adequate handling of the samples [46].Therefore, any error in the test results can have serious consequences for the health of patients.

IQC minimizes sources of error and ensures that product analysis results are reliable and accurate[47, 48]. Medical laboratories implement defined internal quality control procedures, including regular calibration of instruments, verification tests, quality controls, verification of the accuracy and reliability of analysis techniques, and regular internal audits [49]. These procedures ensure that analytical instruments and techniques are properly calibrated and that analytical results are consistent and reproducible.

IQC also allows for early detection of errors and deviations from written standards, allowing for rapid correction and quality assurance of product analysis results. In the event of non-compliance, medical laboratories can implement corrective actions to prevent the error from occurring in the future [50, 51].

The main concepts of the IQC

Loyalty:

The concept of accuracy is essential in medical laboratories, as it is directly linked to the precision and reliability of the analysis results. Fidelity can be defined as the ability of an analytical method to produce consistent and reproducible results for the same measurement performed multiple times on the same sample [52, 53].

To measure the precision of an analytical method, medical laboratories can use indicators such as the coefficient of variation (CV), which is the ratio between the standard deviation and the average of the analytical results for the same sample analyzed several times. The lower the CV, the more reliable and accurate the method is considered to be [54].

There are several sources of error that can affect the fidelity of analytical results, such as sample preparation errors, instrument calibration errors, measurement errors, and transcription errors in the results [55]. To minimize these sources of error, medical laboratories can implement defined internal quality control procedures, including regular instrument calibrations, verification tests, quality controls, checks on the accuracy and reliability of analytical techniques, and regular internal audits[56] [57]. The concept of fidelity ensures that results are consistent and reproducible, which is crucial to ensure optimal patient care. Laboratories should have defined internal quality control procedures in place to minimize sources of error and ensure the fidelity of test results[58].

Correctness:

The concept of accuracy is one of the essential characteristics of internal quality control (IQC) in medical laboratories [59]. Trueness is defined as the ability of a test to produce results that are close to the true value of the measurement or concentration of the biological parameter being measured [60]. In medical biology laboratories, the accuracy is attributed through the performance of verification tests or realization with reference methods[61]. These tests are consistent with analyzing known samples with the methods used by the laboratory and with a reference method, considered the most reliable and accurate method of measurement. The results obtained are then compared to evaluate the accuracy of the methods used by the laboratory [62].

The objective of the trueness assessment is to ensure that the results by the laboratory methods are reliable and close to the true value of the measurement [63]. If the results are not close enough to the true value, this may indicate a systematic bias in the analysis method. Systematic biases may be due to instrument calibration errors, sample preparation errors, or analytical protocol errors [64]. Detection and correction of these biases is essential to ensure the quality and reliability of the results by the laboratory.

In summary, the concept of accuracy is an essential component of internal quality control in medical laboratories. Accuracy assessment ensures that the results of the laboratory methods are reliable and close to the true value of the measurement. This evaluation is crucial to detect and correct systematic biases in analytical methods, ensure the quality of the results produced and guarantee the safety and optimal management of patients [65].

Total error:

The notion of total error is an important concept in the internal quality control of medical laboratories [66]. The total error is the sum of the random and systematic errors that can occur when measuring a biological parameter in a sample [67]. Random errors are due to random variations in the measurements, which may be caused by fluctuations in the sample, in the instrument used, or in the analysis process. Systematic errors, on the other hand, are errors that occur consistently and repeatedly in the analysis process.

These errors may be due to incorrect instrument calibration, interference with other substances in the sample, or other factors [68]. The total error is designated using known quality control samples, which are analyzed in parallel with the test. By comparing the test results with the results of quality control samples, random and systematic errors can be diffused and quantified[69].The concept of total error is important because it helps determine the reliability and accuracy of product results by the analytical methods used by the laboratory. If the total error is too high, it may indicate a problem with the analytical method or with the instruments used, which may compromise the quality and accuracy of the results produced [70].

It is therefore crucial that medical laboratories continuously monitor the total error of their analytical methods, using quality control samples and implementing rigorous internal quality control protocols. This ensures that the laboratory results are reliable and accurate, which is essential to ensure optimal patient care and avoid negative health consequences.

Quality controls in laboratories: challenges and limitations

To guarantee the accuracy and dependability of laboratory test findings, quality control methods are crucial [71]. Nevertheless, establishing quality controls in laboratories is fraught with difficulties and restrictions [72].

Time and Cost Restraints

The cost and time restrictions involved with putting quality control measures into place are one of the biggest problems with quality control in laboratories [73]. To ensure quality, laboratories may need to spend a lot of money on tools, chemicals, and other supplies. Furthermore, performing quality control tests might take time, which could prevent the release of test findings [74].

Staff Training and Expertise

Another challenge is ensuring that laboratory staff are adequately trained and have the necessary expertise to conduct quality control tests. Staff members must be trained on the correct use of equipment and procedures for quality control testing to ensure accurate results. However, staff turnover and inadequate training can lead to errors and inaccuracies in test results [75].

Laboratory to Laboratory Variability

Another issue with quality control in laboratories is inter-laboratory variability [76].Different laboratories may provide different test results due to variances in their equipment, protocols, and personnel competence [77]. This can be particularly difficult when comparing data from several laboratories or multi-center investigations [78].

Technology development and new testing techniques

Implementing quality control measures in laboratories is difficult due to the quick speed of technological progress and the creation of new testing procedures [79]. To ensure the accuracy and dependability of test findings, laboratories may need to establish new quality control protocols as traditional quality control techniques may not be relevant to new testing methodology [80].

In spite of these difficulties, quality control procedures are essential for guaranteeing the dependability and accuracy of laboratory test findings. By addressing these issues and constraints, laboratories may enhance the quality of their services and support improved patient outcomes. This can be done by continuing to invest in employee training, technology developments, and new quality control techniques [81].

Managing the implementation of iqc in the laboratory

How to choose samples

It is important to choose the most effective control method, and take into consideration the effect of the sample matrix to ensure the reliability of test results when establishing an internal IQC quality control system in a medical laboratory [82, 83]. In fact, two types of internal controls can be used: titrated controls and un-titrated controls. A titration control, also known as a calibration quality control, is a sample with a known and stable concentration of the analyte of interest. These controls verify the accuracy of the test by comparing the measured concentration of the assay to the actual concentration [84]. The choice between titrated and un-titrated controls depends on several factors, including assay sensitivity and specificity, assay complexity, cost, and control availability.

Tests with low sensitivity or a narrow concentration range may require the use of titration controls to ensure maximum accuracy. Tests with a wider concentration range can use untested controls to monitor the accuracy of the results [85]. The choice between titrated and un-titrated controls depends on the characteristics of the test and the goals of the laboratory. Titrated controls allow high accuracy but are predictable, while un-titrated controls are usually cheaper and easier to use but do not allow accurate quantification of analyte concentrations.

In order to minimize the influence of matrix effects on the analysis results, the control samples used should preferably be as close as possible to real biological samples. To do this, laboratories must work with their analyzer and control sample suppliers to develop specifications.

These specifications should identify substances that may cause matrix interferences and indicate the properties that control samples must exhibit to meet the laboratory's analytical requirements [86].

Quality control samples of various types

Quality control samples of various types can be used in managing IQC. For instance, kit controls are important for quality control samples. This is an internal quality control method used in medical laboratories results [87]. Control samples provided by the test kit manufacturer were used to evaluate the performance of the test kit. These control samples undergo the same analytical process as the patient biological samples, using the same methods and reagents as the biological samples [88]. Suite validation verifies that the test suite is working properly and providing reliable and accurate results.

Supplier dependency/independence control of reagents is also useful. Reagent Analyzer dependent control means an internal quality control provided by a test kit supplier for use with a test kit on an analyzer supplied by the same supplier. This type of internal quality control is often used to evaluate the performance of the pair of reagent analyzers under specific conditions such as calibration, test and incubation conditions, and is considered an important part of the internal quality control process in medical laboratories [89].

Independent supplier controls for reagent analyzer pairs are internal quality control materials not supplied by the analyzer or reagent manufacturers. It is designed and manufactured by a third party and can be used to evaluate the performance of any type of analyzer or reagent, independent of the vendor [90].

Biological cell control is another internal quality control method used in medical laboratories. This involves preparing sample mixtures that reflect the different values expected for a particular analysis. This mixture, called a pool, is then used as a control sample to assess the accuracy and precision of the results obtained by the laboratory for that particular analysis [91]. Due to the potential for contamination, it is important to use the same precautions when handling control samples as you would for patient samples [92]. Control sample handling and storage procedures must be clearly defined and followed to ensure the integrity and reliability of control results. It is recommended that laboratories do not rely solely on control samples provided with the kit, but also use independent controls [93].

The concept of series in laboratory quality control is also use, this concept refers to a set of internal quality control samples that are tested concurrently with patient samples. The series may contain several internal quality control samples of varying concentration or reactivity to ensure reliable and reproducible results. Testing frequency refers to the frequency with which internal quality control samples are tested to verify test performance [94]. This is a period of time when laboratories use both old test methods and new methods to assess the consistency of results and ensure the validity of the new method before abandoning the old method entirely. Each lab sets a target value that represents the average of the values determined during the trial period. This value is used as a reference for the control chart [95].

When using control samples, adjust the target value if necessary. Justify any adjustments by examining potential sources of variation, e.g. B. Calibration, reagent lot changes, maintenance. Selecting alert and action thresholds is an important step in implementing a laboratory quality control system. An alert threshold is a defined cutoff value for control samples, exceeding which indicates a potential problem during the analysis. The action level is the less critical value that, if exceeded, indicates that corrective action is required to avoid compromising the quality of patient outcomes. Alert and action levels should be determined based on results obtained during the trial period and the laboratory's performance history. They should be reassessed periodically to ensure they remain appropriate for the laboratory's current circumstances [96].

Strategy for exploiting ICQ results

Levey-Jennings representation

The Levey-Jennings representation is a graphical tool used in pharmaceutical biology to track the quality of biological test results over time [97]. It is a two-dimensional graph with test results on the y-axis and time on the x-axis. The results of the quality control are then entered into the graph as points or lines (Figure 1). Under conditions where the analytical method is stable, it is important for the laboratory to determine the mean and standard deviation or coefficient of variation for each control sample [98, 99]. This allows to account for changes due to new calibrations or new reagent batches, so that standard deviations are not underestimated and too many points are not rejected [100].If a new batch of control is used, it is recommended to repeat the coefficient of variation (CV) from the previous batch, unless the concentration levels are different. In this case, during the trial period it is only necessary to determine the average value of the new test batch[101].

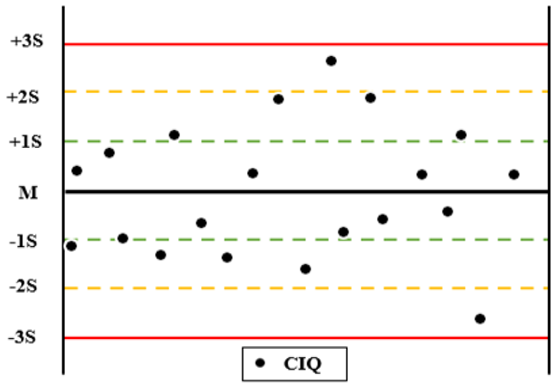

Fig. 1: *Example of a control chart with the actual coefficient of variation*

Follow-up on IQC s with established CVs

Internal quality control (IQC) monitoring using an established coefficient of variation (CV) is a common practice in medical analytical laboratories, eg B. CVs are set and sometimes mean values are set. The method involves setting upper and lower limits of acceptable deviation for each DIC based on laboratory history. The results of each new IQC are compared against these limits to identify significant deviations and take appropriate corrective action [102].

The advantage of this method is that it is easy to use and allows for quick and easy interpretation of results. However, possible systematic bias or bias in the analytical methods was not considered. Therefore, it is important to combine this method with other tools for interpreting DIA results, such as B. control charts and Westgard's rules to better assess the quality of the analysis results. (Figure 2)

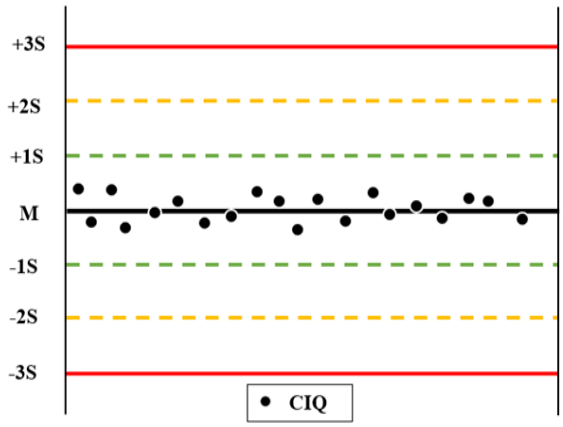

Fig. 2: *Example of a control chart with the coefficient of variation set.*

Statistical exploitation of data from the Levey-Jennnings representation

Statistical evaluation of Levey-Jennings plot data is a key step in the analysis of quality control data in the field of medical biology. It involves using the information contained in the control charts to evaluate the performance of the analytical method and detect any anomalies that may affect the quality of the results [103].

Levey-Jennings control charts are widely used in medical laboratories to assess the quality of results of analytical methods. It allows to visualize the distribution of results obtained for each control level and to quickly identify significant deviations in the results [104]. In general, assay results follow a normal distribution, meaning that most values are around the mean, and the probability of finding values far from the mean decreases rapidly as you move away from the mean [105]. So, statistically, when an analytical process is in control, 68% of QC values are within one standard deviation (standard deviation), 95.5% of values are within two standard deviations, and 99.7% of all values are on either side of the mean within three standard deviations [106].

The first step in the process is to assess the stability of the analytical method by determining the mean and standard deviation of the control points obtained over a period of time. If the analytical method is stable, it is assumed that the mean and standard deviation calculated from these values remain constant over the period [107].This information can then be used to define upper and lower control limits to detect any significant deviations in the results obtained by the analytical method. These limits are usually defined as the mean of the standard deviation +/- 2 or 3, depending on the Westgard rule used [108, 109].

Once the control limits are defined, a Levey-Jennings chart can be generated and the results tracked periodically. If a point falls outside the control limits, it indicates a significant difference in the results and the analytical method should be reviewed to determine the cause of the difference. Furthermore, it is important to consider trends and biases that also affect the quality of the results. This can be done by drawing a trendline on the control chart to see if the results tend to increase or decrease over time. It is also recommended to use external quality control to confirm the stability of the analytical method [110].

In short, statistical evaluation of data represented by Levey-Jennings is a critical step in ensuring the quality and reliability of medical biology results. It enables you to quickly identify any significant deviations in results and take corrective action to minimize errors and improve result quality [111].

Westgard rules

Westgard rules are a commonly used quality control method in medical laboratories to monitor the quality of analytical results [112]. The Westgard rule provides an objective way to assess the technical quality of a set of analyzes by examining the statistical distribution of values obtained from control samples. These rules represent a decision criterion for determining whether an analysis series is in control or not based on defined control limits.

It is important to note that these rules apply only to coefficients of variation (CVs) that represent the actual observed variation in the analytical parameters. Westgard rules are expressed by notation, where the first part represents an abbreviation for the statistical parameter or quantity of control value, and the second part, usually written as an index, represents the control limit[113, 114].

Warning rules:

12S rule: refers to the control rule commonly used on the Levey-Jennings diagram when the control limit is defined as the mean ± 2s. This rule is used as an alert rule to trigger a thorough check of the control data via the deny rule below (Figure 3).

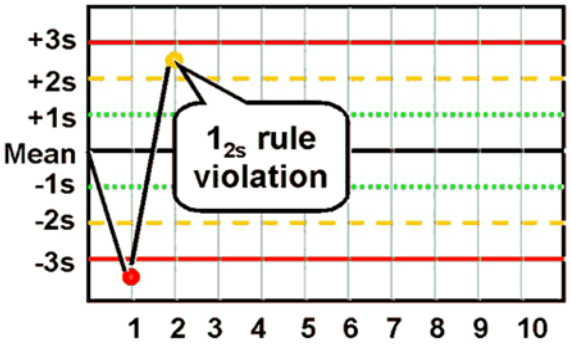

Fig. 3: 12S 1-point rule beyond 2 ET.

Deny rule:

- Rule 13S: A control point is rejected if its value is greater than or less than three times the standard deviation (±SD) of the mean (figure below).

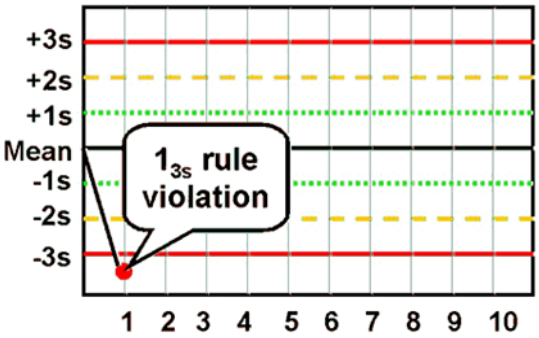

Fig. 4: *Rule 13S 1 point beyond 3 ET*

- Rule 22S: If consecutive control points at the same control level consider the same limit at -2 SD or +2 and, or if two points at two different control levels consider the same limit at -2 AND or +2 AND, then deny they must be rejected. This rule can be applied within runs and between runs to detect errors or deviations in the analysis process.

- RuleR4S: Reject if one set of four consecutive control points exceeds the +2 second average and the other exceeds the -2 second average.

- Rule 41S: Reject a set of four consecutive control points if their standard deviation is greater than a multiple of the standard deviation (SD) of the mean.

- 10X rule: A control point will be rejected if it is 10 times above the mean and on the same side of the mean [115].

How to choose the right test procedure (number of test values and westgard rule(s)

In paragraph 5.6.2.1 of the ISO 15189 2012 edition requires laboratories to implement internal quality control procedures to ensure that the results obtained are of the specified quality. In medical biology, the expected quality of results must meet clinical requirements and needs [116, 117].

The choice of control method must be adapted to the analytical performance of the method used [118] and the clinical requirements of the analytical parameters, including the number of values and the choice of rules. Therefore, it is important not to use the same control method for all analyzes [119]. The analytical power of an assay can be assessed using the Sigma capability index, which is calculated as: (TAE% - B%)/CV%. The index compares the assay's analytical performance (expressed as true bias (B) and average precision coefficient of variation (CV)) to available clinical requirements or total acceptable error (TAE) derived from biological data. Ricos database of parameters under consideration. For example, the sigma capability index is very high for parameters with wide reference intervals determined by biological variation and low measurement uncertainties related to analytical performance [120].On the other hand, for parameters with poor analytical performance and narrow reference intervals, the Sigma capability index decreases.

In order to meet the clinical needs, the internal quality control (IQC) strategy must consider the Sigma capability index of the parameter, and the lower the more specified. Parameters with high sigma indices will receive "light" IQC, which will reduce false rejections compared to strategies that control all analyzes in the same way. In practice, by applying a limited number (3 or 4) of different internal quality control (IQC) strategies, it is possible to cover all assays routinely tested in medical biology laboratories [121]. The 2010 expert meeting made recommendations for this purpose[122, 123].

When Sigma > 6: performance is considered excellent. In this case, a single rule, the 13.5s rule, should be applied to interpret the results, and quality control performed once a day. A possible strategy in this case is Level 1 Quality Control (QC) for patients, with the 13.5s rule activated.

When Sigma is between 6 and 4: performance is adapted as fit for purpose. In this case, two levels of quality control should be applied once a day, with interpretation of results based on a single rule, the 12.5s rule. One possible strategy for achieving these objectives is to use Level 1 Quality Control (QC) for patients combined with Level 2 QC, with the 12.5s rule activated.

When Sigma is between 4 and 3: performance is limited as poor. In this case, two levels of QC must be applied twice a day, with interpretation of results based on several rules, including rules 13s, 22s, R4s and 41s. One possible strategy for achieving these objectives is to use Level 1 and 2 Quality Control (QC) for patients, combined with Level 1 and 2 QC, with rules 13s, 22s, R4s and 41s activated.

When the Sigma index is less than 3: this indicates inadequate parameter performance. It is then recommended to use a more applied internal quality control (IQC) strategy, using three levels of control, performed three times a day, with interpretation of the results based on as many rules as possible. In this case, it may also be necessary to assay duplicate patient samples. An example of an appropriate IQC strategy would be the combination of QC Levels 1+2+3 for control levels and QC Levels 1+2+3 for patients, with activation of rules 13s, 22s, R4s and 41s.

As a general rule, most medical analyzes fall into the first two performance categories where lean control procedures are sufficient (Sigma > 6 and 4 < Sigma < 6) [124], resulting in very low false rejection rates.

Therefore, if a medical laboratory has decided on an appropriate control strategy based on the Sigma capability index, only changes in analytical behavior that have clinical impact will be identified. On the other hand, if the laboratory uses a uniform control procedure for all parameters regardless of the sigma index, such as 13s/22s/R4s/10x, the false rejection rate can be higher.

Using a single control method for all parameters means reporting all changes in analytical behavior, even those that do not have clinically significant effects on patients [125]. This practice forces laboratories to adopt two solutions: either widen their control limits to reduce false rejections, or set analytical and clinical targets that allow patient results to be published when adjusted to control limits (however, violations of Westgard rules need to be considered retroactively), including the lack of impact assessment in cases where spurious rejections are detected. The structure of the control chart makes it possible to define alert and action thresholds, target values and control frequencies according to the analytical performance of the laboratory and the recommendations of regulatory and standardization bodies [126].

Conclusion

Setting up an effective quality system in a medical biology laboratory requires a substantial implementation period, involving adequate training of staff members, preparation of specific documents and organization of meetings. This implementation process cannot be achieved without thorough communication both within the laboratory and with the associated clinical departments.

If the strategy for running and interpreting internal quality controls is uniform for all parameters, this can lead to a considerable number of potential problems within the laboratory, likely to block day-to-day operations. This approach can be laborious and costly for laboratories, which have to learn how to juggle re-runs with clinical analytical objectives.This approach can even be detrimental to patients if it hinders the communication of results due to false IQC rejections. In addition, it leads laboratories to widen the coefficients of variation (CVs) of control chart follow-up, using Westgard rules for CVs that do not faithfully retrograde the true dispersion of IQC values. A more efficient approach is to use the Sigma index.

This strategy involves selecting the number of controls required, their frequency and the Westgard rules to be applied, based on the performance of each technique and the clinical requirements associated with each parameter.Despite its simplicity and effectiveness, the Sigma index strategy remains little-known among laboratories, which could nevertheless benefit greatly from it. In general, only 3 or 4 strategies are sufficient to cover all parameters and enable rapid detection of over 90% of problems, while limiting the rate of false rejections. Quality must first and foremost be geared to patient benefit, while remaining realistic, practical and effective. It is crucial not to fall into the trap of over-quality, which can be costly, demotivating and often harmful, and never to lose sight of what is essential and most important: service to the patient.

CONFLICT OF INTEREST

The author declares that there is no conflict of interests regarding the publication of this manuscript. In addition, the ethical issues, including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, and redundancy have been completely observed by the authors.

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CORRESPONDING AUTHOR

Lhajjam, H
lhajjamhajar@gmail.com