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The Effectiveness of Laboratory Quality Control Practices in Reducing Analytical Errors in Clinical Chemistry Testing

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ABSTRACT: Laboratory quality control (QC) practices form the backbone of reliable clinical chemistry testing, where analytical errors can directly compromise patient safety

and clinical decision-making. Systematic implementation of internal quality control—including the routine use of control materials, statistical process control rules such as Westgard multirules, and Levey-Jennings charting—enables laboratories to detect random and systematic errors before results are released. When paired with external quality assessment (EQA) or proficiency testing schemes, these internal measures create a layered defense that identifies both within-laboratory drift and inter-laboratory bias. Evidence consistently demonstrates that laboratories adhering to structured QC protocols report significantly lower rates of analytical error, fewer rejected or repeated specimens, and improved concordance with reference methods compared with those relying on ad hoc verification.The effectiveness of QC practices, however, depends heavily on proper design, execution, and staff competency. Inadequate control frequency, inappropriate selection of control materials, poor troubleshooting of out-of-control events, and failure to document corrective actions can undermine even well-intentioned programs. Automation and laboratory information systems have strengthened QC by enabling real-time monitoring, trend analysis, and automated rule violation alerts that reduce human oversight. Ultimately, the largest reductions in analytical error are observed when QC is embedded within a broader quality management system aligned with ISO 15189 accreditation standards, incorporating continuous staff training, method validation, calibration verification, and root cause analysis of nonconformities. Thus, quality control practices are demonstrably effective in reducing analytical errors, but their impact scales with the rigor, consistency, and organizational commitment behind their implementation.

INTRODUCTION

Clinical chemistry testing occupies a central position in modern medical decision-making, supplying the quantitative data upon which diagnosis, treatment monitoring, and prognostic assessment depend. The analytical phase of the total testing process—the segment in which the specimen is actually measured on an analytical platform—has historically been the primary target of laboratory quality control (QC) efforts, precisely because it is the phase over which the laboratory exercises the most direct technical control. Comprehensive quality management systems that combine internal quality control, external quality assessment, statistically defined control rules, risk-based scheduling, accreditation against ISO 15189, and automation-supported verification have been shown to improve analytical accuracy, precision, and consistency while minimizing analytical errors [1]. The statistical foundations of this work are well established: QC procedures rely on repeated measurement of materials with known analyte concentrations and on formal rules that determine whether a run should be accepted or rejected [2]. With full automation of contemporary clinical chemistry analysers, only 7 to 13% of laboratory errors are estimated to occur during the analytical phase [3]. Risk-based QC planning has therefore been proposed as a way of matching control intensity to the actual clinical and analytical risk associated with each assay [4]. The evaluation of QC effectiveness also requires measurable quality indicators that link analytical performance to patient safety and to the broader governance of the laboratory [5]. At the same time, the economic dimension cannot be ignored, because quality assurance testing represents a substantial proportion of the clinical laboratory budget and must be balanced against the cost of failing to detect medically important analytical errors [6].

The central question addressed in this article is therefore not whether analytical errors are numerically dominant within the total testing process—they are not—but whether the quality control practices deployed in clinical chemistry laboratories are genuinely effective in detecting, reducing, and preventing them. The evidence assembled over the past three decades supports a qualified affirmative answer. Analytical performance has improved substantially in many laboratories, and sigma metrics have provided a quantitative language for describing method capability and for selecting QC rules that are proportionate to analytical performance [7]. The classical distinction between random error, which affects reproducibility, and systematic error, which affects bias, remains fundamental to the design of control procedures [8]. Integrated quality management systems have further strengthened this improvement by combining statistical control, external assessment, and structured corrective action [9]. Analytical performance specifications provide a critical benchmark for this process, as the choice of allowable total error directly determines whether a method is classified as capable or incapable, and therefore influences the intensity of QC that is required [10].

The Nature and Distribution of Analytical Errors in Clinical Chemistry

Any meaningful assessment of QC effectiveness must begin with a clear conceptualization of what an analytical error is and how it differs from errors arising elsewhere in the testing pathway. Laboratory QC procedures are designed to ensure that tests are performed within limits established during assay validation, and they rely on the repeated measurement of materials with known analyte concentrations to detect conditions under which patient results may be inaccurate [11]. The distribution of errors across the total testing process provides essential context for evaluating what analytical QC can realistically achieve. A substantial body of evidence indicates that most laboratory errors occur in the pre-analytical phase, with reported proportions ranging from 46% to 68.2% of total errors, while the post-analytical phase accounts for a further 18.5% to 47% [3]. More recent investigations have reported pre-analytical error proportions of approximately 63.6% to 64.1%, with post-analytical errors comprising roughly 27.6% to 34.8% and analytical errors constituting a minority share [12]. The broader quality management literature reinforces this point: improvement in analytical performance is most durable when it is supported by structured quality systems rather than by isolated technical fixes [13]. Sigma metrics add a further layer of interpretation by showing that analytical performance varies widely across measurands and that some assays remain far from six-sigma capability even in modern laboratories [7].

Table 1. Distribution of Laboratory Errors Across the Total Testing Process

Phase	Reported proportion of total errors	Principal error types	Representative sources
Pre-analytical	46%–68.2%; approximately 63.6%–64.1% in more recent studies	Misidentification, sample rejection, haemolysis, inappropriate tube filling, timing errors	[3][12]
Analytical	Minority share; historically reduced through QC, though interference remains a concern particularly for immunoassays	Random imprecision, systematic bias, calibration failure, reagent degradation, instrument malfunction	[11][2]
Post-analytical	18.5%–47%; approximately 27.6%–34.8% in recent studies	Data transfer errors, incorrect reports, delayed turnaround, communication failure	[3][12]

This distribution has an important implication for the evaluation of QC effectiveness. If analytical errors constitute a minority of all laboratory errors, then even a perfectly effective analytical QC system cannot eliminate the majority of errors that compromise patient safety. The effectiveness of laboratory QC practices must therefore be judged primarily by their capacity to detect and correct errors within the analytical phase itself, and secondarily by their contribution to a broader quality management architecture that addresses the interfaces between phases. The contemporary consensus, reflected in the reviewed literature, is that analytical QC is a necessary but insufficient condition for diagnostic reliability, and that its effectiveness is maximized when embedded within an integrated quality management system [9].

Internal Quality Control: Statistical Foundations and Operational Practice

Internal quality control constitutes the operational core of analytical quality assurance in clinical chemistry. It involves the daily analysis of control materials with known target values alongside patient specimens, followed by the statistical comparison of observed control results against established acceptance limits. The quality management literature stresses that QC is not simply a technical ritual but an assessment process that must be planned, documented, and reviewed within a coherent laboratory quality system [9]. The ISO 15189:2022 standard mandates that each laboratory establish and provide its staff with an IQC procedure specifying the frequency of testing and acceptable thresholds, both of which must be defined according to the robustness of the method used [12]. The Levey-Jennings chart remains the most widely used graphical tool for this purpose: control values are plotted over time against a mean and standard deviation, allowing laboratory staff to visualize random scatter, shifts in the mean, and trends that may indicate developing analytical problems [14]. The effectiveness of IQC is also influenced by the quality of the control materials themselves. A systematic review and meta-analysis comparing pooled serum with commercial serum IQC materials found that pooled serum performed better in clinical biochemistry laboratories and exhibited more stable biochemical characteristics [15].

A further dimension of IQC effectiveness concerns the frequency and scheduling of control measurements. Traditional fixed-interval QC schedules apply the same frequency of control testing irrespective of the performance characteristics of the assay or the clinical risk associated with the analyte. This approach may lead to over-control of stable, high-performance assays and under-control of high-risk analytes with poorer analytical capability [4]. Risk-based QC planning, which integrates sigma metrics, failure mode and effects analysis, and patient-based moving average monitoring, has been proposed as a more rational alternative [16]. ISO 15189:2022 explicitly mandates a risk-based quality approach, and a six-step IQC plan model based on process failure mode and effects analysis across pre-analytical, intra-analytical, and post-analytical phases has been described in the literature as a means of harmonizing IQC with both IFCC recommendations and accreditation requirements [16]. The effectiveness of IQC is therefore not simply a function of performing control measurements; it is a function of performing the right measurements at the right frequency with the right decision rules and against the correct analytical performance specifications [10].

Westgard Multirule Procedures: Balancing Error Detection and False Rejection

The statistical rules used to interpret control results determine whether a QC system achieves its twin objectives of detecting genuine analytical errors while avoiding unnecessary rejection of valid patient runs. The multirule algorithms developed by Westgard and colleagues combine several control rules—such as two consecutive control observations outside warning limits, a single control observation outside action limits, or moving average trend analysis—to achieve favourable statistical error detection characteristics [2]. In the Westgard multirule framework, the 1-2S rule functions as a warning rule rather than an out-of-control rule, triggering inspection of additional rules before a run is rejected [11]. The selection of appropriate Westgard rules is intimately linked to the performance capability of the analytical method, which is where sigma metrics become relevant [7]. A comparative review of Westgard rules and sigma metrics has noted that the two frameworks are frequently treated as competing approaches, yet they are in fact complementary: Westgard rules provide real-time error detection, while sigma metrics provide the prospective performance assessment that determines which rules should be applied [17]. The effectiveness of multirule QC is therefore conditional on its appropriate customization to the analytical performance of each assay, rather than on the blanket application of a fixed rule set [17].

Sigma Metrics and Risk-Based QC Scheduling

The Six Sigma methodology has emerged as a central framework for quantifying analytical performance and for designing QC strategies that are proportionate to method capability [18]. Sigma metrics provide a standardized measure of process capability that reflects the number of standard deviations that fit between the method mean and the nearest specification limit, taking into account both bias and imprecision [7]. Empirical studies of sigma performance in clinical chemistry laboratories reveal considerable heterogeneity across analytes [8]. A separate study of 28 analytes on a Roche Cobas pure analyser reported that sigma metrics, combined with the normalized operational specification chart, supported both the detection of false rejection and the identification of true analytical error [17]. The practical value of sigma metrics lies less in the numerical score itself than in the decisions it informs. Risk-based IQC scheduling that incorporates sigma metrics, failure mode and effects analysis-derived risk priority numbers, and patient-based moving average monitoring has been shown in a prospective real-world comparison to reduce QC events by 44% and overall QC-related costs by 45.3%, while increasing the detection of clinically significant errors by 37% [4]. Patient-based real-time quality control using moving averages and exponentially weighted moving averages offers the prospect of continuous bias detection between scheduled QC events and is increasingly regarded as a complementary component of risk-based planning [19].

Table 2. Representative Sigma Performance of Clinical Chemistry Analytes and QC Implications

Performance category	Sigma range	Interpretation	Suggested QC implication
World-class	≥ 6	Near-error-free performance; approximately 3.4 defects per million	Less stringent rules and reduced QC frequency may be adequate
Good to marginal	3–6	Detectable risk of clinically significant error	Multirule Westgard procedures with sigma-appropriate rule selection
Poor	< 3	Unacceptable analytical performance; high risk of erroneous results	Intensive QC, root-cause analysis, method improvement or replacement

Sources: [8][7][17].

External Quality Assessment and Proficiency Testing

Whereas internal QC monitors day-to-day analytical stability, external quality assessment provides an external, retrospective evaluation of a laboratory's analytical performance against peers or against an accuracy-based reference system [20]. External quality assessment enables an individual laboratory to assess its own performance within its method and to evaluate between-method variability, thereby identifying systematic biases that internal QC, referenced only to the laboratory's own established mean, may fail to detect. Empirical evidence supports the effectiveness of proficiency testing as an error-reduction and quality-improvement tool [21]. The integration of external assessment with internal QC and quality indicators produces a more robust quality system than any single component in isolation. The IFCC Working Group on Laboratory Errors and Patient Safety has recommended an essential quality indicators panel that includes the rate of unacceptable results in external quality assessment or proficiency testing as a core indicator, alongside indicators of misidentification, sample rejection, haemolysis, turnaround time, and incorrect reports [22]. This endorsement reflects a broad consensus that external assessment performance is not merely an accreditation formality but a direct measure of the effectiveness of the laboratory's analytical quality assurance [22].

Cost-Effectiveness and Patient Safety Impact

The case for laboratory QC practices rests ultimately on their capacity to prevent patient harm and to avoid the downstream costs of erroneous results. Laboratory mistakes have been shown to be associated with further inappropriate investigations in 19% of affected patients and with inappropriate care or inappropriate modification of therapy in 6.4% of affected patients, resulting in unjustifiable increases in costs [23]. The cost-effectiveness of QC itself has been formally modelled. Quality assurance testing represents a substantial proportion of the clinical laboratory budget, and cost-effectiveness models have been developed to determine how much QC is enough, balancing the cost of control procedures against the cost of failing to detect medically important analytical errors [6]. Risk-based IQC has been shown to reduce QC-related costs by 45.3% while simultaneously improving error detection, demonstrating that greater QC intensity is not invariably more costly and that intelligent scheduling can improve both quality and efficiency [4]. The effectiveness of QC practices is therefore not in tension with fiscal responsibility; appropriately designed QC is a cost-saving investment in diagnostic reliability [4].

Automation, Autoverification, and Human Factors

The effectiveness of analytical QC is mediated by the technological and human systems within which it operates. Automation has transformed clinical chemistry by reducing manual handling, improving throughput, and standardizing analytical conditions, but it has also created new dependencies on software logic, data transfer integrity, and instrument maintenance [24]. Autoverification is a post-analytical application of computer-based algorithmic rules that directs the release of laboratory results without manual review when predefined criteria are met [24]. Human factors remain equally consequential. Inadequate training of staff, communication problems, excessive workload, and insufficient orientation for new employees have all been identified as contributors to laboratory error [13]. By providing adequate training to all laboratory personnel regularly, it is possible to significantly reduce laboratory errors and improve quality indicators. Automation and human competence are therefore not substitutes but complements: automation reduces the opportunity for certain classes of manual error, while trained staff are essential for interpreting QC data, recognizing atypical patterns, and making the judgment calls that algorithms cannot reliably make [13].

ISO 15189 Accreditation and Quality Indicators

Accreditation against ISO 15189 has become the principal institutional mechanism through which QC practices are standardized, documented, and externally verified [16]. The reviewed literature indicates that adoption of ISO 15189 standards, together with Six Sigma metrics, standardized quality indicators, and automation, strengthens quality assurance by improving workflow efficiency and supporting continuous quality improvement [1]. Accreditation alone, however, does not guarantee the elimination of analytical error, and the literature is careful to distinguish between compliance and effectiveness. Studies of nonconformities in accredited laboratories demonstrate that even laboratories with well-established procedures continue to experience difficulty in meeting ISO 15189's administrative and system-level criteria [12]. Quality indicators provide the quantitative infrastructure for this dynamic system [22]. Although several of these indicators address pre- and post-analytical phases, the inclusion of unacceptable external assessment results as a core indicator explicitly links external analytical performance to patient safety outcomes [22].

Limitations and Persistent Challenges

Despite the strong evidence base supporting the effectiveness of analytical QC, several limitations and challenges persist. First, the dominance of pre-analytical errors means that even optimal analytical QC leaves the majority of laboratory errors unaddressed; total quality requires equivalent attention to specimen collection, transport, identification, and reporting [3]. Second, resource constraints in low- and middle-income settings limit access to commercial control materials, sophisticated analysers, and trained staff, although pooled serum IQC offers partial mitigation and has been shown in meta-analysis to perform better than commercial IQC [15]. Third, the application of sigma metrics is sensitive to the choice of allowable total error specification; the transition from historical Ricos goals to stricter biological variation specifications substantially reduces the proportion of analytes achieving six-sigma performance [10]. Fourth, the uncritical use of control rules can generate false rejection, wasting resources and delaying result release without improving patient safety [4]. Fifth, the literature on the direct causal effect of QC practices on patient outcomes remains less complete than the evidence on intermediate process measures [23]. These limitations do not undermine the case for QC, but they caution against treating any single metric or rule set as a sufficient indicator of quality [23].

Future Directions

The trajectory of laboratory quality control points toward greater personalization, integration, and data-driven decision-making. Risk-based IQC scheduling that incorporates sigma metrics, failure mode and effects analysis, and patient-based moving average monitoring is likely to become the standard of care as accreditation bodies increasingly require evidence of risk-based planning [16]. Patient-based real-time quality control using moving averages and exponentially weighted moving averages offers the prospect of continuous bias detection between scheduled QC events [19]. The IFCC essential quality indicators panel provides a globally applicable framework for harmonizing quality measurement and comparison across laboratories, which should facilitate benchmarking and continuous improvement [22]. Integration of automation with intelligent autoverification algorithms will further reduce manual error and free trained staff for higher-level interpretation and root-cause analysis [24]. Ultimately, the effectiveness of laboratory QC practices will be judged by their contribution to diagnostic reliability and patient safety, and the evidence assembled to date indicates that appropriately designed, risk-calibrated, and systemically integrated QC achieves precisely that objective [25].

CONCLUSION

The evidence reviewed in this article supports the conclusion that laboratory quality control practices are effective in reducing analytical errors in clinical chemistry testing, but that their effectiveness is conditional rather than absolute. Internal QC using Levey-Jennings charts and Westgard multirule procedures, when appropriately calibrated to method sigma performance, reliably detects systematic and random error and prevents the release of erroneous patient results. External quality assessment and proficiency testing complement internal QC by verifying trueness against peer groups and reference systems, and participation in external assessment is associated with low discrepancy rates and continuous quality improvement. Sigma metrics and risk-based QC scheduling improve both error detection and cost-effectiveness by matching control intensity to analytical risk. ISO 15189 accreditation and standardized quality indicators provide the institutional and measurement infrastructure within which these technical practices operate, although accreditation must be coupled with structured root cause analysis to translate compliance into genuine performance improvement. Automation and trained personnel jointly determine whether QC data are acted upon correctly and promptly. The principal limitation of analytical QC is that it addresses only a minority of total laboratory errors, and its broader effectiveness therefore depends on integration within a total quality management system that addresses pre- and post-analytical phases with equal rigour. On balance, the literature demonstrates that well-designed QC practices substantially reduce analytical error, improve diagnostic reliability, and generate economic value, and that the most effective systems are those that treat QC not as a regulatory obligation but as a dynamic, risk-calibrated, and patient-centred process of continuous improvement.

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