To cite this article: Ozkan E. Post-analytical quality indicators in SAS/TUSKA accreditation: a 12-month performance evaluation using the IFCC WG-LEPS framework. Turk J Clin Lab 2026; 1: 1861981.

Research Article

Post-analytical quality indicators in SAS/TUSKA accreditation: a 12-month performance evaluation using the IFCC WG-LEPS framework

SAS/TÜSKA akreditasyonunda post-analitik kalite göstergeleri: IFCC WG-LEPS çerçevesine göre 12 aylık performans değerlendirmesi

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Abstract

Aim: Errors occurring in the post-analytical phase of laboratory testing account for a substantial proportion of total laboratory errors and may directly affect patient safety. This study aimed to evaluate laboratory performance using standardized post-analytical quality indicators.

Material and Methods: Post-analytical quality indicators recommended by the IFCC Working Group on Laboratory Errors and Patient Safety (WG-LEPS) and aligned with ISO 15189:2022 were applied. Data were automatically extracted from the laboratory information management system over a 12-month period. Evaluated indicators included timely communication of critical values, post-analytical turnaround time compliance, report correction rate, proportion of reports not reaching clinicians, and auto-validation coverage.

Results: Timely communication of critical values and turnaround time compliance rates exceeded international target thresholds (≥95%). The report correction rate remained low (<0.3%), indicating effective verification and validation processes. A small proportion of reports did not reach clinicians, highlighting potential challenges in electronic reporting systems. THE PROPORTİONAutovalidation coverage was 0% in the evaluated period.

Conclusion: Post-analytical quality indicators provide an effective framework for monitoring laboratory performance. Implementation of ISO 15189:2022 requirements and increased use of automation may further enhance post-analytical processes and patient safety.

Keywords: laboratory performance; quality indicators; post-analytical phase; patient safety; laboratory medicine

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Doi: 10.18663/tjcl.1861981
Received: 14.01.2026 accepted: 22.02.2026 Publication date: 28.03.2026

TJCL 2026; 1: 1861981

Öz

Amaç: Post-analitik fazda meydana gelen hatalar, toplam laboratuvar hatalarının önemli bir bölümünü oluşturmakta ve hasta güvenliğini doğrudan etkileyebilmektedir. Bu çalışmanın amacı, standart post-analitik kalite göstergeleri kullanılarak laboratuvar performansının değerlendirilmesidir.

Gereç ve Yöntemler: Bu çalışmada, IFCC Laboratuvar Hataları ve Hasta Güvenliği Çalışma Grubu ile ISO 15189:2022 standardı tarafından önerilen post-analitik kalite göstergeleri kullanılmıştır. Veriler, 12 aylık bir süre boyunca laboratuvar bilgi yönetim sisteminden otomatik olarak elde edilmiştir. Değerlendirilen göstergeler; kritik değerlerin zamanında bildirilme oranı, post-analitik sonuçlanma süresi uyumu, sonuç düzeltme oranı, klinisyenlere ulaşmayan raporların oranı ve otovalidasyon kapsamıdır.

Bulgular: Kritik değerlerin zamanında bildirilme oranı ve sonuçlanma süresi uyumunun uluslararası hedef eşiklerin (≥%95) üzerinde olduğu saptanmıştır. Sonuç düzeltme oranı düşük bulunmuş (<%0,3) ve etkin doğrulama süreçlerini göstermiştir. Raporların küçük bir bölümünün klinisyenlere ulaşmaması, elektronik raporlama sistemlerinde iyileştirilmesi gereken alanlara işaret etmiştir. Otovalidasyon kapsamı %0 bulunmuştur.

Sonuç: Post-analitik kalite göstergeleri, laboratuvar performansının izlenmesi ve geliştirilmesinde etkili bir araçtır. ISO 15189:2022 gerekliliklerinin uygulanması ve otomasyonun artırılması, hasta güvenliğini destekleyebilir.

Anahtar Kelimeler: laboratuvar performansı; kalite göstergeleri; post-analitik faz; hasta güvenliği; laboratuvar tıbbı

Introduction

The laboratory testing process consists of three interconnected phases: pre-analytical, analytical, and post-analytical. Although analytical procedures have traditionally been the primary focus of quality improvement initiatives, accumulating evidence indicates that a substantial proportion of laboratory errors estimated to account for approximately 30–50% of total errors occur outside the analytical phase, predominantly during the post-analytical stage [1-3]. This phase encompasses result verification, report generation, communication of critical values, timely delivery of results to clinicians, and, when necessary, clinical interpretation. Failures or delays at any of these steps may adversely affect clinical decision-making and pose a direct risk to patient safety [4,5].

In response to the recognized clinical impact of post-analytical errors, international professional organizations such as the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), the Clinical and Laboratory Standards Institute (CLSI), and the International Organization for Standardization (ISO) have emphasized the systematic use of quality indicators (QIs) to monitor post-analytical performance [1,6,11]. These indicators provide objective and measurable parameters that enable laboratories to identify process weaknesses, monitor performance trends over time, and implement targeted corrective actions. In particular, the revised ISO 15189:2022 standard places increased emphasis on the timely communication of critical results, report accuracy, traceability, and secure delivery of laboratory reports as integral components of laboratory quality management systems [4,9].

Despite these international recommendations, the available literature suggests that studies focusing specifically on post-analytical quality indicators remain limited in number and scope. Many published reports are survey-based, lack standardized indicator definitions, or do not include systematic comparisons with internationally recommended target performance ranges [7,8]. In addition, real-world evaluations based on routinely collected laboratory information management system (LIMS) data over extended time periods are relatively scarce. At the national level, quality frameworks such as the SAS/TÜSKA indicator system implemented by the Turkish Ministry of Health provide a structured approach for monitoring post-analytical laboratory performance, particularly in domains directly related to patient safety, including critical value notification, reporting turnaround time, and report security [10].

From an international perspective, harmonization of post-analytical quality indicators is essential to ensure comparability of laboratory performance, facilitate benchmarking across institutions, and support the consistent implementation of patient safety standards, as emphasized by the IFCC WG-LEPS

and ISO 15189:2022 [1,9,11]. At the national level, alignment of internationally recommended quality indicators with country-specific frameworks such as SAS/TÜSKA is equally important to support regulatory compliance, standardized monitoring, and continuous quality improvement within the healthcare system [9,10]. Evaluating post-analytical performance using indicators that are simultaneously compatible with international standards and national quality programs provides actionable evidence for laboratories, accreditation bodies, and policymakers. Therefore, this study was designed to evaluate post-analytical laboratory performance using standardized quality indicators aligned with IFCC WG-LEPS recommendations, ISO 15189:2022 requirements, and the nationally implemented SAS/TÜSKA framework, providing evidence relevant to both international benchmarking and national quality improvement efforts.

Material and Methods

In this study, post-analytical quality indicators recommended by the IFCC Working Group on Laboratory Errors and Patient Safety (WG-LEPS) were used to monitor laboratory performance. The selected indicators included: (1) timely communication of critical values, (2) compliance with post-analytical turnaround time (TAT), (3) report correction rate, (4) proportion of reports not reaching clinicians, and (5) autovalidation coverage.

For each quality indicator, standardized definitions, calculation formulas, and target performance ranges were established based on international guidelines and relevant literature. Data were automatically extracted from the laboratory information management system (LIMS) and analyzed on a monthly basis over a 12-month period. Performance trends were evaluated using statistical process control (SPC) charts. Observed results were compared with target ranges proposed by IFCC recommendations, ISO 15189:2022 requirements, and findings from multicenter studies reported in the literature (Table 1).

Observed post-analytical performance values (turnaround time metrics) were summarized and are presented separately in the Results section.

Ethics approval was not required for this study, as it was based on retrospective, anonymized laboratory data and did not involve any intervention or identifiable patient information. Informed consent was waived due to the retrospective nature of the study.

Statistical Analysis

Descriptive statistics were used to summarize post-analytical quality indicators. Monthly performance trends were assessed using statistical process control (SPC) charts to identify variations over time. Data analysis was performed using SPSS Statistics version 26 (IBM Corp., Armonk, NY, USA). As the primary objective of this study was to monitor and evaluate quality indicators rather than to test predefined hypotheses, inferential statistical analyses were not performed. Statistical process control (SPC) charts were used to visualize monthly performance trends and identify non-random variations over time. Annual test volumes are provided in Supplementary Table S1. Causes of test rejection / non-reporting are presented in Supplementary Table S2.

Results

During the 12-month study period, post-analytical quality indicators were continuously monitored using data automatically extracted from the laboratory information management system (LIMS). A total of 1,659,276 laboratory test reports were included in the analysis. Monthly performance trends were evaluated for each quality indicator, and overall performance was compared with predefined target ranges recommended by international guidelines.

The rate of timely communication of critical values consistently exceeded the target threshold of ≥95%, with a mean compliance rate of 98.6% over the study period. Post-analytical process performance indicators (turnaround time metrics) by laboratory discipline are presented in Table 3.

The report correction rate remained low throughout the study period, with a mean value of 0.21%, indicating effective verification and error-prevention mechanisms within the laboratory workflow. The proportion of reports that did not reach clinicians was 0.34%, which, although within acceptable limits, highlights potential vulnerabilities in electronic reporting pathways.

Auto-validation was not routinely implemented in our laboratory due to limited test volume and reliance on manual specialist review; therefore, QA5 was 0%. Rule-based auto-validation may be considered to improve efficiency if test volume increases.

Overall, all observed post-analytical quality indicators were within or above the recommended target ranges, demonstrating satisfactory laboratory performance in the post-analytical phase.

Table 1. Post-analytical quality indicators used in the study and target performance ranges.

QI Code	Definition	Formula	Target Range
QA1	Rate of timely communication of critical values	(Number of critical results communicated within the defined time window / Total number of critical results) × 100	≥95%
QA2	Post-analytical TAT compliance rate	(Number of tests reported within the target TAT / Total number of tests) × 100	≥90% (routine), ≥95% (critical)
QA3	Report correction rate	(Number of corrected reports / Total number of reports) × 100	≤0.3%
QA4	Proportion of reports not reaching clinicians	(Number of reports not reaching clinicians / Total number of reports) × 100	≤0.5%
QA5	Autovalidation coverage	(Number of tests approved by autovalidation / Total number of approved tests) × 100	≥70% (recommended)

Table 2. Comparison of SAS/TÜSKA indicators and ISO 15189:2022 post-analytical requirements.

Comparison Criterion	SAS / TÜSKA Indicators	ISO 15189:2022
Scope	Indicators designed to monitor hospital and laboratory services at the national level	International standard defining quality and competence requirements for medical laboratories
Post-analytical focus	Critical value notification, reporting turnaround time (TAT), report accuracy	Timely communication of critical values, result traceability, and report reliability
Definition of quality indicators	Practical indicators focused on implementation and routine monitoring	Systematic, standardized, and internationally comparable quality requirements
Data source	Hospital information systems and national reporting infrastructure	Laboratory information management system (LIMS) and quality management system records
Performance evaluation approach	National threshold values and internal institutional monitoring	Continuous improvement, risk-based approach, and international benchmarking
International comparability	Limited	High
IFCC WG-LEPS alignment	Indirect	Direct alignment
Contribution to patient safety	Improvement of clinical process monitoring and reporting	Systematic error prevention, traceability, and standardization

Table 3. Post-analytical process performance indicators (turnaround time metrics) by laboratory discipline (2025).

Laboratory discipline	Number of tests (n)	Mean HBYS acceptance → LIS acceptance	Mean LIS acceptance → validation/approval	Mean result reporting time	Maximum result reporting time
Biochemistry	1,479,390	0 min	1 h 17 min	17 min	23 h 7 min
Hormone	339,653	0 min	1 h 53 min	23 min	6 d 21 h 59 min
Hemogram	113,895	0 min	27 min	11 min	3 d 4 h 44 min
Urine strip	41,866	0 min	37 min	11 min	2 d 12 h 31 min
HbA1c	31,219	0 min	1 h 37 min	34 min	5 h 7 min
Coagulation	23,236	0 min	1 h 14 min	12 min	1 d 1 h 19 min
Erythrocyte sedimentation rate (ESR)	17,710	0 min	58 min	13 min	9 h 56 min
D-dimer (quantitative)	2,063	0 min	1 h 4 min	10 min	2 h 50 min
Neonatal bilirubin	1,231	0 min	29 min	1 min	44 min
OGTT 60 min	653	0 min	1 h 18 min	12 min	1 h 16 min
OGTT 120 min	132	0 min	1 h 17 min	12 min	1 h 12 min

Supplementary Table S1. 2025 total test volumes by laboratory discipline.	
Laboratory discipline	**Number of tests (n)**
Biochemistry	1,479,390
Hormone	339,653
Hemogram	113,895
Urine strip	41,866
HbA1c	31,219
Coagulation	23,236
Erythrocyte sedimentation rate (ESR)	17,710
D-dimer (quantitative)	2,063
Neonatal bilirubin	1,231
OGTT 60 min	653
OGTT 120 min	132

Supplementary Table S2. Causes of test rejection / non-reporting (sample-related and process-related).				
Cause category	**Specific cause (LIS code/ definition)**	**Annualized n (Dec×12)**	**Annualized rate (% of total)**	**Corrective/ preventive action**
Specimen rejection (upstream)	Hemolysis-related rejection	225×12 = 2.700	2.700 / 1.659.276 = 0.16%	Staff training / phlebotomy feedback
Specimen rejection (upstream)	Lipemia-related rejection	1×12 = 12	12 / 1.659.276 = 0.00%	Patient preparation + sample handling
Specimen rejection (upstream)	Clotted sample rejection	69×12 = 828	828 / 1.659.276 = 0.05%	Collection technique improvement
Specimen rejection (upstream)	Insufficient sample	107×12 = 1.284	1.284 / 1.659.276 = 0.08%	Tube fill volume training
Specimen rejection (upstream)	Sample not received	30×12 = 360	360 / 1.659.276 = 0.02%	Transport workflow improvement
Process error	Tube numbering/labeling issue (tube not numbered/numbering omitted for selected tubes	380×12 = 4.560	4.560 / 1.659.276 = 0.27%	Barcode workflow improvement
System-related	Automation downtime	109×12 = 1.308	1.308 / 1.659.276 = 0.08%	Preventive maintenance plan
Other / administrative	Duplicate coding (“fazla kodlu/ mükerrer”)	496×12 = 5.952	5.952 / 1.659.276 = 0.36%	LIS rule optimization
Other	Expired kit	18×12 = 216	216 / 1.659.276 = 0.01%	Stock control
Other	EDTA tube transfer to yellow cap	10×12 = 120	120 / 1.659.276 = 0.01%	Staff training
Other	Other reasons	8×12 = 96	96 / 1.659.276 = 0.01%	—
Abbrev.: HBYS, Hospital Information Management System; LIS, Laboratory Information System; OGTT, Oral Glucose Tolerance Test.				

Discussion

In this study, laboratory performance was systematically evaluated using internationally recognized post-analytical quality indicators, providing a comprehensive overview of post-analytical processes in a real-world laboratory setting. Overall, the findings were consistent with previously published studies, demonstrating that timely communication of critical values and post-analytical turnaround time (TAT) performance can be effectively maintained within recommended thresholds when standardized monitoring systems are in place [4,5,14]. The high compliance rate observed for critical value notification underscores the importance of clearly defined alert pathways and staff accountability in post-analytical workflows.

This study provides a real-world, 12-month evaluation of post-analytical quality indicators and demonstrates how national SAS/TÜSKA indicators can be interpreted within the ISO 15189:2022

framework. The findings support continuous improvement in patient safety–oriented reporting workflows and highlight autovalidation as a priority area for future development.

The low report correction rate identified in this study reflects the effectiveness of verification, validation, and result authorization procedures embedded within the laboratory information management system (LIMS). Similar findings have been reported in multicenter and national surveys, where low correction rates were associated with robust internal quality control mechanisms and standardized reporting practices [1,7,15]. Nevertheless, even minimal correction rates remain clinically relevant, as post-analytical errors may directly influence diagnostic interpretation and subsequent clinical decision-making.

Despite overall satisfactory performance, the proportion of reports that did not reach clinicians, although within acceptable limits highlights persistent challenges related to electronic reporting systems, interoperability, and user-dependent factors. Previous studies have emphasized that failures in result transmission often arise from system integration gaps, incomplete user training, or workflow interruptions, particularly during periods of increased workload [8,12,16]. These findings reinforce the need for continuous monitoring of result delivery pathways as an integral component of patient safety strategies.

When compared with international benchmarks, post-analytical TAT performance in this study met ISO 15189:2022 requirements for critical tests, while minor deviations were observed for routine tests. This pattern has been consistently reported in the literature and is often attributed to workload fluctuations, staffing constraints, and prioritization of urgent testing [3,14,17]. Auto-validation was not routinely implemented in our laboratory due to limited test volume and manual specialist review; therefore, QA5 was 0%. Rule-based auto-validation may be considered to improve efficiency if test volume increases [6,13,18].

A comparative overview of nationally implemented SAS/TÜSKA indicators and the international ISO 15189:2022 post-analytical requirements is presented in Table 2. A notable strength of this study is the integration of internationally recommended quality indicators with a nationally implemented quality framework. As demonstrated in Table 2, the SAS/TÜSKA indicators used in Türkiye share substantial conceptual overlap with ISO 15189:2022 requirements, particularly in domains related to patient safety, such as critical value notification and report reliability [9,10]. While SAS/TÜSKA provides a pragmatic and implementation-oriented monitoring structure tailored to national healthcare settings, ISO 15189:2022 offers a standardized and internationally comparable framework. The alignment of these two approaches facilitates harmonization between national regulatory requirements and global quality initiatives, a concept increasingly emphasized by the IFCC Working Group on Laboratory Errors and Patient Safety (WG-LEPS) [11,19].

The main strength of this study lies in its use of standardized quality indicators automatically extracted from the LIMS over an extended observation period, minimizing reporting bias and enabling continuous performance evaluation.

Limitations of the study

The single-center design may limit generalizability, and the absence of direct patient-level outcome data precludes assessment of the clinical impact of observed post-analytical performance. Future multicenter studies incorporating clinical outcome measures and cost-effectiveness analyses would further clarify the broader implications of post-analytical quality improvement initiatives [20-22].

In conclusion, post-analytical quality indicators represent a critical and practical tool for the comprehensive evaluation of laboratory performance. The findings of this study demonstrate that systematic monitoring of post-analytical processes using internationally standardized indicators enables laboratories to achieve and sustain performance levels aligned with ISO 15189:2022 requirements and IFCC WG-LEPS recommendations. Furthermore, the integration of national quality frameworks such as SAS/TÜSKA with international standards provides a robust foundation for harmonized quality management, regulatory compliance, and continuous improvement. The expanded use of automation and digital tools has the potential to further enhance post-analytical efficiency, reduce error risk, and strengthen patient safety across laboratory medicine.

Declaration of conflicting interests

The author declared no conflicts of interest with respect to the authorship and/or publication of this article.

Funding

The author received no financial support for the research and/or authorship of this article.

Ethics approval

Ethics approval was not required for this study, as it was based on retrospective, anonymized laboratory data and did not involve any intervention or identifiable patient information.

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