

The Impact of ISO 15189 Laboratory Accreditation on Diagnostic Quality and Patient Care Outcomes: A Systematic Review

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Abstract

Background: The medical laboratory produces information that is the basis for the vast majority of clinical decisions, but the laboratory testing process can be flawed at every stage. The international standard for quality and competence in medical laboratories, ISO 15189, has emerged as the world's main laboratory accreditation standard. Despite ISO 15189 accreditation being broadly

used, the empirical evidence of measurable improvements in diagnostic quality and patient outcomes is fragmented in heterogeneous literature from high-, middle- and low-income settings. **Objective:** To gather existing evidence of the relationship between ISO 15189 accreditation and patient care results, as well as diagnostic accuracy and error reduction. **Methods:** A narrative systematic review of peer-reviewed literature on the ISO 15189 accreditation, external quality assessment, total testing process errors and laboratory process improvement methodologies. 21 sources were included that fulfilled

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the relevance and verifiability criteria, and they were synthesized thematically. **Results:** Accreditation and the elements of accreditation, external quality assessment, structured error monitoring, and continuous improvement systems were consistently linked to enhanced analytical reliability, lower pre-analytical error rates, and better organizational quality culture in the various contexts, but the evidence on direct, causally attributable improvements in patient-level clinical outcomes was comparatively limited and methodologically heterogeneous. **Conclusion:** ISO 15189 accreditation is a legitimate structural proxy for laboratory quality, but it is not the accreditation itself that directly affects patient outcomes, but rather implementation fidelity, resource context, and associated quality systems.

Keywords: ISO 15189 accreditation, Medical laboratory quality, Lab accreditation, Diagnostic accuracy, Quality management systems.

1. Introduction

Laboratory medicine has an undue influence on clinical decision making compared to its share of healthcare expenditure: up to 70-80% of clinical decisions about diagnosis, treatment and discharge are based on laboratory data, which accounts for a small proportion of the total cost of healthcare. The testing process itself does not necessarily require a high amount of resources; moderate error rates in the testing process can, in turn, cause significant delays in diagnosis or harm the patient.

The International Organization for Standardization (ISO) created ISO 15189, Medical laboratories Requirements for quality and competence, as a laboratory-specific quality framework that builds on the general requirements of ISO/IEC 17025 which are relevant to medical laboratories and include requirements for handling specimens, clinical interpretation, and patient safety (De la Villa Porras, 2023). The latest revision of ISO 15189 (2022) streamlined the standard into five groups of clauses, adding new requirements for risk management, impartiality, Director accountability and governance of point-of-care testing (de la Villa Porras, 2023; Yang et al., 2026).

While the almost universal adoption of ISO 15189 has occurred in very different resource settings and contexts (from tertiary academic centres to district level labs in sub-Saharan Africa and South/Southeast Asia), the rapid uptake of the standard has outpaced the evidence that it improves diagnostic quality and patient outcomes. This

review had two goals: to bring together evidence of the association between ISO 15189 accreditation and objective measures of diagnostic quality that is, analytical accuracy, error rates and turnaround time and to explore the more limited evidence linking accreditation to patient-level outcomes and to identify gaps in this line of evidence.

2. Methods

2.1 Design and Search Strategy

This was a narrative systematic review designed around the general principles of the PRISMA for identification, screening and synthesis, but tailored for a mixed type of literature that included systematic reviews, umbrella reviews, observational studies, cross sectional surveys and standard setting commentary. Literature was retrieved using structured searches with the following terms, and appropriate Boolean combinations: ISO 15189, medical laboratory accreditation, external quality assessment, proficiency testing, total testing process, pre-analytical errors, laboratory quality indicators, Lean Six Sigma laboratory, point-of-care testing accreditation and hospital accreditation patient outcomes. The search was conducted in indexed biomedical literature databases available via PubMed indexed sources, Biochemia Medica, PLOS One, BMC journals, African Journal of Laboratory Medicine and other laboratory medicine and health services databases.

2.2 Eligibility Criteria

Sources were eligible for inclusion if they (a) directly referred to the ISO 15189 accreditation, implementation or revision in 2012/2022; (b) mentioned external quality assessment or proficiency testing as a mechanism related to ISO 15189 accreditation; (c) reported on the total testing process or pre-analytical error rates in laboratory quality management; (d) assessed the process-improvement methodologies (Lean and Six Sigma) used in clinical laboratories; (e) addressed the governance of point-of-care testing in relation to accreditation frameworks; or (f) provided a systematic or umbrella review of hospital or laboratory accreditation and patient outcomes. Promotional or vendor data that is not peer-reviewed were not included, nor were data sources that could not be independently documented.

2.3 Synthesis Approach

Quantitative meta-analysis was inappropriate, due to the diversity of designs, populations and outcome measures. Findings are summarized narratively under nine thematic areas: (1) the structure and evolution of ISO 15189; (2) general accreditation-quality evidence; (3) implementation of ISO 15189 in LMICs; (4) external quality assessment as part of accreditation; (5) the total testing process and trends in pre-analytical error patterns; (6) process-improvement methodologies; (7) governance of point-of-care testing; (8) professionals' attitudes toward accreditation; and (9) trends in the laboratory quality-improvement literature. The evidence base is comprehensive because it is from verifiable, peer-reviewed or standard-setting sources, but it is a sample that is focused and thematically organized, and not in the strict sense a systematic review of the literature.

Results

3.1 Structure and Evolution of the ISO 15189 Standard

The standards-based approach to quality management, ISO 15189, is structured and evolved in the following manner. The standards have also come a long way from their first editions with ISO 15189. The 2022 revision reorganized the standard in five clause groups (general, structural/governance, resource, process, and management system requirements), integrating risk-based thinking throughout the standard, instead of addressing risk management as a stand-alone clause (de la Villa Porras, 2023). Some of the most impactful changes were the accountability of the laboratory director, standards for impartiality, and the first time explicit inclusion of governance of point-of-care testing in the core standard (de la Villa Porras, 2023; Yang et al., 2026).

Internal and external assessments recorded very different types of risk during the initial implementation of ISO 15189 in a Chinese pediatric hospital laboratory, as evidenced by a risk-mapping study of 35 internal-assessment and 67 external-assessment nonconformities, which concluded that internal and external assessments do not overlap but are complementary (Yang et al., 2026). It indicates that accreditation has quality benefit from an ongoing interaction between internal and external monitoring.

Progress towards the new standard is uneven across the region. The survey by the 2025 Asia-Pacific Federation of Clinical Biochemistry and Laboratory Medicine (APFCLBM) revealed that 85% of 303 respondents were aware of the changes

introduced in ISO 15189:2022 and understood that it has a stronger focus on risk-management, but significant challenges remained, including lack of training (72%), financial constraints (65%) and resistance to change within the organization (45%) (Pant et al., 2026). Interestingly, 82% felt that the transition would enhance quality and patient care, even in cases of lower capacity to implement the transition.

3.2 General Evidence on Hospital and Laboratory Accreditation and Quality Outcomes

It is helpful to first examine the standard in relation to the accreditation literature as much of what is known about the relationship between accreditation and outcomes comes from hospital-level studies, and not laboratory-level studies.

In this early systematic review of 915 abstracts, Brubakk and colleagues (2015) selected 20 studies for detailed review, and found the evidence for the effectiveness of accreditation to be methodologically weak; few studies included multiple groups (control or non-control) and many studies were susceptible to the influence of concurrent quality improvement efforts. This discovery has since been influential as a warning against confusing associations between accreditation and outcomes as causality.

A more comprehensive systematic review by Hussein et al. (2021) found 17,830 studies of which 76 were empirical studies from 20 years ago. A consistent positive relationship between accreditation and safety culture, process-related performance, efficiency, and patient length of stay were revealed, with no association found between accreditation and employee satisfaction or patient satisfaction measures or between accreditation and mortality or healthcare-associated infections (HAIs); inconclusive findings were reported for patient satisfaction measures and 30-day readmission rates. The strong evidence for process and culture outcomes, weak evidence for the most clinically significant patient outcomes, is found throughout the accreditation literature and is directly relevant to the interpretation of the findings made in the ISO 15189-specific evidence.

Similarly, a review by Lewis and Hinchcliff (2023) of 33 reviews identified from 2545 possible references found: accreditation had the strongest associations with effectiveness, efficiency, patient-centredness, and safety, and persistent use of observational designs over experimental designs. The chronological mapping of the

review indicates that the number of publications about accreditation had increased steadily since the mid-2000s, indicating a growth instead of a decrease in interest in resolving the uncertainty Brubakk et al. (2015) perceived.

3.3 ISO 15189 Implementation in Low- and Middle-Income Countries

The interaction between baseline and accreditation mandated practice is greatest, and most visible, there, hence the abundance of literature on the topic in the LMIC implementation literature.

Adane, Girma, and Deress (2019) conducted a systematic review of all the literature pertaining to the role of ISO 15189 in Ethiopian healthcare, which included 883 materials at full text and 28 articles and one report were kept. The review found that there were steps that had been identified to be associated with quality improvement as well as better institutional management culture, but found that the vast majority of laboratories in Africa were not accredited and that the majority of those that were accredited were predominantly in the private sector.

The 2020 case study, conducted in Ghana's 37 Military Hospital pathology laboratory, accredited as a ISO 15189:2012 laboratory in 2017, interviewed staff and gave them a checklist of 16 potential obstacles and asked them to rate them on a 0–5 scale (Attoh et al., 2022) providing a rare worker level account of what is required organisationally to sustain compliance to ISO 15189:2012.

El Karaoui and Assaf (2023) investigated whether the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) checklist designed to direct laboratories in a step-by-step process towards ISO 15189:2012 compliance could also be used as a readiness indicator for the Joint Commission International (JCI) accreditation. Their analysis indicates that there is some alignment of the two but it is not perfect; this indicates that a pathway of stepwise tools could be useful for laboratories looking to go down more than one pathway.

3.4 External Quality Assessment and Proficiency Testing as Accreditation Pillars

External quality assessment (EQA) is required by ISO 15189 accreditation, includes proficiency testing, blinded sample re-checking and on-site evaluation, and is perhaps the most direct way in which the accreditation process leads to the assurance of analytical accuracy.

In resource-limited countries, Carter (2017) found that proficiency testing is being delivered by a mosaic of commercial providers, partnerships with higher-income institutions, and national vertical programs that are mainly based on single diseases, like TB, malaria, and HIV. The review revealed ongoing challenges such as the logistics of transporting samples, variable communication of EQA results, and a lack of capacity to take action on corrective findings, highlighting the fact that participation in EQA is not enough if there is no capacity to act on the findings of EQA.

Ibrahim and colleagues (2012) conducted a study of clinical trial laboratories in Ghana and Burkina Faso before accreditation who are involved in the College of American Pathologists' proficiency testing program. The laboratories put into place a continuous improvement process, recognizing that methodological errors, not clerical errors as are more common at well-resourced U.S. laboratories, were to blame for most unsatisfactory results, and that process resulted in a 35% reduction in the number of results due to methodological errors. This is an example of the context-specific nature of the type of laboratory error and the fact that accreditation-related EQA is a diagnostic tool for the context-specific error profile of the laboratory, rather than a verification tool.

Gershy-Damet and colleagues (2010) presented the laboratory accreditation process of the World Health Organization (WHO) African Region, which recognizes the binary pass/fail requirements of ISO 15189 accreditation as an unnecessary obstacle to achieving quality improvement, and introduces two alternative approaches, namely EQA and stepwise accreditation, which are deliberate methods to make quality improvement attainable without requiring full ISO 15189 accreditation, particularly where this is not a near-term objective.

3.5 Total Testing Process and Pre-Analytical Error Patterns

Since the diagnostic quality is influenced by the accuracy of the testing pathway as a whole, and not just the analytical phase, many studies have been published on error patterns in the entire testing pathway (TTP), which include pre-analytical (pre-testing), analytical (test), and post analytical (post-testing) stages.

The review by Mrazek et al. (2020) identified that the majority of error types recorded in TTP continue to be in the extra analytical phase of testing, specifically in the pre analytical area, where specimen handling is a frequent source of errors, and not

during the analytical phase of testing which is now comparatively well controlled through modern quality management systems. The review suggested that increased attention should be paid to the selection of tests and to the interpretation of the results, which take place partly outside the direct laboratory control, because errors at these boundary points are easily missed by laboratory-centred quality indicators.

Giménez-Marín et al. (2014) quantified this pattern in a study of the pre-analytical errors of a Spanish hospital laboratory over five years, during which 751,441 analytical requests were made, of which 13.54% were considered to be sampling errors and 0.047% critical errors (Six Sigma value of 4.9), all of which were mainly due to haemolysed samples (8.76%). This granularity – that is, distinguishing between critical and major non-critical error rates – is a good example of the reason that aggregate error-rate data can mask the clinically important subset of errors that accreditation driven quality indicators seek to highlight.

3.6 Process-Improvement Methodologies in Accredited Laboratories

In addition to accreditation's core requirements, a number of accredited laboratories have embraced structured process-improvement methods, such as Lean and Six Sigma, as ancillary techniques to turn accreditation-driven quality monitoring into quantifiable benefit for the operation.

This lean six sigma DMAIC (define, measure, analyze, improve, control) study was applied to a before-after study in the central laboratory of a teaching hospital in Turkey to specimen-reception and pre-analytical workflow (Inal et al., 2018). The intervention reduced the number of non-value-adding tasks by 3 hours and 22 minutes, the time for turning samples from a stat by 68 minutes to 59 minutes and the percentage of error/hazard prone process steps from 30% to 3%. This proves that accreditation's documentation and process-mapping tools can be used for efficiency interventions and not as a passive compliance activity.

Thakur, Akerele, and Randell (2022) placed Lean and Six Sigma in the larger context of continuous-quality-improvement, and found that its effectiveness requires strong utilization-management practices and previous organized quality systems that are more likely to be provided by an accredited laboratory than a non-accredited one.

3.7 Point-of-Care Testing Governance and Accreditation

Point-of-care testing (POCT) is an increasing and historically little-regulated extension of diagnostic testing away from the central laboratory, and accreditation integration has been a clearly defined priority of ISO 15189:2022. The scoping review of POCT regulation and governance in Australia revealed 40 academic and 37 grey literature sources, and that there was a lack of consistency in reporting on the formal accreditation of POCT programs despite the presence of national standards, which reference ISO 15189:2012/22870:2016 (now combined into ISO 15189:2022) framework (Prestedge et al., 2025). The authors proposed that COVID-19 dramatically hastened the uptake of POCT before the governance mechanisms to ensure its quality. A systematic review and meta-analysis of POCT in paediatric ambulatory care, reviewed until January 2020, found 35 studies (Van Hecke et al., 2020), with the clinical implications of this gap highlighted. For the children with ARI, use of POCT was linked to more targeted antibiotic use in LMIC settings that included structured interpretation guidance, training or diagnostic algorithms but not in high-income settings, and evidence to support the broader clinical-outcome impact was weak. This is yet another theme of this review: Accreditation infrastructure and diagnostic technology are not enough unless there is also investment in clinical decision support and training.

3.8 Laboratory Professionals' Attitudes toward Accreditation

The attitude of laboratory professionals towards accreditation is important in predicting the sustainability of accreditation as a quality mechanism, since there is no single accreditation event, but instead it requires ongoing staff involvement. Of the 225 staff members that responded to the anonymous survey at three ISO 15189:2012-accredited medical laboratories in Croatia, 70% stated that the best part of working in an accredited laboratory was better documentation of the processes, while 56% said that they were generally positive about working in an accredited laboratory (Lapić et al., 2021). 68% said that accreditation added to their workload, mostly because of documentation requirements, and 14% said they were completely aware of the requirements of the standard. The positive attitudes on Net appear to be coupled with a significant burden report and limited staff level understanding, pointing to a

requirement for ongoing training investment beyond accreditation, to achieve quality gains.

3.9 Trends in the Laboratory Quality-Improvement Literature

Chaudhry, Inata, and Nakagami-Yamaguchi (2023) did a systematic methodological review of 726 articles on clinical laboratory quality-improvement and quality-control, scoring them with a validated instrument for assessing methodological rigor, Quality Improvement Minimum Quality Criteria Set (QI-MQCS). There was a significant improvement in the rigor with which laboratory quality interventions (including accreditation-related interventions) have been studied and reported as reflected in the average QI-MQCS score, which increased from 2.5 (1981-2000) to 6.8 (2001-2020). The authors nevertheless drew the conclusion that there is no existing uniform system of evaluating the quality of clinical laboratory literature, and that this is particularly relevant to the present review, in which a methodological caveat has been expressed about causal interpretation.

4. Discussion

The literature discussed indicates a number of interrelated findings. First, accreditation according to ISO 15189 works best as a tool for enhancing indicators of laboratory quality at the process level, such as documentation rigor, analytical reliability demonstrated through EQA, structured error monitoring and quality culture within the organization. This evidence is widespread, comprehensive, and geographically diverse in the general hospital accreditation literature (Brubakk et al., 2015; Hussein et al., 2021; Lewis & Hinchcliff, 2023) and in ISO 15189-specific implementation literature, both in high income countries (Lapić et al., 2021; Yang et al., 2026) and LMIC (Adane et al., 2019; Attoh et al., 2022; Carter, 2017; Gershy-Damet et al., 2010; Ibrahim et al., 2012).

Second, the relationship between accreditation and patient-level clinical outcomes is far from solid and direct, compared to the link with process outcomes. Association with accreditation and patient satisfaction, readmission, and mortality have been inconsistent or null in general hospital literature, and even in the context of laboratory outcomes, studies have been more likely to show improvement in error rates, turnaround time, or workflow risk (Giménez-Marín et al., 2014; Inal et al., 2018; Mrazek et al., 2020) than downstream improvements in clinical decision-making that are directly

related to accreditation status. This gap is well demonstrated in the POCT literature – diagnostic technology that is made available within the governance framework of accreditation has been shown to boost clinical outcomes only when accompanied by interpretative training and decision algorithms, and not just by the technology itself and/or governance compliance (Prestedge et al., 2025; Van Hecke et al., 2020).

Third, there is supporting evidence of effectiveness in the four theory of change areas that are theorized to drive accrued value from accreditation, in addition to the certification status: accreditation of practices that are theorized to drive independent value for accreditation (organized practices that drive structured error monitoring, Lean/Six Sigma, and EQA), as well as the certification itself. This is in line with the “double-helix” approach of complementary internal/external monitoring (Yang et al., 2026), as well as accredited laboratories having a better documentation infrastructure to implement Lean Six Sigma (Thakur et al., 2022). Fourth, the apparent benefit of accreditation is highly contingent on implementation context. The challenges of resource limitations, training needs, and workload burden occur in vastly different contexts, including financial limitations in the 2025 Asia-Pacific survey (Pant et al., 2026); documentation burden among otherwise positive disposed workers at the laboratory level in Croatia (Lapić et al., 2021); and structural barriers to resources across sub-Saharan Africa's laboratory systems (Carter, 2017; Gershy-Damet et al., 2010). The additional value of accreditation is therefore not guaranteed to be the same for all health systems and policy expectations need to be tailored to the implementation capacity of the particular system under consideration.

5. Limitations

This review has the following limitations. The evidence base was not obtained with a systematic search of all available databases, but is limited to those databases that did return verifiable peer-reviewed or standard-setting sources, and should be viewed as a synthesis of the evidence, focused and thematically structured, and not as a database exhausting systematic review of the evidence. In addition, the heterogeneity of designs and results, and reporting standards, prevented a quantitative meta-analysis and reduced the precision of the estimates of the effect of accreditation. Third, most of the studies included in the analysis were of an observational, cross-sectional, or before-after

type, which reflects the limitations found in the general accreditation literature (Brubakk et al., 2015; Hussein et al., 2021); causal inferences about the independent impact of accreditation, beyond the concurrent quality-improvement efforts, remain limited. Finally, although the geographic and linguistic scope covers African, Asian, European and North American settings, it may not fully reflect the geographic distribution of ISO 15189 accredited laboratories, especially in countries with a lower volume of publication in English.

6. Conclusion

ISO 15189 accreditation offers a credible and internationally recognized framework of medical laboratory quality. The evidence reviewed here confirms that organizationally driven practices that are linked to accreditation, error management through EQA, structured error monitoring, and approaches to continuous improvement, when measured, have been associated with increases in analytical reliability, improvements in error reduction, and the culture of quality within a health organization in a wide range of healthcare settings. The association of accreditation status and direct, attributable improvements in patient-level clinical outcomes is much more attenuated and context specific, and depends on implementation fidelity and resource availability as well as on complementary, clinical decision-support infrastructure rather than necessarily being automatic. Prospective, controlled studies with the ability to separate the independent effect of accreditation from concurrent quality improvement efforts and increased support for implementation research in settings with limited resources and where the gap between aspiration and capacity for accreditation is highest would be valuable.

Conflict of interest

The authors declared no conflict of interest.

Author Contribution

All authors reviewed the results and approved the final version of the manuscript. they are also accountable for the study's integrity.

References

Adane, K., Girma, M., & Deress, T. (2019). How does ISO 15189 laboratory accreditation support the delivery of healthcare in Ethiopia? A systematic review. *Ethiopian Journal of Health Sciences*, 29(2), 251–262. <https://doi.org/10.4314/ejhs.v29i2.13>

- Attoh, S., Tetteh, F. K. M., McAddy, M., Ackah, K., Kyei, R., Moroti, M., Boateng, C., Adusu-Donkor, L., Boafo, J., Yakubu, A., Kwao, S., Sarkodie, E., Koranteng, N.-B., Addo, M. A., Hobenu, F., Agyeman-Bediako, K., & Fatchu, R. D. (2022). Challenges with the pursuit of ISO 15189 accreditation in a public health laboratory in Ghana. *African Journal of Laboratory Medicine*, 11(1), Article 1448. <https://doi.org/10.4102/ajlm.v11i1.1448>
- Bouchet, N. (2015). ISO 15189:2012: What changes for African laboratories? *African Journal of Laboratory Medicine*, 4(1), Article 325. <https://doi.org/10.4102/ajlm.v4i1.325>
- Brubakk, K., Vist, G. E., Bukholm, G., Barach, P., & Tjomsland, O. (2015). A systematic review of hospital accreditation: The challenges of measuring complex intervention effects. *BMC Health Services Research*, 15, 280. <https://doi.org/10.1186/s12913-015-0933-x>
- Carter, J. Y. (2017). External quality assessment in resource-limited countries. *Biochimica Medica*, 27(1), 97–109. <https://doi.org/10.11613/BM.2017.013>
- Chaudhry, A. S., Inata, Y., & Nakagami-Yamaguchi, E. (2023). Quality analysis of the clinical laboratory literature and its effectiveness on clinical quality improvement: A systematic review. *Journal of Clinical Biochemistry and Nutrition*, 73(2), 89–96.
- de la Villa Porras, I. (2023). Novelties in the ISO 15189:2023 standard. *Advances in Laboratory Medicine*, 4(4). <https://doi.org/10.1515/almed-2023-0139>
- El Karaoui, A. K., & Assaf, N. (2023). Using the SLIPTA checklist to assess laboratory readiness for Joint Commission International accreditation. *African Journal of Laboratory Medicine*, 12(1), Article 2044. <https://doi.org/10.4102/ajlm.v12i1.2044>
- Gershy-Damet, G. M., Rotz, P., Cross, D., Belabbes, E. H., Cham, F., Ndiokubwayo, J. B., Fine, G., Zeh, C., & Nkengasong, J. N. (2010). The World Health Organization African region laboratory accreditation process: Improving the quality of laboratory systems in the African region. *American Journal of Clinical Pathology*, 134(3), 393–400.
- Giménez-Marín, A., Rivas-Ruiz, F., Pérez-Hidalgo, M. del M., & Molina-Mendoza, P. (2014). Pre-analytical errors management in the clinical laboratory: A five-year study. *Biochimica Medica*, 24(2), 248–257. <https://doi.org/10.11613/BM.2014.027>

- Hussein, M., Pavlova, M., Ghalwash, M., & Groot, W. (2021). The impact of hospital accreditation on the quality of healthcare: A systematic literature review. *BMC Health Services Research*, *21*, 1057. <https://doi.org/10.1186/s12913-021-07097-6>
- Ibrahim, F., Dosoo, D., Kronmann, K. C., Ouedraogo, I., Anyorigiya, T., Abdul, H., Sodiomon, S., Owusu-Agyei, S., & Koram, K. (2012). Good clinical laboratory practices improved proficiency testing performance at clinical trials centers in Ghana and Burkina Faso. *PLOS ONE*, *7*(6), e39098. <https://doi.org/10.1371/journal.pone.0039098>
- Inal, T. C., Goruroglu Ozturk, O., Kibar, F., Cetiner, S., Matyar, S., Daglioglu, G., & Yaman, A. (2018). Lean six sigma methodologies improve clinical laboratory efficiency and reduce turnaround times. *Journal of Clinical Laboratory Analysis*, *32*(1), e22180. <https://doi.org/10.1002/jcla.22180>
- Lapić, I., Rogić, D., Ivić, M., Tomičević, M., Kardum Paro, M. M., Đerek, L., & Alpeza Viman, I. (2021). Laboratory professionals' attitudes towards ISO 15189:2012 accreditation: An anonymous survey of three Croatian accredited medical laboratories. *Biochemia Medica*, *31*(2), 020712. <https://doi.org/10.11613/BM.2021.020712>
- Lewis, K., & Hinchcliff, R. (2023). Hospital accreditation: An umbrella review. *International Journal for Quality in Health Care*, *35*(1), mzad007. <https://doi.org/10.1093/intqhc/mzad007>
- Mrazek, C., Lippi, G., Keppel, M. H., Felder, T. K., Oberkofler, H., Haschke-Becher, E., & Cadamuro, J. (2020). Errors within the total laboratory testing process, from test selection to medical decision-making – A review of causes, consequences, surveillance and solutions. *Biochemia Medica*, *30*(2), 020502. <https://doi.org/10.11613/BM.2020.020502>
- Pant, V., Parchwani, D., Upadhyay, M., Ohkawa, R., Sherpa, M. L., & Dabla, P. K. (2026). Urgent call for action: Bridging gaps in Asia-Pacific laboratories' transition to ISO 15189:2022. *EJIFCC*, *37*(1), 166–170.
- Prestedge, J., Kaufman, C., & Williamson, D. A. (2025). Regulation and governance for the implementation and management of point-of-care testing in Australia: A

- scoping review. *BMC Public Health*, 25, 758. <https://doi.org/10.1186/s12889-025-21894-2>
- Thakur, V., Akerele, O. A., & Randell, E. (2022). Lean and Six Sigma as continuous quality improvement frameworks in the clinical diagnostic laboratory. *Critical Reviews in Clinical Laboratory Sciences*, 60(1), 63–81. <https://doi.org/10.1080/10408363.2022.2106544>
- Van Hecke, O., Raymond, M., Lee, J. J., Turner, P., Goyder, C. R., Verbakel, J. Y., Van den Briel, A., & Hayward, G. (2020). In-vitro diagnostic point-of-care tests in paediatric ambulatory care: A systematic review and meta-analysis. *PLOS ONE*, 15(7), e0235605. <https://doi.org/10.1371/journal.pone.0235605>
- Yang, S., Zhou, Y., Wang, C., Luo, M., & Johannssen, A. (2026). The “double helix” model of quality monitoring: Risk mapping of quality management system during initial ISO 15189 implementation in a medical laboratory. *PLOS ONE*. <https://doi.org/10.1371/journal.pone.0342129>