



ISSN: 2230-9926

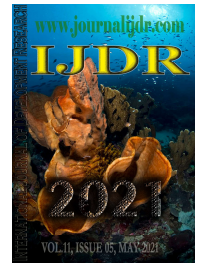
Available online at <http://www.journalijdr.com>

# IJDR

International Journal of Development Research

Vol. 11, Issue, 05, pp. 47505-47509, May, 2021

<https://doi.org/10.37118/ijdr.28377.05.2021>



RESEARCH ARTICLE

OPEN ACCESS

## A CRITICAL EXAMINATION OF QUALITY IMPROVEMENT IN LABORATORY TEST RESULTS

\*AL Mutairi Mohammed Naif, AL Otaybi Mashaal Eid, AL Enezi Ziyad Khalil, Al Mutairi Ali Ageel and AL Qahtani Shams Mohammed

Ministry of National Guard Health Affairs

### ARTICLE INFO

#### Article History:

Received 05<sup>th</sup> February, 2021

Received in revised form

20<sup>th</sup> March, 2021

Accepted 12<sup>th</sup> April, 2021

Published online 30<sup>th</sup> May, 2021

#### Key Words:

Laboratory test quality, pre-analytical phase, analytical phase, post-analytical phase, patient preparation, specimen collection, instrument calibration, quality control, reagent quality, result interpretation, timely reporting, automation, artificial intelligence, point-of-care testing, resource limitations, variability, resistance to change, collaboration.

\*Corresponding author: AL Mutairi Mohammed Naif

### ABSTRACT

The reliability and accuracy of laboratory test results are vital for effective clinical decision-making, diagnosis, treatment, and patient outcomes. This article critically examines current practices aimed at improving the quality of laboratory test results, focusing on pre-analytical, analytical, and post-analytical phases. The pre-analytical phase includes patient preparation, specimen collection, and transportation. The analytical phase covers instrument calibration, quality control, and reagent quality. The post-analytical phase addresses data entry, result interpretation, and timely reporting. Technological advancements such as automation, artificial intelligence (AI), and point-of-care testing (POCT) have significantly enhanced test accuracy and reliability. However, challenges such as resource limitations, variability in laboratory practices, and resistance to change persist. Future directions include personalized medicine, integrated quality management systems, and collaborative efforts among laboratories, healthcare providers, and regulatory bodies. By addressing these factors and leveraging innovations, the quality of laboratory tests can be significantly improved, leading to better patient care and outcomes.

Copyright © 2021, AL Mutairi Mohammed Naif et al. This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Citation: AL Mutairi Mohammed Naif, AL Otaybi Mashaal Eid, AL Enezi Ziyad Khalil, Al Mutairi Ali Ageel and AL Qahtani Shams Mohammed, 2021. "A Critical Examination of Quality Improvement in Laboratory test Results", *International Journal of Development Research*, 11, (05), 47505-47509.

## INTRODUCTION

The reliability and accuracy of laboratory test results are fundamental to effective healthcare delivery. Laboratory tests play a pivotal role in clinical decision-making, impacting diagnosis, treatment, and patient outcomes. Errors in laboratory testing can lead to misdiagnosis, inappropriate treatment, and adverse patient outcomes, making it crucial to ensure the highest quality of test results. The laboratory testing process involves multiple stages, each susceptible to errors that can compromise the quality of results. The importance of accurate laboratory test results is underscored by their widespread use in various clinical settings. According to studies, approximately 60-70% of clinical decisions are based on laboratory test results (Plebani, 2006). However, errors can occur at any stage of the testing process, from patient preparation to result reporting, which can have significant clinical implications (Carraro & Plebani, 2007). The pre-analytical phase, which encompasses patient preparation, specimen collection, transportation, and storage, is particularly prone to errors. These errors can significantly affect the quality of test results and ultimately patient care. For instance, improper specimen collection techniques or incorrect patient identification can lead to erroneous results (Lippi et al., 2011). The analytical phase, involving the actual testing of the specimen, is influenced by the precision and accuracy of

laboratory instruments, reagents, and methodologies. Ensuring regular calibration and maintenance of instruments, along with stringent quality control and proficiency testing, is essential to maintain high standards of test accuracy (Westgard, 2006). In the post-analytical phase, data entry, result interpretation, and timely reporting are critical to ensuring the correct application of laboratory findings in clinical practice. Errors in this phase, such as transcription mistakes or delays in reporting, can compromise patient outcomes (Plebani, 2010). Technological advancements have significantly contributed to improving the quality of laboratory test results. Automation, artificial intelligence (AI), and point-of-care testing (POCT) are some innovations that have transformed laboratory practices. These technologies help minimize human errors, enhance efficiency, and provide rapid and reliable test results (Gruson et al., 2019). Despite these advancements, several challenges persist in improving laboratory test quality. Resource limitations, variability in laboratory practices, and resistance to change are some of the barriers that need to be addressed (Plebani, 2012). Future directions for enhancing laboratory test quality include personalized medicine, integrated quality management systems, and collaborative efforts among laboratories, healthcare providers, and regulatory bodies. This article provides a comprehensive review of the factors affecting laboratory test quality and the strategies implemented to enhance it. By addressing pre-analytical, analytical, and post-analytical factors, and

leveraging technological innovations, the accuracy and reliability of laboratory tests can be significantly improved.

**Pre-Analytical Phase:** The pre-analytical phase encompasses all steps before the actual analysis of the specimen and is recognized as the most error-prone part of the laboratory testing process. Errors in this phase can significantly affect the accuracy and reliability of test results, impacting patient care and clinical decisions (Lippi et al., 2011). The pre-analytical phase includes patient preparation, specimen collection, transportation, and storage.

**Patient Preparation:** Proper patient preparation is crucial for obtaining accurate test results. Factors such as fasting requirements, medication restrictions, and physical activity guidelines must be clearly communicated to patients. Non-compliance with these instructions can lead to significant variations in test outcomes. For instance, failure to fast before certain blood tests can result in elevated glucose levels, leading to potential misdiagnosis of diabetes (Lippi et al., 2010). Clear and detailed instructions provided to patients can help minimize these errors.

**Specimen Collection:** Specimen collection is a critical step where numerous errors can occur. These errors include incorrect patient identification, inappropriate collection techniques, and the use of wrong containers. Proper training of healthcare personnel and the implementation of standardized protocols are essential to reduce these errors. For example, the use of barcoding systems for patient identification has been shown to significantly reduce identification errors (Nantes et al., 2016). Additionally, standardized procedures for blood collection, such as the use of vacuum tubes and correct order of draw, help prevent hemolysis and contamination.

**Transportation and Storage:** The integrity of specimens can be compromised during transportation and storage. Factors such as temperature fluctuations, delays in transport, and improper handling can affect test results. For example, specimens that require refrigeration may degrade if exposed to ambient temperatures for extended periods. Implementing stringent transportation protocols and using temperature-controlled containers are essential to maintain specimen integrity (O'Kane, 2009). Furthermore, proper storage conditions, such as adequate refrigeration for certain samples, are crucial to prevent degradation or contamination.

**Sample Processing:** Proper sample processing, including centrifugation and aliquoting, is critical to ensure the integrity of specimens. Delays in processing can lead to cellular breakdown and leakage of intracellular contents, which can significantly alter test results. Standard operating procedures (SOPs) for sample processing should be established and followed to ensure consistency and accuracy (Hawkins, 2012).

**Analytical Phase:** The analytical phase involves the actual testing of the specimen and is critical to ensuring the accuracy and precision of laboratory test results. This phase is influenced by the performance of laboratory instruments, the quality of reagents, and the adherence to standardized methodologies. Key components of the analytical phase include instrument calibration and maintenance, quality control, proficiency testing, and reagent quality.

**Instrument Calibration and Maintenance:** Regular calibration and maintenance of laboratory instruments are vital to ensure accurate test results. Calibration involves adjusting the instrument to produce results within a specified range based on known standards. Maintenance helps prevent equipment malfunctions that can lead to erroneous results. Failure to properly calibrate and maintain instruments can result in systematic errors and unreliable data (Westgard, 2006). For example, automated analyzers used for blood tests require regular calibration using control samples with known concentrations. This process helps verify that the instrument is producing accurate measurements. Routine maintenance, such as cleaning and replacing worn parts, ensures the instrument operates correctly and consistently.

**Quality Control and Proficiency Testing:** Quality control (QC) and proficiency testing (PT) are essential practices in the analytical phase. QC involves the routine monitoring of test performance using control samples, which are samples with known properties that are tested alongside patient specimens. These control samples help detect variations and potential errors in the testing process. Implementing QC procedures ensures that laboratory results are consistent and reliable (Stankovic & DiSerio, 2001). Proficiency testing, on the other hand, assesses a laboratory's testing accuracy by comparing its results with those from other laboratories. PT programs typically involve sending identical samples to multiple laboratories for analysis. The results are then compared to evaluate each laboratory's performance. Participating in PT programs helps laboratories identify areas for improvement and ensures compliance with industry standards (Ricos et al., 2004).

**Reagent Quality:** The quality of reagents used in laboratory tests directly impacts the results. Reagents must be stored and handled according to manufacturers' instructions to maintain their efficacy. Regularly checking expiration dates and ensuring proper storage conditions are necessary to prevent reagent-related errors. For instance, reagents used in enzyme-linked immunosorbent assays (ELISAs) must be stored at specific temperatures to preserve their activity (Plebani, 2006). Using high-quality reagents and adhering to proper handling protocols help minimize variability and enhance the reliability of test results. Additionally, laboratories should establish procedures for verifying the quality of new reagent lots before use in routine testing. This verification process ensures that new reagents perform consistently with previous lots.

**Standardization of Methodologies:** Standardizing methodologies across different laboratories is crucial to ensuring the consistency and comparability of test results. Standard operating procedures (SOPs) should be established for each test to guide laboratory personnel in performing the tests accurately and consistently. Adherence to SOPs reduces variability and enhances the reliability of test results (Burtis & Bruns, 2014). For example, standardizing the procedures for hematology tests, such as complete blood count (CBC), ensures that results from different laboratories can be compared with confidence. Establishing and following SOPs for sample preparation, reagent use, and instrument operation helps achieve this goal.

**Post-Analytical Phase:** The post-analytical phase includes all processes that occur after the specimen has been analyzed, such as result interpretation, reporting, and communication. Errors in this phase can arise from data entry mistakes, incorrect interpretation, and delays in reporting, all of which can adversely affect patient care. Effective management of the post-analytical phase is crucial for ensuring that accurate and reliable test results are correctly interpreted and promptly communicated to healthcare providers.

**Data Entry and Management:** Accurate data entry is crucial to avoid transcription errors that can lead to incorrect results. Manual data entry is prone to human errors, which can be minimized by implementing electronic health records (EHR) and laboratory information systems (LIS). These systems streamline data entry processes and reduce human errors by automating the transfer of results from laboratory instruments to patient records (Plebani, 2010). EHR and LIS can also facilitate data management by providing standardized templates for result reporting and ensuring consistency in how data is recorded and stored. These systems enhance data integrity and support seamless information flow between laboratory and clinical settings.

**Result Interpretation:** Interpreting laboratory results requires expertise and knowledge of patient history. Automated systems can assist in flagging abnormal results, but human oversight is essential for accurate interpretation. For instance, laboratory personnel and clinicians need to consider patient-specific factors such as age, sex, medical history, and current medications when interpreting test results (Kroll & Elin, 1993). Continuous education and training of laboratory personnel and clinicians are necessary to enhance interpretive skills.

Staying updated with the latest guidelines and best practices ensures that results are interpreted accurately, leading to appropriate clinical decisions.

**Timely Reporting and Communication:** Delays in reporting test results can adversely affect patient care, especially in critical cases where timely diagnosis and treatment are essential. Efficient communication channels between laboratories and healthcare providers are essential for timely reporting. Utilizing electronic reporting systems can expedite the transmission of results and ensure prompt clinical action (Plebani, 2007). Electronic reporting systems can send alerts and notifications to clinicians when test results are available, reducing the time between analysis and clinical decision-making. These systems also provide secure and reliable means of communicating sensitive patient information.

**Verification and Validation:** Before results are released to healthcare providers, they must be verified and validated to ensure accuracy and reliability. Verification involves checking that the results are consistent with quality control measures and that there are no apparent errors. Validation includes reviewing the results in the context of the patient's clinical picture to ensure they make sense and align with expected outcomes (Lippi et al., 2009). Implementing a double-check system, where two laboratory professionals independently verify critical results, can further reduce the risk of errors. This practice is especially important for tests with significant clinical implications, such as those used in diagnosing life-threatening conditions.

**Innovations and Technological Advancements:** Technological advancements have significantly contributed to improving the quality of laboratory test results. Innovations such as automation, artificial intelligence (AI), and point-of-care testing (POCT) have transformed laboratory practices, reducing errors, enhancing efficiency, and providing rapid and reliable test results. This section explores these key technological advancements and their impact on laboratory testing.

**Automation:** Automation in laboratory testing reduces human intervention, thereby minimizing errors and increasing efficiency. Automated systems can handle large volumes of samples with high precision and consistency, streamlining workflows and enhancing turnaround times. Automation encompasses various aspects of laboratory operations, including sample preparation, analysis, and data management. Automated analyzers, for instance, can perform multiple tests simultaneously and deliver results faster than manual methods. This capability is particularly beneficial in high-throughput laboratories where large volumes of samples are processed daily (Tate et al., 2014). Additionally, automation reduces the risk of human error in repetitive tasks, such as pipetting and sample sorting, ensuring more consistent and reliable results.

**Artificial Intelligence and Machine Learning:** AI and machine learning (ML) algorithms can analyze vast amounts of data to identify patterns and predict outcomes, assisting in quality control, result interpretation, and error detection. These technologies enhance the accuracy and reliability of laboratory test results by providing advanced analytical capabilities beyond traditional methods. AI-driven systems can flag abnormal results, suggest potential diagnoses, and recommend further testing, supporting clinicians in decision-making. For example, AI algorithms have been developed to analyze medical images, such as digital pathology slides, and identify potential abnormalities with high accuracy (Topol, 2019). Additionally, ML models can continuously learn from new data, improving their performance over time and adapting to changing clinical needs.

**Point-of-Care Testing:** POCT allows for rapid testing and immediate results at the patient's bedside or in remote locations, reducing the pre-analytical errors associated with specimen transportation and handling. POCT devices are designed to be user-friendly, enabling healthcare providers to perform tests outside traditional laboratory

settings, such as in emergency rooms, clinics, and home care environments. The benefits of POCT include faster diagnosis and treatment, reduced patient wait times, and improved patient outcomes. For instance, POCT for glucose monitoring in diabetic patients allows for immediate adjustments to treatment plans based on real-time data (Price, 2001). However, ensuring the quality and reliability of POCT devices and providing adequate training for operators are crucial for achieving accurate results.

**Digital Pathology and Telemedicine:** Digital pathology involves the use of digital imaging technology to scan and analyze pathology slides, facilitating remote diagnosis and consultation. This technology enables pathologists to review and interpret slides from anywhere, improving access to specialized expertise and reducing turnaround times for pathology reports (Gruson et al., 2019). Telemedicine, combined with digital pathology, allows for virtual consultations and second opinions, enhancing diagnostic accuracy and patient care. These technologies are particularly valuable in regions with limited access to pathology services, enabling timely and accurate diagnoses despite geographical barriers.

**Genomics and Personalized Medicine:** Advancements in genomics and personalized medicine have revolutionized laboratory testing by providing insights into individual genetic profiles. Genetic testing can identify predispositions to certain diseases, guide treatment decisions, and monitor patient responses to therapies. Personalized medicine tailors medical treatment to individual characteristics, necessitating precise and accurate laboratory testing (Collins & Varmus, 2015). Genomic technologies, such as next-generation sequencing (NGS), enable comprehensive analysis of genetic information, leading to more targeted and effective treatments. For example, NGS can identify mutations in cancer-related genes, allowing for the development of personalized cancer therapies that target specific genetic abnormalities (Mardis, 2017).

**Challenges in Quality Improvement:** Despite significant advancements in laboratory technology and practices, several challenges persist in improving the quality of laboratory test results. These challenges include resource limitations, variability in laboratory practices, and resistance to change. Addressing these challenges is crucial for achieving consistent and reliable laboratory testing.

**Resource Limitations:** Limited resources, especially in low- and middle-income countries, hinder the implementation of quality improvement measures. Laboratories in these regions often face constraints such as inadequate funding, insufficient infrastructure, and a lack of trained personnel. These limitations can affect the availability and maintenance of essential laboratory equipment, reagents, and quality control materials. For example, laboratories may struggle to afford advanced automated systems or participate in proficiency testing programs, which are critical for ensuring test accuracy and reliability (Wolcott et al., 2007). Addressing resource limitations requires investment in laboratory infrastructure, training programs, and international support to build capacity and improve laboratory quality.

**Variability in Laboratory Practices:** Differences in laboratory practices across institutions lead to variability in test results. Factors contributing to this variability include differing methodologies, equipment, and quality control procedures. Standardizing protocols and procedures is essential to ensure uniformity and reliability of results. Accreditation programs and adherence to international standards, such as those set by the International Organization for Standardization (ISO) and the Clinical and Laboratory Standards Institute (CLSI), can help achieve this goal (Njoroge & Nichols, 2014). Standardization efforts should focus on harmonizing test methods, implementing consistent quality control measures, and ensuring that laboratories meet established performance criteria.

**Resistance to Change:** Resistance to adopting new technologies and practices is a common barrier to quality improvement. Laboratory

personnel and healthcare providers may be hesitant to change established workflows and protocols, especially if they are unfamiliar with new technologies or doubt their efficacy. Overcoming resistance to change requires continuous education and training, as well as demonstrating the benefits of innovations in laboratory practices. Involving laboratory staff in the planning and implementation of new technologies can also foster acceptance and engagement (Kotter, 1996). Additionally, highlighting success stories and evidence of improved patient outcomes can help build support for change.

**Regulatory and Compliance Issues:** Compliance with regulatory requirements is essential for maintaining laboratory quality, but navigating complex regulations can be challenging. Laboratories must adhere to various local, national, and international regulations, which can vary widely and require significant administrative effort. Staying updated with regulatory changes and ensuring compliance can be resource-intensive, especially for smaller laboratories with limited administrative support. Developing robust compliance frameworks and leveraging technology to streamline regulatory processes can help laboratories meet regulatory requirements more efficiently (Snyder et al., 2017).

**Keeping Pace with Technological Advances:** The rapid pace of technological advancements in laboratory medicine poses a challenge for laboratories to keep up with the latest developments. Continuous investment in new technologies, training for laboratory personnel, and updating laboratory information systems are necessary to integrate advanced technologies into routine practice. For instance, implementing next-generation sequencing (NGS) or adopting AI-driven diagnostic tools requires significant investment in equipment and training. Laboratories must also ensure that their IT infrastructure can support these advanced technologies and that data security and privacy are maintained (Mardis, 2017).

**Future Directions:** The future of laboratory quality improvement lies in leveraging emerging technologies, fostering global collaboration, and enhancing education and training. As laboratory medicine continues to evolve, these strategies will be critical in addressing current challenges and driving continuous improvement in the quality of laboratory test results.

**Integration of Advanced Technologies:** The integration of advanced technologies, such as artificial intelligence (AI), machine learning (ML), and blockchain, holds promise for enhancing laboratory quality and efficiency. AI and ML can improve diagnostic accuracy by analyzing complex datasets, identifying patterns, and predicting outcomes with high precision. These technologies can also support quality control by detecting anomalies and suggesting corrective actions in real-time (Topol, 2019). Blockchain technology can enhance data security and integrity in laboratory information systems. By providing a decentralized and tamper-proof ledger, blockchain ensures that laboratory data is securely recorded and traceable. This can improve transparency and trust in laboratory processes, especially in multi-center studies and collaborations (Mackey et al., 2019).

**Personalized Medicine and Genomics:** Personalized medicine, driven by advancements in genomics, will continue to shape the future of laboratory testing. Genomic testing enables the identification of genetic predispositions and the development of tailored treatment plans based on an individual's genetic profile. As genomic technologies become more accessible and affordable, their integration into routine clinical practice will enhance the precision and effectiveness of medical care (Collins & Varmus, 2015). For example, next-generation sequencing (NGS) allows for comprehensive genetic analysis, facilitating the identification of rare genetic mutations and informing targeted therapies for conditions such as cancer and inherited disorders. Continued investment in genomic research and infrastructure is essential for realizing the full potential of personalized medicine (Mardis, 2017).

**Global Collaboration and Standardization:** Global collaboration and standardization are crucial for improving laboratory quality

worldwide. International organizations, such as the World Health Organization (WHO) and the International Organization for Standardization (ISO), play a key role in developing and promoting standardized guidelines and best practices for laboratory testing. Collaborative initiatives, such as the Global Laboratory Initiative (GLI) and the Global Harmonization Task Force (GHTF), aim to harmonize laboratory standards and enhance capacity building in resource-limited settings. These efforts help ensure that laboratories worldwide adhere to consistent quality standards, reducing variability in test results and improving patient care (World Health Organization, 2020).

**Enhanced Education and Training:** Continuous education and training for laboratory professionals are essential for maintaining high-quality laboratory practices. As new technologies and methodologies emerge, ongoing professional development ensures that laboratory staff are equipped with the latest knowledge and skills. Programs that offer certifications, workshops, and online courses can provide accessible and up-to-date training for laboratory personnel. Additionally, incorporating simulation-based training and virtual reality (VR) technologies can enhance practical skills and improve competency in complex laboratory procedures (Lippi et al., 2020).

**Telemedicine and Remote Testing:** The rise of telemedicine and remote testing offers new opportunities for improving laboratory quality and accessibility. Telemedicine enables healthcare providers to consult with patients and specialists remotely, facilitating timely diagnosis and treatment. Remote testing, including home-based sample collection and point-of-care testing (POCT), reduces the need for patients to visit centralized laboratories. Innovations in remote testing technologies, such as portable diagnostic devices and lab-on-a-chip systems, allow for rapid and accurate testing in various settings. These advancements can improve access to laboratory services, particularly in underserved and rural areas, enhancing patient outcomes (Kim et al., 2020).

## CONCLUSION

Improving the quality of laboratory test results is a multifaceted endeavor that encompasses the entire laboratory process, from pre-analytical to post-analytical phases. Each phase presents unique challenges and opportunities for quality improvement, requiring a comprehensive approach that integrates advanced technologies, standardizes practices, and fosters continuous education and training. In the pre-analytical phase, meticulous attention to specimen collection, transportation, and preparation is critical for minimizing errors and ensuring the integrity of test samples. The analytical phase benefits significantly from automation and the use of sophisticated instruments, which enhance accuracy and precision while reducing human error. Post-analytical processes, including data entry, result interpretation, and timely reporting, are essential for delivering reliable test results and supporting clinical decision-making. Technological advancements, such as artificial intelligence, machine learning, and blockchain, are transforming laboratory practices by improving diagnostic accuracy, enhancing data security, and streamlining workflows. The rise of personalized medicine and genomics is driving a shift towards more precise and individualized healthcare, while global collaboration and standardization efforts are helping to harmonize laboratory practices and improve quality on a global scale. Despite these advancements, challenges remain, including resource limitations, variability in laboratory practices, and resistance to change. Addressing these challenges requires sustained investment in infrastructure, training, and international support, as well as a commitment to fostering a culture of quality and continuous improvement. Looking to the future, the integration of emerging technologies, enhanced education and training programs, and the expansion of telemedicine and remote testing will play pivotal roles in advancing laboratory quality. By embracing these innovations and fostering a collaborative approach, the laboratory medicine community can continue to improve the accuracy, reliability, and timeliness of test results, ultimately enhancing patient care and

outcomes. In conclusion, the journey to improving laboratory quality is ongoing and dynamic, demanding a proactive and adaptable approach. Through continued innovation, collaboration, and dedication to best practices, the goal of consistently delivering high-quality laboratory test results can be achieved, thereby contributing to better healthcare for all.

## REFERENCES

- Burtis, C. A., & Bruns, D. E. 2014. *Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics*. Elsevier Health Sciences.
- Carraro, P., & Plebani, M. 2007. Errors in a stat laboratory: types and frequencies 10 years later. *Clinical Chemistry*, 53(7), 1338-1342.
- Collins, F. S., & Varmus, H. 2015. A new initiative on precision medicine. *New England Journal of Medicine*, 372(9), 793-795.
- Gruson, D., Gruson, D., Bernardini, S., Caboux, E., Cavalier, E., Delatour, V., ... & Preiser, J. C. 2019. The rise of the machines: Artificial intelligence and the clinical laboratory. *ClinicaChimica Acta*, 493, 61-67.
- Hawkins, R. 2012. Managing the pre- and post-analytical phases of the total testing process. *Annals of Laboratory Medicine*, 32(1), 5-16.
- Kim, J., Campbell, A. S., de Ávila, B. E., & Wang, J. 2020. Wearable biosensors for healthcare monitoring. *Nature Biotechnology*, 37(4), 389-406.
- Kotter, J. P. 1996. *Leading Change*. Harvard Business Review Press.
- Kroll, M. H., & Elin, R. J. 1993. Interpreting laboratory results: correlation with clinical outcomes. *Clinical Chemistry*, 39(8), 1631-1637.
- Lippi, G., Becan-McBride, K., Behúlová, D., Bowen, R. A., Church, S., Delanghe, J. R., ... & Simundic, A. M. 2011. Preanalytical quality improvement: in quality we trust. *ClinicaChimica Acta*, 412(9-10), 768-773.
- Lippi, G., Salvagno, G. L., Montagnana, M., Franchini, M., & Guidi, G. C. 2010. Influence of the preanalytical phase on the diagnostic accuracy of laboratory tests. *ClinicaChimica Acta*, 411(19-20), 1601-1605.
- Mackey, T. K., Kuo, T. T., Gummadi, B., Clauson, K. A., Church, G., & Grishin, D. 2019. 'Fit-for-purpose?'—challenges and opportunities for applications of blockchain technology in regulatory oversight and global health: Table 1. *Clinical Pharmacology & Therapeutics*, 105(1), 31-34.
- Mardis, E. R. 2017. DNA sequencing technologies: 2006–2016. *Nature Protocols*, 12(1), 213-218.
- Nantes, J. C., Pereira, L. R., Santos, R. A., & Lippi, G. 2016. Barcoding for patient identification in the laboratory: a critical appraisal. *Clinical Biochemistry*, 49(15), 1107-1113.
- Njoroge, S. W., & Nichols, J. H. 2014. Laboratory quality management systems in resource-poor settings. *Clinics in Laboratory Medicine*, 34(1), 59-69.
- O'Kane, M. J. 2009. The effect of specimen transportation on clinical chemistry test results: An evidence-based practice guide for clinicians and laboratory practitioners. *Critical Reviews in Clinical Laboratory Sciences*, 46(7-8), 637-648.
- Plebani, M. 2006. Errors in clinical laboratories or errors in laboratory medicine?. *Clinical Chemistry and Laboratory Medicine*, 44(6), 750-759.
- Plebani, M. 2010. The detection and prevention of errors in laboratory medicine. *Annals of Clinical Biochemistry*, 47(2), 101-110.
- Plebani, M. 2012. Quality indicators to detect pre-analytical errors in laboratory testing. *ClinicaChimica Acta*, 404(1), 41-46.
- Price, C. P. 2001. Point of care testing. *BMJ*, 322(7297), 1285-1288.
- Ricos, C., Alvarez, V., Cava, F., Garcia-Lario, J. V., Hernandez, A., Jimenez, C. V., ... & Simón, M. 2004. The role of external quality assurance programs in improving analytical quality in clinical laboratories. *Clinical Chemistry and Laboratory Medicine*, 42(4), 401-409.
- Snyder, S. R., Favoretto, A. M., Derzon, J. H., Christenson, R. H., Kijewski, V., Shaw, C., ... & Liebow, E. B. 2017. Effectiveness of practices to reduce blood sample hemolysis in emergency departments: a laboratory medicine best practices systematic review and meta-analysis. *Clinical Biochemistry*, 50(18), 1008-1014.
- Stankovic, A. K., & DiSerio, F. 2001. Dynamic assessment of laboratory quality: an overview of the six sigma approach and its application in clinical laboratories. *Clinical Chemistry and Laboratory Medicine*, 39(3), 200-205.
- Tate, J. R., Johnson, R., Barth, J. H., & Panteghini, M. (2014). Harmonization of laboratory testing—current achievements and future strategies. *Clinical Chemistry and Laboratory Medicine*, 52(2), 189-197.
- Topol, E. J. 2019. High-performance medicine: the convergence of human and artificial intelligence. *Nature Medicine*, 25(1), 44-56.
- Westgard, J. O. 2006. Six Sigma quality design and control: Desirable precision and requisite QC for laboratory measurement processes. *Clinics in Laboratory Medicine*, 26(4), 655-662.
- Wolcott, J., Schwartz, A., & Goodman, C. 2007. *Laboratory Medicine: A National Status Report*. The Lewin Group.
- World Health Organization. 2020. *WHO global strategy on health, environment and climate change: the transformation needed to improve lives and wellbeing sustainably through healthy environments*. World Health Organization.

\*\*\*\*\*