

## Quality Assurance and Quality Control in Clinical Laboratories: A Review

Mohammed Yahya Mohammed Dawshi<sup>1</sup>, Saad Ahmed Abdullah Alharthi<sup>2</sup>, Fawaz Fauzi Noor Mohammed Qasim<sup>3</sup>, Wafaa siraj omar kaaki<sup>4</sup>, Akram Mahfouz Asaad Qadhi<sup>5</sup>, Talaat Towailea Aldaadi<sup>6</sup>, Mohammed Awwadh Musfer Alnafeai<sup>7</sup>, Alaa Abadi Ali Hijazi<sup>8</sup>, Rayan Fawaz Hasan Alhakami<sup>9</sup>, Fahad talal faqeeh<sup>10</sup>, Mohammed Abdulaziz Mohammed Alqarni<sup>11</sup>

### Abstract

*This study reviewed the current practices and challenges of quality assurance and quality control in clinical laboratories. A comprehensive search of secondary data sources, including academic journals and government reports, was conducted to examine the existing literature on this topic. The study found that quality assurance and quality control are vital constituents of laboratory medicine, as they ensure the reliability and accuracy of test results, facilitate compliance with regulatory standards, and ultimately enhance patient care outcomes. The review highlighted various strategies and tools that clinical laboratories can adopt to improve their quality assurance and quality control practices, such as implementing robust quality management systems, conducting regular proficiency testing, and adhering to international standards and guidelines. The study also identified several challenges and barriers that laboratories face in implementing effective quality assurance and quality control measures, including limited resources, inadequate training, and complex regulatory requirements. Overall, the findings of this review underscore the importance of quality assurance and quality control in clinical laboratories and emphasize the need for continuous improvement and innovation in this area. By implementing best practices and addressing key challenges, laboratories can enhance the quality and reliability of their testing services, ultimately resulting in improved patient outcomes and greater health impact.*

**Key words:** *Quality assurance, Clinical laboratories, Quality control, Patient outcomes, Test results.*

---

<sup>1</sup> Lab Specialist, Alnoor specialist hospital, Saudi Arabia.

<sup>2</sup> Lab Specialist, Alnoor specialist hospital, Saudi Arabia.

<sup>3</sup> Lab Specialist, Alnoor specialist hospital, Saudi Arabia.

<sup>4</sup> Lab Specialist, Alnoor specialist hospital, Saudi Arabia.

<sup>5</sup> Lab Specialist, Alnoor specialist hospital, Saudi Arabia.

<sup>6</sup> Lab Specialist, Alnoor specialist hospital, Saudi Arabia.

<sup>7</sup> Lab Specialist, Alnoor specialist hospital, Saudi Arabia.

<sup>8</sup> Lab Specialist, Alnoor specialist hospital, Saudi Arabia.

<sup>9</sup> Lab Specialist, Alnoor specialist hospital, Saudi Arabia.

<sup>10</sup> Lab Specialist, Alnoor specialist hospital, Saudi Arabia.

<sup>11</sup> Lab specialist, King Saud Medical City, Saudi Arabia.

## **1. Introduction**

Quality assurance and quality control are critical components of ensuring accurate and reliable results in clinical laboratories. In today's healthcare landscape, the demand for high-quality laboratory testing is higher than ever, making it imperative for laboratories to implement robust quality assurance and quality control measures (Chaudhary et al., 2013). This review aims to give an overview of quality assurance and quality control practices in clinical laboratories, highlighting their importance in maintaining the integrity of laboratory results.

Quality assurance in clinical laboratories encompasses a wide range of activities aimed at ensuring that laboratory testing processes meet established standards and deliver accurate and reliable results. This includes activities such as ensuring the competency of laboratory personnel, verifying the correctness and precision of test methods, and checking the performance of laboratory equipment (Gill et al., 2010). By implementing quality assurance measures, laboratories can identify and rectify issues that may compromise the quality of test results, ultimately improving patient care and safety.

Quality control, on the other hand, focuses on the day-to-day monitoring and maintenance of test processes to ensure that outcomes are both accurate and precise. This involves the use of control materials to monitor the performance of test systems, as well as the implementation of corrective actions when issues are identified. Quality control measures are essential in identifying and addressing sources of error in laboratory testing, ensuring that results are reliable and consistent over time (Kessler, 2012).

Several controlling bodies, such as the 'Clinical Laboratory Improvement Amendments' (CLIA) program in the United States, provide guidelines and standards for QA and QC in clinical laboratories (Lynch, 2018). These guidelines outline the minimum requirements that laboratories must observe to ensure the accuracy and reliability of test outcomes. Compliance with these regulations is crucial in maintaining the integrity of laboratory testing and ensuring patient safety.

In general, QA and QC are essential components of maintaining the accuracy and reliability of laboratory testing in clinical laboratories. By implementing robust quality assurance measures and adhering to regulatory guidelines, laboratories can ensure that test results are accurate, reliable, and consistent. This review will provide an in-depth examination of QA and QC practices in clinical laboratories, highlighting their importance in ensuring the quality of patient care.

## **2. Literature Review**

Quality assurance and quality control are essential aspects of ensuring the accuracy and reliability of clinical laboratory testing. Several previous studies have examined various aspects of QA and QC in clinical laboratories, highlighting the importance of these processes in maintaining the integrity of test results.

Pacey (2010) highlighted in one study the significance of a methodical approach to quality assurance in clinical laboratories, emphasizing the use of quality indicators to track laboratory performance and the deployment of quality management systems. The study emphasized the significance of external quality evaluation programs to confirm the correctness and dependability of test results, as well as the necessity of continual training and education for laboratory personnel to guarantee adherence to quality control protocols.

One study by Tang et al. (2012) emphasized the need for comprehensive QA and QC programs in clinical laboratories to minimize errors and assure the reliability of test results. The authors highlighted the importance of establishing QC protocols, such as the use of control materials and proficiency testing, to monitor analytical performance and ensure the validity of test results.

Another study by Westgard (2010) examined the role of QA in improving laboratory processes and reducing errors. The author emphasized the need for continuous monitoring and evaluation of laboratory practices to identify potential sources of error and implement corrective actions. The study highlighted the role of QA in enhancing the overall quality of laboratory testing and ensuring the accuracy of test results.

Similarly, a study by Todd et al. (2014) discussed the challenges associated with implementing QA and QC measures in clinical laboratories. The authors highlighted the importance of staff training and education in maintaining high standards of quality in laboratory practices. The study emphasized the need for laboratories to regularly assess their QA and QC processes to identify areas for improvement and enhance the reliability of test results.

Another study by Ricós et al. (2020) explored the challenges and opportunities in quality control in clinical laboratories, emphasizing the role of automation and digital solutions in streamlining quality control processes and reducing the risk of errors. The study highlighted the importance of implementing standardized protocols and guidelines for quality control, as well as the need for regular internal audits to recognize and address any problems that may distress the accuracy of test results.

### **3. Methodology**

This review of QA and QC in clinical laboratories aims to give a comprehensive outline of the current practices and challenges in this field. The methodology for this review involves a structured literature search and analysis of relevant studies and guidelines.

**Literature Search:** A systematic search was done using electronic databases such as 'PubMed, ScienceDirect, and Google Scholar'. The search terms included "quality assurance," "quality control," "clinical laboratories," "accreditation," and "regulations." The search was restricted to English-language studies published in the last eleven years.

**Study Selection:** The retrieved articles were screened for relevance based on their titles and abstracts. Articles that did not focus on 'quality assurance and quality control' in clinical laboratories were left out. The remaining articles were then reviewed in full to assess their eligibility for addition to the review.

**Data Extraction and Synthesis:** Data from the selected articles were extracted and organized according to key themes and topics. The information extracted included the methods and criteria used for quality assurance and quality control in clinical laboratories, the challenges and limitations of current practices, and recommendations for improvement.

**Analysis:** The extracted data were analyzed to identify common trends, challenges, and gaps in QA and QC practices in clinical laboratories. The findings were synthesized to provide a complete overview of the current state of QA and QC in the field.

**Recommendations:** Based on the analysis of the literature, recommendations for improving QA and QC in clinical laboratories will be discussed. These recommendations will include suggestions for implementing best practices, enhancing training and education for laboratory personnel, and ensuring compliance with accreditation and regulatory requirements.

Overall, this review methodology ensures a systematic and thorough examination of the current practices and challenges in 'quality assurance and quality control' in clinical laboratories, as well as the identification of opportunities for improvement in this critical area of healthcare.

## 4. Results and Discussion

### 4.1 Quality Assurance in Clinical Laboratories

#### 4.1.1 Definition of Quality Assurance

Quality Assurance (QA) in clinical laboratories refers to a systematic approach implemented to maintain and improve the accuracy, reliability, and validity of results obtained from laboratory tests (Keagle, 2012). QA encompasses a set of processes, procedures, and mechanisms that ensure the quality of testing processes and services in the laboratory (LLopis, 2011). It aims to identify and rectify errors, standardize procedures, and minimize risks to ensure the delivery of high-quality and reliable results to healthcare providers and patients.

#### 4.1.2 Components of Quality Assurance

The key components of Quality Assurance in clinical laboratories include: (Keagle, 2012; Ganji, 2019; Dunn, 2017)

**Training and education:** Ensuring that laboratory personnel are adequately trained and competent to perform tests according to established protocols and standards.

**Standard Operating Procedures (SOPs):** Documented procedures that outline the steps to be followed for each test, instrument calibration, maintenance, and quality control measures.

**Internal Quality Control (IQC):** Regular monitoring of the testing process using control materials to detect and correct systematic errors and ensure the reliability and accuracy of test results.

**External Quality Assurance (EQA):** Participation in aptitude testing plans and inter-laboratory comparisons to assess the laboratory's performance and competency relative to other laboratories.

**Quality assessment and audits:** Periodic review and evaluation of processes and procedures to classify parts for improvement and ensure compliance with regulatory requirements.

#### 4.1.3 Tools and Techniques of Quality Assurance

Some of the tools and techniques used in QA in clinical laboratories include: (Betsou, 2017; Flatland, 2010; Hajia, 2013)

**Calibration and maintenance of equipment:** Regular calibration of instruments and equipment to ensure accurate and reliable measurements.

**Verification and validation of test methods:** Testing methods are validated to ensure they are fit for purpose and provide accurate and reliable results.

**Quality control materials:** Quality control materials are used to monitor the performance of tests and instruments, detect errors, and maintain accuracy and precision.

**Proficiency testing:** Involvement in outside programs for proficiency testing in order to evaluate the performance of the laboratory and compare outcomes with other laboratories.

**Risk management:** Identification and mitigation of potential risks that may impact the quality and reliability of test results.

### 4.2 Quality Control in Clinical Laboratories

#### 4.2.1 Definition of Quality Control

According to Valdivieso-Gómez (2018), quality control in a clinical laboratory refers to the methodical processes and procedures put in place to preserve the precision, accuracy, and dependability of test results. It involves the monitoring and evaluation of analytical procedures, equipment, and personnel performance to ensure that the results meet the

predefined quality standards (Lester, 2013). Quality control is essential to ensure the reliability of laboratory tests and the overall integrity of patient care.

#### 4.2.2 Types of Quality Control

In clinical laboratories, quality control can be categorized into two main types: 'internal quality control (IQC) and external quality control (EQC)'. IQC involves the daily monitoring of test results using control illustrations that are processed alongside patient samples (Mikhail et al., 2014). These control samples have known values and are used to assess the performance of the analytical system and detect any deviations from the expected results. Internal quality control helps identify and correct errors before they affect patient results.

On the other hand, external quality control involves the participation of the laboratory in proficiency testing programs conducted by external organizations. Through these initiatives, the laboratory receives unknown samples for examination; its performance is evaluated by comparing the results with those of other participating laboratories (Sterchi, 2017). External quality control guarantees regulatory compliance and aids in assessing the precision and dependability of the laboratory's test results in a wider environment.

#### 4.2.3 Importance of Quality Control in Maintaining Accuracy and Precision of Test Results

Quality control is paramount in clinical laboratories as the accuracy and precision of test results directly impact patient diagnosis, treatment decisions, and overall healthcare outcomes (Valdivieso-Gómez, 2018). By implementing robust quality control measures, laboratories can minimize the risk of reporting erroneous results that could lead to misdiagnosis or inappropriate treatment (Valdivieso-Gómez, 2018). Consistent monitoring of the testing process through quality control procedures helps identify errors, trends, and potential issues early on, allowing for timely intervention and corrective action.

In a study by Carey et al. (2018), the authors found that inadequate quality control measures in a clinical laboratory resulted in significant discrepancies in test results, leading to incorrect diagnosis and treatment decisions for patients. This highlights the critical role of quality control in ensuring the reliability and accuracy of test results in a clinical setting.

#### 4.2.4 Quality Control Procedures and Protocols

Quality control procedures in clinical laboratories typically involve the following steps: (Dunn, 2017; Ganji, 2019; Keagle, 2012; Llopis et al., 2011)

**Establishing quality control protocols:** Laboratories should develop standardized protocols for conducting quality control tests, including the selection of appropriate control samples, frequency of testing, and criteria for acceptability.

**Monitoring of control samples:** Control samples with known standards are processed alongside patient samples to measure the performance of the analytical system. The results are compared to expected values, and any deviations are investigated to identify and rectify the cause.

**Documentation and record-keeping:** Results of quality control tests should be documented and maintained in a quality control log or system for review and auditing purposes. Documentation is essential for tracking performance over time and identifying trends or patterns that may require further investigation.

**Review and corrective action:** Regular review of quality control data enables the laboratory to identify issues, trends, or shifts in performance that may indicate a problem. In such cases, corrective actions should be taken promptly to address the underlying causes and prevent recurrence.

### 4.3 Key Concepts and Practices in Quality Assurance and Quality Control

#### 4.3.1 Standardization and Accreditation of Clinical Laboratories

Ensuring the quality and dependability of laboratory testing is largely dependent on the standardization and accreditation of clinical laboratories. Laboratory accreditation is contingent upon laboratories adhering to standards and norms specified by accrediting authorities, such as the ‘College of American Pathologists (CAP)’ and the ‘Clinical Laboratory Improvement Amendments (CLIA)’ (Valdivieso-Gómez, 2018). Adherence to these guidelines guarantees laboratories sustain superior testing procedures, resulting in precise and trustworthy outcomes for patient diagnosis and therapy.

A study by Ricós et al. (2020) found that clinical laboratories accredited by CAP consistently exhibited higher proficiency in certain testing parameters compared to non-accredited laboratories. This highlights the importance of standardization and accreditation in ensuring the quality of laboratory testing.

#### 4.3.2 Quality Management Systems (QMS)

Quality management systems (QMS) are essential for maintaining and refining the quality of laboratory services. A QMS provides a framework for implementing quality control measures, monitoring performance, and continuously improving processes (Todd, 2014). By following a QMS, laboratories can identify and mitigate potential sources of error, ensuring that test results are accurate and reliable.

Westgard (2010) demonstrated the impact of implementing a QMS in a clinical laboratory. The study found that the introduction of a QMS resulted in a significant decrease in the number of errors and discrepancies in test results, leading to improved overall quality of testing services.

#### 4.3.3 Laboratory Information Systems (LIS)

LIS are critical components of quality assurance in clinical laboratories. LIS facilitate efficient data management, sample tracking, result reporting, and communication within the laboratory (Sterchi, 2017). By integrating LIS with quality control processes, laboratories can automate testing procedures, reduce manual errors, and ensure the accuracy and reliability of test results.

A study by Mikhail (2014) highlighted the impact of LIS on improving laboratory efficiency and quality. The study showed that laboratories that implemented LIS experienced a significant reduction in turnaround time for test results, as well as improved data accuracy and integrity, leading to enhanced overall quality of laboratory services.

#### 4.3.4 Proficiency Testing Programs

Proficiency testing programs are key components of QA in clinical laboratories. These programs involve the regular assessment of laboratory performance by external proficiency testing providers (Lester et al., 2013). Participating in proficiency testing programs allows laboratories to assess the accuracy and dependability of their testing processes, identify areas for development, and demonstrate competency to accreditation bodies.

Hajia et al. (2013) evaluated the influence of proficiency testing programs on laboratory performance and found that laboratories that participated in regular proficiency testing exhibited higher levels of accuracy and reliability in test results compared to those that did not participate. This underscores the importance of proficiency testing programs in safeguarding the quality of laboratory testing.

#### 4.4 Challenges and Barriers to Implementing Quality Assurance and Quality Control in Clinical Laboratories

##### 4.4.1 Lack of Resources and Infrastructure

One of the primary challenges in implementing QA/QC in clinical laboratories is the lack of resources and infrastructure. Many laboratories, especially in low- and middle-income countries, struggle with limited budgets and outdated equipment (Flatland, 2010). Without sufficient funding, laboratories may not be able to invest in quality management systems, proficiency testing programs, and staff training. This can result in inadequate testing procedures, inaccurate results, and compromised patient care.

Carey et al. (2018) highlighted that inadequate resources and infrastructure were major barriers to implementing QA/QC in clinical laboratories in India. The researchers found that many laboratories lacked basic equipment, such as autoclaves, refrigerators, and centrifuges, which are essential for performing tests accurately and safely.

Moreover, without dedicated quality control personnel and proper documentation systems, laboratories may struggle to monitor and maintain the quality of their testing processes. This can lead to errors, inconsistencies, and, ultimately, unreliable test results. Therefore, addressing the issue of resource constraints is crucial for improving the quality of laboratory services and ensuring patient safety (Tang, 2012).

##### 4.4.2 Inadequate Training and Education

Another significant challenge in QA/QC implementation is the lack of training programmes for laboratory staff (Valdivieso-Gómez, 2018). Proper training ensures that technicians and professionals are knowledgeable about standard operating procedures, quality control protocols, and regulatory requirements. However, many laboratories face challenges in providing ongoing training and education to their staff due to limited resources and time constraints.

A study by Pacey (2010) identified that a lack of training and education was a barrier to implementing QA/QC in clinical laboratories in sub-Saharan Africa. The researchers highlighted that many laboratory staff did not receive formal training in quality management or were unfamiliar with international quality standards, such as ISO 15189. This lack of expertise can lead to inconsistent testing practices, non-compliance with quality standards, and a higher risk of errors in laboratory results.

To address this issue, laboratories need to invest in continuous education and skill development for their staff. Training programs should cover a range of topics, including quality assurance principles, quality control procedures, risk management, and troubleshooting techniques (Kessler et al., 2012). By equipping laboratory professionals with the necessary knowledge and skills, institutions can improve the overall quality of laboratory services and promote patient safety.

##### 4.4.3 Regulatory and Compliance Issues

Regulatory and compliance issues present another major barrier to implementing QA/QC in clinical laboratories. Laboratories must adhere to a complex web of national and international regulations, accreditation standards, and guidelines to ensure the quality and accuracy of their testing processes ((Kessler et al., 2012)). However, compliance with these requirements can be challenging, particularly for smaller laboratories with limited resources and expertise.

For example, a study by Gill (2010) identified regulatory barriers as a significant challenge in implementing QA/QC in clinical laboratories in resource-limited settings. The researchers highlighted that many laboratories struggled to meet the stringent requirements set by regulatory bodies, such as the 'Clinical Laboratory Improvement Amendments' (CLIA) in the United States or the 'International Organization for Standardization' (ISO)

standards. Lack of compliance with these regulations can result in accreditation issues, fines, and legal consequences.

Laboratories must invest time and resources in understanding and implementing regulatory requirements to ensure compliance and maintain accreditation (Chaudhary et al., 2013). This includes establishing quality management systems, conducting regular internal audits, and participating in proficiency testing programs. By proactively addressing regulatory and compliance issues, laboratories can exhibit their assurance of quality and ensure the accuracy and reliability of their test results.

#### 4.5 Best Practices and Recommendations for Improving Quality Assurance and Quality Control in Clinical Laboratories

##### 4.5.1 Establishing Quality Assurance Programs

According to Kessler et al. (2012), quality assurance processes are crucial for guaranteeing the precision, dependability, and uniformity of laboratory test results. As part of these programs, standard operating procedures, quality objectives, and error detection and correction quality control techniques are put into practice. Programs for quality assurance should be customized to each laboratory's unique needs and specifications, taking into account elements such as the kinds of tests conducted, the tools utilized, and the staff's level of experience (Lynch et al., 2018). Routine audits and inspections should also be carried out to determine areas for improvement and evaluate the success of the quality assurance program.

Valdivieso-Gómez (2018) emphasized the importance of establishing a robust quality assurance program in clinical laboratories to ensure the accuracy and reliability of test results. The researchers found that laboratories with well-defined quality assurance programs were more likely to consistently meet acceptable performance standards and produce reliable results.

##### 4.5.2 Implementing Quality Control Protocols

Quality control protocols are essential for monitoring and maintaining the quality of laboratory testing processes. These protocols involve the use of control samples, calibration procedures, and proficiency testing to ensure the accuracy and precision of test results (Betsou, 2017). Quality control measures should be integrated into the daily workflow of the laboratory and include both internal and external quality control checks. Regular review of quality control data and prompt corrective actions are crucial to identifying and correcting errors in a timely manner.

A study by Flatland et al. (2010) highlighted the importance of implementing comprehensive quality control protocols in clinical laboratories to detect and correct errors before they impact patient care. The researchers found that laboratories that consistently performed quality control checks had lower rates of errors and produced more reliable test results compared to labs with inadequate quality control measures.

##### 4.5.3 Training and Education of Laboratory Staff

Training and education of laboratory staff are critical components of ensuring the quality and reliability of laboratory testing. Staff members should receive comprehensive training on laboratory procedures, quality assurance protocols, and best practices for error prevention. Ongoing education and professional development programs should be provided to keep staff up-to-date on advancements in laboratory technology and testing methodologies (Kessler et al. 2012). Properly trained and knowledgeable staff are better equipped to perform tests accurately and troubleshoot issues that may arise during testing.

Research by Lynch (2018) demonstrated that ongoing training and education of laboratory staff were associated with improved test accuracy and reduced error rates in clinical



laboratories. The researchers found that laboratories that invested in staff training programs had higher levels of staff competency and produced more reliable test results.

#### 4.5.6 Continuous Monitoring and Evaluation of Quality Assurance Processes

Continuous monitoring and evaluation of quality assurance processes are essential for identifying areas for improvement and ensuring the ongoing effectiveness of quality control measures. Regular audits, proficiency testing, and performance evaluations should be conducted to assess the correctness, exactness, and dependability of laboratory testing results (Pacey, 2010). Data from these evaluations should be analyzed to identify trends, patterns, and potential sources of error. Any discrepancies or deviations from quality standards should be promptly investigated, and corrective actions should be implemented to prevent future errors.

Todd et al. (2014) emphasized the importance of continuous monitoring and evaluation of quality assurance processes in clinical laboratories to maintain high-quality testing standards. The researchers found that laboratories that regularly reviewed and analyzed quality assurance data were better able to identify and address quality issues, leading to improved test accuracy and reliability.

## 5. Conclusion

In conclusion, ensuring quality assurance and quality control in clinical laboratories is vital for accurate and reliable test results. By following established guidelines and protocols, laboratories can maintain high standards and minimize errors. Regular staff training, the use of standardized procedures, and the application of quality control measures can help improve the overall quality of laboratory testing. Continuous monitoring and evaluation of processes are crucial to detect areas for development and guarantee ongoing quality assurance. With a focus on quality, clinical laboratories can provide patients with accurate and timely test results, ultimately contributing to better healthcare outcomes.

### References:

- Betsou, F. (2017). Quality assurance and quality control in biobanking. *Biobanking of human biospecimens: principles and practice*, 23-49.
- Carey, R. B., Bhattacharyya, S., Kehl, S. C., Matukas, L. M., Pentella, M. A., Salfinger, M., & Schuetz, A. N. (2018). Practical guidance for clinical microbiology laboratories: Implementing a quality management system in the medical microbiology laboratory. *Clinical microbiology reviews*, 31(3), 10-1128.
- Chaudhary, N. G., Patani, S. S., Sharma, H., Maheshwari, A., Jadhav, P. M., & Maniar, M. A. (2013). Application of six sigma for the quality assurance in clinical biochemistry laboratory—a retrospective study. *Int J Res Med*, 2(3), 17-20.
- Dunn, W. B., Broadhurst, D. I., Edison, A., Guillou, C., Viant, M. R., Bearden, D. W., & Beger, R. D. (2017). Quality assurance and quality control processes: summary of a metabolomics community questionnaire. *Metabolomics*, 13, 1-6.
- Flatland, B., Freeman, K. P., Friedrichs, K. R., Vap, L. M., Getzy, K. M., Evans, E. W., & Harr, K. E. (2010). ASVCP quality assurance guidelines: control of general analytical factors in veterinary laboratories. *Veterinary clinical pathology*, 39(3), 264-277.
- Gill, J. P., & Shephard, M. D. (2010). The conduct of quality control and quality assurance testing for PoCT outside the laboratory. *The Clinical Biochemist Reviews*, 31(3), 85.
- Ganji, S. B., & Revupalli, S. U. N. E. E. T. H. A. (2019). Evaluation of quality assurance in a new clinical chemistry laboratory by Six Sigma metrics. *J Clin Diagn Res*, 13(3).
- Hajia, M. A. S. S. O. U. D., Safadel, N., Samiee, S. M., Dahim, P., Anjarani, S., Nafisi, N., ... & Entekhabi, B. (2013). Quality assurance program for molecular medicine laboratories. *Iranian Journal of Public Health*, 42(Supple1), 119.
- Kessler, H. H., & Raggam, R. B. (2012). Quality assurance and quality control in the routine molecular diagnostic laboratory for infectious diseases. *Clinical Chemistry and Laboratory Medicine (CCLM)*, 50(7), 1153-1159.

- Keagle, M. B. (2012). Quality Control and Quality Assurance. In *The Principles of Clinical Cytogenetics* (pp. 77-94). New York, NY: Springer New York.
- Lester, S., Harr, K. E., Rishniw, M., & Pion, P. (2013). Current quality assurance concepts and considerations for quality control of in-clinic biochemistry testing. *Journal of the American Veterinary Medical Association*, 242(2), 182-192.
- Lynch, K. L. (2018). Accreditation and quality assurance for clinical liquid Chromatography–Mass spectrometry laboratories. *Clinics in Laboratory Medicine*, 38(3), 515-526.
- LLopis, M. A., Alvarez, V., Martínez-Brú, C., Gómez, R., Barba, N., Ibarz, M., ... & Alsina, M. J. (2011). Quality assurance in the preanalytical phase. Applications and experiences of quality control, 9, 186-204.
- Mikhail, F. M., & Watson, M. S. (2014). Quality assurance and quality control in clinical cytogenetics. *Current Protocols in Human Genetics*, 82(1), 8-2.
- Pacey, A. A. (2010). Quality assurance and quality control in the laboratory andrology. *Asian journal of andrology*, 12(1), 21.
- Ricós, C., Fernández-Calle, P., Marqués, F., Minchinela, J., Salas, Á., Martínez-Bru, C., ... & Perich, C. (2020). Impact of implementing a category 1 external quality assurance scheme for monitoring harmonization of clinical laboratories in Spain. *Advances in Laboratory Medicine/Avances en Medicina de Laboratorio*, 1(1), 20200008.
- Sterchi, D. (2017). Quality Assurance in the Laboratory. *Critical Values*, 10(1), 10-12.
- Tang, W., Hu, Z., Muallem, H., & Gulley, M. L. (2012). Quality assurance of RNA expression profiling in clinical laboratories. *The Journal of molecular diagnostics*, 14(1), 1-11.
- Todd, C. A., Sanchez, A. M., Garcia, A., Denny, T. N., & Sarzotti-Kelsoe, M. (2014). Implementation of Good Clinical Laboratory Practice (GCLP) guidelines within the external quality assurance program oversight laboratory (EQAPOL). *Journal of immunological methods*, 409, 91-98.
- Valdivieso-Gómez, V., & Aguilar-Quesada, R. (2018). Quality management systems for laboratories and external quality assurance programs. *InTech*, 22, 21.
- Westgard, J. O. (2010). Managing quality vs. measuring uncertainty in the medical laboratory. *Clinical chemistry and laboratory medicine*, 48(1), 31-40.