Tuijin Jishu/Journal of Propulsion Technology
ISSN: 1001-4055
Vol. 45 No. 4 (2024)

# The Importance of Quality Assurance Practices, Proficiency Testing, and Integrity of Laboratory Test Results

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***Abstract***

This paper explains the important role of quality assurance practices in generating accurate and reliable laboratory test data. Specification conformance or product performance, as evidenced by laboratory test results, has an economically significant bearing on the users and clients of these services. Uplifting the general understanding of the science behind proficiency testing practices and the methods for expressing uncertainty in test results is the public goods aspect of this essay. The paper offers two important lessons for stakeholders and managers of quality control and quality assurance within the mechanics of proficiency testing in the laboratory industry. First, it is only by regularly conducting proficiency testing that any laboratory can provide compelling evidence of its technical competence. Second, differences in performance can sometimes detect that the reliability of test data within the laboratory has been compromised. People have casually confused accuracy with reliability; the two terms are well defined in national and international standards. Newspapers run big stories on the accuracy of test data when, in actual fact, they are talking about reliability, implying that accuracy can only be challenged when the certified values are too close to a given test method's limits of detection or quantification. Policymakers who support private sector testing services without funding activities to train, develop, and upskill laboratory managers and staff not only can undermine the confidence users have in this body of scientific results but also make these bodies of scientific facts irrelevant to their countries' socio-economic and legal specifications. (Brander et al.2020)

***Keywords*** – compelling Compromised casually detection

Turn qualities and their management is not just a matter of product quality, but it is a matter of all business processes and systems that provide a guarantee that they do what they are supposed to do, and the product or result has all the quality that is normal for these types of products or results. These days, it is becoming more and more important to have a good quality system. According to this, it is very important for any business involving laboratory activities to guarantee flawless laboratory test results, and consequently, loyalty and confidence from customers and other stakeholders. The implementation of quality management systems in laboratories is referred to as laboratory quality management. One of the key principles of quality management, such as fulfilling customer requirements, confidence inside and outside the organization, open and correct internal communication, human resources and motivation, continuous improvement, ethical behavior, responsibility, and a strong customer service mindset, can be achieved through laboratory quality management.

## 1. Introduction

Analyses of experiencing state-of-the-art laboratory technology are presented. It is indicated that laboratories that want to be successful should use advanced techniques. Furthermore, they need a proper infrastructure, advanced knowledge, and should be well-qualified. However, there are some other important factors that affect the analyses,

the importance of which is often neglected. One of them is the quality assurance practices in the laboratory. (Brander et al.2020)

It is a fact that a laboratory may have the best and most expensive equipment, including the latest technology, but still get inconsistent results. The system has become very sophisticated and is essential for controlling quality. Factors such as the staff of the laboratory need to keep up to date with their knowledge, work carefully and accurately, and also need proper methods, detailed controls, validation of results, calibration, and control of the measurement systems, as well as systematic conducting and record-keeping of laboratory jobs. Laboratories are responsible for ensuring that their produced data are reliable and sustainable and for clarifying their reliability range. Data quality should be controlled during the planning stage of environmental monitoring and research studies, and the appropriate field control, calibration, and quality assurance procedures that have to be performed should be specified. (Sheldon et al.2022)

## 2. Quality Assurance Practices

Quality assurance (QA) in clinical laboratories comprises a range of procedures, processes, and functions designed to monitor and regulate laboratory processes and functions and other systems in ways that assure quality patient care. Those QA activities unique to the examination of survey samples, proficiency testing samples, or other evaluation samples must be performed by the clinical laboratory during the testing of each evaluation sample to ensure that the test system is reliable and the results of the testing are valid. External QA functions performed in the examination of materials are also important at the local, national, and international levels to validate long-term accuracy and performance parameters and allow test system monitoring and proper patient care through accurate results reporting. Proficiency testing measures the result of the interplay between procedure standardization, internal QA practices, local diagnostic accuracy performance from healthcare provider input, continuing education, new technology assessments, and overall public health program improvement. (Al et al.2022)

Good clinical laboratory practice includes the use of new technology, traditional technology, and customer service processes appropriately balanced through fiscally sound budgeting, easy staff access to quality information, clinical supervision of preparation techniques and personnel, accurate and validated clinical laboratory results, and proper records control maintained to minimize patient testing errors and maintain continuous cycle and patient sample integrity. Proficiency testing is the formal tool used to assess the long-term performance of the test method as well as to prevent problems when a test method is used incorrectly or results are not reported accurately. Proficiency testing, therefore, should be a monitored routine component of a continuous quality management program to assure the clinical laboratory service and the results of the tests performed are valid. All the tests performed by the clinical laboratory must be found to be accurate and precise as part of the laboratory QC program. Because testing requires the examination of a known substance, the process adds to the information available for test validation. (Badrick et al.2022)

### 2.1. Definition and Importance

Quality assurance (QA) practices ensure that tests are properly selected, correctly performed by qualified persons, and reported accurately. Proficiency testing (PT) provides an evaluative tool that measures the accuracy and reliability of a laboratory's performance. External PT is an important component of QA, and it is a mechanism by which a laboratory can determine the accuracy of its selected tests, methodologies, and personnel. The primary goal of PT is to improve the testing quality of the participants. PT supplies laboratory customers with evidence that testing handled by that laboratory meets appropriate requirements. Management uses PT as an audit of laboratory operations, a check on the validity of internal QA policies, and a method to determine that the generated results are valid as they are produced. (Health Organization, 2024)

Accuracy of test results is an important indicator of a respected clinical laboratory. The generation of accurate results is the responsibility of the laboratory. While all the laboratory personnel participating in daily testing activities directly affect the generated test results, management is responsible for maintaining quality in testing activities. Accuracy in test results reflects the laboratory's integrity and its ability to serve the public interest in primary healthcare, biomedical research, and public safety in the criminal justice system. The quality assurance

function ensures that tests are properly selected by trained professionals, correctly performed by competent trained laboratory personnel, and results are accurately reported. The proficiency testing assessments and the reliability of laboratory results are critical evaluation components. (Gao et al.2020)

### 2.2. Components of Quality Assurance

Quality assurance (QA) practices are an essential component of the analytical testing process. No matter the testing environment, QA practices are necessary in order to produce valid scientific results upon which decisions are made. The formalization of QA practices allows for better organization and oversight of testing within the laboratory and increases the probability of producing valid results. Fundamental components of most, if not all, laboratory QA programs are training and documentation outlining how a particular type of analysis is to be performed. To ensure that the testing meets the documented requirements, measurement traceability to a national or internationally accepted standard is implemented in the analytical process. Data validation measures, such as evaluation of method detection limits and measurement uncertainty calculations, allow the laboratory to numerically evaluate the quality of the data produced and to defend that quality in a court of law if necessary. (Zonnenshain & Kenett, 2020)

Quality control (QC) is the collection of measurements, such as the use of statistical control charts, that monitors the measuring system on a routine, ongoing basis to validate ongoing performance. Certification and use of primary and/or secondary reference materials, or good laboratory practices compliance requirements, among other QA practices, contribute immensely to the overall quality of the data produced. These practices ensure that the data are not only valid but also accurate, that results are legally defensible, and further, that the data are consistent, particularly when the laboratory is involved in regulatory or contractual testing. The use of standards that are traceable combined with a system of independent QA evaluations has created a national network of tests that are considered valid. (Santos et al., 2021)

## 3. Proficiency Testing

Proficiency testing (PT) measures the participant's ability to satisfactorily perform in testing specimens in a specific discipline or analyte. PT evaluates the type, frequency, and judgment of participant errors and provides feedback to the participant and referring authority regarding the degree of importance associated with PT at minimum standards and suggested corrective action to minimize participant effect on patient medical outcomes. Based on the testing methodology, testing coverage, available test menu, program frequency, and participant volume, an individual PT determination may involve multiple participant errors that necessitate careful judgment by the PT provider when issuing PT and evaluating PT results. Upon receiving an unsatisfactory PT evaluation, the participant is expected to perform immediate self-assessment to confirm that the necessary pre-analytical activities are being performed and to eliminate any potential errors that may compromise patient test results. (Davis & Norris, 2021)

Quality System Essentials influence the effectiveness and efficiency of the process control procedures and PT strategies at identifying participant error or test system deficiencies that may compromise test quality. During PT, outcome errors are identified based on the performance of the participant's entire testing system including the assessment selection of methods, reagents, equipment, and work environment, as well as including the participant performance and maintenance of pre-and post-examination factors such as patient specimen/reagent identification, specimen acquisition and transport, specimen collection, preparation and storage, specimen analysis, results review, general laboratory specimen and test identification, and testing results interpretation. (Challa et al.2024)

### 3.1. Purpose and Benefits

Testing has become indispensable for global trade and market access, and the growing concern about quality has been reflected in numerous trade and industrial agreements from the past to the present. The illegal practice of adulterating or substituting products for profit has generated problems of public health, distrust in the economic, social, and environmental impacts of globalization, and international conflicts. In this sense, tests become fundamental and must be performed with a lot of responsibility and quality assurance. Test-based decisions are delicate and of fundamental importance for the correct interpretation of possible subsequent tests, and bad

decisions can significantly impact global trade by leading to a feeling of distrust in technology. (Baldwin & Freeman, 2020)

Quality assurance is a way of preventing problems through planned and systematic activities. When it comes to recognizing the accuracy of test results, organizations must use adequate techniques. Techniques can include analytical quality practices that validate processes, providing safer and more accurate data for decision-making in a wide variety of situations, as well as proficiency testing. Proficiency is described in the scientific literature as an ability obtained through education, training, and a period of experience. The main purpose of proficiency testing is to determine laboratory performance, discussing the accuracy and quality of the tests carried out. (Mejia et al., 2020)

### 3.2. Types of Proficiency Testing

Proficiency testing has become one of the most effective tools for monitoring laboratory capability to produce valid results. Such tools have been designed to fit the changing needs of laboratory services. They include: Inter-laboratory comparisons, Proficiency testing schemes. Proficiency testing should be carried out on a continuous basis. It may be achieved in various ways depending on the requirements and objectives. The frequency of proficiency testing will be determined by the specific requirements in each case. There are proficiency testing scenarios for start-up laboratories, potential or existing clients of laboratory services. Clients will require evidence of the laboratory's participation in proficiency testing in order to assess the suitability of the laboratory to perform the analysis required. (Arifin & Mohd-Yusof, 2022)

In other cases, proficiency testing may be made mandatory as a prerequisite for obtaining and maintaining laboratory accreditation. Proficiency testing may also be used to establish in-house data quality and to evaluate the laboratory's improvement capability. Furthermore, it may also be used to assess changes in laboratory data quality over time and its performance relative to competing laboratories. Proficiency testing also helps detect the possibility of unsound analytical procedures due to contamination, chemically or biologically, of samples or any other occurrence of non-sampling influence that will affect the credibility of the results. Proficiency testing should continuously check the technical competence of laboratory service capabilities required. (Ilinca & Ganea, 2023)

## 4. Integrity of Laboratory Test Results

In a situation where patients, their immediate attendants, or health practitioners want to make decisions based on laboratory test results generated by medical laboratories, there is always a need for such test results to be accurate and reliable. Medical laboratory management, regulators, and organizations define the characteristic quality specifications that such laboratory test results should have and put in place measures to check if the required quality specifications are met. Quality assurance practices such as the use of internal quality control, participation in an external quality assurance program or proficiency testing, and implementing an appropriate corrective action procedure are put to work so that the possibility of false negatives, false positives, and analytical results with values that are not fit for purpose that could affect patient safety and medical decision-making is reduced. Clinical risk associated with an inaccurate test result can be categorized as one of the following: delayed diagnosis and treatment of disease, failure to establish a diagnosis, additional cost to the patient and healthcare providers, psychological complications for the patient, inadequate follow-up of the patient, unnecessary treatment. (Hager et al.2024)

### 4.1. Factors Affecting Test Result Integrity

Introduction The importance of quality assurance practices, proficiency testing, and the integrity of laboratory test results cannot be overemphasized. Laboratory test results are used in medical diagnosis, disease monitoring, therapeutic decision-making, drug dosing and dosage adjustment, and for monitoring disease risk factors. Thus, the level and range of acceptable performance need to be adequately defined and enforced to ensure laboratory analytical tests provide optimum outcomes. Quality assurance testing is the sum total of all the operations performed by the laboratory to guarantee the quality of the laboratory test results. Proficiency Testing is also an external quality assurance measure designed to determine the performance of the laboratory for specific tests or the accuracy of patient test results. Despite the presence of these quality assurance measures, when laboratory test

results recorded or reported from a good number of laboratories are checked, it is observed that there are lapses and problems that exist both in government-supported health facilities and in private laboratories. (Johannesen et al.2020)

Inaccurate results may have adverse effects on patients. The administration of too much of a test may result in toxicity and/or an adverse effect on the patient due to overtreatment, while underdosing may lead to an adverse event or therapeutic failure, as well as an increased risk of disease severity or spread, and even fatalities in both hospital and non-hospital environments. Other problems with the inaccuracy of laboratory results, such as extraneous costs and incorrect diagnoses, may also occur. Some of the reasons given for the false reports arising from the laboratories include the performance of inaccurate test methods, inaccurate operation of test methods, prohibitive temperature and humidity conditions affecting result reliability, inadequate calibration, lack of quality control processes, lack of staff to perform the analysis, and lack of pre-analytical zone controls. If these inadequacies exist, the reliability of the integrity of the results emanating from the laboratory comes into question. (Lee, 2024)

### 4.2. Ensuring Data Integrity

With all the variables that must be maintained at their most elusive peak, there is still no greater factor for a well-run laboratory to address than the integrity of data. Not the accuracy, precision, or reliability of data, but integrity. Data that is incontrovertible and true; not views on the interpretation of observations or manipulation of experimental results to intentionally show differences or relationships not actually observed, but the inherent integrity of the data from which the views and conclusions are drawn. Public trust in the quality of submitted data is paramount; the costs of checking submitted data, addressing the consequences of improperly checked or untestable data, or defending questions of compromised integrity can be catastrophic. Contrary to this fact, there is today an unparalleled recognition of the extent to which submitted data may be inaccurate, and often the original raw data cannot be verified without great effort; data obtained using analytical studies performed with ulterior motivation or for a result designed by the investigator or a group engaged in the process; data obtained from tests for which the quality of results is unknown, unchecked, and unverified. Data obtained with quality assurance practices inadequately designed and improperly implemented and managed. (Mansoor, 2021)

Maintaining and assessing integrity is difficult because there is no simple or universal model for appropriate, reliable, and legally defensible data checking procedures, nor for developing and identifying the many different indicators or criteria that identify deficiencies of integrity that, if not addressed, will impair the usability of the data. There must, however, be uniformity in identifying the processes or indicators that implement defect-free systems controls and in identifying the appropriate place of systems in the broad range of quality assurance activities that maintain the integrity of laboratory operations. Building and maintaining competent management controls and quality systems that provide tested and proven means for assessing the integrity of laboratory result data can help allay some of the doubts surrounding the questions that can make the end uses of the data feel vulnerable, uncomfortable, and unprotected. (Lücking et al.2020)

The success of the quality systems approach will be assured only when management recognizes it as an integral part of laboratory operations and of the soundness of the data upon which they base their decisions. The quality systems approach depends on a well-instructed, enthusiastic, and motivated staff supported by and supportive of the laboratory mission. Staff participation, positive comprehension, and acceptance of management controls and checks over the integrity of data become key activities to the success of data submissions. (Zonnenshain & Kenett, 2020)

## 5. Conclusion and Future Directions

The development and implementation of quality assurance practices can significantly minimize the likelihood of common laboratory errors, contribute to improving the integrity of laboratory analytical results, and promote a culture of ongoing improvement within laboratory operations. Conventional approaches are often costly, time-consuming, and can discourage regular participation due to feelings of inadequacy, competition, or perceived difficulty in gaining proficiency to perform effectively, particularly for developing countries. The implementation

of acceptable practices and a continuous attempt to overcome the challenges faced in implementing proficiency testing have contributed to the robustness of the study, thus significantly improving the quality and reliability of analytical measurements. In conclusion, quality-assured intervention programs are invaluable for any laboratory legal decision-making process and provide substantial assurance for consumers that the results are accurate and reliable. The importance of laboratory testing and economic benefits is relatively dependent on the quality, reliability, and accuracy of analytical findings. Without a demonstrated level of quality in the data, it is difficult at best to establish evidence-based policies, and incorrect interventions may produce bias, waste expenses, time, and resources, i.e., applying the wrong solution to analytical challenges. Although proficiency testing and internal audit programs have been, for the most part, beneficial in addressing them, extensive attention and advancement are still necessary to adopt, design, implement, evaluate, and sustain proficiency testing coverage and quality assurance practices, particularly for laboratories and organizations in the developing world. (Babyar, 2020)

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