

ALAPAC/ML:

Asociación Latinoamericana de Patología Clínica

y Medicina de Laboratorio

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ALAPAC/ML 2018: 002. LATIN AMERICAN GUIDE TO IMPROVE
QUALITY, BIOETHICS AND RELEVANCE OF MEDICAL LABORATORIES

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INTRODUCTION

To efficiently meet the needs of Evidence-Based Medicine, Medical Laboratory Professionals shall provide verifiable support through constantly growing activities, demonstrating expertise in multiple disciplines including medical biochemistry, cytology, haematology, immunology, endocrinology, microbiology, molecular diagnostics, genetics and nuclear medicine.

This requirement has generated increasing impact of Total Quality Management on performance. Given this situation, last decades have evolved in the three stages of the analytical process in accordance with ISO / IEC 15189 covering quality comprehensively, including ISO/IEC 17043 for Proficiency Testing Providers. In order to achieve the highest level of quality medical laboratories must work on the basis of the Code of Ethics of the Pan American Health Organization which significantly emphasizes combating “dichotomy” that shall be considered as illegitimate paybacks that inevitably harm patients and other customers.

In the Latin American Association of Medical Pathology and Laboratory Medicine ALAPAC/ML we are committed to continuously working with improving the quality of Latin American Medical Laboratory. Once we understood this and took on the task in order to provide an instrument of international level and particularly tailored to fulfil the needs and possibilities of our region. Indeed, we proceeded to consult with members of ALAPAC/ML with a proposal that was overwhelmingly accepted to carry it forward. This is how PROMECAL was born a Program for Improving the Quality of Latin American Medical Laboratories. A free and voluntary program for all laboratories wishing to participate can do so without cost problems inherent in programs Accreditation and Certification.

The fundamental quality of this program is that it provides to be treated on the basis of the principles of ethics, suitability, competence and medical relevance for what can only be carried out between pairs exclusively, i.e. only between authentic medical laboratory professionals.

QUALITY, BIOETHICS AND MEDICAL RELEVANCE

In the field of medicine, quality is synonymous with safety. The Latin expression “primum non nocere” translates into “the first thing is not to hurt”. It is an aphorism applied in the field of medicine, and health sciences, often attributed to the Greek physician Hippocrates (460-370 BC).

In the XXI century, in the context of the technological age, medicine has been transformed becoming increasingly scientific. It has been fully documented that evidence-based medicine depends primarily on the quality of medical laboratory, starting from test indication and analytical control to outcome, when results and data interpretation has conditioned that on the basis of information obtained through Medical Laboratory determine more than 70% of medical decisions.

- 1. Bioethics is the systematic study of human behaviour in the field of life sciences and health care, examined in the light of the values and moral principles. Its application is critical in the medical laboratory quality assurance. Being ethical is to prevent unfair practices. Being ethical is to combat dichotomy. Being ethical is to manage internal quality control and external proficiency programs. Being ethical is to comply with the rules, regulations and best practices. Being ethical is to be responsible for the design, implementation, maintenance and improvement of quality management system, including policies and procedures to ensure the protection of confidential information. Being ethical is put the welfare of the patient as the fundamental premise. Based on the above, it is clear that all medical laboratories must have a code of ethics.*
- 2. The fundamental premise of medical laboratory is Medical Relevance that constitutes the main value on which above all, patient safety stands. Quality medical care, seen from the point of view of efficiency, lies precisely in the medical laboratory where there is a clear need for quality systems and technical competence that include traceable validated and well-controlled methods. The first stage to achieve quality is to develop a strategic plan that includes specific, measurable, achievable and challenging analytical goals, which today tend to be established on the*

basis of biological variability which consequently have greater Medical Relevance.

JUSTIFICATION

- 1. Scientific evidence has demonstrated that analytical errors are a major cause of problems that create risks and damages while mishandling patients. More than eighty percent of problems are generated before and after the analytical stage. Even when analytical errors are the less frequent, it is important to notice that these can be considered to be the most significant, since according to Plebani & Carraro (Clin Chem: 2007), these analytical errors are the cause of more than fifty percent of the errors in the medical management of patients.*
- 2. There is an opportunity for improvement in counselling, technical assistance, training and evaluations of medical laboratories and physicians including medicine in general and all specialties in particular throughout all the diagnostic and the process from the pre to the post analytical, which should be performed primarily by professionals in laboratory medicine among the participation of experts in various health sciences to ensure that these activities are carried out by "peers".*
- 3. In Latin America, unfortunately, assessments of quality management systems and technical competence are frequently handled by public and private entities through staff & personnel of various fields without demonstrable experience in medicine, with curricula lacking suitability since these individuals have never ever worked in a hospital, clinic or medical laboratory. In consequence Evaluations of Medical Laboratories and Proficiency Testing Providers are carried out taking as template documents ISO 15189 and ISO 17043 standards respectively which were generated, written and approved by qualified medical laboratory sciences and quality management experts including leaders of the WASPaLM & IFCC / LM (World Association of Societies of Pathology and Laboratory Medicine and the International Federation of Clinical Chemistry and Laboratory Medicine) but not always are ideal when you try to apply these standards to the reality of our countries.*

VISION

Revision of current situation, prevailing in the Latin America Medical Laboratories allowed our organization to conclude that it is important to do more on the issues of quality, bioethics and medical relevance developing growing strength as specialists in medical laboratories science.

Mutual Recognition Agreement. Through this strategy we are committed to reduce the high costs of achieving accreditation. Our formal mission is to promote the development of medical laboratory professionals in Latin America through the planning, organization, development and continuous improvement of education, training, assessment and technical assistance.

PROCESS

According to our commitment we developed “PROMECA” a specific training program that includes a Guide with specific requirements, in addition to pre and post analytical exercises gratuitously available on our website www.alapacml.net with a corresponding Diploma of Recognition, which respectfully contemplates the Official Rules for each country.

As a fundamental part of the Guide we included the essence of the Code of Ethics of the Pan American Health Organization in order to frontally confront the phenomenon of dichotomy that as we know is a sort of widespread corruption throughout the region, and warn that it is an issue that should never be ignored by Local Authorities of the Health Sector of our region that should be combated through policies and procedures that rely on economists and administrators who generally put value of business above the true values of medicine.

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APPROVAL

ALAPAC/ML 1976-2014 Directive Commission gathered on March 2013 in Montevideo, Uruguay, concluded on the need for a document that homogenizes quality control criteria among member countries.

On the same meeting ALAPAC/ML 2016-2018 Directive Commission decided to take cognizance of the documents that constitute the LATIN AMERICAN GUIDE FOR QUALITY IMPROVEMENT, BIOETHICS AND MEDICAL RELEVANCE OF MEDICAL LABORATORY PROMECAL 2013: 001.

After five years, ALAPAC/ML Directive Commission gathered on September 2018 in Lima Peru, concluded on the need for an English version of the document emphasizing pre and post analytical process in order to strengthen de importance of test indication and data outcome interpretation through the expertise of Medical Pathology and Laboratory Medicine Specialists that shall be published as ALAPAC/ML 2018: 002. LATIN AMERICAN GUIDE TO IMPROVE QUALITY, BIOETHICS AND RELEVANCE OF MEDICAL LABORATORIES

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1. SCOPE

- 1.1 *This guide aims to establish specifications to be met for the organization and operation of Medical Laboratories. This for practical purposes herein referred as the Laboratory.*
- 1.2 *This document is the cornerstone of PROGRAM FOR QUALITY, BIOETHICS AND MEDICAL RELEVANCE ON LATINAMERICAN MEDICAL LABORATORIES that in the Spanish version is known as PROMECAL 2013:001.*
- 1.3 *PROMECAL is an academic and non-profit resource available to medical laboratory professionals and related personnel worldwide. www.alapacml.net. This Guide is voluntary compliance for laboratory as well as for professionals and technicians in the health of the public, social and private sectors involved in the organization and operation of such establishments.*

2. BIOETHICS

2.1 Principles

- 2.1.1 *The laboratory shall not engage in practices at odds with the law. The reputation of the profession shall be preserved and improved continuously.*
- 2.1.2. *The laboratory should be administered under the responsibility of a professional authorized and properly qualified under the laws and regulations in force in their country.*
- 2.1.3. *It is the duty of every professional working have as a fundamental purpose fully aware of their professional responsibility, offer their services efficiently and capable, basing their analysis and research on the following concepts.*
- *Scientific and practical knowledge acquired during their training.*
 - *The study, reading and research of recent scientific advances in what refers to the branch of the Laboratory.*
 - *Ethical principles and respect for human rights.*

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2.1.4 The personal and professional integrity are concepts that must be maintained always present in order not to prejudice the rights of the professionals of this branch and community rights.

2.1.5 It is unethical to provide unjustified professional signature even if or when it is given non profit.

2.1.6 The laboratory will not make financial arrangements with referring physicians or with financial agencies when such agreements act as incentives for the generation of applications for analysis and patient referral, or interfere with the physician's assessment of what is best for the Patient.

2.1.7 For the sake of mutual professional and moral respect, the professional should not perform laboratory practices of dichotomy with other professionals in or outside health field, as this is an act contrary to professional dignity and harms the country's health system. The practice of Dichotomy automatically disqualifies for the Recognition Diploma in Bioethics, Medical Quality and Medical Relevance regardless of compliance with all other requirements of this Guide.

2.1.8. Laboratory shall be independent and shall be separated from the Physician Offices except for inpatient health facilities.

2.1.9. Laboratory shall avoid situations that give rise to a conflict of interest, but where this is not possible should declare interests and take stages to minimize the impact. In this sense, it should be avoided:

- Practice dichotomy in collusion with doctors, companies, etc.*
- Patient pursued by means incompatible with professional dignity.*
- Private conduct examinations in state institutions which provide professional services.*
- Advertise analysis by newspaper, radio and television.*

2.2 Rights

2.2.1 The laboratory must ensure the safety and well-being of the patient and respect their interests and dignity, ensuring informed consent.

2.2.2 The laboratory shall not discriminate against its members on grounds of birth, age, ethnicity, race, gender, congenital condition or health status, social origin, language, religion, political affiliation, economic status, sexual orientation, disability or difference of any kind.

2.2.3 Honesty, professionalism and respect for human rights, will be Rules should always keep Laboratory Professionals wherever they are.

2.2.4 The primary sample collection must be performed with adequate privacy and respect for cultural aspects of the patient and the community. Patient information requested should be treated with absolute confidentiality.

2.2.5 When the sampling procedure is more invasive than venipuncture detailed information shall be provided to the patient and prior written consent shall be required. In addition, it will be warned about the probable risks, possible complications, side effects and adverse reactions thereof.

2.2.6 Information necessary for correct patient identification is must be collected, but no unnecessary personal information will be sought.

2.2.7 Patient and other lab users will be aware of the information collected and the purpose for which it is intended. Information requested may include data to provide security staff and other patient as when the possibility of communicable diseases or when such information is required to epidemiological data requested by the competent authority. All these data are confidential and the identity of the patient is always respected. You can also request the information needed for billing, financial audit, management review and use of resources.

2.2.8. All procedures performed on a patient require the informed consent. When the patient concurs Laboratory with a doctor's order for a

procedure preparation usual samples can be considered to have already been informed and is being submitted voluntarily to this procedure. If in doubt about it, you will be informed and asked to consent. The laboratory must have written instructions available for the staff concerned, where the types of sampling and analysis in a new consent must be asked and which do not need to be specified.

2.2.9. When in emergency situations is not possible to require prior consent may be carried out necessary procedures, provided they are in the best interest of the patient and applying the law and strict adherence to the principles of confidentiality.

2.2.10. When the type of analysis requires it, as some genetic or serologic, it will properly advise the patient about the procedures, objectives and risks of research. In these cases, although the applicant has informed the Medical Patient, it is recommended to strengthen counselling.

2.2.11. When the analytical results obtained may have serious implications, they must be communicated by well trained personnel hierarchical advising the patient on the nature and severity of their condition.

2.3 Collaboration

3.3.1 It is the duty of every laboratory to call of institutions or competent authorities in case of emergencies, epidemics, pandemics, disasters, natural and deliberate disasters or national emergency situations.

2.4 Policies

2.4.1 *Samples should be collected under the responsibility of a trained, qualified and authorized personnel.*

2.4.2. *When the laboratory receives samples from another laboratory, medical or places outside their laboratory, personnel must ensure they arrive in the right conditions. Otherwise, you should refuse and inform the Direction of the applicant laboratory.*

2.4.3. *Laboratory tests should be performed according to recognized and published scientific standards and a level of skill and competence expected of the profession.*

2.4.4 *Any falsification or alteration of the results is absolutely unacceptable*

2.4.5. *You must ensure that the material obtained is suitable for the analysis requested and should be avoided getting higher than necessary volumes.*

2.4.6 *Notification of the results obtained with the best available accuracy must ensure, as far as possible, to be interpreted correctly and applied in the patient's best interest.*

2.4.7. *Laboratory staff must be properly trained to provide advice on:*

- *The selection of analysis.*
- *Using services.*
- *The type of sample needed.*
- *Frequency of testing.*
- *Reporting units.*
- *The interpretation of test results.*

The laboratory must document the periodic meetings of laboratory personnel with the medical staff on a regular basis regarding the use of laboratory services and for the purpose of consultation on scientific matters.

Responsible and Collaborating Laboratory should participate in medical sessions, providing advice on diagnostic efficacy both in general and in particular cases.

2.4.8 The stored information must ensure adequate protection against loss, unauthorized access, tampering or other misuse of it.

2.4.9. Each laboratory will establish its protocols output file, while respecting the legal requirements and recommendations of professional bodies, setting the time during which the results will be retained, how to access them and those for which information is available. It is recommended when there are no legal obligations or recommendations of professional bodies, this time not for routine analysis and special analysis 5 years to less than 3 years.

2.4.10. Samples that require or may require further study by legal or health issues should be stored.

2.4.11. For different biological samples as requested by the attending physician purposes without prior consent may not be used.

2.4.12. The use of residual patient samples for purposes other than those provided may be allowed for the development of quality control or external evaluation programs, non-profit, always ensure that use anonymously. It may also include the use of residual samples for use for teaching (material is donated to universities for use in academic practices) including the use of crop strains obtained for scientific research.

2.4.13 Primary pure samples shall not be processed together with diagnostic or analytical purposes samples.

2.4.14 It is recommended that the laboratory counts with documented policies for the treatment legislation dichotomy. However, it is clear that this is just the beginning, even being on the agenda of bioethics many of the points that touch on ISO 15189:2003 Standard for Quality Management System and the technical competence of the laboratory, the as in the Code of Ethics of the Pan American Health Organization, which describes issues such as

- 1. Essentials and suitability of ethical principles*
- 2. Patients Rights*
- 3. Procedures on internal and external quality control.*
- 4. Respect the personality, dignity and privacy of all users.*
- 5. Provide complete information, in understandable terms, on services and procedures which will subject the patient as well as the requirements for its realization.*
- 6. Maintain the confidentiality of all information related to the results of the analysis, except when requested by the competent authority.*
- 7. Inform users, if any, if the procedures that will be used to submit a project based on research or teaching. In these cases, it is essential that consent be made in writing before two competent witnesses, with the formalities for the purpose by the Regulations of the General Law of Health in Research for Health.*
- 8. Laboratory personnel should not issue opinions or suggest interpretations of the results except the doctor or laboratory requesting the service.*
- 9. Techniques and procedures performed in the medical laboratory will be subject to scientific principles that underpin.*
- 10. When the doctor requires the services of a private laboratory, you must offer at least three options to the patient, can not condition the provision of professional services, presentation of the results of one laboratory only.*

3. MANUALS

3.0.1 All documents shall be available electronically. All documentation should include dates and signatures of review and approval

3.0.2 The Quality Manual must describe the Quality Management System and Structure Laboratory Documentation.

3.0.3 It should instruct all staff in the use and application of the Quality Manual and all documents that refer, as well as the requirements for implementation.

3.0.4 The Quality Manual should be updated under the authority and responsibility of the Quality Manager which must be designated by laboratory management person.

3.0.5 There should be an array of documents including all manuals, forms and records

3.0.6 The documentation available in the work area must correspond to the specific practices of the area including in each case.

All manuals and programs should be developed by the laboratory itself and must be approved and signed by the Director. Documents can be contained in a single Quality Manual or in several volumes depending on the size and complexity of the laboratory.

3.1 Organization

3.1.1 Index

3.1.2 Introduction: purpose of the manual

3.1.3 Corporate purpose. Quality policy, values, mission, vision and code of ethics.

3.1.4 Organic structure. Organization chart

3.1.5 Profile and job descriptions and functions.

3.1.6 Programs of preventive medicine, health and safety, vaccination and personnel evaluation.

3.2. Administration

3.2.1 Index.

3.2.2 Introduction: purpose of the manual.

3.2.3 Procedures and description of activities, if any, flowcharts.

3.2.4 Forms and instructions.

3.3 Pre-Analysis

3.3.1 Index.

3.3.2 Introduction and purpose of the manual

3.3.3 Medical indications and laboratory assessment.

3.3.4 List of available studies in the laboratory

3.3.5 Type of sample required for each test

3.3.6 Instructions and precautions for sampling

3.3.7 Instructions for transport and storage of samples.

3.4 Analysis

3.4.1 Index

3.4.2 Introduction and purpose of the manual

3.4.3 Name the method used

5.4.4 Foundation

5.4.5 Preparation

5.4.6 Procedure

5.4.7 Results

5.4.8 Reference limits

5.4.9 Program internal quality control

5.4.10. Program external quality assessment

5.4.11 Bibliography

3.5 Post-Analysis

3.5.1 Index

3.5.2 Introduction

3.5.3 Results report

3.5.4 Delineation of responsibility

3.5.5 Delimitation of turn around time "TAT" for emergency, routine, special tests

3.5.6 Panic and Alert Values Alert.

3.5.7 Review Criteria

3.5.8 Bibliography

3.6 Instrumentation

3.6.1 Index.

3.6.2 Introduction

3.6.3 Purpose of the manual

3.6.4 Computer name, model and serial number

3.6.5 Date of receipt and date of commencement of operations

3.6.6 Methods of Use

3.6.7 Special care

3.6.8 Preventive maintenance schedule: Checks and calibrations

3.6.9 Corrective maintenance program: Checks and calibrations

3.6.10 Bibliography

3.7 Biosafety

3.7.1 Index

3.7.2 Introduction and purpose

3.7.3 Laboratory Layout: Electrical, Hydraulics and installation of each equipment including refrigerators, ovens, analyzers

3.7.4 Equipment, procedure, program and log disinfection of the establishment

3.7.5 Equipment, procedure, program and logbook for handling infectious biological waste

3.7.6 Equipment, procedure, program and log for hazardous waste management

3.7.7 Equipment, procedure, program and logbook for the prevention and control of fires

3.7.8 Equipment, procedure, program and log radioactive wastes

4.0. PROVISION

4.0.1 *The laboratory must meet the requirements and have the authorization to operate under the laws and regulations of your country.*

4.0.2 *In addition to the above, establishments using ionizing radiation sources must meet the requirements of the applicable national regulations*

4.0.3 *The laboratory must have a responsible, which must meet the requirements of the applicable national regulations*

4.0.4 *The provision of laboratory should be subject to scientific and ethical principles that support it and the following.*

4.0.5 *Dignity and privacy of all users must be respected, always avoiding discriminatory practices.*

4.0.6 *Patient must provide complete information in understandable terms, on the services and procedures that will be subjected, and the requirements and risk to their implementation.*

4.0.7 *The procedures considered high risk, should be sought the letter of informed consent, in accordance with the provisions of the applicable national regulations*

4.0.8 *Confidentiality of all information related to the results of laboratory studies should be maintained except when requested in written form by the competent authority and in the cases provided for in the applicable legal provisions relating to epidemiological surveillance.*

4.0.9 *Users should be informed, where appropriate, whether the procedures that will be used to submit a project based on research or teaching in accordance with the provisions of the applicable national regulations*

4.0.10 *When the doctor requires the services of a private laboratory must give users at least three different options may not condition the provision of professional services, presentation of the results of one laboratory only.*

4.0.11 *The laboratory must keep a log of laboratory studies conducted, in the record. date, user name, type of laboratory studies, results issued with name and signature, if any, digitized or electronic of the person who made it.*

4.1. Responsibility

The laboratory must have an authorized charge which must meet national requirements to carry out its functions effectively, efficiently and with efficacy including the following.

4.1.1 Communicate in writing to the Competent Authority of the date of appointment, resignation or replacement.

4.1.2 Communicate in writing to the Competent Authority Assistance schedule establishment and any amendments thereto.

4.1.3 Report writing to the Competent Authority in the terms, manner and frequency that it determines, cases of communicable diseases and take the necessary measures for surveillance, to comply with the provisions of the applicable legal provisions.

4.1.4 Notify the Competent Authority when the commission of wrongful acts presumed.

4.1.5 Address, document and monitor directly to the claims made in the provision of services and contribute to its resolution, whether those caused by the staff of the establishment, by professionals or independent technicians who provide it their services, referral services or subcontracting with that link, by the provider or by the user, without prejudice to professional liability that might be incurred.

4.1.6 Monitor and maintain the proper functioning of the reception, take, storage, transportation and processing of samples within and outside the establishment.

4.1.7 Ensure that carried out the administrative technical control systems, and quality, both internal and external to determine this Guide.

4.1.8 Signing reports from laboratory studies or monitoring that are signed by the professional or technical personnel authorized by him, of handwritten or in your case, scanned or electronically, in accordance with the applicable legal provisions.

4.1.9 Ensure that within the institutions in charge, the health and safety measures to protect the health of occupationally exposed, in accordance with the provisions of the existing rules of your country apply.

4.1.10 Ensure that the curriculum and staff working documentation is kept current.

4.1.11 Ensure that professional and technical personnel receive ongoing training and has the supporting documentation.

4.1.12 To establish the necessary measures for laboratory personnel, do not issue opinions or suggestions to users about the results of laboratory studies.

4.1.13 Keep a log of analyzes they perform and keep copies of the reports for a period of at least 24 months.

4.1.14 Ensure that reports test results are printed reference limits according to the techniques employed. Biological reference intervals must be checked periodically. The review of biological reference intervals must also take place when the laboratory makes changes to the examination procedure.

4.1.15 The others that indicate other legal provisions.

4.2 Duties and Responsibility

The director of laboratory and medical system responsible for the quality management should

4.2.1 Establish and promote the Vision, Mission, Values, Quality Policy and Code of Ethics of the Organization which must be fully documented in the Quality Manual.

4.2.2 Direct and control the organization with regard to quality to drive it towards improving their performance through continuous improvement of its structure, processes and results.

4.2.3 Ensure that personnel be trained in the use and application of the Standard Operating Procedures (SOPs) that make up the Quality Management System (QMS) and other documents referenced by the system and to the requirements for its development.

4.2.4 To participate with other staff to achieve and maintain the effectiveness of the QMS, as well as its continuous improvement, based on the identification, planning, organization, development and process control.

4.2.5 To ensure the availability of resources necessary for the maintenance of the QMS.

4.2.6 To ensure that SOPs used are consistent with the SGC and that are available at their place of use.

4.2.7 Establish SOPs for identification, data collection, analysis, design, development and monitoring of corrective and preventive to improve and update processes actions.

4.2.8 To ensure that documents are identified and their distribution is properly controlled.

4.2.9 To ensure confidentiality and safekeeping of information and documents required.

4.2.10 To ensure that obsolete documents are properly identified and do not remain in use.

4.2.11 Have a policy and procedures for addressing and resolving complaints or other feedback received from doctors, patient or other user, records of complaints and of investigations and corrective actions taken by the laboratory must maintain, as required.

4.3 Staff

4.3.1 Medical Laboratory must have sufficient staff trained, qualified and suitable.

4.3.2 The laboratory must have signed individual records for each employee and the Director of the Laboratory in demonstrating that.

- *There is a profile and job description*
- *Know the Code of Ethics and Confidentiality, Quality Policy, Mission, Vision, Values.*
- *There Curriculum Vitae that includes basic training, work experience and training*
- *Productivity indices apply. Number of Studies / Employee*
- *Performance evaluation be conducted by the supervisor.*

4.3.3 The laboratory must have professional staff with qualification awarded by higher education institution officially recognized and registered by the competent educational authority.

4.3.4 Technical personnel must have a diploma legally issued and registered by the competent educational authorities.

4.3.5 Laboratory personnel who perform preventive maintenance should provide documentary evidence that has been trained for this activity.

4.3.6 The Laboratory can also hire nurses and administrative clerks in their respective areas of competence.

4.3.7 The laboratory must have an organizational chart that includes the responsibility assigned and documented for each area that is available in the organization.

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- *Archive*
- *Bacteriology*
- *Biochemistry*
- *Central sterilization*
- *Computing*
- *Control Sample*
- *Customer services*
- *Cytology*
- *Genetics*
- *Haematology*
- *Histopathology*
- *Hormones*
- *Immunology*
- *Material laundering*
- *Molecular biology*
- *Mycology*
- *Parasitology*
- *Pathology*
- *Quality assurance*
- *Radioimmunoassay*
- *Sampling*
- *Toxicology*
- *Warehouse*
- *Urinalysis*

5. FACILITIES

The laboratory should have separate and clearly identified areas including:

5.1 Pre-analytical.

5.1.1 Area for patient registration and waiting room for sampling, for receipt of requests for laboratory studies and delivering results.

5.1.2 Sampling area, which provides privacy, comfort and patient safety.

5.1.3 Specific areas for taking bacteriological or gynaecological specimens, to provide patient privacy

5.1.4. Adequate services, comprehensive and optimal hygienic sanitation.

- *General aspect.*
- *Space*
- *Cleaning*
- *Illumination*
- *Access*
- *Order*
- *Ventilation*
- *Temperature*
- *Maintenance program*

5.2. Analytical

5.2.1 The laboratory should have specific areas for different sections in which laboratory studies are conducted in the case of performing incompatible activities, separation with a physical barrier is necessary.

5.2.2 The laboratory should have a locating each analyzer and equipment available in each specific area including electrical, gas and hydraulic plane.

5.2.3 All systems must have maintenance logs and calibration of equipment included.

- *Computer name, manufacturer and serial number.*
- *Date of receipt and date of commencement of operations of the team. Maintenance dates, specifying calibrations and verifications equipment, according to a preventive maintenance program.*

5.2.4 The laboratory shall ensure that it has the material and technological resources, according to the type of studies carried out.

- *General aspect*
- *Space*
- *Cleaning*
- *illumination*
- *Access*
- *Order*
- *Ventilation*
- *Temperature*
- *Electrical installations*
- *Hydraulic*
- *Gases*
- *Instrumentation*
- *Calibrators*
- *Reagents*
- *Controls*
- *Maintenance program*

5.3 Support Areas

5.3.1 Specific area for equipment cleaning, sterilization.

5.3.2 Storage Guardian substances, materials and reagents, as provided in the applicable national regulations.

5.3.3 Where appropriate, area for temporary storage tank and biological-infectious hazardous waste (RPBI) in accordance with the provisions of the applicable national regulations

5.4 Administration

5.4.1. The laboratory should have specific administrative activities which should be separate sections in which laboratory studies are conducted, separation with a physical barrier for safety and hygiene areas still needed.

5.5 Information Technologies and Computing

5.5.1 The results and information represent the fundamental product of the laboratory. Because computer systems can be damaged or altered in a variety of ways, it is important that the laboratory establishes policies and compliance requirements to protect users from damage caused by the possible loss or change of data highlighting the following critical issues:

- *Computer name and model, hardware and software*
- *Methods of use, input, storage and retrieval of data.*
- *Validation Team*
- *Special care, safety and environment system*
- *Preventive and corrective maintenance.*
- *Bibliography.*

6. QUALITY ASSURANCE

6.1 INTERNAL QUALITY CONTROL

6.1.1 To ensure the quality of the laboratory must implement a program of internal control for all laboratory studies conducted, including the pre-analytical stages, analytical and post-analytical.

6.1.2. To ensure accuracy Laboratory should include daily controls including at least two checks, one at the normal level and one in the pathological range in addition to documenting, graph and statistically analyze the results

6.2 EXTERNAL EVALUATION OF QUALITY

6.2.1 To ensure accuracy the laboratory must participate in at least one external program quality assessment, recognized by the Latin American Association of Medical Pathology and Laboratory Medicine ALAPAC / ML, which should integrate laboratory studies conducted and includes the program, according to the needs of the laboratory's quality.

6.2.2 It is strongly recommended that the laboratory participates on academic exercises in order to validate and improve their capacity on test indication, medical microscopy and the interpretation of pathological information. These exercises are freely available through www.i-qualitat.net and virtually represent an advanced resource of telemedicine.

6.3 QUALITY IMPROVEMENT

6.3.1 The laboratory must document each area has carried out the evaluation of performance of each of the tests included in the external proficiency programs and develop research aimed to solve the problems of these laboratory studies in which quality is not satisfactory.

6.3.2 The laboratory must demonstrate documented the effectiveness of program quality improvement in all that have been found non-compliant.

6.4 QUALITY MANUAL

6.4.1 Pre-Analytic

There must be a specific manual of the pre analytical stage for preparing, storing and transporting samples. There must be copy of this manual in several areas including reception, control and distribution of samples. There should be clear instructions to send samples to reference laboratories.

The laboratory shall have an effective documented procedure for evaluating and selecting reference laboratories, as well as consultants who provide second opinions for histopathology, cytology and related disciplines. Laboratory management, with the recommendation of the users of laboratory services where appropriate, should be responsible for selecting and monitoring the quality of Subcontracted Laboratory and Consultants. Laboratory must ensure that such consultants are fully competent to perform the tests and other services requested including the indication of studies and the interpretation of results.

A Guide for the obtaining, identification, handling, storage and transport of samples should include.

- *Index*
- *Introduction*
- *Health and safety policy emphasizing that the material must be disposable venipuncture*
- *List of tests to be conducted*
- *Patient Preparation*
- *Sample type, volume and containers*
- *Instructions and special precautions for taking and preserving samples of each type.*
- *Where appropriate, instructions for the transport of samples.*
- *Collection time (i.e. Creatinine clearance)*
- *Anticoagulant and preservative.*
- *Time and transport temperature*

- *Tags. Emergency and Routines*
- *Medical data*
- *Bibliography*

6.4.2 Analytic

There must be a copy of the manual in local language of each and every analytical method in each laboratory test process which should contain

- *Index.*
- *Introduction.*
- *List of tests to be conducted.*
- *Name the methods used.*
- *Basis.*
- *Preparation.*
- *Procedures.*
- *Results.*
- *Reference limits.*
- *Medical relevance*
- *Bibliography.*

6.4.3 Post-Analytic

6.4.3.1 There must be a document for post analytical stage which must contain

- *Index.*
- *Introduction.*
- *Results report.*
- *Delineation of responsibility*
- *Delimitation of time and motion for urgency, routine, special tests*
- *Alert figures. Review Criteria*
- *Bibliography*

6.4.3.2 Reports for the outcome of laboratory studies should have printed reference limits according to the methods used, in addition to gender and

age group to which they relate, using the international general system of units of measurement in accordance with the provisions in force, except for the cases where National Standards in those cases where it is not required. Where appropriate, reports results of laboratory studies that are printed must include the name of the Laboratory, business address, and the name and professional certificate of health officials.

6.4.3.3 The results may be transmitted by electronic means as long as describe and include the name of the laboratory, the name and signature of besides requesting the same data that conducted the study, the name age and sex of the patient, the tests proper identification, the date and time it was taken, the sample is received, the test was performed and the result is transmitted in the report including the name of the test, the result and the reference limits.

7. BIOSAFETY

7.1 The laboratory must demonstrate that a free surface rate per worker is larger than two square meters.

7.2 All laboratory personnel should take preventive measures to protect samples in storage, transport and handling of toxic substances or biological-infectious hazardous waste taking into account the requirements of the applicable national regulations.

7.3 The health official must inform staff about the risks involved in the use and management of toxic, corrosive or irritant substances and, where applicable, sources of ionizing radiation. Infectious germs as well as the materials and processes inherent in samples, in order to comply with the Guidelines relevant safety and use personal protective equipment.

7.4 The area of microbiology to process bacteria, fungi or viruses, with potentially high biological risk of infectious diseases, must have Biosafety cabinet.

8. REFERENCE LABORATORY

8.1 Service contracts subcontracting reference labs shall be in written format and conform to the provisions of this guide and other applicable legal provisions. In the case of referral services or subcontracting carried out abroad, providers of such services, must comply with the regulations of the country in which they are established, while the laboratory reference shall be obligated to comply with the provisions for human biological materials.

8.2 Managers who sign service contracts or subcontracting reference jointly assume responsibility for the results.

8.3 Data results may be transmitted electronically provided means and when describing and include the name of the laboratory, the name and signature of addition to requesting the same data that conducted the study, the name of the age and sex of the patient, the key single exam, date and time when the sample was received, the test was performed and the result, the name of the test, the result and the reference limits aired.

9. ADVERTISING

9.1 It shall be exclusively informative about the type, characteristics and purposes of the provision of services and comply with applicable laws.

9.2 The advertising message should be guiding service, education and local language content.

9.3 Advertising techniques and may not offer preventive, curative and rehabilitative nature of medical or paramedical treatments.

10. AUDIT

To verify compliance with the requirements of the Quality Management System, it is necessary to carry out internal audits on predefined intervals. The audits must be formally planned, organized and carried out by the Quality Manager and by Laboratory Professionals. Personnel should not audit their own activities. The procedures for internal audit must be defined and documented and include the type of audit, frequency, methodology and required documentation. When they are detected deficiencies or opportunities for improvement, the laboratory shall undertake appropriate corrective or preventive actions, which must be met and documented in agreed time. There must be documentary evidence of monitoring of each area highlighting the following paragraphs.

10.1. Organization

- *Availability of Services*
- *Responsibility for solving problems*
- *Employee monitoring*
- *Availability of Headquarters*
- *Special Testing Catalogue*
- *Titles Responsible Service*
- *Flowcharts and Job Descriptions*
- *Sufficiency in number of employees to grow*
- *Staff degrees and diplomas*

10.2. Training

- *Participation in academic activities*
- *Continuing education*
- *Regular staff training*
- *Participation in conferences*
- *Use of library materials*
- *Scientific productivity*
- *Academic productivity*

10.3 Facilities

- *Illumination*
- *Access*
- *Clean and neat*
- *Adequate distribution of space*
- *Ventilation*
- *Temperature*
- *Fumigation*
- *Health and safety*

10.4 Instrumentation

- *Equipment maintenance*
- *Operation manuals*
- *Automation*
- *Preventive maintenance computer equipment*
- *Logbooks equipment*
- *Technological resources to increase volume*

- *Supplies Calibrators*
- *Reagents*
- *Controls*
- *Sterilization and waste management*
- *Protection materials*
- *Reagent storage*

11. REVIEW

Laboratory management should review the Quality Management System of all its services, including screening activities and consultations to ensure their adequacy and effectiveness in supporting patient care and to introduce any necessary changes or improvements. The results of the review should be incorporated into a plan that includes goals.

There must be documentary evidence of the monthly review by laboratory management highlighting the following subsections.

- *Audit*
- *Compliance review*
- *Clarifications and complaints*
- *Productivity rates*
- *Quality Manual*
- *System manuals Quality Management*
- *Code of ethics*
- *General disposition*
- *Responsibility*
- *Material Resources and Technology*
- *Pre Analytical Process*
- *Analytical process*
- *Instrumentation and Equipment*
- *Quality assurance*
- *Biosafety*
- *Reference services. Outsourcing*
- *Advertising*

12. GLOSSARY

- **ACCREDITATION:** *The act by which an Official Entity recognizes the technical competence and reliability of certification bodies, testing laboratory, calibration laboratory and verification units for conformity assessment*
- **ACCURACY:** *ISO defines this term as a combination of two types of observational errors including random and systematic, so high accuracy requires both high precision and high trueness.*
- **ANALYTICAL SYSTEM:** *Set of elements necessary to process an analysis, which may include reagents, standards, equipment and operator, among other components*
- **ASSESSMENT OF CONFORMITY:** *Determining the degree of compliance with official national standards, national voluntary standards, international standards or other specifications, requirements or characteristics Includes, inter alia, procedures for sampling, testing, calibration, certification and verification*
- **AUDIT EXTERNAL:** *Evaluation whose purpose is to analyze and assess the Quality Management System of the Laboratory with a view to the possible corrective actions, of the organization to ensure the integrity of its assets, the veracity of their information and maintain the effectiveness of its management systems .In the specific case of PROMEDLAB 2018: 002 audit can only be carried out by specifically trained, qualified and documented "peer" laboratory professionals*
- **AUDIT INTERNAL:** *Verification activity that has been planned, scheduled, documented and performed by the laboratory through separate staff area from the one that is audited to determine by means of an inquiry and evaluation of objective evidence, the environment adaptation and observation standards, specifications, procedures, instructions, codes, activities , administrative or operational programs and other relevant documents as well as the effectiveness of the implementation thereof and the results obtained*

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- *AUTOMATIC VERIFICATION: System allowing release results for laboratory results reporting, without direct human interference, through rules and incorporated into a computer program criteria*
- *BIOETHICS: Systematic study of human behaviour in the field of life sciences and health care, examined in the light of the values and moral principles. Its application is critical in the medical laboratory quality assurance.*
- *BIOLOGICAL VARIATION: "In vivo" level analysis around a homeostatic point between different individuals On this basis it is to be established reference limits and analytical goals laboratory tests considering multiple factors such as age, sex, race, nationality, etc.*
- *BIOSAFETY: Set of actions to prevent, reduce, or eliminate the risks of the activities of research, production, education, technological development and services, risks that can compromise human health, animals, environment or quality work performed*
- *CALIBRATION: Set of operations that establish, in specific conditions, the relationship between results obtained by an instrument or measuring system or values represented by the measurement of a reference material, and the values provided by standards*
- *CERTIFICATION: Procedure which ensures that a product, process, system or service meets the standards, guidelines or recommendations of national and international organizations dedicated to standardization*
- *CLIA: Clinical Laboratory Improvement Amendments It is the North American Government Agency Centres for Medicare & Medicaid Services (CMS) which regulates the activity of medical laboratories*
- *CODE OF ETHICS: Written and signed document on which each and every individual in the organization declares and details compromise with Bioethics and Total Quality Management including Medical Relevance*
- *COMPARISON OF RESULTS: Demonstrable statistically or otherwise of two or more analytical systems are capable of generating capacity for the*

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- *same patient samples clinically equivalent results. Processing capacity of knowledge, skills and attitudes in results*
- *CONTINUOUS IMPROVEMENT: recurring to increase capacity to meet the requirements by setting goals and through the audit results, analysis of data, management review or other means that lead to corrective action activities Part of quality management that acts on continuous process improvement through cost reduction, improvement of performance and customer satisfaction*
- *CORRECTION: Action to remove a non-compliance found The correction does not involve the study of the causes of non-compliance and is only done to solve a problem or defect found immediately Known as "available", "repair" and other terms applicable to different ways of correction*
- *CORRECTIVE ACTION PLAN: Document in which they are defined the actions implemented to eliminate the root causes of non compliance Involves establishing responsibilities and deadlines*
- *CORRECTIVE ACTION: Activity taken to eliminate the cause of the detected nonconformity existing or other undesirable situation in order to prevent its recurrence It is considered as a reactive action*
- *CRITERIA FOR ACCEPTABILITY OF RESULTS OF CONTROL: Rules generally statistical origin, which can be used to help the technical judgment of the results of controls in a given analytical system.*
- *CRITERIA: rules established for judging a process that can be validated or not and should be based on a standard or published scientific judgment*
- *CRITICAL ACTIVITY: Any activity which directly influence the result of the analysis, including phase activities ready-analytical (sampling, transportation and storage of biological samples), the analytical phase (controls analytical quality, reagents, equipment) and post-analytical (signature issuance and report results, automatic transcription by the Laboratory Information System phase*

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- *CRITICAL ANALYSIS: Activity carried out to determine the medical relevance, suitability and effectiveness of what is being examined, so that the process is analyzed and evaluated and that meets the stated objectives*
- *CRITICAL OUTCOME: Laboratory data that are located in a range that can be related to potentially serious medical situations and should be reported to the doctor immediately Alert figures*
- *CRITICAL VALUES OR RESULTS: Results of laboratory analysis found in a range of quantitative and qualitative results that may be associated with potentially serious medical situations and should be reported to the doctor immediately Alert figures*
- *CUSTOMER: Organization or person that receives a product This standard refers to users of laboratory services*
- *DICHOTOMY: The concept refers itself to the law which states that any proposition can be true and false at the same time. Payment performing certain private sector Laboratory Physicians and businesses to send more customers to them is an unfair practice. For mutual professional and moral respect, professional laboratory should not perform practices dichotomy with other professionals within or outside the field of health, as this is an act contrary to professional dignity and harms the health system in the country. The practice of Dichotomy disqualifies the laboratory in achieving Recognition Diploma in Bioethics, Medical Quality and Medical Relevance automatically regardless of compliance with all other requirements of this Guide.*
- *EFFECTIVENESS: Perform the correct action to change the existing reality Health, effectiveness means the actual effect on certain individual Evidence of achieving results*
- *EFFICACY: Ability to achieve objectives Health, efficacy was initially defined as the cost / benefit or effect of the activity, by WHO, or meeting goals in health management textbooks More recently, the efficacy has been translated as the potential effect of an action or effect under certain experimental conditions*

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- *EFFICIENCY: Productive use of resources in terms of economy, time and effort Health, this productive use corresponds to the relationship between costs and outcomes, or between results and supplies*
- *ENABLED: Legally qualified professional who can assume technical responsibility of the Medical Laboratory Post Number of Sampling*
- *EXTERNAL ALTERNATIVE EVALUATION: Evaluation of the accuracy of the performance of an analytical system, when there is no available material analysis in proficiency testing provider They are alternative methods for evaluating the reliability of analytical systems, such as exchange of samples between laboratories, analysis of reference samples and medical validation*
- *EXTERNAL QUALITY ASSESSMENT: CLSI Clinical and Laboratory Standards Institute has used this term as a synonym or proficiency testing-*
- *EXTERNAL QUALITY EVALUATION: It is the evaluation periodically by a Proficiency Testing Provider recognized by ALAPAC / ML or other Accreditation, analysis or tests which performs an establishment and which is to verify the accuracy of the results*
- *FINAL REPORT RESULTS: A document containing the results of analyzes, validated and authorized by a legally qualified professional*
- *FITNESS TEST: Consult External Quality Assessment*
- *FITNESS: Requisites and conditions to perform a specific function including attitude, aptitude, ability and sufficiency. Adequacy that should exist between the characteristics of a person, or the characteristics of a particular element and the function, activity or work to be performed.*
- *FORMAL CONTRACT: Formalized in writing, with the delineated clauses*
- *GOALS: Objectives described in terms of magnitude and timing In analytical stage it is considered that the coefficient of variation analytical percentage selected must be set on the basis of biological variability in accordance with the recommendation of Tonks, Aspen and Six Sigma*

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- *GOOD PRACTICE: Each of the elements established practice that together guarantee systems (structures, processes and results) consistently meet the specifications defined rules and effectively, efficiently and effectively*
- *GROSS DATA: Set of records and documents that allow the possibility of reconstituting a results report for analysis or playback when needed*
- *INFORMAL SERVICE: Tacit contract between generally verbal stakeholders based on a routine*
- *INTERNAL QUALITY CONTROL: The process of evaluating precision, a statistical procedure that relies on the stability of the analytical system whose main objective is to prevent the release results that represent potential errors with medical relevance. It can be done through the analysis of materials with known or determined by the laboratory result. Usually it involves the specification of analytical errors and limits of acceptability Criteria must be applied statistically valid judgment.*
- *LABORATORY ADDRESS: A person or institution responsible for the decisions of an organization can be of different legal constitutions: sole proprietorship, joint partners, elected by a board director members Administration may or may not include or correspond to the technical manager of the laboratory*
- *LABORATORY ANALYSIS: Physical, chemical or biological analysis of various components and products of the human body, whose measurements and results are obtained through the use of various technologies, duly qualified personnel, in a Laboratory legally established Measurement and analysis results of components and products of the human body, through test strips or similar technologies, which are offered to the general public, will be considered a laboratory study*
- *LABORATORY EQUIPMENT: Generic designation for a device used by the medical laboratory as part of the analysis process*

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- *LABORATORY INFORMATION SYSTEM. LIS: Electronic data set that allows the traceability of all information defined as a document of the quality which remains orderly and protected by a time defined by law*
- *LABORATORY SUPPORT: medical laboratory performing tests on samples sent by other medical laboratories*
- *LIMITS FOR ACCEPTABILITY OF RESULTS OF CONTROL: Range (with lower and upper limits) defining the expected results of control materials made in a particular analytical system, within a defined statistical range*
- *MEDICAL RELEVANCE: Quality or condition of transcendence, significance, usefulness or significance for establishing the diagnosis, prognosis or individual treatment or public health from the epidemiological point of view*
- *MEDICAL INDICATION: Document made in recipes or format for laboratory analysis application, dated and signed by doctors*
- *MEDICAL LABORATORY: An organization that has been legally established, independent or linked to another facility, for medical care for inpatients or outpatients, that is intended to perform physical, chemical or biological analyzes of various components and products of the human body, public, social or private organization, whose results contribute in the study, prevention, diagnosis, resolution and treatment of health problems*
- *MEDICAL RELEVANCE: The fundamental premise of medical laboratory that constitutes the main value on which above all, patient safety stands. Quality or condition of transcendence, significance, usefulness or significance for establishing the diagnosis, prognosis or individual treatment or public health from the epidemiological point of view*
- *MOBILE POSITION: Local sampling done to assist a group of people for a certain period in a company or institution*
- *MUTUAL RECOGNITION: Consideration of two people or organizations have reciprocal suitability and value*

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- *NON CONFORMITY: Failure to comply with a specified requirement*
- *OPERATIONAL INTERVAL: Interval in which we can obtain reliable results of an analysis in a given analytical system It may be equal to or larger than the range of linearity*
- *OWN METHODS: reagents and analytical systems produced and validated by the Medical Laboratory itself exclusively for own use in research or diagnostic support*
- *POINT OF CARE UNIT ANALYSIS: laboratory performing routine sampling and sent to another laboratory for conducting analyzes, through a contract or as an integral part of a group of companies legally constituted The PICKUP Analysis Unit may or may not perform some of the analysis of collected routine*
- *POSITION OF SAMPLING: Service related to a medical laboratory, which performs pre-analytical activities, but does not run the analytical phase of operational processes, except presential analysis, when the realization occurs in the act of sampling*
- *PRECISION: A description of random errors, a measure of statistical variability.*
- *PREVENTIVE ACTION: Activity taken to eliminate the cause of a potential nonconformity or other potential situations or other undesirable situation If you should be noted that preventive action, by the nature of its definition, does not apply to non-compliances already identified It is considered a proactive action*
- *PROCESSING UNIT ANALYSIS LABORATORY: laboratory performing analyzes of samples taken at sampling stations or health units and is not directly linked to the laboratory sampling, but does so through a contract The processing unit of analysis may or may not also have sampling positions directly linked to it*

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- *PROMEDLAB 2018.002: LATIN AMERICAN GUIDE FOR THE IMPROVEMENT OF MEDICAL LABORATORIES ON QUALITY, BIOETHICS AND RELEVANCE*
- *QUALITY CONTROL: The operational activities and techniques developed to meet the quality requirements The process aims, through tests every time an analysis or assay or set of assays is performed the same technique to ensure accuracy also detect and correct any errors.*
- *QUALITY INDICATORS: Measurements performed to assess whether the performance of a process is in accordance with the established objectives or customer expectations*
- *QUALITY MANAGEMENT SYSTEM.QMS: Set of interrelated standards of an organization which is administered in an orderly manner the quality of it, in the search for continuous improvement. Set of procedures with the aim of establishing, monitoring, implementing and managing operations to ensure Total Quality.*
- *QUALITY MANAGEMENT: Set of coordinated activities to direct and control an organization with regard to service delivery at all levels of the establishment activities*
- *QUALITY: Degree to which a set of inherent characteristics fulfils preset requirements*
- *RECOGNITION: The action of distinguishing the suitability of an organization or person from the others because of their characteristics, qualities, performance and results*
- *REFERRAL SERVICES: Studies that are provided by a laboratory at the request of another*
- *REPORT OF PROVISIONAL RESULTS: Any written information transmitted to the doctor or person concerned and it was not yet validated by legally qualified professional*
- *RESPONSIBILITY: Capacity and ability to respond positively and obviously including thought, speech and behaviour.*

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- *ROOT CAUSE ANALYSIS: Systematic and thorough method for determining the underlying nonconformity or other undesirable event cause.*
- *ROOT CAUSE: The original cause of non-compliance, that is, the most basic or fundamental cause to have happened the defect or problem in a product or service. Checking that the root cause was found is its elimination, and non-compliance should not happen again, but we can find more than one root cause for nonconformity. The root cause is also known as "fundamental cause"*
- *SCOPE: The vision and mission of an organization for audit purpose*
- *SOP: STANDARD OPERATING PROCEDURE: Document that contains the instructions necessary to carry out reproducibly activity*
- *SPECIFICATIONS REQUIREMENTS: Analytical Quality Criteria previously defined by the laboratory, according to the state of the art, for evaluating the performance of analytical systems*
- *STATE OF THE ART: The highest level of development of equipment, technology or science area, reached at the present time*
- *SUPPLIERS FITNESS TEST / PROFICIENCY: Company or organization that manages the results of biological samples sent to a group of laboratories, through distribution, receipt of results, evaluation and issuance of consolidated reports participants*
- *TAT: Turnaround Time. Recurred time between customer inputs in the laboratory to the delivery of its report*
- *The laboratory should have a Code of Ethics and dated and signed by the Director of the Laboratory, the Quality Manager and each of the Partners Confidentiality.*
- *TONKS: Author who established criteria for assessing the quality of an analytical system based on data from the normal population*
- *TRACEABILITY. Property of the result of a measurement or the value of a standard where it may be related to specified references, usually*

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- *national or international standards, through an unbroken chain of comparisons all with specified uncertainties*
- *TRUENESS: ISO defines this term as a description of systematic errors, a measure of statistical bias; as these cause a difference between a result and a "true" value.*
- *VALIDATION: It is a part of the quality assurance system that assesses early stages involved in operating or product preparation procedures to ensure the quality, effectiveness and reliability*
- *VERIFICATION: Visual observation or testing by sampling, measurement, laboratory tests, or examination of documents conducted to assess compliance at a given time.*

13. REFERENCES

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