

## **INTRODUCTION TO PROMECAL. QUALITY IMPROVEMENT PROGRAM. BIOETHICS AND MEDICAL RELEVANCE FOR CLINICAL LABORATORIES IN LATIN AMERICA.**

Dr. José Carreón Moldíz  
Permanent Secretary  
ALAPAC/ML

Dr. Arturo M. Terrés Speziale  
Representative  
WASPaLM at PAHO

Dr. Enrique Navarrete Cadena  
Editor  
REV.LAT.PATOL.CLIN.ML

### **KEY WORDS:**

ALAPAC/ML: Latin-American Association of Clinical Pathology and Laboratory Medicine.

EBM: Evidence Based Medicine.

PAHO: Pan-American Health Association.

PROMEAL: Latin American Program for Quality Improvement

WASPaLM: World Association of Societies of Pathology and Laboratory Medicine.

### **JUSTIFICATION**

In order to respond efficiently to Evidence-Based Medicine our task as Clinical Laboratory Professionals is to provide medically relevant, verifiable sustenance for this constantly growing activity on multiple disciplines. This requirement generates a greater challenge, workload and impact on Total Quality Control. Given this situation in the last decade, Quality has evolved not only through ISO / IEC 15189:2007 but also, to ensure accuracy ISO / IEC 17043:2010 is now also required for Proficiency Testing Providers.

Given this, in the Latin American Association of Clinical Pathology and Laboratory Medicine ALAPAC / ML we felt the need and obligation to contribute to quality improvement of Latin American Clinical Laboratories. Thus, we developed PROMECAL the Latin American Program for Quality Improvement, a gratuitous and voluntary program for all laboratories willing to participate solving the inherent problem of unaffordable costs of Accreditation and Certification Programs. The central feature of this program is that it provides sustention to be treated on the basis of a principle of suitability and competition, in order to be carried out exclusively among peer connoisseurs, between authentic Clinical Laboratory Professionals.

### **DESCRIPTION**

PROMEAL arises on the principles of bioethics and medical relevance with extensive knowledge and experience on Clinical Laboratory Science, providing two basic tools.

1. 2013.001 GUIDE: Latin American Guide for Clinical Laboratory Quality: Bioethics and Medical Relevance.
2. 2013.001 CHECKLIST: Audit For Analysis Of Clinical Laboratories, Bioethics, Quality, and Medical Relevance

### **SCOPE AND PURPOSE**

The Latin American Guide for Clinical Laboratory: Bioethics, Quality and Medical Relevance has great importance since it summarizes the specifications that must be met for the organization and operation of the Medical Laboratories under PROMECAL. The Guide was developed based on five basic references, five premises, and an accurate glossary.

1. Latin-American Guide to the Implementation of Code of Ethics in Health Laboratories. Washington D.C., 2007. [www.paho.org/spanish/ad/ths/ev/labs-guia\\_imp\\_codetica.pdf](http://www.paho.org/spanish/ad/ths/ev/labs-guia_imp_codetica.pdf)
2. ISO / IEC 15189: 2003. Particular Requirements for Quality and Competence on Medical Laboratory.
3. NOM-007-SSA3-2011. Mexico: For the Organization and Operation of Clinical Laboratory.
4. PALC-2007. Laboratory Accreditation Program. Brazilian Society of Clinical Pathology / Laboratory Medicine
5. Continuous Quality Improvement. Guide for Clinical Laboratories in Latin America. Produced in collaboration with COLABIOCLI: Latin American Confederation of Clinical Biochemistry. © 1995 Editorial Medica Pan Americana Mexico DF ISBN 968-7157-66-6

**PREMISES**

1. **MEDICAL RELEVANCE.** Quality or condition of transcendence, significance, usefulness or significance for the diagnosis, prognosis or treatment. Individually or in public health perspective.
2. **FITNESS.** Necessary conditions to perform a function (attitude, aptitude, ability, sufficiency). Evidence that must exist between the characteristics of a person, or the characteristics of a particular element and function, activity or work to be performed.
3. **DICHOTOMY.** The concept refers itself to the law that states that any proposition can be true and false at the same time. The payment made by certain private Laboratories to Physicians and Businesses in order to receive more customers is an unfair practice. For the sake of mutual professional respect and morality, professional laboratory practices should not perform dichotomy with others inside or outside the health field, as this is an act contrary to professional dignity which harms the country's health system. **NOTE.** The practice of dichotomy disqualifies the Laboratory in achieving Recognition Diploma on Bioethics, Quality and Medical Relevance automatically regardless of compliance with all other requirements of GUIDE 2013:001 PROMECAL.
4. **AUDIT.** Internal or external evaluation whose purpose is to analyze and assess, with a view to the possible corrective actions, internal control of organizations to ensure the integrity of its assets, the veracity of their information and maintain the effectiveness of its management systems . **NOTE.** In the specific case of the audit GUIDE 2013:001 PROMECAL, peer audits can only be made by trained, qualified and documented Laboratory Professionals
5. **RECOGNITION.** The action of distinguishing the suitability of an organization or a person among others due to their characteristics, qualities, performance and results. **MUTUAL RECONOGNITION.** Consideration of two people or organizations that have reciprocal suitability and value.

**PROMEAL HAS A GLOSSARY OF 102 TERMS INCLUDING THE FOLLOWING:**

- **QUALITY:** The degree to which a set of inherent characteristics fulfills the established requirements.
- **COMPETITION:** Comprehensive action to identify, interpret, argue and resolve problems with competence and ethical context, integrating the knowledge being, knowing how and knowledge to know.
- **QUALITY MANAGEMENT:** Set of coordinated activities to direct and control an organization with regard to quality management at all levels of the establishment.
- **CLINICAL LABORATORY:** A public, private or social organization, independent or linked to another healthcare facility whose purpose is to perform physical, chemical or biological analysis of various biological components and products of the human body the results contribute to the study, prevention, diagnosis, resolution and treatment of health problems.

**DESCRIPTION**

To facilitate implementation, PROMECAL has [www.qualitat.cc](http://www.qualitat.cc) internet support where there are several freely available tools, among including:

1. **EVALUATION OF THE STRUCTURE, PROCESSES AND PERFORMANCE.** As previously mentioned PROMECAL fundamental axis is the GUIDE 2013:001 which in turn has an automated Audit Tool that allows laboratories to conduct an internal evaluation to qualify: structure, process and outcomes to detect opportunities for improvement.
2. **MEDICAL RELEVANCE EXERCISES:** In addition to participating in the Internal Audit Program Laboratory Professionals can participate monthly in Clinical Cases, Medical Microscopy, and Medical Knowledge Assessment through multiple-choice exercises. The annual round of Medical Relevance Programs consists of twelve monthly cycles.

3. **DIPLOMA PROMECAAL ON BIOETHICS, QUALITY AND MEDICAL RELEVANCE:** The achieve recognition it is necessary to have participated in at least 10/12 monthly cycles. In addition to demonstrating compliance with all requirements of the Audit. The Diploma will be awarded to the Laboratory. No personal recognition is available.
4. **IMPROVEMENT PLAN:** Upon detecting the presence of opportunities for improvement or when there are non-compliant results during audits and relevant exercises, participants can resort to the availability of articles, books, atlases, tutorials and even consulting via email with whom they can find useful guidance and recommendations to improve performance.

## **CONCLUSION**

Our Mission is to collaborate with Clinical Laboratory Professionals reliably, detecting and exploiting improvement opportunities, providing a Comprehensive System including Planning, Organization Development and Control through Training Programs, Counseling and Assistance using the latest technology with high efficiency, effectiveness and efficiency, capable to continually improve the quality and opportunity in decision-making, to ensure that participants report more reliable results that minimize risks and costs for the benefit of their patients and customers.