Quik S.A.S. Report as JCTLM Member organization

Organization Name: Quik SAS
JCTLM Member status: Stakeholder Member
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1. Promoting traceability in laboratory medicine

During the 2024–2025 period, **Quik SAS** has carried out several initiatives aimed at strengthening metrological traceability and promoting standardization practices within laboratory medicine.

1) A major line of work has been the development and delivery of educational programs focused on the implementation of **ISO 17511:2020**, which defines the requirements for establishing metrological traceability of values assigned to calibrators, control materials, and human samples in in vitro diagnostic medical devices.

2) Dr Aída Porras, Scientific director of Quik, organized a **12-session training course** providing comprehensive guidance on this standard, including both synchronous and asynchronous components, in collaboration with **ONAC – Organismo Nacional de Acreditación de Colombia**.

3) In addition to formal training, Quik actively participated in professional scientific events. At the **XIX International Congress of the Colegio Nacional de Bacteriología**, held in Bogotá, Colombia (October 3–6, 2024), Dr. Aída Porras, Scientific director of Quik, delivered the lecture **"Reference Materials and Procedures in the Clinical Laboratory"** on October 5, 2024. This presentation addressed the role of reference materials and reference measurement procedures in assuring traceability and improving the reliability of clinical laboratory results.

4) Quik also contributed to regional capacity building by providing **metrological traceability training at the Honduras Medical Center Hospital** on May 7, 2024, and in 2025 These academic sessions strengthened technical competencies among laboratory staff by reinforcing best practices applicable to the measurements performed in the facility's clinical laboratory.

5) Furthermore, through its **External Quality Assurance Program (QAP)**, Quik routinely guides participants on evaluating their performance in comparison with **JCTLM-endorsed reference laboratories**. This includes the use of a informatic diagnostic matrix to help laboratories understand their level of traceability and ensure alignment with recognized international standards

2. Open questions and suggestions to be addressed by JCTLM

Based on Quik's experience during training, consulting, and interaction with laboratories in the region, the following points are proposed for consideration by the JCTLM:

1) **Enhanced dissemination of practical guidance for ISO 17511:2020 implementation** Many laboratories express difficulties in understanding how to integrate the traceability requirements of ISO 17511:2020 into daily practice. Additional JCTLM-endorsed practical tools, case studies, or implementation guides would support laboratories.

2) **Greater visibility and accessibility of reference measurement systems** Expanding outreach regarding available JCTLM-listed reference materials, reference procedures, and reference laboratories would help laboratories more clearly identify traceable pathways for their analytes of interest.

3) **Support for regional reference networks in Latin America.**
Encouraging the creation or strengthening of regional collaborations could improve awareness of traceability concepts and promote equitable access to reference services, especially for laboratories in low-to-middle income countries.

4) **Clarification on evaluation models for external quality assessment (EQA) providers**
Local EQA organizations often need clearer guidance on the expectations for traceability in their schemes, especially when using commutable materials or comparing results to JCTLM-recognized references. Additional recommendations from the JCTLM would enhance alignment across EQA programs globally.

5) **Engagement with professional associations of clinical laboratory scientists.**
We propose continuing outreach efforts aimed at national and regional professional associations of clinical laboratory personnel. Presenting the conceptual framework of metrological traceability to these organizations will contribute to integrating traceability principles into routine practice and professional standards.

6) **Collaboration with universities and academic programs.**

Introducing metrological traceability as an academic topic within undergraduate and graduate programs related to clinical laboratory sciences would build foundational competencies among future professionals. JCTLM could support this by developing academic modules, educational materials, or university-focused seminars to foster early adoption of traceability concepts.

7) **Regional engagement with manufacturers of in vitro diagnostic (IVD) systems**
To promote the organization of a meeting or forum specifically for in vitro diagnostic (IVD) manufacturers operating in the region. The objective would be to present the fundamental concepts of metrological traceability and highlight the importance of providing laboratories with clear information on the reference materials and procedures to which their measurement systems are traceable.

To increase awareness among manufacturers at the local level. These suggestions aim to enhance the dissemination, understanding, and implementation of metrological traceability across all stakeholders involved in clinical laboratory measurement—laboratories, accreditation bodies, academia, EQA providers, and diagnostics manufacturers.

These suggestions derive from the recurring needs identified during Quik's training programs, conferences, and interactions with laboratories and accreditation bodies across the regio