CLINICAL ENZYMOLOGY REFERENCE LABORATORY (LREC)
FRANCESCA CANALIAS

PROFILE

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RESEARCH

RESEARCH INTERESTS

To collaborate with the international organizations for standardization in the development of reference measurement procedures and enzymes reference materials in the field of clinical laboratories. Establish collaborations with companies of the diagnostic *in vitro* (IVD) to help them to meet the requirements to the European Directive 98/79/CE on *in vitro* diagnostic medical devices.

STRATEGIC OBJECTIVES

In 2008 the LREC was accredited by the Spanish accreditation body (*Entidad Nacional de Acreditación,* ENAC) as calibration and reference laboratory according to the International Standards ISO/IEC 17025:2005 and ISO 15195:2003 (accreditation 195/LC10.141). Since 2009, the LREC is a supplier of the reference services of the Joint Committee for Traceability in Laboratory Medicine (JCTLM). The strategic objective is to maintain the accreditation based on international standards for the enzymes of the scope and the maintenance of the quality management system through the accomplishment of quality objectives and action plans.

MAIN RESEARCH LINES

- Develop, validate and verify the transferability of new primary reference measurement procedures.
- Characterize new enzyme reference materials performing homogeneity, stability and commutability studies.
- Assign and certifies catalytic concentration values to already developed reference materials by means of certification campaigns among laboratories.
- Assign traceable values of catalytic concentration to internal calibrator materials of in vitro diagnostic manufacturers (facilitating to meet the requirements of the European Directive 2017/746 on in vitro diagnostic medical devices).
- Assign traceable values of catalytic concentration to control materials of external evaluation quality programs (EQAS) and internal quality control (facilitating the accomplishment to the international standard ISO/IEC 17043).
- Validate measurement procedures and commercial analytical systems for the measurement of catalytic concentration in patient samples in routine.
- Evaluate the commutability of commercial calibrator and control materials.