Biennial activity report from Research Centre for Metrological Traceability in Laboratory Medicine (CIRME), University of Milan

Organization: Research Centre for Metrological Traceability in Laboratory Medicine (CIRME), University of Milan, Milan, Italy

JCTLM Member status: JCTLM Stakeholder Member

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Major achievements in supporting standardization and promoting traceability in laboratory medicine

CIRME was created in 2006 with the scope to promote standardization in the field of the Laboratory Medicine through the application of the metrological traceability concepts, with the main objective of improving the clinical value of laboratory information and permitting a common global approach to diseases. The ‘CIRME traceability revolution manifesto’, launched in 2014 (available in https://sites.unimi.it/cirme/public/UploadAttach/Pubblications%202018/Foreword.pdf), well summarizes the main points that are object of attention by CIRME. One can find the most important contributions displayed as ‘CIRME cardinal points for implementing traceability in Laboratory Medicine’ in the CIRME website homepage (https://sites.unimi.it/cirme/).

CIRME has a reference laboratory for the following measurands: ALT, ALP, AST, CK, GGT, LDH, Glucose, HbA1c, by using the reference procedures listed in the JCTLM database, working to the characterization and certification of reference materials and assessment of their commutability, validation of metrological traceability of commercial IVD measuring systems, and value targeting of EQAS materials. Recent activities related to the validation and verification of IVD measuring systems are described in the following papers published in peer-reviewed journals:


Furthermore, the analytical performance specifications for measurement uncertainty of a group of common biochemical measurands were defined and published. This was preparatory to the activity of the JCTLM Task Force on Reference Measurement System Implementation that recently published a paper summarizing its work.


Finally, in collaboration with the Clinical Pathology Unit of the ‘Luigi Sacco’ academic hospital, one of the two Italian reference centers for infectious diseases, in the last two years CIRME has supervised studies on hospitalized COVID-19 patients to evaluate the role of laboratory tests as clinical predictors of disease severity. One of the major strengths of the published results is represented by the use of methodologies for which standardization and metrological traceability had been verified and validated, enabling the universal application of results obtained in our clinical studies and permitting their unambiguous interpretation, providing institutions implementing them also use standardized assays. This work provides an excellent example showing that the implementation of assay standardization is an absolute priority for optimizing healthcare. Only the use of assays providing standardized results allows the application of common decision limits, as those defined in our COVID-19 studies, worldwide and the comparability of clinical studies performed in different institutions. Related papers are in the following list:


Planned activities in support of standardization in laboratory medicine

R&D projects to be finalized soon:
1. TOP-HOLE (Towards OPTimal glycoHemOgLobin tEsting) project
2. A project on trueness evaluation and verification of inter-assay agreement of serum ferritin measuring systems
3. Extend the list of analytical performance specifications for measurement uncertainty to other laboratory measurands

Organization of 14th International CIRME Meeting on ‘Implementation of metrological traceability in laboratory medicine: where we are and what is missing (Milan, November 2022).

Collaborations focusing on developing/implementing reference measurement systems

Participation as member in:
1. ISO/TC 212 WG2 ‘Reference systems’
2. JCTLM WG-DB and related RTs (Enzymes and Proteins)
3. JCTLM Task Force on Reference Measurement System Implementation
4. European Commission Expert panels in the field of medical devices
5. IFCC Committee on Traceability in Laboratory Medicine
6. IFCC WG on Commutability in Metrological Traceability
7. IFCC WG on Standardization of Troponin I
8. IFCC WG on Standardization of HbA2
9. IFCC WG on Standardization of Albumin Assay in Urine
10. IFCC WG on Pancreatic Enzymes
11. EFLM WG on Biological Variability and Task Group on Biological Variability Database
12. CLSI EP30ed2 – DDC on Commutable Reference Material