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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Period covered: 2015 – 2017

Major achievements in support of standardization in laboratory medicine

1. Accreditation of reference laboratory services for the following measurands (all listed in the JCTLM database): ALT, ALP, AST, CK, GGT, LDH, Glucose, HbA1c.
2. Participation to the campaign for value assignment using the IFCC Reference Procedure for LDH, CK and ALT ERM-AD453/454/455k European Commission Joint Research Centre.
3. Many other activities related to the validation and verification of IDV measuring systems as described in the following papers published in peer-reviewed journals:


Planned activities in support of standardization in laboratory medicine
The main activities of CIRME are:
• Characterization and certification of reference materials
• Evaluation of commutability of reference and calibration materials
• Value targeting of EQA materials
• Validation of traceability of commercial IVD systems

Promoting traceability in laboratory medicine
1. See list of publications above.
2. Organization of International CIRME Meetings:
   a. 9th International Scientific Meeting, 2015 - Structuring EQAS for meeting metrological criteria: ready for prime time
   b. 10th International Scientific Meeting, 2016 - CIRME - Ten years after
   c. 11th International Scientific Meeting, 2017 - Measurement uncertainty in medical laboratories: friend or foe?
3. Organization of a symposium entitled "Traceability in laboratory medicine: a matter of patient safety" at the 22nd IFCC-EFLM EuroMedLab, June 2017, Athens (Greece)
4. Presentations on traceability at the following international and national conferences or congresses:
   a. Verification of IVD metrological traceability: responsibilities and strategies in the EU context. Conference on “Laboratory diagnostics - past, present and future” (Kielce, Polonia, February 6th, 2015) M. Panteghini
   b. Verification of in vitro medical diagnostics (IVD) metrological traceability: role and responsibilities of laboratory medicine specialists in the EU context. EFLM Symposium on “Education in Clinical Chemistry and Laboratory Medicine” (Prague, Czech Republic, April 25th, 2015) M. Panteghini
   c. Verification of in vitro medical diagnostics (IVD) metrological traceability: role and responsibilities of laboratory medicine specialists. 11th EFLM Symposium for Balkan Region. (Belgrade, Serbia, May 14, 2015) M. Panteghini
   e. Plenary Lecture: Global harmonization in laboratory medicine. 8th Congress of the Croatian society of medical biochemistry and laboratory medicine (Rijeka, Croatia, 23 September 2015) M. Panteghini
   f. Opening Lecture: Defining performance specifications in laboratory testing. 23rd Meeting of the Balkan Clinical Laboratory Federation (Sarajevo, Bosnia & Herzegovina, October 7, 2015) M. Panteghini
g. Plenary Lecture: Performance criteria for measurement methods and reference materials in clinical analyses. 14th International Symposium on Biological and Environmental Reference Materials (National Harbor, Maryland, USA, October 13, 2015) M. Panteghini

h. Who, what and when to do validation/verification of methods. 15th EFLM Continuous Postgraduate Course in Clinical Chemistry and Laboratory Medicine (Zagreb, Croatia, October 24, 2015) M. Panteghini

i. How to assess the quality of your method? (Zagreb, Croatia, October 24, 2015) I. Infusino

j. Harmonization of laboratory testing in Europe and at the global level. 13th Hellenic Congress of Clinical Chemistry (Heraklion, Crete, October 29, 2015) M. Panteghini

k. Verification of in vitro medical diagnostics (IVD) metrological traceability: Role and responsibilities of laboratory medicine specialists. 6th International Conference on Quality of Medical Laboratories (Ljubljana, Slovenia, December 4, 2015) M. Panteghini

l. Allowable limits for measurement uncertainty across the traceability chain. Quality in the Spotlight Conference Quality 2016 (Antwerp, Belgium, March 14, 2016) M. Panteghini


n. Progress and impact of enzyme measurement standardization. Protein and Peptide Therapeutics and Diagnostics: Research and Quality Assurance. International Workshop PPTD-2016 (Chengdu, China, June 3, 2016) M. Panteghini

o. Promoting clinical and laboratory interaction by harmonization. 4th Joint EFLM-UEMS Congress (Warsaw, Poland, September 23, 2016) M. Panteghini

p. Standardization in Laboratory Medicine: progresses, barriers and solutions. Workshop on Standardization of Clinical Laboratory Testing. (Shanghai, China, October 19, 2016) M. Panteghini

q. Implementation of metrological traceability in agreement with EU IVD Directive to improve comparability of laboratory results. 14th Asia Pacific Federation for Clinical Biochemistry and Laboratory Medicine Congress 2016 (APFCB Congress 2016) (Taipei, Taiwan, November 28, 2016) M. Panteghini


s. Progress and impact of enzyme measurement standardization. Ilenia Infusino, EuroMedLab Athens 2017, 12-14 June 2017

t. Traceability of HbA1c measurements: weak and strong points. Andrea Mosca, EuroMedLab Athens 2017, 12-14 June 2017

u. Defining performance specifications in laboratory testing. 22nd IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine (Athens, Greece, June 14, 2017) M. Panteghini

v. The role of EQA in the verification of in-vitro medical diagnostics. EQALM Symposium 2017 (Dublin, Ireland, October 19, 2017) M. Panteghini

Collaborations focusing on developing/implementing reference measurement systems

Participation as member in:
1. ISO/TC 212 WG2
2. JCTLM WG-DB and related RTs (Enzymes and Proteins)
3. IFCC Committee on Traceability in Laboratory Medicine
4. IFCC WG on Commutability
5. IFCC WG on Standardization of Troponin I
6. IFCC WG on Standardization of HbA2
7. IFCC WG on Standardization of Albumin Assay in Urine
8. EFLM Task Force on Performance Specifications in Laboratory Medicine
9. EFLM Task and Finish Group on Allocation of laboratory tests to different models for performance specifications
10. EFLM Task and Finish Group on Analytical Performance Specifications for EQAS
11. EFLM WG on Biological Variability and Task and Finish Group on Biological Variability Database

Suggestions to be addressed by JCTLM

1. Definition and approval of reference measurement systems, in their entirety and not just in their main components (reference materials and methods).
2. Promote the implementation by IVD industry of traceability to such reference systems in a scientifically sound and transparent way, i.e. they should include in their assay or calibrator package inserts:
   a. an indication of higher order references (materials and/or procedures) used to assign traceable values to calibrators,
   b. which internal calibration hierarchy has been applied by the manufacturer, and a detailed description of each step,
   c. the expanded combined uncertainty value of commercial calibrators, and which, if any, acceptable limits for uncertainty of calibrators were applied in the validation of the measuring system.