

## Draft template for biennial activity report from JCTLM Member organizations

All JCTLM Members are invited to attend the Members' and Stakeholders' Meeting, which is held once every two years, and submit a report of their activities in support of traceability in laboratory medicine over the preceding period.

For that purpose this template document provides guidance to JCTLM Members for drafting their biennial activity report. Organizations are invited to provide the information below for submission to the Executive Committee.

**Organization Name: LNE**

**JCTLM Member status: Stakeholder Member**

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**Period covered: 2024 – 2025**

### 1. Major achievement(s) in support of standardization in laboratory medicine

(Please describe what activities your organization has undertaken related to the implementation of reference measurement systems in laboratory medicine during the last two years, including but not limited to information on: the production of certified reference materials; the development of reference measurement methods; or the establishment of calibration (reference) measurement services. Outline the measurement area(s)/measurands covered, and provide a listing of the relevant technical/scientific publications.)

- As part of EMPIR project NeuroMet2, a candidate reference measurement procedure for the measurement of **total Tau protein** measurement in CSF has been developed and candidate CRMs have been produced and tested for commutability. This work directly supports activities of IFCC WG-BND.
- After developing peptide-based and protein-based primary calibrators, a candidate reference measurement procedure for the measurement of **procalcitonin (PCT)** in human serum has been developed and candidate CRMs have been produced and tested for commutability. This work is directly supporting activities of IFCC WG-PCT that is chaired by LNE;
- As part of EMPIR project SEPTIMET, an antibody-free LC-HRMS/MS method has been developed for simultaneous quantification of NGAL, CRP and SAA in serum with the objective to develop a candidate reference measurement procedure for a **panel of sepsis markers**.

#### Relevant publications:

- Development of a candidate reference measurement procedure by ID-LC-MS/MS for total tau protein measurement in cerebrospinal fluid (CSF). Giangrande C, Vaneeckhoutte H, Boeuf A, Lalere B, Hirtz C, Lehmann S, Quaglia M, Delatour V. Clin Chem Lab Med. 2023 Feb 24;61(7):1235-1244. doi: 10.1515/cclm-2022-1250.
- Antibody-free LC-HRMS/MS method for simultaneous quantification of NGAL, CRP and SAA in serum from sepsis patients. Derbez-Morin M, Delatour V, Fenaille F, Perrot C, Dupuy AM, Boeuf A, Becher F. J Proteomics. 2025 Apr 15;314:105396. doi: 10.1016/j.jprot.2025.
- Candidate High-Resolution Mass Spectrometry-Based Reference Method for the Quantification of Procalcitonin in Human Serum Using a Characterized Recombinant Protein as a Primary Calibrator. Huynh HH, Delatour V, Derbez-Morin M, Liu Q, Boeuf A, Vinh J. Anal Chem. 2022 Mar 15;94(10):4146-4154. doi: 10.1021/acs.analchem.1c03061.
- Harmonization status of procalcitonin measurements: what do comparison studies and EQA schemes tell us? Huynh HH, Bœuf A, Pfannkuche J, Schuetz P, Thelen M, Nordin G, van der Hagen E, Kaiser P, Kessler D, Badrick T, Poggi B, Tiikkainen U, Davies GJ, Kessler A, Plebani M, Vinh J, Delatour V. Clin Chem Lab Med. 2021 Jun 21;59(10):1610-1622. doi: 10.1515/cclm-2021-0566.

- Development of an antibody-free ID-LC MS method for the quantification of procalcitonin in human serum at sub-microgram per liter level using a peptide-based calibration. Huynh HH, Bœuf A, Derbez-Morin M, Dupuy AM, Lalere B, Delatour V, Vinh J. *Anal Bioanal Chem.* 2021 Aug;413(19):4707-4725. doi: 10.1007/s00216-021-03361-0.
- Evaluation of the necessity and the feasibility of the standardization of procalcitonin measurements: Activities of IFCC WG-PCT with involvement of all stakeholders. Huynh HH, Bœuf A, Vinh J, Delatour V; IFCC Working Group on Standardization of Procalcitonin assays (WG-PCT). *Clin Chim Acta.* 2021 Apr;515:111-121. doi: 10.1016/j.cca.2021.01.004.

## 2. Planned activity(ies) in support of standardization in laboratory medicine

(Please outline R&D project(s) and/or programme(s) planned by your organization in the next two years including information on: new measurement area(s)/measurands of interest for your organization; new CRMs and renewals of materials; development of methods (new measurands and improved measurement technique/principle); and extensions of your calibration measurement service(s) portfolio.)

- As part of EPM project NEuroBioStand, LNE works on the development of a candidate reference measurement procedure and CRMs for the measurement of **pTau(217)** in human plasma. LNE also works on the development of commutable CRMs for the measurement of **NfL** in human serum.
- As part of EPM project COMET, LNE works on the development of commutable CRMs and EQA materials for **testosterone, Calcium, ALT, Neonatal Bilirubin and PTH**.
- As part of EPM project PROMET, LNE works on the development of CRMs for **structural analysis of protein-based biomarkers**
- LNE and other members of IFCC WG-PCT will continue the work aiming to document the feasibility and necessity to standardize PCT assays through the organization of an EQA Scheme relying on candidate CRMs of proven commutability.
- LNE will pursue the development of a candidate reference measurement procedure for a panel of **sepsis markers**.

## 3. Promoting traceability in laboratory medicine

(Please describe activities your organization has undertaken during the last two years for promoting traceability in laboratory medicine including but not limited to a listing of your publication(s), presentation(s) and other communication(s) on traceability at international and national conferences or congresses, or other forums for clinical laboratory medicine)

- Through its membership in the IFCC Working Group on Commutability, LNE contributed in the preparation on recommendations on commutability assessment that were subject to 5 publications.
  - Recommendations for Setting a Criterion for Assessing Commutability of Secondary Calibrator Certified Reference Materials. Miller WG, Keller T, Budd J, Johansen JV, Panteghini M, Greenberg N, Delatour V, Ceriotti F, Deprez L, Rej R, Camara JE, MacKenzie F, Lyle AN, van der Hagen E, Burns C, Fauskanger P, Sandberg S; IFCC Working Group on Commutability in Metrological Traceability. *Clin Chem.* 2023 Sep 1;69(9):966-975. doi: 10.1093/clinchem/hvad104.
  - Recommendations for Setting a Criterion and Assessing Commutability of Sample Materials Used in External Quality Assessment/Proficiency Testing Schemes. Sandberg S, Fauskanger P, Johansen JV, Keller T, Budd J, Greenberg N, Rej R, Panteghini M, Delatour V, Ceriotti F, Deprez L, Camara JE, MacKenzie F, Lyle AN, van der Hagen E, Burns C, Greg Miller W; IFCC Working Group on Commutability in Metrological Traceability. *Clin Chem.* 2023 Nov 2;69(11):1227-1237. doi: 10.1093/clinchem/hvad135.
  - Recommendations for assessing commutability of a replacement batch of a secondary calibrator certified reference material. Deprez L, Johansen JV, Keller T, Budd J, Greenberg N, Weykamp C, Sandberg S, Panteghini M, Ceriotti F, Barczak E, Rej R, Fauskanger PK, MacKenzie F, Camara JE, Lyle AN, Miller WG, Delatour V. *Clin Chim Acta.* 2025 Feb 1;567:120097. doi: 10.1016/j.cca.2024.120097.
  - Demonstrating commutability of an existing certified reference material for use with an end-user measurement procedure that was not included in the original commutability assessment. Miller WG, Deprez L, Sandberg S, Johansen JV, Greenberg N, Weykamp C, Keller T, Budd J, Delatour V, Barczak E, Rej R, Fauskanger PK, MacKenzie F, Camara JE, Lyle AN, Panteghini M. *Clin Chim Acta.* 2026 Jan 1;578:120548. doi: 10.1016/j.cca.2025.120548.

- Quantification of Difference in Nonselectivity Between In Vitro Diagnostic Medical Devices. Fauskanger PK, Sandberg S, Johansen J, Keller T, Budd J, Miller WG, Stavelin A, Delatour V, Panteghini M, Støve B. *Biom J.* 2025 Feb;67(1):e70032. doi: 10.1002/bimj.70032.
- o Through its membership in JCTLM Task Force on Reference Measurement Systems Implementation, LNE contributed 2 publications:
  - Feasibility of Metrological Traceability Implementation Using the Joint Committee on Traceability in Laboratory Medicine Database Entries Including the Fulfillment of "Fit-for-Purpose" Maximum Allowable Measurement Uncertainty. Panteghini M, Camara JE, Delatour V, Van Uytfaange K, Vesper HW, Zhang T. *Clin Chem.* 2024 Nov 4;70(11):1321-1333. doi: 10.1093/clinchem/hvae131.
  - Optimizing Available Tools for Achieving Result Standardization: Value Added by Joint Committee on Traceability in Laboratory Medicine (JCTLM). Panteghini M, Braga F, Camara JE, Delatour V, Van Uytfaange K, Vesper HW, Zhang T; JCTLM Task Force on Reference Measurement System Implementation. *Clin Chem.* 2021 Nov 26;67(12):1590-1605. doi: 10.1093/clinchem/hvab178.

#### **Relevant presentations :**

- Amandine Bœuf, C Giangrande, Calibration of RMPs with peptides vs recombinant proteins: Example of procalcitonin and ptau, miniworkshop CCQM PAWG, 07 octobre 2024, Berlin
- V Delatour, Presentation of the COMET project. EQALM Symposium, 17 Octobre 2024, Vienna (Austria).
- V Delatour, EURAMET Workshop "Metrology for regulation – Health Event" 21 October 2024.
- V Delatour, "The central role of commutability of materials used for trueness verification and postmarket surveillance", UMK Congress 2024, 29 november 2024, Bydgoszcz (Poland).
- C. Giangrande, Standardisation of Measurements of Neurodegenerative Disease Biomarkers: The NEuroBioStand Project. 3 June 2024, Paris
- C. Giangrande, Standardisation of Measurements of Neurodegenerative Disease Biomarkers: The NEuroBioStand Project. Symposium « Biomarkers in Neurodegenerative diseases », 6-7 June 2024, Montpellier (France)

#### **4. Reference laboratory networks /collaborations focusing on developing /implementing reference measurement systems**

(Please describe your participation in laboratory networks, forums or professional/technical committees linked to reference measurements system development/implementation, and contributions to JCTLM Working Group activities.)

- LNE Chairs the European Metrology Network "TraceLabMed"
- LNE is a full member of IFCC Scientific Division Executive Committee (IFCC SD-EC)
- LNE participates in JCTLM Working Group on Traceability Education & Promotion (JCTLM WG-TEP)
- LNE participates in JCTLM Task Force on Reference Measurement Systems Implementation (JCTLM TF-RMSI)
- LNE chairs IFCC WG-PCT on Standardization of Procalcitonin measurements
- LNE participates in IFCC WG-ApoMS on Apolipoproteins by Mass Spectrometry
- LNE participates in IFCC WG-BND on Biomarkers of Neurodegenerative Diseases
- LNE participates in IFCC WG-CMT on Commutability in Metrological Traceability
- LNE participates in IFCC WG-NB on Neonatal Bilirubin
- LNE participates in IFCC C-BM on Bone Metabolism
- LNE Chairs SFBC working group on Urine Albumin
- LNE is a member of the CRMLN (Cholesterol Reference Method Laboratory Network)
- LNE participates in ISO TC 212 WG2
- LNE participates in CCQM Working Group on Proteins (PAWG)

**5. Open questions and suggestions to be addressed by JCTLM**

(Suggestions on issues related to standardization and metrological traceability that should be considered by the JCTLM)

N/A