

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: Reference Institute for Bioanalytics, Stiftung für Pathobiochemie und Molekulare Diagnostik

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.)

Publications:

- a) Staaen A, Canalias F, Ceriotti F, Infusino I, Veuger M, Weber F, Grote-Koska D, „IFCC primary reference procedure for the measurement of catalytic activity concentrations of enzymes at 37 °C. Part 10: Reference procedure for the measurement of catalytic concentration of **pancreatic α -amylase**,“ *Clin Chim Acta*. **2026**;579, 120657 (accepted 10-2025)
- b) CLSI EP32, **2025**, 2nd edition, Johansen JV, Vesper HW, Badrick T, Beasley Green A, Budd JR, Danilenko U, Grote-Koska D, Horan K, Kessler A, Miller WG, Okoye NC, Panteghini M, Theodorsson E. Implementation of Metrological Traceability in Laboratory Medicine.
- c) Oostendorp M, Van der Hagen EA, Lo S, Delatour V, Grote-Koska D, Staaen A, Frasa MA, Kootstra-Ros JE, Westenberg L, Vitek L, Dvořák A, Křepelka D, Weykamp C, Hulzebos CV, Van Berkel M. The analytical performance of neonatal total **bilirubin** assays does not meet the clinical need due to a lack of standardization. *Clin Chem*. **2025** (submitted).
- d) [24 authors...Grote-Koska D,... et al.] Physikalisch-Technische Bundesanstalt. **2025**. Richtlinie DKD-R 0-1: Technische Kompetenzbereiche für Vergleichsmessungen. Braunschweig und Berlin. DOI:10.7795/550.20250331
- e) Kaiser P[#], Grote-Koska D[#], Freckman G, Petersmann A, Nauck M, Heinemann L. **Glukose**-Messungen und Rili-BÄK: Anpassung der Akzeptanzgrenzen bei der internen und externen Qualitätskontrolle.

Diabetologie und Stoffwechsel. **2024**;19: 208-213

equal contribution

- f) C. Seger, A. Kessler, J. Taibon, Establishing metrological traceability for small molecule measurands in laboratory medicine, *Clin. Chem. Lab. Med.*, 61, 1890-1901 (2023)
- g) Buchta C, Benka B, Delatour V, Faé I, Griesmacher A, Hellbert K, Huggett J, Kaiser P, Kammel M, Kessler A, Kessler HH, Müller D, Rosendahl J, Scheiblaue H, Schweiger CR, Zeichhardt H, Cobbaert CM. Reference, calibration and referral laboratories - a look at current European provisions and beyond. *Clin Chem Lab Med*. 2024 Oct 14;63(4):656-669. doi: 10.1515/cclm-2024-1066. PMID: 39389923.

JCTLM Database :

- a) Total **bilirubin** : reference measurement method, application for listing (*submitted 05-2025*)
Klauke R, Kytzia HJ, Weber F, Grote-Koska D, Brand K, Schumann G. Reference measurement procedure for total bilirubin in serum re-evaluated and measurement uncertainty determined. *Clin Chim Acta*. **2018**;481:115–120.
- b) Total **bilirubin** : reference service, application for listing (*submitted 05-2025*)

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.)

- a) **Pancreatic alpha-amylase:**
Accreditation of reference method (2026) in RfB-calibration laboratory
JCTLM-DB listing application (2027)
- b) Meetings, workshops, conferences:
2026-03-24 Symposium 'Metrological Traceability in IVD: Value, Challenges, and Innovations for Industry', analytica conference, Munich, Germany

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)

Meetings, Workshops, conferences:

- a) Meetings, workshops, conferences:
- 2024-02-21 FB5 "Metrology", ABK/DAkKS, Berlin, Germany
 - 2024-04-12, ISO 15193, writing team, online
 - 2024-04-19, ISO 15193, writing team, online
 - 2024-05-13, ISO 15193, writing team, online
 - 2024-05-28 IFCC C-TLM (Committee for traceability in laboratory medicine), WorldLab, Dubai, UAE

- 2024-05-28 IFCC WG-NB (Working Group Neonatal Bilirubin), WorldLab, Dubai, UAE, online participation
- 2024-05-28 IFCC WG-ID (Working Group Immunosuppressive Drugs), WorldLab, Dubai, UAE
- 2024-06-14/13, ISO 15193, writing team, online
- 2024-06-03, ISO 15193, Annex Z, writing team, online
- 2024-09-05 German Calibration Service (DKD), Technical committee Measurands in Laboratory Medicine, Berlin, Germany (Chair)
- 2024-10-29 IFCC C-TLM (Committee for traceability in laboratory medicine), online
- 2025-03-26 ISO TC212, WG2, Reference Systems, 37th meeting, online
- 2025-04-08 ISO 15195, writing team, online
- 2025-05-12 ISO 15195, writing team, online
- 2025-05-13 ISO 25459 (commutability), project team meeting, online
- 2025-05-20 IFCC WG-ID (Working Group Immunosuppressive Drugs), EuroMedLab, Brussels, Belgium
- 2025-05-21 IFCC C-TLM (Committee for traceability in laboratory medicine), EuroMedLab, Brussels, Belgium
- 2025-05-21 IFCC WG-NB (Working Group Neonatal Bilirubin), EuroMedLab, Brussels, Belgium
- 2025-06-30 ISO 25459 (commutability), project team meeting, online
- 2025-08-18 IFCC WG-ID (Working Group Immunosuppressive Drugs), online
- 2025-09-25 German Calibration Service (DKD), Technical committee Measurands in Laboratory Medicine, Berlin, Germany (Chair)
- 2025-11-13 IFCC WG-NB (Working Group Neonatal Bilirubin), online

b) Poster:

- Luque-Perez E, Deprez L, Grote-Koska D, Staadten A, Infusino I, Gutierrez X, Glady L, Orth M, Ceriotti F, Varani M, Commutability Assessment of three candidate Reference Materials for Alkaline Phosphatase (ALP), *Clin Chem Lab Med.* **2025**;63, Special Suppl, S1912.
- 2025-10-23, “Ensuring Clinical Reliability of Neurofilament Light Chain as a Biomarker: Insights from a Pilot External Quality Assurance Study”, M. Enders, DKLM, Leipzig

c) Presentations

- 2024-04-09, “Reference Systems – All for one and one for all”, A. Kessler, analytica conference 2024, Munich, Germany
- 2024-04-09, “Reference Measurement Services – The (missing) link between NMIs and end-users”, C. Stobe, analytica conference 2024, Munich, Germany
- 2025-10-23, “Digitalisierung der Qualitätsinfrastruktur: Die zentrale Rolle des digitalen Kalibrierscheins (DCC)“, C. Stobe, DKLM 2025, Leipzig, Germany
- 2025-10-23, „Qualität mit System: Was Sie über Rili-BÄK, Ringversuche und den B1-Teil wirklich wissen sollten“, M. Enders, DKLM 2025, Leipzig
- 2025-10-27, “Das Globale Dach der Rückführung“, A. Kessler, 23rd User Meeting of the DGKL Section “Clinical Mass Spectrometry in Laboratory Medicine”, Bad Staffelstein, Germany
- 2025-10-27, “Umsetzung der metrologischen Rückführung im Kalibrierlabor“, R. Landsberg, 23rd User Meeting of the DGKL Section “Clinical Mass Spectrometry in Laboratory Medicine”, Bad Staffelstein, Germany
- 2025-10-28, “Wie viel Unsicherheit darf’s sein? Praxisnutzen & Grenzen der Messunsicherheitsbetrachtung in der Kalibrierung labormedizinischer Messgrößen“, C. Stobe, 23rd User Meeting of the DGKL Section “Clinical Mass Spectrometry in Laboratory Medicine”, Bad Staffelstein, Germany

d) Further activities:

- JCTLM review teams: Dr. Grote-Koska is member of two review teams (enzymes; electrolytes and blood gases)

- ERM of alkaline phosphatase under development: characterisation study (2025), participation as calibration laboratory
- ERM-AD456/IFCC (amylase): stability study, participation as calibration laboratory
- ERM-AD452/IFCC (GGT): stability study, participation as calibration laboratory
- ERM-AD457k/IFCC (AST): stability study, participation as calibration laboratory
- ERM-DA451/IFCC (cortisol): stability study, participation as calibration laboratory
- ERM-DA192/IFCC (cortisol): stability study, participation as calibration laboratory

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.)

RfB is active and participates in:

- RfB organizes the annual EQA scheme RELA for calibration laboratories and candidate laboratories,
- Till 2024: EMPIR 18HLT10 “CardioMet”, WP2 and WP3,
- Since 12/2024: EURAMET 23IND02 “COMET”, partner and member of scientific advisory board
- EMN Trace Lab Med,
- HbA1c IFCC network campaign and EurA1c-study,
- ISO TC212, Work Group 2, Reference Systems – revision of ISO 15193 and 15194,
- CLSI revision of EP32 Metrological Traceability and Implementation
- AKB of DAkkS (German Accreditation Body),
- DKD (German Calibration Service), Technical committee Measurands in Laboratory Medicine,
- BÄK (German Medical Association),
- IFCC C-TLM (Committee Traceability in Laboratory Medicine, chair)
- IFCC WG-PE (Working Group Pancreatic Enzymes, chair),
- IFCC WG-ID (Working Group Immunosuppressive Drugs, chair),
- IFCC WG-NB (Working Group Neonatal Bilirubin, member),
- IFCC WG-NP (Working Group Natriuretic Peptides, member),
- Joint project of CCQM, C-TLM and C-EUBD on HbA1c,
- JCTLM Review Team Enzymes,
- JCTLM Review Team Electrolytes and Blood Gases,
- JCTLM WG TEP,
- JCTLM Executive Board.

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)

The lack of RM is a critical point for standardization, which should be focused on. Could it be worth, to bring a central observer into being, who displays the availabilities of RM and perhaps even communicates with manufacturers of RM (e.g. NMI) to figure out schedules and reasons for a lack of particular material. This international observer might be settled at the JCTLM.

Note: The information of this report will be accessible publicly on the relevant JCTLM Members webpage, unless the author of the report states otherwise. In the case the organization does not authorize the publication of the report in part or full, the author will add a statement to clarify which part(s) of the report will /will not be rendered public.