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:

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.)

1.1 Development of (candidate) reference measurement methods

Snibe reference laboratory was established in early 2021. Up to now, we are equipped with three LC-MS/MS instruments and one UV-VIS spectrophotometer and running the quality management system in accordance with ISO/IEC 17025 and ISO 15195. In May 2023, our laboratory was CNAS Accredited with 9 measurands (AST, ALT, ALP, AMY, GGT, CK, LDH, 25-OH-vitamin D3, and 17-OH-Progesterone). In 2025, three more measurands(Testosterone, Thyroxine, and Triiodothyronine) were accredited by CNAS.

18 reference measurement methods had been established according to the RMPs listed in the JCTLM database by the end of 2023. Since then, 22 new (candidate) reference measurement methods were established and several more are under development. The measurands covers enzymes, non-peptide hormones, drugs, vitamins, peptides, and proteins.

1.2 Establishment of calibration measurement services

3 reference measurement services (ALT, AMY, CK) has been listed in the JCTLM database since 2024.

1.3 Participation in the EQA/PT for reference laboratory

a) IFCC-RELA:

In 2024, we enrolled for 13 measurands, including AST, ALT, ALP, AMY, GGT, CK, LDH, 25-OH-vitamin D3, 17-OH-Progesterone, ALD, T3, T4 and Estradiol-17β. Most results are within the equivalent limits while CK results are a bit lower.

In 2025, we enrolled for 8 measurands, including 17-OH-Progesterone, ALD, Estradiol-17β, total Thyroxine, total Triiodthyronine, Progesterone, testosterone, and Cortisol. The results are satisfactory according to the pre-evaluation feedback by RELA.

b) NCCL-EQARL(organized by China NCCL):
In 2024, we enrolled for 19 measurands, including AST, ALT, ALP, AMY, GGT, CK, LDH, 25-OH-vitamin D3, 25(OH)D2, 17-OH-Progesterone, ALD, Estradiol-17β, Folic acid, 5-methyltetrahydrofolate, FK506, CSA, Everolimus, and Sirolimus. The results are basically satisfactory.

In 2025, we enrolled for 15 measurands, including AST, ALT, ALP, AMY, GGT, CK, LDH, 25-OH-vitamin D3, 25(OH)D2, Folic acid, 5-methyltetrahydrofolate, FK506, CSA, Everolimus, and Sirolimus. Only enzymes results were evaluated up to now, and all are satisfactory.

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)/meaurands 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.)

- In the next two years, Snibe reference laboratory intends to develop more reference measurement procedures, mainly in protein/peptide measurement areas, like C-peptide and PTH.
- Based on the established RMPs, proper master calibrators will be prepared and value-assigned to calibrate Snibe's commercial assay kits.
- As for the developed RMPs, Snibe plans to apply them gradually in traceability and quality control of IVD assays.
- Besides, Snibe is in the process of establishing the ISO17034 QMS and is manufacturing an aldosterone reference material.
- The application of at least 2 reference measurement services concerning vitamins and non-peptide hormones will be submitted to JCTLM for reviewing in 2026.

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)

- Snibe has becoming the corresponding members of IFCC C-BM, C-STFT, C-TLM, WG APO MS, WG-CMT, WG-NB, WG-PCT and WG-TMH. Our colleagues attended the on-site meeting during 2024WORLDLAB and 2025EUROMEDLAB and also attended the on-line meetings held by difference committee and working groups regularly.
- Snibe joined the MTC21(Measurement Technical Committee 21) organized by SAMR(State Administration for Market Regulation) and take part in reviewing JJF documents concerning RMPs.
- One manuscript collaborated with GPHCM has been submitted to CCLM, the other one has been submitted to a journal (Chinese Journal of Clinical Laboratory Science) in China. Both are under review.

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.)

- Participate in IFCC-RELA and NCCL–EQARL EQA/PT activities for reference laboratory annually.

- During 2024-2025, developing FT3/FT4 reference measurement systems collaborated with NCCL and GPHCM.
- In 2024, participated in the CDC CSP PTH and free testosterone interlab comparison.
- In 2024, participated the 3rd IFCC TSH harmonization panel value assignment organized by C-STFT.
- During 2024-2025, continuing the cooperation with Prof. Christa Cobbaert on the standardization of serum apolipoproteins by implementing a method comparison between RMP and Snibe assay.
- In 2025, participated in 17α-hydroxyprogesterone, Testosterone and Progesterone reference materials collaborative value assignment organized by National Institutes for Food and Drug Control (NIFDC).
- In 2024 and 2025, participated in inter-lab comparison on TDM and Vitamin measurands(Tacrolimus, CSA, Sirolimus, Everolimus, 25(OH)D3, and 25(OH)D2) with Maccura.

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)

a) As the measurement instruments' analytical performance boosts, some RMPs established decades ago may be not so suitable for now. Besides, authors may make some corrections afterwards. Is there any plan to review and update the RMPs periodically?

b) The number of reference materials is limited in the JCTLM database and is sometimes hard to purchase.

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 authorizes 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.