

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: Shanghai Center for Clinical Laboratory

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.)

During the last two years from 2024 to 2025, our reference measurement methods were actively established with the purpose to provide more service to meet the market needs and quality monitoring needs where our center's responsibility locates. In addition to enzymes, metabolites, Non-peptide hormones, proteins, vitamins and Electrolytes, blood cell counting has also passed ISO 15195, with a total of 31 analytes.

With the increasing number of RMP that passed ISO 15195, we actively applied for JCTLM listing. In 2024 and 2025, there are 18 RMP service listed by JCTLM, such as ALT、AST、GGT、CK、LDH、AMY、ALP、Crea、HbA_{1c}、Chol、Glucose、UA、Urea、K、Ca、Li、Na and Estriol and 1 RMP as Na.

As for reference measurement services that we provided, the **domestic** services were mainly on trueness verification program (TVP). It is organized by our center which includes about 25 items, covering the range of clinical chemistry, clinical hematology and clinical mass spectrometry. The customers are nationwide. It is provided once per year. Reference Measurement Laboratory performed RMP to assign values for TVP samples. The **overseas** services were value assignment for IRMM reference materials (AMY and ALP) ordered by JRC and for IFCC HbA_{1c} secondary calibrators ordered by IFCC.

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)/meurands 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 following 2 years, we are going to expand the RMP and RM in width and depth. Take hormones for example, mass spec technique shows advantages over conventional methods and meanwhile their RMP are not enough. We will explore establishing LC-MS based RMP for specific hormones that are targets for certain disease e.g. rare disease. As for RM, we will cooperate with IVDs to develop and submit for certificate with priority to face actual market needs and fill the market blank.

It's an honor to be listed by JCTLM. We will continue to apply for listing by submitting our best and robust items to JCTLM. We will actively participate the international activities with respect to standardization in lab medicine.

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)

We undertook several scientific research projects as follows:

1. Establishment and application of a candidate reference method for glycated albumin;
2. establishment of a candidate reference measurement procedure for catecholamine metabolites;
3. LC-MS mass spectrometric methods for the detection of urinary proteins and small molecules;
4. ICP-MS mass spectrometric method for human serum β -hCG;
5. Establishment and application of a reference method for serum total bilirubin;
6. Developing national secondary reference materials, such as GGT, ALP, GBS DNA and HPV6 DNA.

We also published a book in 2025, named *Reference Measurement Practice in Laboratory Medicine*. It refers to reference measurement procedures, method development, uncertainty evaluation, and introductions to ISO standards, and other relevant topics. It gives practical guides for staff in the area.

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.)

We participate the IFCC HbA1c Network. It organizes twice per year HbA1c inter laboratory comparison and value assignment for secondary calibrators.

We established a reference laboratory network in Yangtze Delta Region of China in 2021. The network currently has 13 laboratories, of which 11 have passed ISO 15195 accreditation. We organize an annual inter-laboratory comparison and hold a network meeting to promote standardization.

In July 2025, we were commissioned by CNAS to provide a one week training program for professionals from SADCAS, which comprehensively introduced the operational strategies and practical experience of PT and TVP.

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)

None.

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.