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: Shanghai Center for Clinical Laboratory

JCTLM Member status: Stakeholder

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Period covered: 2022 – 2023

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 Production of certified reference materials: NONE

1.2 Participation of RELA, IFCC HbA1c Network and NCCL study.

a) **RELA:** In 2022, 28 measurands got involved in RELA study, including HbA1c, Glucose, Cholesterol, Urea, Uric acid, Creatinine, Triiodthyronin, Thyroxin, Cortisol, Testosterone, Progesterone, 17OH-Progesterone, Estriol, Estradiol-17β, 25(OH)VD3, Digoxin, Sodium, Calcium, Potassium, Lithium, Magnesium, ALT, AST, ALP, AMY, GGT, CK and LDH. In 2023 the number increased to 29 with addition of total glycerol. All results in 2022 were satisfactory and final feedback in 2023 are still in progress.

b) **IFCC HbA1c Network:** as a member of IFCC HbA1c Network, we participated Kotten study in 2022, Rome study in 2023. We maintain our certificates as Primary Reference Measurement Laboratory on HbA1c.
c) **NCCL:** we participated reference inter-laboratory comparison study organized by National Center for Clinical Laboratory (NCCL). The measurands were HCY, Triiodthyronin and Sodium in 2022; HCY and 25(OH)VD2 in 2023. Results were satisfactory.

1.3 Value assignment services:

a) **Shanghai Center for Clinical Laboratory:** our center provides Trueness verification programs (TVP), which values are assigned by RMP. In 2022, it included HbA1c, Glucose, Urea, Uric acid, Creatinine, Triiodthyronin, Thyroxin, Cortisol, Testosterone, Sodium, Calcium, Potassium, Lithium, ALT, AST, ALP, AMY, GGT, CK and LDH, 25(OH)VD2, 25(OH)VD3, Cholesterol, HCY. In 2023, except for those analytes in 2022, total glycerol is also included.
b) **Guangdong Hospital of Traditional Chinese Medicine:** in 2023, we assigned values to their reference materials on the following measurands, 17OH-Progesterone, Estriol, creatinine, uric acid, urea, glucose, cortisol, Testosterone, 25(OH)VD3, ALP, AMY, GGT, CK and LDH.
c) **National Institute of Metrology:** in 2023, we assigned values to their Estradiol-17β reference materials.
d) **Yangtze Delta Region Institute of Tsinghua University:** in 2023, we assigned values to their CK reference materials.

1.4 On-going development of RMP includes C peptide, glycated albumin, total bilirubin, etc.

1.5 Measurands include HbA1c, Glucose, Cholesterol, Urea, Uric acid, Creatinine, Triiodthyronin, Thyroxin, Cortisol, Testosterone, Progesterone, 17OH-Progesterone, Estriol, Estradiol-17β, 25(OH)VD3, Digoxin, Sodium, Calcium, Potassium, Lithium, Magnesium, total glycerol, ALT, AST, ALP, AMY, GGT, CK, LDH, HCY and 25(OH)VD2.

1.6 At the end of 2023, 25 analytes passed the CNAS accreditation of ISO15195, including HbA1c, Glucose, Cholesterol, Urea, Uric acid, Creatinine, Triiodthyronin, Thyroxin, Cortisol, Testosterone, 17OH-Progesterone, Estriol, Estradiol-17β, 25(OH)VD3, Sodium, Calcium, Potassium, Lithium, ALT, AST, ALP, AMY, GGT, CK and LDH.

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.)

2.1 We plan to establish more reference measurement procedure. Extension of our reference measurement services may be achieved by including more measurands into accreditation of ISO 15195 and by application of more into trueness verification programs and into the reference materials value assignment.

2.2 We will start more continual educational courses on standardization in laboratory medicine in Shanghai and nationwide.

2.3 We will publish more papers on method development and application.

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)

Publications in 2022 and 2023 are as follows:

- Fan X, Li Q, Fang H, Ju Y*, Jin Z, Li H, Zhang X. Development and application of a high accuracy method for measuring Pb in blood[J]. Clin Chim Acta. 2023, 538:164-168.
- Xiaoyu Fan, Qing Li, Yi Ju*. A standard addition method to quantify serum lithium by inductively coupled plasma mass spectrometry[J]. Ann Clin Biochem, 2022; 59(3):166-170.
- Yu Keying, Sun Hewei, Jin Zhonggan, Zhang Sujie, Li Qing, Ju Yi*. Analytical performance of a candidate reference measurement procedure for serum 17α-hydroxyprogesterone based on liquid chromatography tandem mass spectrometry[J]. Chinese Journal of Laboratory Medicine, 2022, 45:449-455.

- YANG Xue, JU Yi*, OU Yuanzhu, et al. Analysis on the results of external quality assessment of mutual recognition quantitative items in Shanghai[J]. Laboratory Medicine, 2022, 37(12):1129-1134.

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.)

4.1 **IFCC HbA1c Network** study: As a member of IFCC HbA1c Network, we participated its annual inter laboratory comparison study and value assignment for new calibrators.

4.2 **Yangtze Delta Region reference laboratory network** study: In 2021, our center established the Yangtze Delta Region reference laboratory network and organized an annual inter-laboratory comparison. There are currently 12 laboratories, of which 8 have passed ISO 15195 accreditation.

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 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.