SCCL biennial activity report

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: 2020 – 2021

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 Participation of RELA, IFCC HbA1c Network and NCCL study.

a) RELA study: in 2020, 28 measurands got involved in RELA study, including 17OH-Progesterone, 25-OH-Vitamin D3, ALT, Amylase, ALP, AST, Calcium, CK, Cortisol, Creatinine, Digoxin, Estradiol-17β, Estriol, GGT, Glucose, HbA1c, LDH, Lithium, Magnesium, Potassium, Progesterone, Sodium, Testosterone, Thyroxin, Total Cholesterol, Triiodothyronin, Urea and Uric acid. In 2021, the number increased to 29 with addition of Total Hemoglobin. The results are basically satisfactory.

b) IFCC HbA1c Network study: as a member of IFCC HbA1c Network, we participated Seoul 1 and Seoul 2 study in 2020, Munich 1 and Munich 2 study in 2021, including inter laboratory comparison and value assignment. We keep our certification as Primary Reference Measurement Laboratory on HbA1c.

c) NCCL study: we participated reference inter-laboratory comparison study organized by National Center for Clinical Laboratory (NCCL). The measurands were Calcium and Triiodothyronin in 2020, 25-OH-Vitamin D3 and HCY in 2021. Results were satisfactory.

1.2 Value assignment services:

a) Trueness verification programs (TVP): Our center’s TVP: in 2020, it included 25-OH-Vitamin D3, ALT, ALP, Calcium, Cortisol, Creatinine, GGT, Glucose, HbA1c, Lithium, Potassium, Sodium, Testosterone, Triiodothyronin, Urea and Uric Acid. In 2021, the number increased to 23 with addition of 25-OH-Vitamin D2, Amylase, AST, CK, HCY, LDH and Thyroxin.

b) National Institute of Metrology’s order: in 2020, 17OH-progesterone, Estradiol-17β and Estriol for scientific research.
c) Guangdong Hospital of Traditional Chinese Medicine’s order: in 2021, we assigned values to their reference materials on the following measurands, such as Progesterone and Estradiol-17β.

d) Autobio’s order: in 2020, it was on Cortisol, Thyroxin and Triiodothyronin.

1.3 On-going development of RMP includes Apolipoproteins and Cystatin C, etc.

1.4 In 2021, eight mass spectrometry analytes passed the CNAS accreditation of ISO15195, including Calcium Estradiol-17β, Estriol, Lithium, Potassium, Sodium, Testosterone and Thyroxine. Thus, the total number of analytes approved was 23.

1.5 In 2020, we performed a collaborative study to estimate the Nucleic Acid Testing(NAT)-detectable units as a copies/μL of a synthetic RNA transcripts reference material (GBW(E)091111) using droplet digital PCR (ddPCR) on QX ONE Droplet Digital PCR (ddPCR) System (Bio-Rad).

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.)

2.1 We plan to establish methods on mass spec platform with measurands about C-peptide and Glycated albumin, etc. Extension of our calibration measurement services may be achieved by including more measurands into accreditation of ISO 15195 and by application of more into trueness verification programs.

2.2 We plan to establish the Yangtze River Delta regional reference laboratory network (7 laboratories have passed the ISO15195 accreditation of CNAS by the end of 2021) to further improve the equivalence of clinical laboratory test results.

2.3 We will continue to carry out education courses on standardization in laboratory medicine in Shanghai and nationwide.

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)

3.1 We actively cooperate with the Quality Control Center (QCC) of Medical Laboratory of University of Medicine Pharmacy at Ho Chi Minh city in Vietnam. Prof. Yi Ju was invited to give a video speech entitled “How SCCL ensures traceability in PT and stresses its importance to participants?” at the Workshop on the 10 years Celebration of QCC entitled: "Establish a Reference Laboratories Network in Viet Nam" on July 30, 2020.

3.2 Publications in 2020 and 2021 are as follows:

• OU Yuanzhu, CHEN Baorong*, JU Yi *. Current situation of standardization of clinical chemistry measurement[J]. Laboratory Medicine, 2021,36(3): 240-244.
• JU Yi. Research and application of reference measurement system in laboratory medicine[J]. Laboratory Medicine, 2021, 36(3): 237-239.

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

4.2 IFCC working group on CGM: we participated in the discussion of the working group on continuous glucose monitoring. See the paper Standardization process of continuous glucose monitoring: Traceability and performance[J]. CCA, 2021, 515: 5-21.

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.