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: Shanghai Center for Clinical Laboratory |
| JCTLM Member status: Stakeholder |
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| Period covered: 2018 – 2019 |

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 list of the relevant technical/scientific publications.)

1.1 Production of certified reference materials:
- Alkaline phosphatase (ALP): Code GBW(E)090920;
- Aspartic acid transferase (AST): Code GBW(E)090919;
- Human papillomavirus type 18 deoxyribonucleic acid (HPV18DNA): Code GBW(E)090957;
- Human papillomavirus type 16 deoxyribonucleic acid (HPV16DNA): Code GBW(E)090956;
- Hepatitis C virus (HCV DNA) Ribonucleic Acid Serum: Code GBW(E)090628;
- Hepatitis B virus (HBV DNA) deoxyribonucleic acid Serum: Code GBW(E)090627.

1.2 Participation of RELA, IFCC HbA1c Network and NCCL study.
- RELA study: in 2018, 24 measurands got involved in RELA study, including HbA1c, Glucose, Cholesterol, Urea, Uric acid, Creatinine, Triiodothyronin, Thyroxin, Cortisol, Testosterone, Progesterone, Estriol, Estradiol-17β, 25(OH)VD3, Digoxin, Sodium, Calcium, Potassium, Lithium, ALT, AST, ALP, AMY and GGT. In 2019, the number increased to 26 with addition of LDH and CK. Results were satisfactory.
- IFCC HbA1c Network study: as a member of IFCC HbA1c Network, we participated Chicago 1 and Chicago 2 study in 2018, Barcelona 1 and Barcelona 2 study in 2019, including inter laboratory comparison and value assignment. We keep our certification as Primary Reference Measurement Laboratory on HbA1c.
- NCCL study: we participated reference inter-laboratory comparison study organized by National Center for Clinical Laboratory (NCCL). The measurands were LDH, CK and Progesterone in 2018, Progesterone and uric acid in 2019. Results were satisfactory.
1.3 Value assignment services:

a) Trueness verification programs (TVP): Our center’s TVP: in 2018, it included HbA1c, Creatinine, Urea, Uric Acid, AST, ALT, GGT, ALP, LDH and Calcium. In 2019, it included ALT, AST, GGT, ALP, LDH, AMY, CK, Ca, Na, HbA1c, Creatinine, Urea, Uric Acid and Cortisol.

b) NCCL’s order: in 2018, it was on HbA1c.

c) Guangdong Hospital of Traditional Chinese Medicine’s order: in 2018, we assigned values to their reference materials on the following measurands, such as estradiol, creatinine, ALT, AST, ALP, AMY and GGT.

d) National Institute of Metrology’s order: Testosterone and HCY for scientific research.

1.4 On-going development of RMP includes apolipoproteins, HCY, Cyc-C, 17OH progesterone, etc. On-going development of RM includes 25(OH)VD3 and 25(OH)VD2.

1.5 Measurands include HbA1c, Glucose, Cholesterol, Urea, Uric acid, Creatinine, T3, T4, Cortisol, Testosterone, Progesterone, estradiol, estrogen, 25(OH)VD3, digoxin, sodium, calcium, potassium, lithium, ALT, AST, GGT, LDH, AMY, CK and GGT.

1.6 At the end of 2018, six LC/MS projects passed the CNAS accreditation of ISO15189, including glucose, cholesterol, urea, uric acid, cortisol and 25 (OH) VD3.

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)/measurerands 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.)

First, we plan to establish methods on mass spec platform with measurands about apolipoproteins, HCY, Cyc-C, 17OH progesterone, 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. Besides, we also plan to develop RM on 25(OH)VD3 and 25(OH)VD2.

Second, we will start more continual educational courses on standardization in laboratory medicine in Shanghai and nationwide.

Third, 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, other forums for clinical laboratory medicine)

Publications in 2018 and 2019 are as follows:

- Zhonggan Jin, Yi Ju*, Qing Li, etc. Analysis on the results of creatinine,uric acid and urea determination trueness verification in Shanghai,2016.Laboratory Medicine, 2018,33(4): 348-352.
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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 Participation of certification campaign for the new CRM for alpha-amylase: ERM-AD456/IFCC.** In 2018-2019, we participated the value assignment activity for ERM-AD456/IFCC which was organized by JRC.

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)

If JCTLM list on reference measurement procedure could expand more quickly, it would help its downstream application and benefit traceability establishment for more measurands.

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.