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: National Center for Clinical laboratories (NCCL)

JCTLM Member status: Stakeholder Member

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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 listing of the relevant technical/scientific publications.)

- **Nominations for JCTLM database**

  — NCCL ID LC-MS/MS reference measurement procedure for glucose in blood serum has been accepted for listing in the JCTLM Database in 2018. Identification Number: C14RMP11.

  — NCCL CRM GBW 09181a & 09182a & 09183a "Glycated Hemoglobin in Human Hemolysate buffer" have been accepted for listing in the JCTLM Database in 2018.

  —The nominations of reference service for Glucose, Sodium, Potassium, Magnesium, Calcium, total cholesterol, Total thyroxine (TT4) as well as reference measurement procedure for total triglyceride was submitted for listing under JCTLM database in 2019.

- **Trueness-verification Program**

  NCCL continues to run the national trueness verification Program once a year. The total number of participating laboratories is 2001in 2019.

  Currently available for:

  - Lipids and lipoproteins (TC, TG, HDL, LDL)
  - Metabolites (Glu, Creatinine, UA, urea)
  - Total protein
  - HbA1c
  - Enzymes (ALT, ALP, AST, AMY, CK, GGT, LDH)

- Electrolytes (Potassium, Sodium, Calcium, Magnesium, Chlorine)

A pilot trueness verification Programs for non-peptide hormones was organized in 2019. 50 clinical laboratories using routine methods and 60 laboratories using mass spectrometry methods were invited to take part in the survey.

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.)

- **Development of reference systems**

— A candidate reference measurement procedure for 17-OH progesterone were developed and this method is under review for method validation
— The commutability study in certified reference material "Progesterone, cortisol, testosterone and estradiol in frozen human serum" GBW 09197a, 09198a and 09199a is in progress. The CRMs will be nominated for JCTLM database when the work is done.

- **Trueness verification for steroid hormones, Vitamins and thyroid hormone**
—National trueness verification for Steroid hormones, Vitamins and Thyroid hormone will be formally open to public in 2020.

- **IFCC certification of Manufacturers for HbA1c**
In cooperate with IFCC Network, NCCL plan to carry out the IFCC certification of Manufacturers for HbA1c in 2020.

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)

- **Publication**

Yan Y, Pu Y, Long Q, Zhang J, Zhang T, Zhou W, Zeng J, Zhang C, Chen W, Zhang C. Commutability of external quality assessment materials for serum magnesium and calcium measurements. Scand J Clin Lab Invest. 2019 Oct;79(6):404-411.

Yu S, Zhou W, Cheng X, Meng Q, Li H, Hou L, Lu J, Xie S, Cheng Q, Zhang C, Qiu L. Comparison of Six Automated Immunoassays with Isotope-Diluted Liquid Chromatography-

Tandem Mass Spectrometry for Total Thyroxine Measurement. Ann Lab Med. 2019 Jul;39(4):381-387.

Wang Y, Zhang T, Zhao H, Zhou W, Zeng J, Zhang J, Zhang C, Chen W. Measurement of serum progesterone by isotope dilution liquid chromatography tandem mass spectrometry: a candidate reference method and its application to evaluating immunoassays. Anal Bioanal Chem. 2019 Apr;411(11):2363-2371.

Zhang J, Luo W, Zeng J, Zhang T, Zhou W, Zhao H, Yan Y, Hu C, Ma R, Wang J, Chen W, Zhang C. Standardization of measurement procedures for serum uric acid: 8-year experience from Category 1 EQA program results in China. Clin Chem Lab Med. 2019 Mar 26;57(4):476-482.

He S, Wang W, Zhao H, Zhang C, He F, Zhong K, Yuan S, Wang Z. The Observation and Analysis of Internal Quality Control of Cystatin C in China from 2014 to 2017. Clin Lab. 2018 Oct 1;64(10):1709-1718.

Huang Y, Zhang T, Zhao H, Wang W, Zhang C, He F, Zhong K, Yuan S, Du Y, Wang Z. Performance evaluation of HbA1c measurement systems with sigma metric for 1066 laboratories in China. Clin Chim Acta. 2018 Dec;487:281-286.

Han B, Zeng J, Yan Y, Zhao H, Zhang T, Zhou W, Zhang J, Wang J, Wang Y, Zhang C. A Simple and Accurate Measurement Procedure for Serum Chloride by Ion Chromatography and Bias Evaluation of Six Ion Selective Electrode Measurements in China. Clin Lab. 2018 Sep 1;64(9):1457-1467.

Wang J, Wang Y, Zhang T, Zeng J, Zhao H, Guo Q, Yan Y, Zhang J, Zhou W, Chen W, Zhang C. Evaluation of serum alkaline phosphatase measurement through the 4-year trueness verification program in China. Clin Chem Lab Med. 2018 Nov 27;56(12):2072-2078.

Yan Y, Han B, Zhao H, Ma R, Wang J, Wang D, Hu C, Chen W, Zhang C. Commutability of external quality assessment materials for serum sodium and potassium measurements. Clin Chem Lab Med. 2019 Mar 26;57(4):465-475.

Sun H, Wang W, Zhao H, Zhang C, He F, Zhong K, Yuan S, Wang Z. Internal quality control status for BNP and NT-proBNP in China from 2014 to 2017. J Clin Lab Anal. 2019 Jan;33(1):e22643.

Duan M, Wang W, Zhao H, Zhang C, He F, Zhong K, Yuan S, Wang Z. National surveys on internal quality control for blood gas analysis and related electrolytes in clinical laboratories of China. Clin Chem Lab Med. 2018 Oct 25;56(11):1886-1896.

Zeng J, Qi T, Wang S, Zhang T, Zhou W, Zhao H, Ma R, Zhang J, Yan Y, Dong J, Zhang C, Chen W. Commutability of control materials for external quality assessment of serum apolipoprotein A-I measurement. Clin Chem Lab Med. 2018 Apr 25;56(5):789-795.

Duan M, Kang F, Zhao H, Wang W, Du Y, He F, Zhong K, Yuan S, Chen B, Wang Z. Analysis and evaluation of the external quality assessment results of quality indicators in laboratory medicine all over China from 2015 to 2018. Clin Chem Lab Med. 2019 May 27;57(6):812-821.

Yu S, Zhou W, Wang D, Yin Y, Cheng Q, Xie S, Sun D, Li H, Cheng X, Qiu L.Rapid liquid chromatography-tandem mass spectrometry method for determination of 24,25(OH)(2)D and

25OHD with efficient separation of 3-epi analogs. J Steroid Biochem Mol Biol. 2019 Mar;187:146-151.

Huang Y, Wang W, Zhao H, Du Y, Liu J, He F, Zhong K, Yuan S, Wang Z. Quality assessment of interpretative commenting and competency comparison of comment providers in China. Clin Chem Lab Med. 2019 May 27;57(6):832-837.

Wang J, Wang Y, Zhang T, Zeng J, Zhao H, Guo Q, Yan Y, Zhang J, Zhou W, Chen W, Zhang C. Evaluation of serum alkaline phosphatase measurement through the 4-year trueness verification program in China. Clin Chem Lab Med. 2018 Nov 27;56(12):2072-2078.

Fu Y, Zhang R, Wu Q, Zhang J, Bao L, Li J. External quality assessment of p210 BCR-ABL1 transcript quantification by RT-qPCR: Findings and recommendations. Int J Lab Hematol. 2019 Feb;41(1):46-54.

Sun H, Wang W, Zhao H, Zhang C, He F, Zhong K, Yuan S, Wang Z. Internal quality control status for BNP and NT-proBNP in China from 2014 to 2017. J Clin Lab Anal. 2019 Jan;33(1):e22643.

Duan M, Ma X, Fan J, Guo Y, Wang W, Zhao H, Ye Y, Fei Y, He F, Wang Z, Zhang Z. National surveys on 15 quality indicators for the total testing process in clinical laboratories of China from 2015 to 2017. Clin Chem Lab Med. 2018 Dec 19;57(2):195-203.

Fu Y, Zhang R, Wu Q, Zhang J, Bao L, Li J. Development and evaluation of armored RNA-based standards for quantification of BCR-ABL1(p210/p190) fusion gene transcripts. J Clin Lab Anal. 2018 Nov;32(9):e22612.

Li T, Zhao H, Zhang C, Wang W, He F, Zhong K, Yuan S, Wang Z. Reasons for Proficiency Testing Failures in Routine Chemistry Analysis in China. Lab Med. 2019 Jan 1;50(1):103-110.

Lin G, Zhang X, Zhang K, Han Y, Tan L, Li J. Evaluation of tacrolimus-related CYP3A5 genotyping in China: Results from the First External Quality Assessment Exercise. J Clin Lab Anal. 2018 Oct;32(8):e22563.

.Guo X, Zhang T, Gao X, Li P, You T, Wu Q, Wu J, Zhao F, Xia L, Xu E, Qiu L, Cheng X. Sigma metrics for assessing the analytical quality of clinical chemistry assays: a comparison of two approaches: Electronic supplementary material available online for this article. Biochem Med (Zagreb). 2018 Jun 15;28(2):020708.

Wang W, Zhong K, Yuan S, He F, Du Y, Hu Z, Wang Z. National survey on internal quality control for tumour markers in clinical laboratories in China. Biochem Med (Zagreb). 2018 Jun 15;28(2):020702.

Zhang D, Lin G, Zhang K, Yi L, Zhang R, Xie J, Li J. Implications of and lessons learned from external assurance of eight influenza diagnostics in China. Virus Res. 2018 Apr 2;249:110-115.

Jia S, Zhang R, Lin G, Peng R, Gao P, Han Y, Fu Y, Ding J, Wu Q, Zhang K, Xie J, Li J. A novel cell line generated using the CRISPR/Cas9 technology as universal quality control material for KRAS G12V mutation testing. J Clin Lab Anal. 2018 Jun;32(5):e22391.

Wang Y, Wang S, Zhang L, Zeng J, Yang R, Li H, Tang Y, Chen W, Dong J. Asimple and precise method to detect sterol esterification activity of lecithin/cholesterol acyltransferase by high-performance liquid chromatography. Anal Bioanal Chem. 2018 Feb;410(6):1785-1792.

Li T, Wang W, Zhao H, He F, Zhong K, Yuan S, Wang Z. Quality specification and status of internal quality control of cardiac biomarkers in China from 2011 to 2016. J Clin Lab Anal. 2018 May;32(4):e22324.

- **Conference**

—14th annual national symposium on reference systems in Laboratory Medicine was held by NCCL in shanghai, China, from November 15 to November 18, 2018.

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.)

- **External Quality Assessment for Reference Laboratories (EQARL)**

— NCCL continues to run the External Quality Assessment for Reference Laboratories (EQARL) once a year. There were 16 reference laboratories in China participated in the program in 2018 and 2019 for the reference measurements of Lipids and lipoproteins (TC, TG, HDL, LDL), Metabolites (Glu, Creatinine, UA, urea), Total protein, HbA1c, Enzymes (ALT, ALP, AST, AMY, CK, GGT, LDH), Electrolytes (Potassium, Sodium, Calcium, Magnesium, Chlorine), non-peptide hormone (Progesterone, cortisol, testosterone and estradiol, aldosterone, 17-OH progesterone), Thyroid hormone(TT4 and TT3) and vitamins (25-OH-D3).

- **IFCC External Quality Assessment Scheme for calibration laboratories in clinical chemistry (RELA)**

— NCCL yearly participates in the RELA inter-comparison. In 2018, we successfully participated for Calcium, Chloride, Magnesium, HbA1c,17OH-Progesterone, Cortisol, Estradiol, Aldosterone, Progesterone, Thyroxin, Creatinine, Uric acid, Total protein, 25-OH-Vitamin D3, AST, GGT, LDH.

- **IFCC HbA1c Network**

— NCCL participates annually in IFCC network inter-comparison for HbA1c.

- **JCTLM Database Working Group**

— Prof. Wenxiang Chen is currently serving as the member of Metabolites and Substrates, Non-Peptides Hormones Review Team in the JCTLM Database Working Group.

— Dr. Tianjiao Zhang is appointed as a member of the review teams for Metabolites & Substrates, Non-Peptide Hormones and Vitamins & micronutrients in 2019.

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.