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: National Center for Clinical laboratories, China (NCCL)

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.)

Certified reference materials

— NCCL has develop the secondary reference materials "Aldosterone in frozen human plasma" (GBW 09283, GBW 09284, GBW 09285).
— NCCL has develop a primary reference material for Aldosterone (GBW 09282).

Nominations for JCTLM database

—The nominations of reference service for Glucose and Total thyroxine (TT4) have been accepted for listing in the JCTLM Database in 2020.

Trueness-verification Program

NCCL continues to run the national trueness verification Program once a year. The total number of participating laboratories was 3238 in 2020 and 4173 in 2021.
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)

The new trueness verification Programs for non-peptide hormones, vitamins and Homocysteine were established in 2019.

- Steroid hormones (Progesterone, cortisol, testosterone, estradiol)
- Vitamins (25-OH VD_3, 25-OH VD_2)
- Total thyroid; Total Triiodothyronine
- Homocysteine
- Aldosterone

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

— The candidate reference measurement procedures for metanephrines, c-peptide, folic acid and immunosuppressant were developed and these methods are 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.

IFCC certification of clinical Laboratories for HbA_{1c}

In cooperate with IFCC Network, NCCL plan to carry out the IFCC certification of clinical Laboratories for HbA_{1c} in 2021.

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

Liu Z, Liu Q, Deng Y, Zhao H, Zeng J, Zhang T, Zhang J, Wang J, Zhou W, Zhang C. Quantitation of plasma metanephrines using isotope dilution liquid chromatography tandem mass spectrometry (ID-LC/MS/MS): a candidate reference measurement procedure and its application to evaluating routine ID-LC/MS/MS methods. Anal Bioanal Chem. 2021 Oct 13. doi: 10.1007/s00216-021-03715-8. Epub ahead of print.

Liu Q, Guo Q, Wang J, Deng Y, Zeng J, Zhou W, Zhao H, Zhang C. Development of a designated comparison method for alkaline phosphatase measurements and its application to evaluating routine methods. Scand J Clin Lab Invest. 2021 May;81(3):218-224.

Long Q, Zhang T, Yan Y, Zhao H, Zhou W, Zeng J, Li S, Zhang J, Zeng Q, Zhao B, Zhang C, Chen W. Measurement of serum 17-hydroxyprogesterone using isotope dilution liquid chromatography-tandem mass spectrometry candidate reference method and evaluation of the performance for three routine methods. Clin Chem Lab Med. 2020 Nov 25;59(3):523-532.

Yi X, Wang Y, Zhang T, Zeng J, Zhao H, Zhou W, Zhang J, Yan Y, Chen W, Zhang C. Commutability of possible external quality assessment materials for progesterone measurement. Clin Biochem. 2021 Jan;87:39-45.

Long Q, Qi T, Zhang T, Wang J, Zeng J, Yan Y, Wang M, Huang W, Zhao H, Chen W, Zhang C. Commutability Assessment of Candidate External Quality Assessment Materials for Aminotransferase Activity Measurements Based on Different Approaches in China. Ann Lab Med. 2021 Jan;41(1):68-76.

Yan Y, Pu Y, Zeng J, Zhang T, Zhou W, Zhang J, Wang J, Zhang C, Chen W, Zhang C. Evaluation of serum electrolytes measurement through the 6-year trueness verification program in China. Clin Chem Lab Med. 2020 Jul 28;59(1):107-116.

Guo Q, Wang J, Yi X, Zeng J, Zhou W, Zhao H, Zhang T, Zhang C. Commutability of reference materials for alkaline phosphatase measurements. Scand J Clin Lab Invest. 2020 Sep;80(5):388-394. doi: 10.1080/00365513.2020.1747111.

Zhang T, Zhao H, Li M, Zeng J, Wang J, Long Q, Wang Y, Zhang C, Chen W. Development and validation of a candidate reference method for serum cortisol by isotope dilution liquid chromatography-tandem mass spectrometry combined with dextran sulfate-Mg2+ precipitation. Anal Bioanal Chem. 2020 Feb;412(6):1325-1333.

4. Reference laboratory networks /collaborations focusing on developing /implementing reference measurement systems

External Quality Assessment for Reference Laboratories (EQARL)

— NCCL continues to run the External Quality Assessment for Reference Laboratories (EQARL) once a year. There were 27 reference laboratories in China participated in the programs 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), Homocysteine, Vitamins (25-OH-VD_3, 25-OH-VD_2) and Thyroid hormone (TT4 and TT3).

IFCC External Quality Assessment Scheme for calibration laboratories in clinical chemistry (RELA)
— NCCL yearly participates in the RELA inter-comparison. In 2021, we successfully participated for 17OH-Progesterone, 25-OH-Vitamin D3, Aldosterone, AST, ALT, Cortisol, Creatinine, Estradiol, Glucose, HbA1c, Magnesium, Testosterone, Calcium, Chloride, Cortisol, Progesterone, Thyroxin, Total cholesterol, Total glycerol, Total protein, Triiodothyronine and Urea.

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

JCTLM Database Working Group - Review Team member
- Enzyme (Wenxiang Chen)
- Non-Peptide Hormones and Vitamins & micronutrients Metabolites (Tianjiao Zhang)
- Electrolytes and Blood Gases (Ying Yan)

JCTLM-TF-RMSI
- member (Tianjiao Zhang)

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)

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.