

## 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:** Maccura Biotechnology Co., Ltd.

**JCTLM Member status:** Stakeholder Member

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**Period covered:** 2018 – 2019

### 1. Major achievement(s) in support of standardization in laboratory medicine

As the IVD internal reference measurement laboratory, our main task is to establish and apply reference measurement procedures and reference materials for assuring the traceability of our products, meanwhile, some new reference measurement procedures were developed in our laboratory. From 2018 to 2019, Maccura had 95 products were traced to reference measurement procedures or reference materials, which were recommended by the JCTLM list or ICSH organization, including the UV reference method, ID-LC/MS/MS reference method and the blood cell count reference method, which cover areas of enzyme, metabolites and substrates, proteins, nonpeptide hormones, and blood cells. From 2013, the reference measurement laboratory of Maccura is accredited according to ISO 17025 and ISO 15195 for 27 measurands and 10 services of them are listed in the JCTLM database. The list of activities is as follows.

- a. 2018, GDHTCM: Value assignment using the Reference Measurement Procedure for 14 kinds of Reference Materials.
- b. 2018, NIFDC: Value assignment using the Reference Measurement Procedure for TBIL Reference Materials
- c. 2019, IRMM: Value assignment using the IFCC Reference Measurement Procedure for AMY Reference Materials
- d. 2019, NIM: Value assignment using the Reference Measurement Procedure for E2 and E3 Reference Materials.
- e. 2019, NIM: Evaluation of commutability of testosterone and homocysteine in serum.

### 2. Planned activity(ies) in support of standardization in laboratory medicine

The next two years, Maccura plans to establish the reference method of FT3, FT4, TC, Digoxin, TG, Glu, Theophylline and Ions, meanwhile, study the traceability of these products. About the reference measurement services, Maccura plans to expand the following areas: Blood cells, Non-peptide hormones, Proteins, and Ions.

Maccura plans to produce domestic secondary reference material for uric acid, creatinine, T3, T4, FT3 and FT4 in the next two years.

### 3. Promoting traceability in laboratory medicine

Conference papers and Speeches at the meetings:

- a. Protein and Peptide Therapeutics and Diagnostics: Research and Quality Assurance International Workshop, October, 2018.  
Speeches: Application of mass spectrometry for metrological traceability in IVD manufacturers.  
Conference posters: Determination of serum chloride by ion chromatography, Precise Determination of Calcium in Serum by Simulated Isotope Dilution Method of Inductively Coupled Plasma Mass Spectrometry, Effect of different antibody dosage on platelet reference measurement results.
- b. 14th Annual Meeting of the Laboratory Medical Reference System. November, 2018.  
Speeches: The metrological traceability of immunochemical chemiluminescence and uncertainty study.  
Conference papers: The establishment of ID-UPLC/MS/MS method for the measurement of Creatinine in human serum and its application in IVD metrological traceability and Application of Blood Cell Reference Method in Traceability of Commercial Calibrators.

**Sponsor of Meetings:**

- c. Protein and Peptide Therapeutics and Diagnostics: Research and Quality Assurance International Workshop(PPTD), October 12nd-14th, 2018, Chengdu Sichuan, China.  
Speech: Application of mass spectrometry for metrological traceability in IVD manufacturers.
- d. The 6th National Symposium on Integrated Traditional Chinese and Western Medicine in Laboratory Medicine, June 28<sup>th</sup> to 29<sup>th</sup>, 2019, Chengdu China.  
Conference papers and Speech: The metrological traceability and standardization of immunoassay.
- e. The 8th Academic conference of laboratory medicine in three northeastern provinces, August 17<sup>th</sup> to 18<sup>th</sup>, 2019, Haerbin China.  
Conference papers and Speech: The metrological traceability of immunochemical chemiluminescence assay kits.

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

- a. Participate in the RELA experiment of IFCC and the Chinese reference laboratory Proficiency Testing each year;
- b. Participate in the reference laboratory network of China; Participate in the evaluation of ADA reference measurement accuracy, 2018.
- c. The member of National Clinical Medicine Metrology Technical Committee, China.
- d. Assist JCTLM, BIPM and NIM in organizing the PPTD meeting in Chengdu, China, 2018.
- e. Participate in the traceability project organized by National Institute of Metrology, China, 2019
- f. Participate in the National Glycohemoglobin Standardization Program(NGSP),2019
- g. Participate in the IFCC reference measurement system for HbA1c.

**5. Open questions and suggestions to be addressed by JCTLM**

About the evaluation of Calibration and Measurement Capability (CMC), whether there can be a consistent standard document for guidance, for different clinical measurement areas, for review teams, for laboratories?

The offered measurands of RELA can be increased as soon as possible?