

Maccura Biotechnology Co., Ltd 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: Maccura Biotechnology Co., Ltd.

JCTLM Member status: Stakeholder Member

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Period covered: 2015 – 2021

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 methods were developed in our laboratory. From 2015 to 2021, 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, ICP-MS and the blood cell count reference method, which cover areas of enzyme, metabolites and substrates, proteins, nonpeptide hormones, electrolytes and blood cells. To 2013, the reference measurement laboratory of Maccura is accredited according to ISO 17025 and ISO 15195 for 38 measurands and fifteen services of them are listed in the JCTLM database; the list of activities is as follows.

- a. 2015, NIFDC: Value assignment using the Immunochemical chemiluminescence Methods for C-peptide Reference Materials (NIBSC)
- b. 2015, NIFDC: Value assignment using the Immunochemical chemiluminescence Methods for TSH Reference Materials
- c. 2015, IRMM: Value assignment using the IFCC Reference Measurement Procedure for LDH, CK and ALT Reference Materials
- d. 2015, NIFDC: Value assignment using the Reference Measurement Procedure for Crea, Urea, UA and TP Reference Materials
- e. 2016, BIMT: Value assignment using the Immunochemical chemiluminescence Methods for Insulin Reference Materials
- f. 2016, NIFDC: Value assignment using the Immunochemical chemiluminescence Methods for Prolactin Reference Materials
- g. 2017, NIFDC: Value assignment using the Immunochemical chemiluminescence Methods for Torch Reference Materials
- h. 2017, SCCL: Value assignment using the IFCC Reference Measurement Procedure for ALP and AST Reference Materials
- i. 2017, NIM: Value assignment using the Reference Measurement Procedure for T and Hcy Reference Materials
- j. 2017, GDHTCM: Value assignment using the Reference Measurement Procedure for 14 kinds of Reference Materials.

- k. Uric acid UV reference measurement procedure drafted by Maccura was under review. The standard documentation JJF1455 drafted by Maccura was officially announced in January 2017.
- l. 2017, GPHCM, the evaluation of GPHCM Reference measurement method for serum estriol.
- m. 2018, IRMM: Value assignment using the IFCC Reference Measurement Procedure for AMY Reference Materials.
- n. 2018, GPHCM, the evaluation of GPHCM Reference measurement method for serum ADA.
- o. 2019, Value assignment using the JCTLM Reference Measurement Procedure for TBIL, crea, Prog, E3, E2 Reference Materials.
- p. 2020, Value assignment using the JCTLM Reference Measurement Procedure for VD3, crea, Prog, hcy Reference Materials.
- q. 2020, Value assignment for fib, Ald, cysc Reference Materials.
- r. 2021, Value assignment for TPO, Crea, UA, CRP Reference Materials.

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

The next two years, Maccura plans to establish the reference method of new analytes, 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.

3. Promoting traceability in laboratory medicine

Conference papers and Speeches at the meetings:

- (1) 11th Annual Meeting of the Laboratory Medical Reference System. November, 2015.
Conference papers and Speeches: TSH-IFCC harmonization Study and The establishment of ID-UPLC/MS/MS method for the measurement of 25-hydroxyvitamin D in human serum based on IFCC reference method.
- (2) 12th Annual Meeting of the Laboratory Medical Reference System. November, 2016.
Conference papers and Speeches: Determination of Testosterone in human serum using ID-UPLC/MS/MS and Improved UPLC/MS/MS method for the measurement of 25-hydroxy vitamin D in human serum based on IFCC reference method

Sponsor of Meetings:

- (1) Protein and Peptide Therapeutics and Diagnostics: Research and Quality Assurance International Workshop, June 1st-3rd, 2016, Chengdu Sichuan, China.
Speech: How to do with the accuracy in IVD manufacturer
- (2) The 17th Beijing Conference and Exhibition on Instrumental Analysis (BCEIA 2017), October 9th to 11th, 2017, Beijing China.
Poster: Establishment of Serum Ferritin Traceability System.
- (3) 13th Annual Meeting of the Laboratory Medical Reference System. November, 2017.
Conference papers and Speech: Determination of Progesterone in human serum using ID-UPLC/MS/MS;
- (4) Protein and Peptide Therapeutics and Diagnostics: Research and Quality Assurance International Workshop, 2018, Chengdu Sichuan, China.
Speech: How to do with the traceability in IVD manufacturer

Study in standardization:

- (1) The study of IVD standardization with NIM, 2017-2021
- (2) The study of reference materials with NIM, 2017-2021
- (3) The study of trueness tests with hospitals, 2021

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. Joined the Activities of the IFCC Committee for Standardization of Thyroid Function Tests, 2015-2021;
- c. Participate in the reference laboratory network of China; Participate in the evaluation of estradiol mass spectrometry reference measurement accuracy, 2017.
- d. The member of National Clinical Medicine Metrology Technical Committee, China.
- e. Assist JCTLM, BIPM and NIM in organizing the PPTD meeting in Chengdu, China, 2016 - 2020.
- f. Participate in the traceability project organized by National Institute of Metrology, China, 2017-2021

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?