

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.

<p>Organization: MedicalSystem Biotechnology Co., Ltd</p> <p>JCTLM Member status: Stakeholder Member</p> <p>Author(s): Min Shen</p> <p>Author(s) email(s): min.shen@nbmedicalsystem.com</p> <p>Period covered: 2015 – 2017</p>

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.)

Reference measurement methods

Analyte category	Analyte	Approach	Matrix
Electrolytes	Sodium	Ion Chromatography	Serum
	Potassium	Ion Chromatography	Serum
	Magnesium	Ion Chromatography	Serum
	Calcium	Ion Chromatography	Serum
	Chloride	Ion Chromatography	Serum
	Lithium	Ion Chromatography	Serum
Vitamins and micronutrients	25-OH-vitamin D	ID-LC-MS/MS	Serum
Non-peptide hormones	Estriol	ID-LC-MS/MS	Serum
	Estradiol-17 β	ID-LC-MS/MS	Serum
	Testosterone	ID-LC-MS/MS	Serum
Enzymes	ALT	IFCC reference measurement procedure (37 °C)	Serum
	AST	IFCC reference measurement procedure (37 °C)	Serum
	LDH	IFCC reference measurement procedure (37 °C)	Serum
	CK	IFCC reference measurement procedure (37 °C)	Serum
	GGT	IFCC reference measurement procedure (37 °C)	Serum
	AMY	IFCC reference measurement procedure (37 °C)	Serum
	ALP	IFCC reference measurement procedure (37 °C)	Serum
Metabolites and substrates	Homocysteine	ID-LC-MS/MS	Serum

	Total bilirubine	Spectrophotometry	Serum
	Glucose	Spectrophotometry	Serum
	Urea	Spectrophotometry	Serum
	Uric acid	Spectrophotometry	Serum
	Creatinine	Spectrophotometry	Serum
Proteins	Total protein	Spectrophotometry	Serum

Calibration (reference) measurement services

Analyte	Approach	Clients	Time
Testosterone	ID-LC-MS/MS	National Institute of Metrology, China	2017.11-2018.05
Homocysteine	ID-LC-MS/MS		
Estriol	ID-LC-MS/MS	Guangdong Provincial Hospital of Chinese Medicine	2017.08-2017.11
AST	IFCC reference measurement procedure (37 °C)	Shanghai Center for Clinical Laboratories (SCCL)	2017.07-2017.08
ALP	IFCC reference measurement procedure (37 °C)		
LDH	IFCC reference measurement procedure (37 °C)	Xi-jing Hospital	2017.08-2017.11
Sodium	Ion Chromatography	National Institutes for Food and Drug Control	2017.02-2017.12
Potassium	Ion Chromatography		
Magnesium	Ion Chromatography		
Calcium	Ion Chromatography		
Chloride	Ion Chromatography		
Lithium	Ion Chromatography		
Glucose	Spectrophotometry	Beijing Chao-yang Hospital	2016.11-2017.02
Sodium	Ion Chromatography	National Center for Clinical Laboratories (NCCL)	2016.05-2017.04
Potassium	Ion Chromatography		
Magnesium	Ion Chromatography		
Calcium	Ion Chromatography		
Sodium	Ion Chromatography	Beijing Center for Clinical Laboratories (BCCL)	2016.04-2016.07
Potassium	Ion Chromatography		
Magnesium	Ion Chromatography		
Calcium	Ion Chromatography		
Chloride	Ion Chromatography		
ALT	IFCC reference measurement procedure (37 °C)		
AST	IFCC reference measurement procedure (37 °C)		
LDH	IFCC reference measurement procedure (37 °C)		

CK	IFCC reference measurement procedure (37 °C)		
GGT	IFCC reference measurement procedure (37 °C)		
AMY	IFCC reference measurement procedure (37 °C)		
ALP	IFCC reference measurement procedure (37 °C)		
Total bilirubine	Spectrophotometry		
Glucose	Spectrophotometry		
Urea	Spectrophotometry		
Uric acid	Spectrophotometry		
Creatinine	Spectrophotometry		
Total protein	Spectrophotometry		
Sodium	Ion Chromatography	Beijing Chao-yang Hospital	2016.03-2016.06
Potassium	Ion Chromatography		
Magnesium	Ion Chromatography		
Calcium	Ion Chromatography		
Chloride	Ion Chromatography		
Urea	Spectrophotometry	National Institutes for Food and Drug Control	2016.01~2016.06
Uric acid	Spectrophotometry		
Total protein	Spectrophotometry		

Publications

Authors	Title	Journal, issue, page
J. Zou, M. Zhang, M. Shen, M. Tu, B. Zou	Establishment and evaluation of candidate reference measurement procedure for serum electrolytes (potassium sodium calcium and magnesium) based on ion chromatography	Laboratory Medicine. 2017. 32: 143-148. (in Chinese)
J. Jia, M. Tu, M. Shen, J. Zou, M. Zhang	Uncertainty Evaluation of serum cations concentrations measured based on ion chromatography as reference measurement procedure	Laboratory Medicine. 2016. 31: 1087-1092. (in Chinese)
B. Zou, J. Zou, M. Shen, M. Zhang, L. Wu, M. Tu	Establishment of reference measurement procedures for serum electrolytes based on ion chromatography	Laboratory Medicine. 2015. 30: 1250-1256. (in Chinese)
B. Zou, J. Zou, X. Yang, M. Shen, L. Wu	Development of a candidate reference measurement procedure for the Determination of Serum 25-Hydroxyvitamin D using isotope-dilution liquid chromatography-tandem mass spectrometry	Clinical Chemistry 2016 AACC Annual Meeting and Clinical Lab Expo
B.Zou,J.Zou,M.Shen,M.Zhang,L.Wu,M.Tu	Ion chromatography as candidate reference method for the determination of chloride in human serum	Clinical Chemistry 2015, 61(10) AACC Annual Meeting and Clinical Lab Expo
B.Zou,J.Zou,M.Shen,M.Zhang,L.Wu,M.Tu,Y.Yan	An improved reference method for serum cations measurement by ion chromatography	Clinical Chemistry 2015, 61(10) AACC Annual Meeting and Clinical Lab Expo

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)/meurands 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.)

In the next two years, we will develop the reference measurement procedures including Aldosterone, Progesterone, Total thyroxine (TT4), Blood cell counting (e.g. red blood cell count(RBC), hemoglobin (HGB), white blood cell count (WBC), hematocrit (Hct) and platelet (PLT)), etc.

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)

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.)

We have participated in RELA (IFCC External Quality assessment scheme for Reference Laboratories in Laboratory Medicine) every year since 2010. In RELA 2015 and 2016, we have participated 20 measurands (including Enzymes, Metabolites and substrates, Proteins, Electrolytes, 25-OH-vitamin D3 etc.) with satisfactory results. In 2017, we also have participated in the inter-lab collaborative research for the detection of serum estriol by using a candidate reference method (based on ID-LC-MS/MS method) which was organized by Guangdong Provincial Hospital of Chinese Medicine in PR China.

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 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.