

## 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 Name: Medicsystem Biotechnology, Co., Ltd.**

**JCTLM Member status: Stakeholder Member**

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**Period covered: 2024 – 2025**

### 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.)

#### 1.1 Matrix certified reference materials

Type	Description	Code
Electrolyte in serum (Copy batch)	Lithium, sodium, potassium, magnesium, calcium and chlorine in compound frozen human serum	Ongoing
Bilirubin in serum (Copy batch)	Total Bilirubin in Frozen Human Serum	Ongoing
Testosterone in serum (Copy batch)	Testosterone in Frozen Human Serum	Ongoing
Antibacterial drugs in serum	Vancomycin, Fluconazole, Voriconazole in Frozen Human Serum	Ongoing
Catecholamines in serum	Norepinephrine, Epinephrine, Dopamine, Metanephrine, Normetanephrine in Frozen Human Serum	Ongoing
Lead in Whole blood	Lead in Frozen Human Whole blood	Ongoing

#### 1.2 Reference measurement methods (New addition)

Stakeholder	Analyte	Approach	Matrix
Medicsystem Biotechnology Co., Ltd	Escitalopram	ID-LC-MS/MS	Serum
	Mirtazapine	ID-LC-MS/MS	Serum
	Duloxetine	ID-LC-MS/MS	Serum
	Paroxetine	ID-LC-MS/MS	Serum

	Sertrulin	ID-LC-MS/MS	Serum
	Venlafaxin	ID-LC-MS/MS	Serum
	O-venlafaxine	ID-LC-MS/MS	Serum
	Fluvoxamine	ID-LC-MS/MS	Serum
	Citalopram	ID-LC-MS/MS	Serum
	Trazodone	ID-LC-MS/MS	Serum
	Agomeiratin	ID-LC-MS/MS	Serum
	Levetiracetam	ID-LC-MS/MS	Serum
	Lamotrigine	ID-LC-MS/MS	Serum
	Phenobarbital	ID-LC-MS/MS	Serum
	Topiramate	ID-LC-MS/MS	Serum
	Okazepin	ID-LC-MS/MS	Serum
	10-hydroxycarbamazepine	ID-LC-MS/MS	Serum
	Phenytoin	ID-LC-MS/MS	Serum
	Amikacin	ID-LC-MS/MS	Serum
	Cefepime	ID-LC-MS/MS	Serum
	Tigecycline	ID-LC-MS/MS	Serum
	Vancomycin	ID-LC-MS/MS	Serum
	Tazobactam	ID-LC-MS/MS	Serum
	Ceftazidime	ID-LC-MS/MS	Serum
	Sulbactam	ID-LC-MS/MS	Serum
	Ampicillin	ID-LC-MS/MS	Serum
	Cefoperazone	ID-LC-MS/MS	Serum
	Levofloxacin	ID-LC-MS/MS	Serum
	Tikoala Ning	ID-LC-MS/MS	Serum
	Fluconazole	ID-LC-MS/MS	Serum
	Piperacillin	ID-LC-MS/MS	Serum
	Moxifloxacin	ID-LC-MS/MS	Serum
	Linezolid	ID-LC-MS/MS	Serum
	Daptomycin	ID-LC-MS/MS	Serum
	Carbophengin	ID-LC-MS/MS	Serum
	Hydroxyitraconazole	ID-LC-MS/MS	Serum
	Posaconazole	ID-LC-MS/MS	Serum
	Itraconazole	ID-LC-MS/MS	Serum
	Imipenem	ID-LC-MS/MS	Serum
	Meropenem	ID-LC-MS/MS	Serum
	Ethapenem	ID-LC-MS/MS	Serum
	Cilastatin	ID-LC-MS/MS	Serum
	Lysine	ID-LC-MS/MS	Serum
	Tryptophan	ID-LC-MS/MS	Serum
	Phenylalanine	ID-LC-MS/MS	Serum
	Methionine	ID-LC-MS/MS	Serum
	Threonine	ID-LC-MS/MS	Serum
	Leucine	ID-LC-MS/MS	Serum
	Isoleucine	ID-LC-MS/MS	Serum
	Valine	ID-LC-MS/MS	Serum
	Glycine	ID-LC-MS/MS	Serum
	Alanine	ID-LC-MS/MS	Serum
	Tyrosine	ID-LC-MS/MS	Serum

	Serine	ID-LC-MS/MS	Serum
	Aspartic acid	ID-LC-MS/MS	Serum
	Asparagine	ID-LC-MS/MS	Serum
	Glutamic acid	ID-LC-MS/MS	Serum
	Glutamine	ID-LC-MS/MS	Serum
	Proline	ID-LC-MS/MS	Serum
	Hydroxyproline	ID-LC-MS/MS	Serum
	Arginine	ID-LC-MS/MS	Serum
	Histidine	ID-LC-MS/MS	Serum
	Ornithine	ID-LC-MS/MS	Serum
	Citrulline	ID-LC-MS/MS	Serum
	Taurine	ID-LC-MS/MS	Serum
	Methotrexate	ID-LC-MS/MS	Serum
	Lead	ICP-MS	Whole blood

### 1.3 Calibration (reference) measurement services

Stakeholder	Analyte	Approach	Clients	Time	Matrix
Medicalsystem Biotechnology Co., Ltd	25-OH-vitamin D <sub>2</sub>	ID-LC-MS/MS	Beijing Institute of Medical Device Testing	2024.01	Serum
	25-OH-vitamin D <sub>3</sub>	ID-LC-MS/MS			
	Vancomycin	ID-LC-MS/MS	National Institutes for Food and Drug Control	2024.10	Serum
	Fluconazole	ID-LC-MS/MS			
	Voriconazole	ID-LC-MS/MS		2024.10	Serum
	Testosterone	ID-LC-MS/MS			
	Progesterone	ID-LC-MS/MS			
	17-OH-progesterone	ID-LC-MS/MS	2025.07	Serum	
	AST	IFCC reference measurement procedure (37 °C)	European Commission Joint Research Centre	2025.09	Serum
	ALP	IFCC reference measurement procedure (37 °C)		2024.06	Serum
	GGT	IFCC reference measurement procedure (37 °C)	Beijing Chaoyang Hospital Capital Medical University	2025.12	Serum
	Sodium	Ion Chromatography		2024.07/ 2025.01/ 2025.08	Serum
	Potassium	Ion Chromatography			
	Calcium	Ion Chromatography			
	Total bilirubine	Spectrophotometry		2025.07- 2025.08	Serum
	Glucose	Spectrophotometry			
	Total protein	Spectrophotometry		2024.12	Serum
	25-OH-vitamin D <sub>2</sub>	ID-LC-MS/MS			
	25-OH-vitamin D <sub>3</sub>	ID-LC-MS/MS			
ALT	IFCC reference measurement procedure (37 °C)	Guangzhou Bangde Sheng Biotechnology Co., LTD	2024.08	Serum	

	Sodium	Ion Chromatography	Shanghai Center for Clinical Laboratories	2024.08/ 2025.08	Serum
	Potassium	Ion Chromatography			
	Calcium	Ion Chromatography			
	Lithium	Ion Chromatography			
	25-OH-vitamin D <sub>2</sub>	ID-LC-MS/MS	Guangzhou Kingmed Diagnostics Co., LTD	2025.10	Serum
	25-OH-vitamin D <sub>3</sub>	ID-LC-MS/MS			

#### 1.4 Publications

Institution	Authors	Title	Journal/issue/page
Medicalseystem Biotechnology Co., Ltd	Huoyan Ji, Huimin Wang, Eric Yang, Qiang Sun, Wenjing Wang, Ling Li, Yunxia Li, Xiaodong Yang, Shuangshuang Chen, Min Shen*, Qingqing Pan	<b>An ID - HPLC–MS/MS based candidate reference measurement procedure for the quantification of valproic acid in human serum</b>	Accreditation and Quality Assurance <a href="https://doi.org/10.1007/s00769-024-01619-5">https://doi.org/10.1007/s00769-024-01619-5</a>
	Jing Lin, Min Shen, Ting Yu, Huimin Wang, Jingjue Pan, Gaipeng Huang, Quanle Li	Quantification of mycophenolic acid in plasma by isotope dilution liquid chromatography - tandem mass spectrometry candidate reference method	Analytical and Bioanalytical Chemistry <a href="https://doi.org/10.1007/s00216-025-05750-1">https://doi.org/10.1007/s00216-025-05750-1</a>
	Xiaodong Yang, Minmin Tu, Chunlan Tang, Min Shen*, Huoyan Ji	Development and Validation of a Candidate Reference Measurement Procedure for Plasma Clozapine Quantification Using ID-LC–MS/MS	Journal of Mass Spectrometry, 2025; 60:e5168
	Jinyue Zhou, Xiaoli Sun, Keren Wang, Min Shen, Jingbo Yu, Qi Yao, Hang Hong, Chunlan Tang, Qinwen Wang	What Information do Systemic Pathological Changes Bring to the Diagnosis and Treatment of Alzheimer’s Disease?	Neurosci. Bull. <a href="https://doi.org/10.1007/s12264-025-01399-z">https://doi.org/10.1007/s12264-025-01399-z</a>
	Quanle Li, Jing Lin, Chunlan Tang, Dewei Song, Tao Yu, Min Shen*, Jihua Zou, Huoyan Ji	Simultaneous quantification of catecholamine and their metabolites in urine via mixed-mode magnetic bead-based extraction coupled with ID-LC-MS/MS: A robust tool for diagnosing catecholamine-secreting tumors	Journal of Chromatography A Volume 1764, 6 December 2025, 466468
	Jing Lin, Qingqing Pan, Weihua Wang, Shuangshuang Chen, Guangliang Wu, Min Shen*, Huoyan Jid	An ID-HPLC-MS/MS based candidate reference measurement procedure for the quantification of imipenem, meropenem and ertapenem in human plasma	Submit to Journal of Chromatography B

#### 1.5 Participation in RELA, NCCL study.

a) RELA study: in 2024, 31 measurands got involved in RELA study, including ALT, AST, Amylase, ALP, CK,LDH, GGT, Sodium,Potassium, Magnesium, Calcium, Chloride,Lithium, 25-OH-Vitamin D<sub>3</sub>, Creatinine,Glucose,Urea, Uric acid, Total Bilirubin, Total Cholesterol, 17OH-Progesterone, Aldosterone, Cortisol, Estradiol-17 $\beta$ , Estriol, Progesterone, Testosterone, Digoxin, Theophylline, Total protein and Total Hemoglobin. All the results are satisfactory. In 2025, 35 measurands got involved in RELA study, ALT, AST, Amylase, ALP, CK,LDH, GGT, pancreatic amylase, Sodium,Potassium, Magnesium, Calcium, Chloride,Lithium, 25-OH-Vitamin D<sub>3</sub>, Creatinine,Glucose,Urea, Uric acid, Total Bilirubin, Total Cholesterol, 17OH-Progesterone, Aldosterone, Cortisol, Estradiol-17 $\beta$ , Estriol, Progesterone, Testosterone, Digoxin, Theophylline, Valproic acid, Total protein ,Total Hemoglobin, Total thyroxine and Total tri-iodothyronine.

b) NCCL study: in 2024, 5 measurands including Cyclosporin A, Sirolimus, Tacrolimus and Everolimus and Hcy; in 2025, 1 measurands including Hcy. All the results are satisfactory.

## **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.)

To establish candidate reference measurement procedures for mass spectrometry-based assays, develop matrix-based reference materials for metrological traceability, and consolidate the traceability chain for products primarily targeting therapeutic drug concentrations.

## **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)

China National EQA Program: Supply whole blood matrix proficiency testing materials for immunosuppressive drug monitoring to the National Center for Clinical Laboratories (NCCL), National Health Commission, for nationwide external quality assessment.

Shanghai Regional EQA Program: Deliver frozen serum proficiency testing panels including: glucose, pooled creatinine/uric acid, pooled electrolytes (sodium, potassium, magnesium, calcium), homocysteine, and pooled lipids (total cholesterol, triglycerides) to the Shanghai Center for Clinical Laboratories (SCCL) for regional inter-laboratory quality evaluation.

## **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.)

Engagement: Member of the Yangtze River Delta Reference Laboratory Network (SCCL-coordinated), a collaborative initiative advancing harmonization of clinical laboratory results across the Yangtze River Delta region.

Contribution: Conducted reference value assignments for electrolyte trueness verification materials within the network's accuracy-based EQA framework.

## **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.