

Organization Name: Medicsystem Biotechnology, Co., Ltd

JCTLM Member status: Stakeholder Member

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Period covered: 2022 – 2023

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 Purity certified reference materials

Description	Code	Researcher

1.2 Matrix certified reference materials

Type	Description	Code	Researcher
Electrolyte in serum	Lithium, sodium, potassium, magnesium, calcium and chlorine in compound frozen human serum	Ongoing	
Glucose in serum	Glucose in Frozen Human Serum	Ongoing	
Antiepileptic drugs in serum	Valproic acid, Phenytoin and Phenobarbital in Frozen Human Serum	Ongoing	
Bilirubin in serum	Total Bilirubin in Frozen Human Serum	Ongoing	
Antimicrobial drugs in Serum	Voriconazole, Vancomycin and Fluconazole in Frozen Human Serum	Ongoing	

1.3 Reference measurement methods (Ongoing and completed)

Stakeholder	Analyte	Approach	Matrix
Medicsystem Biotechnology Co., Ltd	Sodium	Ion Chromatography	Serum
	Potassium	Ion Chromatography	Serum
	Magnesium	Ion Chromatography	Serum
	Calcium	Ion Chromatography	Serum
	Chloride	Ion Chromatography	Serum
	Lithium	Ion Chromatography	Serum
	25-OH-vitamin D	ID-LC-MS/MS	Serum
	Estriol	ID-LC-MS/MS	Serum
	Estradiol-17β	ID-LC-MS/MS	Serum

Testosterone	ID-LC-MS/MS	Serum
Aldosterone	ID-LC-MS/MS	Serum
Progesterone	ID-LC-MS/MS	Serum
Cortisol	ID-LC-MS/MS	Serum
17-OH-progesterone	ID-LC-MS/MS	Serum
TT3	ID-LC-MS/MS	Serum
Total thyroxine	ID-LC-MS/MS	Serum
Carbamazepine	LC-MS/MS	Serum
Cyclosporin A	ID-LC-MS/MS	Whole blood
Sirolimus	ID-LC-MS/MS	Whole blood
Tacrolimus	ID-LC-MS/MS	Whole blood
Everolimus	ID-LC-MS/MS	Whole blood
Vancomycin	LC-MS/MS	Serum
Lamotrigine	ID-LC-MS/MS	Serum
Phenobarbital	ID-LC-MS/MS	Serum
Phenytoin	ID-LC-MS/MS	Serum
Theophylline	ID-MS/MS	Serum
Digitoxin	ID-LC-MS/MS	Serum
Digoxin	ID-LC-MS/MS	Serum
Cholic acid	ID-LC-MS/MS	Serum
Deoxycholic acid	ID-LC-MS/MS	Serum
Chenodeoxycholic acid	ID-LC-MS/MS	Serum
Ursodeoxycholic acid	ID-LC-MS/MS	Serum
Lithocholic acid	ID-LC-MS/MS	Serum
Glycocholic acid	ID-LC-MS/MS	Serum
Glycine deoxycholic acid	ID-LC-MS/MS	Serum
Glycine chenodeoxycholic acid	ID-LC-MS/MS	Serum
Glycine ursodeoxycholic acid	ID-LC-MS/MS	Serum
Glycinocholic acid	ID-LC-MS/MS	Serum
Taurocholic acid	ID-LC-MS/MS	Serum
Taurodeoxycholic acid	ID-LC-MS/MS	Serum
Taurochenodeoxycholic acid	ID-LC-MS/MS	Serum
Tauroursodeoxycholic acid	ID-LC-MS/MS	Serum
Taurolithocholic acid	ID-LC-MS/MS	Serum
Dopamine	ID-LC-MS/MS	Serum
Epinephrine	ID-LC-MS/MS	Serum
Norepinephrine	ID-LC-MS/MS	Serum
Metanephrine	ID-LC-MS/MS	Serum
Normetanephrine	ID-LC-MS/MS	Serum
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
Homocysteine	ID-LC-MS/MS	Serum
Total bilirubine	Spectrophotometry	Serum
Glucose	Spectrophotometry	Serum
Urea	Spectrophotometry	Serum
Uric acid	Spectrophotometry	Serum
Creatinine	Spectrophotometry	Serum
Total Cholesterol	HPLC	Serum
Total protein	Spectrophotometry	Serum
Red blood cell counting		Blood
White blood cell counting		Blood
Hemoglobin		Blood
Hematocrit		Blood
Platelet		Blood
Vitamin A	ID-LC-MS/MS	Serum
Vitamin E	ID-LC-MS/MS	Serum
Vitamin K1	ID-LC-MS/MS	Serum
Olanzapine	ID-LC-MS/MS	Serum
Clozapine	ID-LC-MS/MS	Serum
N-desmethylozapine	ID-LC-MS/MS	Serum
Quetiapine	ID-LC-MS/MS	Serum
Risperidone	ID-LC-MS/MS	Serum
Paliperidone	ID-LC-MS/MS	Serum
Aripiprazole	ID-LC-MS/MS	Serum
Ziprasidone	ID-LC-MS/MS	Serum
Chlorpromazine	ID-LC-MS/MS	Serum
Haloperidol	ID-LC-MS/MS	Serum
Prochlorperazine	ID-LC-MS/MS	Serum
FLUPHENAZINE	ID-LC-MS/MS	Serum
Amisulpride	ID-LC-MS/MS	Serum
Sulpiride	ID-LC-MS/MS	Serum
Thioridazine	ID-LC-MS/MS	Serum
Chlorprothixene	ID-LC-MS/MS	Serum
SERTINDOLE	ID-LC-MS/MS	Serum

1.4 Calibration (reference) measurement services

Stakeholder	Analyte	Approach	Clients	Time	Matrix
Medicalsystem Biotechnology Co., Ltd	ALP	IFCC reference measurement procedure (37 °C)	Beijing Institute of Medical Device Testing	2022.02-2022.05	Serum
	ALT	IFCC reference measurement procedure (37 °C)	Yangtze Delta Region Institute of Tsinghua University, Zhejiang	2023.02-2023.06	Serum
	AST	IFCC reference measurement procedure (37 °C)			Serum
	LDH	IFCC reference measurement procedure (37 °C)			Serum
	AMY	IFCC reference measurement procedure (37 °C)			Serum

CK	IFCC reference measurement procedure (37 °C)			Serum		
AMY	IFCC reference measurement procedure (37 °C)			Serum		
ALP	IFCC reference measurement procedure (37 °C)	Guangdong Provincial Hospital of Chinese Medicine (GPHCM)	2023.03-2023.06	Serum		
GGT	IFCC reference measurement procedure (37 °C)			Serum		
AMY	IFCC reference measurement procedure (37 °C)			Serum		
17-OH-progesterone	ID-LC-MS/MS			Serum		
Cortisol	ID-LC-MS/MS			Serum		
Sodium	Ion Chromatography			National Institutes for Food and Drug Control	2023.03-2023.05	Serum
Potassium	Ion Chromatography					Serum
Magnesium	Ion Chromatography	Serum				
Calcium	Ion Chromatography	Serum				
Chloride	Ion Chromatography	Serum				
Lithium	Ion Chromatography	Serum				
Glucose	Spectrophotometry	2023.08	Serum			
Estradiol-17β	ID-LC-MS/MS	National Institute of Metrology, China	2023.03	Serum		
Sodium	Ion Chromatography	Beijing Chaoyang Hospital Capital Medical University	2023.09	Serum		
Potassium	Ion Chromatography			Serum		

1.5 Publications

Institution	Authors	Title	Journal/issue/page
Medicalseystem Biotechnology Co., Ltd	Xiaodong Yang, Quanle Li, Qingqing Pan, etc	Establishment and performance evaluation of candidate reference measurement procedure for the determination of immunosuppressive drugs in human whole blood by ID-LC-MS/MS	Laboratory Medicine, March 2023, Vol 38, 215-222.
	Dan Liu, Guo Li, Dongdong Liu, Wen Shi, Huimin Wang, Qiaoxuan Zhang, Min Shen, etc	Quantitative detection of 15 serum bile acid metabolic products by LC-MS/MS in the diagnosis of primary biliary cholangitis. Chem. Biodiversity 2023, e202200720	Chem. Biodiversity 2023, e202200720
	Dewei Song,* Haofeng Sun, Lingyun Ma, Jianyi Liu, Yanhong Gao, Qi Zhang, Peng Xiao, Keqi Sun, Min Shen, Xiaojian Wang, and Min Zhou*	In-Vitro Diagnostic Reagent Evaluation of Commercially Available Cardiac Troponin I Assay Kits Using H/D Exchange Mass Spectrometry for Antibody-Epitope Mapping	Analytical Chemistry, 2023, 95, 4, 278-2284.
	Xiaodong Yang, Jing Zhou, Quanle Li, Qingqing Pan, Min Shen, etc.	An Isotope-dilution liquid chromatography-tandem mass spectrometry (ID-LC-MS/MS) as	Submit 3 rd revised draft

		candidate reference method for the measurement of theophylline in human serum.	
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1.6 Activities related to IVD traceability of NIM and reference laboratories in recent two years

Participation of RELA, NCCL study.

- a) RELA study: in 2022 and 2023, 31 measurands got involved in RELA study, including 17OH-Progesterone, Aldosterone, ALT, Amylase, AST, Calcium, Chloride, CK, Cortisol, Creatinine, Estradiol-17 β , Estriol, GGT, Glucose, LDH, Lithium, Magnesium, Potassium, Progesterone, Sodium, Testosterone, Total Bilirubin, Total Cholesterol, Total protein, Urea, Uric acid, Digoxin, Theophylline, ALP, 25-OH-Vitamin D3 and Total Hemoglobin. All the results are satisfactory.
- b) NCCL study: in 2022, 5 measurands including Sodium, Potassium, Magnesium and Calcium and Hcy; in 2023, 3 measurands including 25(OH)D₃, 25(OH)D₂ and 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.)

In the next two years, Medicalsystem will focus on matrix reference material study and ensure the traceability of diagnostic by LC-MS/MS products (including reagents and instruments).

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)

Cooperate with Shanghai Clinical Laboratory Center, provide Glucose in frozen serum, Creatinine and Uric acid in frozen serum, sodium, potassium, magnesium, calcium in compound frozen human serum which used for evaluation of the inter-clinical laboratories quality in Shanghai Region.

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.)

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)