

## 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><b>Organization Name: Guangzhou Wondfo Biotech Co., Ltd.</b></p> <p><b>JCTLM Member status: Stakeholder Member</b></p> <p><b>Author(s): Changfa Huang</b></p> <p><b>Author(s) email(s): changfa.huang@wondfo.com.cn</b></p> <p><b>Period covered: 2022 – 2023</b></p>
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### 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.)

#### a) New reference measurement methods established

Analyte category	Analyte	Measurement principle	Reference
non-peptide hormones	cortisol	ID-LC-MS/MS	NIST LC/MS/MS reference method for cortisol, JCTLM DB identifier NRMeth 95
	testosterone	ID-LC-MS/MS	HSA ID-LC-MS/MS reference measurement procedure for testosterone in human serum, JCTLM DB identifier C17RMP2
	progesterone	ID-LC-MS/MS	NIST LC/MS/MS method for progesterone, JCTLM DB identifier C3RMMP10
	total thyroxine (TT4)	ID-LC-MS/MS	LGC Reference procedure for thyroxine in serum, JCTLM DB identifier CYC_II_L_I_RMP_25
	total tri-iodothyronine (TT3)	ID-LC-MS/MS	NIST LC/MS/MS reference method for total triiodothyronine, JCTLM DB identifier CYC_II_L_I_RMP_24
Vitamins	25-hydroxyvitamin D3	ID-LC-MS/MS	CDC reference measurement procedure for serum 25-hydroxyvitamin D metabolites, JCTLM DB identifier C12RMP2
	25-hydroxyvitamin	ID-LC-MS/MS	CDC reference measurement procedure for serum

	D2		25-hydroxyvitamin D metabolites, JCTLM DB identifier C12RMP3
Proteins	total hemoglobin	Spectrophotometry	Cyanmethemoglobin, JCTLM DB identifier C1RMP_P18
	HbA1c	HPLC/MS-ESI	IFCC method for HbA1c, JCTLM DB identifier C1RMP_P16_MS

**b) New reference measurement services listed in the JCTLM database**

Analyte	Material or matrix	Quantity	Measurement range	Expanded uncertainty
sodium	Blood serum	Amount-of-substance concentration	117 ~ 158 mmol/L	0.6 % to 0.4 %
potassium	Blood serum	Amount-of-substance concentration	1.6 ~ 5.8 mmol/L	1.3 % to 0.4 %
magnesium	Blood serum	Amount-of-substance concentration	0.8 ~ 1.6 mmol/L	1.1 % to 0.8 %
calcium	Blood serum	Amount-of-substance concentration	1.8 ~ 3.4 mmol/L	1.4 % to 0.6 %
ALT	Blood plasma, Blood serum	Catalytic activity concentration	0.28 ~ 4.75 $\mu$ kat/L	2.2 %
AST	Blood plasma, Blood serum	Catalytic activity concentration	0.36 ~ 4.17 $\mu$ kat/L	2.2 %
AMY	Blood plasma, Blood serum	Catalytic activity concentration	1.15 ~ 12 $\mu$ kat/L	2.8 %
CK	Blood plasma, Blood serum	Catalytic activity concentration	0.95 ~ 23.17 $\mu$ kat/L	2.4 %
LDH	Blood plasma, Blood serum	Catalytic activity concentration	1.09 ~ 9.82 $\mu$ kat/L	2.2 %
GGT	Blood plasma, Blood serum	Catalytic activity concentration	0.57 ~ 3.44 $\mu$ kat/L	2.4 %
ALP	Blood plasma, Blood serum	Catalytic activity concentration	0.85 ~ 8.92 $\mu$ kat/L	3 %

**c) Calibration (reference) measurement services**

Analyte	Method	Clients	Date
Urea	Spectrophotometry	Guangdong Provincial Hospital of Chinese Medicine (GPHCM)	2023.03.06
GLU	Spectrophotometry		~ 2023.04.25

LDH	IFCC reference measurement procedure (37 °C)	Guangdong Provincial Hospital of Chinese Medicine (GPHCM)	2023.03.27 ~ 2023.06.30
ALT	IFCC reference measurement procedure (37 °C)		
AST	IFCC reference measurement procedure (37 °C)		
AMY	IFCC reference measurement procedure (37 °C)		
CK	IFCC reference measurement procedure (37 °C)		
ALP	IFCC reference measurement procedure (37 °C)		
GGT	IFCC reference measurement procedure (37 °C)		
cortisol	ID-LC-MS/MS	Guangdong Provincial Hospital of Chinese Medicine (GPHCM)	2023.05.23 ~ 2023.07.02
testosterone	ID-LC-MS/MS		
25-hydroxyvitamin D3	ID-LC-MS/MS		
sodium	Ion chromatography	National Institutes for Food and Drug Control	2023.04.13 ~ 2023.04.21
potassium	Ion chromatography		
magnesium	Ion chromatography		
calcium	Ion chromatography		

## 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.)

- We will continue to participate in RELA and EQARL to ensure the stable operation of reference methods and apply results to the traceability of product values.
- We will develop new reference measurement procedures involving measurands such as estriol, estradiol-17 $\beta$ , aldosterone, 17-OH-progesterone in the next two years.
- A new certified reference material about HbA1c is under developing in our lab and someother CRMs about hormones maybe considered in the future.
- We plan to apply for the calibration measurement service for HbA1c, cortisol and testosterone.

## 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)

### a) Conference

—Therapeutics and Diagnostics: Measurements, Standards, Quality and Safety (TD-MSQS) held by NIM in Chengdu, China, May 5-7, 2023.

### b) Posters presented on the TD-MSQS 2022

Number	Title
1	Development and Evaluation of a Candidate Reference measurement procedure for 25

	Hydroxyvitamin D2 and 25 Hydroxyvitamin D3 in Human Serum by Isotope-Dilution Liquid Chromatography-Tandem Mass Spectrometry
2	Preparation of company's first standard for glycosylated hemoglobin (HbA1c)
3	Candidate reference method for rapid determination of cations in human serum based on microwave digestion-ion chromatography
4	The influence of Alkaline phosphatase Catalytic Concentration at different temperatures was validated using reference methods

**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.)

- a) Participate in the China EQARL and IFCC RELA each year. In EQARL and RELA 2022, we successfully participated for 19 measurands, and all 21 measurands we participated in 2023 were in good agreement with those of other laboratories.
- b) Participate in the National Glycohemoglobin Standardization Program(NGSP) and the IFCC HbA1c Certification Programme each year.
- c) Member of the National Technical Committee on Medical Clinical Laboratory and In Vitro Diagnostic System of Standardization Administration(SAC/TC136).
- d) Member of the CJCTLM.
- e) Member of the National Tool Enzyme Standardization Working Group(SAC/SWG11).
- f) Member of the National Medical Device Clinical Evaluation Standardized Technical Focal Point.

**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)

None.

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 authorizes 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.