



The national infrastructure for traceability in laboratory medicine in China

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Content

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- 2. Reference laboratory networks have developed in China
- 3. Planned activities in support of standardization in laboratory medicine
- 4. Suggestions





1. Reference materials and methods have developed in China

CJCTLM (China Joint Committee for Traceability in Laboratory Medicine)

Sponsoring Organizations

□CJCTLM was founded in March, 2007.



Related institutions



China National Accreditation Service for Conformity Assessment





- NIM provides the Secretariat for CJCTLM
- Developing the CJCTLM IVD Reference Measurement Systems
- Coordinates the nomination and review process for RMP entries

CJCTLM developed to help IVD industry meet metrological traceability requirements of the CHINA IVD Directive

Contains:

- 31 members
- 2 Consultants

CJCTLM Chair: Wu Fangdi (NIM), Vice Chair: Li Hongmei (NIM)

CJCTLM Executive Secretary: Xu Bei (NIM)



Reference Measurement Procedures Coordinated by CJCTLM

JJF 1383-2012	Calibration Specification for Portable Blood Glucose Meters
JJG1051-2009	Calibration Specification for Electrolytes Analyzers
JJG714	Verification Regulation of Blood CELL analyzer
JJF 1353-2012	Calibeation Specification for Hemodialysis Equipment
	Reference method for total bilirubin in serum
Finished in 2015	Reference method for total biliprotein in serum
	Reference method for glucose in serum(UV Spectrometer)
	Reference method for Catalytic activity of alkaline phosphatase in serum
To be finished in 2016	Reference method for Glycosylated hemoglobin concentration in whole blood
	Reference method for uric acid in serum
	Terminology for clinical medical metrology
Ongoing in 2017	Estriol-D3 in serum (LC-MS)



Reference materials (89 CRMs in China)

Analyte category	Number	Comments
Blood Cell counting	5	CRMs for cell counting in whole blood
Hormone purity	6	-17β-Hydrocortisone ,17α-hydroxyprogesterone ,17β estradiol Estriol ,Estrone ,Vanillyl mandelate,
Electrolytes	12	Inorganic spices in urine, serum or hair matrix
Metabolites and substrate	17	UA,CK,UR,GLU,etc. high purity or serum matrix
Non-peptide hormones	10	Anabolic-androgenic steroids (AAS)
Proteins	12	C-reactive protein ,Troponin ,Leptin ,C-peptide ,AFP, C Peptide,BSA ,Glycated Hemoglobin,etc.
Vitamins	8	Emodin, Rg1,Rb1 ,etc.
others	19	Viscosity CRMs
Total	89	



Reference methods

Analyte category	Number	Comments
Blood Cell counting	3	Single channel semi-automatic electronic counting using aperture-impedance principle , microhematocrit method.
Enzymes	6	UV spectrophotometer
Electrolytes	12	ID-ICP MS
Metabolites and substrate	15	ID-LC-MS/MS, LC-MS/MS, LC-UV
Proteins	8	LC-MS/MS, ID-LC-MS/MS



Calibration (reference) measurement services

Analyte category	Approach	Matrix
Blood Cell	Single channel semi-automatic electronic counting using aperture-impedance principle	Fresh whole blood
Enzymes	7 enzymes have been approved by JCTLM to join the JCTLM calibration (reference) measurement services	High-purity material, Calibration solution, Serum
urea, Uric acid, Creatinine, Total cholesterol, AST, ALT, HbA1c,	Urea, Uric acid, Creatinine, Total cholesterol, AST, ALT, HbA1c, Progesterone	Matrix
TBIL	Doumas BT et al., reference method for total bilirubin. Clin.Chem., 1985, 31, 1779-1789.	Calibration materials, control specimens and human serum
LDH	spectrophotometry	purity
СК	IFCC Primary Reference Procedures for the Measurement of Catalytic Activity Concentrations of CK at 37 ° C	High-purity material, Calibration solution, Serum
Unconjugated Estriol	ID-LC-MS/MS	Serum



2.1 Promoting traceability in laboratory medicine





2.1 Promoting traceability in laboratory medicine

Summary of the conferences focused on laboratory medicine traceability in China

Conferences	Date/Location	Topics	Organizers
Protein and Peptide Therapeutics	31 May 2016-3	a. Advance Methods for Peptide and Protein Drug Characterization and Quality Assurance	
and Diagnostics: Research and Quality Assurance International Workshop (PPTD 2016)	June 2016/Chengdu, CHINA	June b. Standards for Peptide and Protein Diagnostics	BIPM/NIM/NIF DC
······································		c. Advances and Challenges in IVD Standards	
IFCC HbA1c Network Annual Meeting	9 Sep 2016/Shanghai, CHINA	Standardization and quality management of HbA1c in China	IFCC/SCCL
Quality Indicators in Clinical Laboratoy	27 Sep 2017 Application and Improvement of the quality indicators in Shanghai		SCCL/SSLM
The 17 th Beijing Conference and Exhibition on Instrumental Analysis (BCEIA 2017)	10 Oct 2017-11 Oct 2017/Beijing, CHINA	Chemical Metrology and Reference Materials	CAIA/NIM



2.2 Reference Laboratory Network Construction in Estriol Measurement











2.3 The activities related to the reference measurement systems





2.3 The activities related to the reference measurement systems





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1) National Institute of Metrology, China

- Launched a new project "Metrological research of IVD reagents and biological drugs in precision medicine" in 2017.
- a) Metrology for Cardiovascular and kidney diseases diagnoses: Important biomarkers CRMs for Cardiovascular and kidney diseases such as NT-proBNP, troponin and Cystatin C etc.
- b) Metrology for absolute bio-imaging to support targeted diagnoses and pathology: Traceable and accurate in-situ measurement methodology in pathology and drug metabolism research is essential.
- c) Metrology and standardization of protein and peptide drugs: Characterization of structure and physicochemical properties for 1-2 kinds of representative therapeutic antibody.



2) Shanghai Center for Clinical Laboratory (SCCL)

Establishment of reference methods on apolipoproteins, such as ApoA1, Apc ApoE, etc; Establishment of reference methods on testosterone, homocysteine, according to JCTLM publications.; Inclusion more items to ISO17025/ISO15195 quality management systems, and application to JCTLM for database list.

Reference measurement service for IVD manufacturers, research, trueness verification program in SCCL, etc., including HbA1c, enzymes, metabolites and substrates.

Organization of activities related to national and international traceabi harmonization, to make use of SCCL's role in PT provider.



3) Aerospace General Hospital (AGH)

To develop reference method of Aldosterone, Lipase, Renin and DBIL; The study of uE3 measurement standardization; The objects including the reference interval of renal function index, matrix study on testosterone/CRP and continuously carry out measurement uncertainty education project.



4) Guangdong Provincial Hospital of Chinese Medicine (GPHCM)

To develop the CRMs like human serum Testosterone, 25-OH Vitamin D, Cystatin C and urinary albumin and about human serum like ALT, AST, GGT, ALP, TP, TBIL, Unconjugated Estriol and 17β-Estradiol etc. in China.

5) Beijing Strong Biotechnologies, Inc.(BSBE)

To build some reference measurement procedures covered metabolites, glycated hemoglobins, hormones, proteins, vitamins. The projects we plan include TB, CHO, TG on the UV spectrophotometer platform, HbA1c,CHO,CRE,GLU,UA,C-peptide,25-VD2,25-VD3 on the LC-



4. Suggestions to be addressed by JCTLM

Suggestion A

The purity CMCs of KCDB should be linked with the Reference Material of JCTLM by a specific procedure to avoid duplicate work. The purity CMCs of KCDB are traceable to SI Units, so they should be traceable Reference Materials for JCTLM.

Suggestion B

During the development of reference method, reference materials are necessary to verify trueness, and we suggest that more attention should be put on analytes that have no reference materials or not enough lots in storage.

We hope the PT organizer can offer more analytes to meet the needs. And more networks like IFCC HbA1c Network are expected in order to promote the application of reference systems in laboratory medicine standardization or harmonization.



CCQM WGs'Autumn Meeting & PPTD workshop

Shangri-La Hotel

Oct. 8-9,2018 Paralell meeting



Shangri-La Hotel Oct. 10-12,2018



Protein and Peptide Therapeutics and

Diagnostics:

Research and Quality Assurance

International Workshop (PPTD 2018)



Chengdu Location

https://en.wikipedia.org/wiki/Chengdu





Protein and Peptide Therapeutics and Diagnostics: Research and Quality Assurance International Workshop (PPTD 2018)

Oct. 10-12, 2018 Sichuan Chengdu , China









Meeting purpose

- Advanced measurement technology is the basis ensuring the accuracy and efficiency of measurement results, which is essential to precision medicine.
- To promote the traceability of IVD and protein medicine industry, ensure product quality, and provide better technology supports from standardization, metrology and traceability.
- Centering on "Measurement and Standard, Quality and Safety" and improve R&D capability and product quality of relevant enterprises.







Meeting arrangements

Plenary theme:

- IVD & Protein Drugs Research and Quality Assurance
- --Measurement and Standard, Quality and Safety

Three sub-themes as:

- 1) Drug Characterization and quality assurance;
- 2) Reference measurement system and quality control of clinical diagnostics;

3) Pharmacopeia, regulation and metrology.

	Oct 10	Oct 11	Oct 12
Morning	Plenary Talk	Sessions	Sessions
Afternoon	Sessions	Sessions	Plenary Talk



Non domestic Committee Members approved

1	Graham BEASTALL	IFCC/JCTLM
2	Gary MYERS	JCTLM
3	Philippe GILLERY	IFCC
4	Mike TARLOV	NIST
5	Karen PHINNEY	NIST
6	Jayne MORROW	NIST
7	Robert WIELGOSZ	BIPM
8	Ralf JOSEPHS	BIPM
9	Sang-Ryoul PARK	KRISS
10	Milena QUAGLIA	LGC
11	Qinde LIU	HSA
12	Marc BAILEY	NIBSC
13	Chris BURNS	NIBSC
14	Fouad ATOUF	USP



Meeting survey

Meeting Language	• The official language of the conference will be English .
The Exhibition	 The workshop Exhibition will take place at the Chengdu at the same time, showing the newly developed techniques, accessories and services concerning IVD and protein drugs.
Size of the Workshop	• ~800-1000 participants and more than 100 orals
Date of the meeting	• Oct. 10-12, 2018
Place of the meeting	 Sichuan Chengdu , China

The website has been opened

Registration, Abstract and poster submission can be finished online.

http://pptd.ncrm.org.cn

