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 Membersfor draftingtheir biennial activity report. Organizations are invited to provide the information below for submission to the Executive Committee.

OrganizationName: Guangdong Provincial Hospital of Chinese Medicine

JCTLM Memberstatus:National and Regional 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 under taken 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.)

   Over the past two years (2024-2025), our organization has made significant strides in supporting standardization in laboratory medicine through the following key achievements:

   Expansion of JCTLM-Recognized Reference Systems: We successfully expanded the portfolio of internationally recognized reference methods and services. Two reference measurement methods (Aldosterone, 17α-Hydroxyprogesterone) and five reference measurement services (Progesterone, Testosterone, 25-Hydroxyvitamin D3, HbA1c, 17α-Hydroxyprogesterone) were newly listed by the JCTLM. This provides the global community with higher-order traceability anchors for these critical measurands in endocrinology and clinical chemistry.

   Development of National Certified Reference Materials (CRMs): We successfully developed and obtained approval for a range of National Secondary CRMs. This includes the replication and approval of 8 CRMs in January 2025, and the approval of a new Frozen Human Serum Testosterone CRM in September 2025. An additional 6 new CRMs have been developed and submitted for approval after refinement. These materials are crucial for implementing metrological traceability within the national framework.

   New Applications for JCTLM CRMs: We have formally applied for JCTLM listing for 4 new candidate CRMs (Glucose, Creatinine, Uric Acid, Urea), aiming to contribute to global standardization in fundamental clinical chemistry tests.

   1.1 The production of certified reference materials

Description	Code
Multi-biomarkers in frozen human serum	GBW(E) 091040a
Total Protein in Frozen Human Serum	GBW(E) 091041a
Catalytic Activity Concentration of γ-Glutamyltransferase and Alkaline Phosphatase in Frozen Human Serum	GBW(E) 091042a

Glucose in Frozen Human Serum	GBW(E) 091043a
Uric Acid in Frozen Human Serum	GBW(E) 091045a
Catalytic Activity Concentration of Alpha-Amylase in Frozen Human Serum	GBW(E) 091046a
Catalytic Activity Concentration of Creatine Kinase in Frozen Human Serum	GBW(E) 091047a
uE3 in Frozen Human Serum	GBW(E)091048a GBW(E)091049a GBW(E)091050a GBW(E)091051a GBW(E)091052a
Testosterone in Frozen Human Serum	GBW(E)091389 GBW(E)091390

1.2 The development of reference measurement methods

Analyte	JCTLM DB Identifier	Applicable matrice	Full description of technique
17α-hydroxyprogesterone	C17RMP6R	human plasma; fresh, frozen or lyophilized	ID-LC-MS/MS
Aldosterone	C20RMP4	human plasma; fresh, frozen or lyophilized	ID-LC-MS/MS

1.3 The establishment of calibration (reference) measurement services

Analyte	Measurement principle	Quantity	Time
17α-hydroxyprogesterone in blood plasma	ID-LC-MS/MS	Amount-of-substance concentration	2024.03
25-Hydroxyvitamin D3 in blood serum	ID-LC-MS/MS	Amount-of-substance concentration	2025.04
Testosterone in blood serum	ID-LC-MS/MS	Amount-of-substance concentration	2025.04
Progesterone in blood serum	ID-LC-MS/MS	Amount-of-substance concentration	2025.04
Glycated hemoglobin (HbA1c) in whole blood	LC-MS/MS	Amount-of-substance fraction [HbA1c/(HbA1c+HbA0)]	2025.04

1.4 Listing of the relevant technical/scientific publications

[1] Zhang Q, Zhan M, Peng X, Jin X, Yan J, Zhang P, Zhuang J, Han L, Huang X. Absolute quantitation of human serum cystatin C: candidate reference method by 15N-labeled recombinant protein isotope dilution UPLC-MS/MS. Clin Chem Lab Med. 2024, 63(4):712-722.

[2] Xu Y, Huang M, Chen Y, Yu L, Wu M, Kang S, Lin Q, Zhang Q, Han L, Lin H, Ke P, Fu W, Tang Q, Yan J, Huang X. Development of simultaneous quantitation method for 20 free advanced glycation end products using UPLC-MS/MS and clinical application in kidney injury. J Pharm Biomed Anal. 2024, 242: 116035.

[3] Du Y, Yan Q, Zhan M, Zhang Q, Huang D, Zhang P, Yan J, Wang J, Huang X, Han L. Evaluation and clinical application of a bracketing calibration-based isotope dilution liquid chromatography-tandem mass spectrometry candidate reference measurement procedure for serum theophylline. Anal Bioanal Chem. 2024, 416(22): 4897-4906.

[4] Yan Q, Huang F, Wang C, Zhan M, Zhang Q, Huang D, Yan J, Lin H, Huang X, Han L. Clinical application of an optimized reference measurement procedure for serum digoxin using bracketing calibration method by ID-LC-MS/MS. Anal Bioanal Chem. 2024, 416(29): 6909-6918.

[5] Qiaoxuan Zhang, Kai Bai, Xing Jin, Min Zhan, Liqiao Han, Junhua Zhuang, Xianzhang Huang*. An Optimized UPLC-MS/MS Method for Human Plasma Amyloid-β 42 and 40 Measurement and application in Alzheimer's Disease Diagnosis. J Pharm Biomed Anal, 2024, 250: 116396.

[6] Lintao Yu, Shiyue Kang, Long Cheng, Qiaoxuan Zhang, Fen Ouyang, Liqiao Han, Min Zhan, Dezheng Liao, Pengwei Zhang, Jun Yan*, Xianzhang Huang*.Establishment and clinical application of a candidate reference measurement procedure for quantification of urinary vanillylmandelic acidand homovanillic acid using ID-LC-MS/MS method. J Pharm Biomed Anal, 2024, 248: 116311.

[7] Xueying Lin, Qiaofang Yan, Yuanyuan Du, Jianbing Wang, Di Huang, Jun Yan, Min Zhan, Pengwei Zhang, Jingyu Cheng, Qiaoxuan Zhang*, Xianzhang Huang* and Liqiao Han*. Evaluation for serum glucose standardization inclinical laboratories of Southern China byconsecutive 6 years proficiency testing based on JCTLM-recommended reference methods. Journal of Laboratory Medicine, 2024, 48(2): 163-171.

[8] Lu Huiman, Huang Fei, Zhang Qiaoxuan,Wang Jianbing, Zhan Min, Huang Di, Han Liqiao. Establishment of a Candidate Reference Method for Serum Fluvoxamine Based on LC-MS/MS. Metrology Science and Technology. 2025, Online publishing.

[9] Zhan Min, Qiu Jiayang, Wang Qian, Han Liqiao, Wang Jianbing, Huang Xianzhang, Zhang Qiaoxuan. Uncertainty Evaluation for 17α-Hydroxyprogesterone in Human Serum Measured by Isotope Dilution Liquid Chromatography-Tandem Mass Spectrometry Based on Mathematical Model. Metrology Science and Technology. 2025, Online publishing.

[10] Min Zhan, Qiaoxuan Zhang, Zijia Ma, Liqiao Han, Jun Yan, Guangya Zheng, Wenxi Zhou, Weiyan Zhou, Xianzhang Huang. Development and validation of a candidate reference measurement procedure for free triiodothyronine and free thyroxine in human serum using equilibrium dialysis Isotope-Dilution Liquid Chromatography-Tandem Mass Spectrometry. Clin Chem Lab Med. 2025. Under Review.

2. Planned activity(ies)in support of standardization in laboratory medicine

(Please outline R&D project(s) and/orprogramme(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.)

Our laboratory will continue its commitment to advancing standardization in laboratory medicine over the next two years through focused efforts on reference methods, reference materials, and reference measurement services.

Development of Reference Methods: We are actively developing candidate reference methods for key measurands. Methods for free T3 and free T4 have been established, with related research currently under submission for peer-reviewed publication. Our subsequent goal is to formally apply for the inclusion of these methods in the JCTLM reference methods list. Additionally, we have initiated research to establish candidate reference methods for important protein-based diagnostic markers, aiming to address standardization challenges in this area.

Development of Certified Reference Materials (CRMs): Our work on CRMs will proceed along two parallel tracks:

- JCTLM Applications: We will complete the submission process for the four CRMs (Glucose, Creatinine, Uric Acid, Urea) that have been successfully developed, pursuing their formal recognition on the JCTLM list.
- New CRM Development: We will continue the research and development of new CRMs based on human serum, targeting a range of clinically significant measurands. Our pipeline includes Aldosterone, Progesterone, 17α-Hydroxyprogesterone, 25-Hydroxyvitamin D3, Estradiol, Theophylline, and Digoxin.

Extension of Reference Measurement Services: We remain dedicated to providing high-quality reference measurement services to the global community. Our services for all JCTLM-listed measurands will continue to be available, ensuring the practical dissemination of metrological traceability for clinical laboratories and in vitro diagnostic manufacturers worldwide.

3. **Promoting traceability in laboratory medicine**
(Please describe activitiesyour 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, orother forums for clinical laboratory medicine)

Our organization has actively promoted the principle and practice of metrological traceability through the following activities over the past two years:

Contributing to International Reference Material Value Assignment: We actively participated in high-profile international collaborative efforts for the value assignment of certified reference materials (CRMs). Our laboratory contributed as a reference method laboratory in the value assignment of the **EU Joint Research Centre's CRMs ERM-AD457k/IFCC for aspartate aminotransferase (AST)** and **ERM-AD458/IFCC for alkaline phosphatase (ALP)**, including the testing of two concentration levels for each enzyme. This direct involvement in characterizing internationally recognized CRMs underscores our commitment to establishing the highest level of metrological traceability for key enzymes in clinical chemistry.

Providing Calibrator Value Assignment Services: A core component of our traceability dissemination is providing high-level metrological services to the diagnostic industry and laboratories. Over the past two years, we have provided **calibrator value assignment services for numerous domestic and international IVD manufacturers and clinical laboratories.** These services cover a wide range of measurands, including **hematology parameters, enzymes, hormones, small molecules, and proteins**, effectively transferring accuracy from higher-order references to the commercial calibrators used in routine testing.

Sustained Participation in Proficiency Testing: We demonstrated our commitment to maintaining the highest measurement standards through active participation in key comparison programs. This includes the successful completion of 25 projects in the international Reference Laboratory (RELA) comparison and 5 projects in the national comparison program organized by the National Health Commission's Center for Clinical Laboratories. All measurements were performed and reported on time.

Long-Term Domestic Collaboration for Accuracy Verification: We have successfully continued our long-term collaborations with provincial clinical centers to transfer and verify traceability. This includes a 10-year continuous partnership with the Guangdong Provincial Center for Clinical Laboratories and a 7-year continuous partnership with the Chongqing Municipal Center for Clinical Laboratories for the production, value assignment, and reporting of accuracy verification samples for liver and kidney function tests. These initiatives have been instrumental in promoting and verifying the accuracy of routine laboratory measurements at the regional level.

Dissemination through Applications and Listings: The successful listing of our methods and services on the JCTLM database serves as a primary and powerful communication of our traceability work to the international laboratory medicine community.

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 not engaged in related work over the past two years.

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)

We respectfully suggest that the JCTLM consider providing more explicit guidance or clarification regarding the expectations for collaborative value assignment studies during the review of candidate reference materials. Currently, while there is no universally mandated minimum number of laboratories required by international standards, some national frameworks (for instance, the technical review for National Secondary Reference Materials in China stipulates a requirement of no fewer than nine participating laboratories) have established specific criteria.

The issuance of clear recommendations from the JCTLM on this matter would be immensely beneficial. It would help to harmonize global best practices, ensure the consistent quality and robustness of value assignment data submitted for review, and provide clearer preparation guidelines for all candidate material producers worldwide.

Note: The information of this reportwill 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.