HIGHTOP Biotech biennial activity report

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:Qingdao HIGHTOP Biotech Co., Ltd.

JCTLM Member status: Stakeholder Member

Author(s): Jinling Song

Author(s) email(s): lchxb@hightopqd.com

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.)

   We have established the Reference Measurement Laboratory in May 2021 and established reference laboratory management system according to ISO 17025 and ISO 15195 in September 2021. Our reference measurement procedures cover areas of enzyme, metabolites and substrates, proteins. On May 18, 2023,we successfully passed the CNAS reference laboratory accreditation and obtained the CNAS Reference Laboratory Accreditation certificate with certificate number L18368, including 7 projects of enzymes(AST, ALT, AMY, ALP, CK, LDH, GGT). On September 26, 2023,we became Stakeholder Member of the Joint Committee for Traceability in Laboratory Medicine (JCTLM).On May 12, 2024, it successfully passed the CNAS supervisory review, and on May 18, 2025, it passed the CNAS re-evaluation.

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.)

   a) 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.

   b) We will develop new reference measurement procedures for Metabolites and Proteins, such as Total bilirubine, Glucose, Urea,Uric acid, Total protein and etc for biochemical items.

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)

We have developed biochemical multiple calibrators and quality control products to ensure the integrity of the test system including instruments, reagents, calibrators and measurement procedures to guarantee the consistency of test results.

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) We participated in international and national comparison of reference measurement capabilities. During the last two years, we have participated in IFCC External Quality Assessment Scheme for calibration laboratories in clinical chemistry (RELA 2024 and RELA 2025) , and achieved qualified results.

b) We participated in the review activities of reference laboratories arranged by China National Accreditation Service for Conformity Assessment.

c) We participated in the EQARL proficiency tests organized by the Clinical Laboratory Center (NCCL) of the National Health Commission in 2024 and 2025, and achieved satisfactory results (passed).

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.