

Autobio Diagnostics Co., Ltd 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: Autobio Diagnostics Co., Ltd

JCTLM Member status: Stakeholder Member

Author(s): Yanlin Han

Author(s) email(s): hanyanlin@autobio.com.cn

Period covered: 2020 – 2021

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) We have run 5 reference measurement procedures(non-peptide hormone, Thyroxine,progesterone, testosterone, estriol, cortisol), and established a reference laboratory management system according to ISO 17025 and ISO 15195. In 2020, we successfully passed THE CNAS accreditation and obtained the CNAS Reference Laboratory Accreditation certificate, certificate number L13885. In 2021, we ran two additional reference measurement procedures (triiodothyronine, 17 β -estradiol) and successfully passed the CNAS extension accreditation. We provide reference measurement services to IVD laboratories in China and work with other reference measurement laboratories to assign values to national standard materials.

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)/measurands 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, we want to continue to develop and run small molecule detection programs, such as vitamins, to expand the scope of recognition. At the same time, we want to develop some reference methods for peptide and protein markers, such as C-peptide and insulin, on the platform of liquid chromatography tandem mass spectrometry.

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)

1) As one of the drafting organizations, we participated in the equivalent transformation of ISO 15195 in China. At present, the transformation of this standard has entered the review stage.

2) In 2020, we participated in the International Symposium on Therapeutics and Diagnostics: measurements, Standards, Quality and Safety, and joined the Metrology and Testing Alliance for Pharmaceutical and Diagnostic Reagent Industry organized by the National Institute of Metrology of China(NIM). We made a speech at the conference and actively discussed the significance of reference laboratory in metrology traceability and how to develop in IVD manufacturers. In 2021, we attended the annual meeting of the Metrology and Testing Alliance for Pharmaceutical and Diagnostic Reagent Industry as scheduled, and participated in the CRP quality control plan organized by the National Institute of Metrology of China(NIM).

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.)

1) We actively participate in international and national comparison of reference measurement capabilities. In the past two years, we have participated in the RELA comparison of the above projects and the reference measurement competency verification of NCCL(CHINA), and achieved qualified results, proving our ability to operate and maintain reference measurement services.

2)Now,we are applying for five projects to join the JCTLM Reference Measurement Service network in order to serve more international laboratories.

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)

1) Are there plans to add more projects to RELA EQA activities in the coming years?

2) Some certified reference materials published in the database are difficult to buy in our practical application, so it is suggested to add the information of suppliers providing these reference materials in the database to facilitate the application of reference materials.