

Biennial activity report –

Reference laboratory of Autobio Biochemistry Co., Ltd., Beijing, China

Organization Name: Reference laboratory of Autobio Biochemistry Co., Ltd., Beijing, China.

JCTLM Member status: Stakeholder Member

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Period covered: 2020 – 2021

1. Major achievement(s) in support of standardization in laboratory medicine

Our laboratory focuses on the traceability of in vitro diagnostic biochemical items. We have participated in 12 items in 2020 RELA, and 20 items in 2021 RELA. At home, we have also participated in the reference measurement capability verification program organized by the National Center for Clinical Laboratories, seven enzymes in 2020, 12 items in 2021. At present, our laboratory has established three detection platforms: ultraviolet-visible spectroscopy, ion chromatography, and LC-MS. At the beginning of 2021, 11 items passed the initial accreditation of CNAS.

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

In the future, our laboratory plans to establish reference methods for blood lipids and small metabolites, such as total glycerides, cholesterol, creatinine, homocysteine and etc for biochemical items. There are some items that will be accredited, includes mainly ionic items, such as potassium, sodium, calcium and magnesium.

3. Promoting traceability in laboratory medicine

Our laboratory participates in various forums and exchange activities, such as conversion of ISO 15195 into Chinese national standard, and development and audit of the domestic traceability-related standards. For example, our laboratory participated in the audit of Evaluation specification of commutability of reference materials for laboratory medicine, which developed by National Institute for Metrology, China.

4. Reference laboratory networks /collaborations focusing on developing /implementing reference measurement systems

- 1) Participated in the applicability verification activities of creatinine reference materials which developed by National Institutes for Food and Drug Control.
- 2) Participated in the quality improvement plan of C-reactive protein reference materials which developed by National Institute for Metrology, China.
- 3) Participated in various activities of National reference Material Metrology Technical Committee every year.
- 4) Participated in various activities of the Mass Spectrometry Group of the Laboratory Medicine Branch of the Guangdong Medical Association every year.
- 5) Participated in the review activities of reference laboratories arranged by China National Accreditation Service for Conformity Assessment.

5. Open questions and suggestions to be addressed by JCTLM

- 1) We recommend adding incentives of entering the reference method list in JCTLM database in order to accelerate the updating and promotion of reference methods.
- 2) We recommend that the review of entering reference measurement service list in JCTLM database would identify with the accreditation granted by CNAS or other members of ILAC to reduce repeated reviews.