Snibe 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:Shenzhen New Industries Biomedical Engineering Co., Ltd.

JCTLM Member status: Stakeholder Member

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Period covered: 2021 – 2023

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.)

1.1 Development of reference measurement methods

Snibe reference laboratory was established in early 2021. Up to now, we are equipped with two LC-MS/MS instruments and one UV-VIS spectrophotometer and running the quality management system in accordance with ISO/IEC 17025 and ISO 15195. In May 2023, our laboratory was CNAS Accredited with 9 measurands (AST, ALT, ALP, AMY, GGT, CK, LDH, 25-OH-vitamin D3, and 17-OH-Progesterone).

We have developed 18 reference measurement procedures and two more are under development. The measurement area covers enzymes, non-peptide hormones, and vitamins.

1.2 Establishment of calibration measurement services

Snibe reference lab has submitted an application wishing our 5 reference measurement services (ALT, AMY, CK, 25-OH-vitamin D3, 17-OH-Progesterone) to be listed on the JCTLM database in May 2023. Still under review until November 2023.

1.3 Participation in the EQA/PT for reference laboratory

a) IFCC-RELA:

In 2022, we enrolled for 9 measurands, including AST, ALT, ALP, AMY, GGT, CK, LDH, 25-OH-vitamin D3, and 17-OH-Progesterone. The results are all within the equivalent limits.

In 2023, we enrolled for 13 measurands, including AST, ALT, ALP, AMY, GGT, CK, LDH, 25-OH-vitamin D3, 17-OH-Progesterone, Aldosterone, Estradiol-17β, total Thyroxine, and total Triiodthyronin. The results are basically satisfactory according to the pre-evaluation feedback by RELA.

b) NCCL-EQARL:

In 2023, we enrolled for 12 measurands, including AST, ALT, ALP, AMY, GGT, CK, LDH, 25-OH-vitamin D3, 25(OH)D2, 17-OH-Progesterone, Aldosterone, Estradiol-17β. The results are all satisfactory.

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.)

In the near future, Snibe reference laboratory intends to develop more reference measurement procedures, mainly in small molecular hormone analytes and protein measurement areas. As for the developed RMPs, Snibe plans to apply them gradually in traceability and quality control of IVD assays.
Besides, Snibe noticed the importance of reference materials and decided to pay more attention to the study, preparation, evaluation, and registration of reference materials.

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)

Attended an international workshop themed Therapeutics and Diagnostics: Measurement, Standards, Quality and Safety (TD-MSQS) with 3 posters:

a) Establishment, performance evaluation and influence factors analysis of α-amylase reference measurement procedure
b) Determination of serum/plasma aldosterone by isotope dilution liquid chromatography-tandem mass spectrometry
c) Adjust the analytical performance with the budget of combined uncertainty to achieve uncertainty target

Attended C-TLM 20th meeting 2022 as a corresponding member via zoom.
Absent at C-TLM 21st meeting 2023 but providing advises for updating the RELA procedure manual.
Attended the WG NB meeting on 25th September 2023.

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) Participate in IFCC-RELA and NCCL–EQARL EQA/PT activities for reference laboratory yearly.
b) In 2022, participated in the commutability study of the PCT reference material initiated by IFCC WG-PCT.
c) Donate €5000 to help update the JCTLM database in 2022.
d) Participate in ALD reference material collaborative value assignment organized by National Institutes for Food and Drug Control (NIFDC) in 2023.
e) In 2023, starting the cooperation with Prof. Christa Cobbaert on the standardization of serum apolipoproteins.
f) Participate in 25-OH vitamin D reference material collaborative value assignment organized by Beijing Institute of medical device testing (BIMT) in 2023.

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)

a) As the measurement instruments' analytical performance boosts, some RMPs established decades ago may be not so suitable for now. Besides, authors may make some corrections afterwards. Is there any plan to review and update the RMPs periodically?
b) The number of reference materials is limited in the JCTLM database and is sometimes hard to purchase.

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.