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 Members for drafting their biennial activity report. Organizations are invited to provide the information below for submission to the Executive Committee.

Organization Name: Reference Institute for Bioanalytics (RfB)

JCTLM Member status: Stakeholder Member

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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.)

   RfB organizes an External Quality Assessment Scheme (EQAS) for medical laboratories internationally and is accredited according to ISO 17043 since 2012. EQAS is performed regularly in accordance with the "Guideline of the German Medical Association for quality assurance in Medical Laboratory Examinations – RiliBAEK" (DOI: 10.3238/arztebl.2019.rili_baek_QS_Labor20192312). This directive was created by the German Medical Association in close cooperation with the national metrology institute (PTB), the scientific society (DGKL), and external assessment providers (e.g. RfB) since 1971 and prescribes the implementation of the traceability concept since 1987. RfB performs the evaluation of the results of medical laboratories by use of reference measurement target values for a variety of reference measurements systems. The latest version of RiliBÄK requires that "*EQA providers operate their own calibration laboratories for the determination of the reference measurement procedure values of samples for EQA … . The suitability of the calibration laboratories is considered proven if an accreditation according to DIN EN ISO / IEC 17025 and DIN EN ISO 15195 as a calibration laboratory as well as a listing at the Joint Committee for Traceability in Laboratory Medicine (JCTLM) with at least 20 entries from the tables of Section B 1 is present.*" RfB fulfils this requirement with its 30 listed services in the JCTLM database. The calibration laboratories of RfB are accredited according to ISO 17025 and ISO 15195 for 33 measurands (electrolytes, enzymes, metabolites and substrates, non-peptide hormones, drugs, proteins). The service for HbA1c is established and the nomination is checked by the JCTLM Review Team. The most recent entry is for total haemoglobin; the reference measurement procedure and the service were listed in 2021.
   The services of the calibration laboratories are offered to IVD manufacturers and EQA organizers.

   Since 2003 RfB organizes - under the umbrella of the IFCC - an External Quality Assessment Scheme (EQAS) for calibration laboratories in clinical chemistry (RELA) annually. RELA surveys are currently provided for 36 measurands. The participants are NMIs, calibration laboratories, and candidate laboratories. More than 60 laboratories participate, and each year RfB receives more than 550 results from these laboratories. All results of RELA 2003 to RELA 2021 are published on the website with open access (www.dgkl-rfb.de:81).

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 cooperation with PTB the calibration laboratories of RfB develop and optimize new reference measurement procedures (RMP) (cardiac markers, pH in blood, valproic acid). Accreditation for total protein is planned. JCTLM listing for total bilirubin is planned.

3. Promoting traceability in laboratory medicine

Presentations and Workshops, Publications

2019-12-02 JCTLM Stakeholder meeting, presentation of reference system for total haemoglobin,
2020-09-10 German Calibration Service (DKD), Technical committee Measurands in Laboratory Medicine, Berlin, Germany,
2021-09-01 German Calibration Service (DKD), Technical committee Measurands in Laboratory Medicine, Berlin, Germany,
2021-09-14/16 ISO TC212, Work Group 2, Reference Systems, sub group meeting ISO 15193, online meeting,
2021-09-29 IFCC, Working Group Pancreatic Enzymes, Development of a reference measurement procedure for pancreatic amylase in serum, online meeting,
2021-10-13 Tosoh Webinar, “Externe Qualitätskontrolle für HbA1c: Internationale Standardisierung und Ringversuche”.

Grote-Koska D, Klauke R, Kaiser P et al., (**2020**) Total haemoglobin - a reference measuring system for improvement of standardisation. *Clin. Chem. Lab. Med*., 58(8):1314-1321.
Grote-Koska D, Brand K. (**2020**). Using ISO/TS 20914:2019 to calculate the measurement uncertainty of immunosuppressive drugs in a clinical laboratory. *Scand. J. Clin. Lab. Invest.* 80:309-312.

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.)

RfB is active and participates in:

RfB RELA,
EMPIR CardioMet, WG2 and WG3,
HbA1c IFCC network compaign and EurA1c-study,
ISO TC212, Work Group 2, Reference Systems – revision of ISO 15193 and 15194,
AKB of DAkkS (German Accreditation Body),
DKD (German Calibration Service), Technical committee Measurands in Laboratory Medicine,
BÄK (German Medical Association),
IFCC C-TLM (Committee Traceability in Laboratory Medicine)
IFCC WG-PE (Working Group Pancreatic Enzymes),
IFCC WG-ID (Working Group Immunosuppressive Drugs),
Joint project of CCQM, C-TLM and C-EUBD on HbA1c
JCTLM Review Team Enzymes,
JCTLM Review Team Electrolytes and Blood Gases,
JCTLM WG TEP,
JCTLM Executive Board.

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)

RfB asks for support to convince JRC regarding the development of an ERM reference material on alkaline phosphatase. In addition, the availability of CRM is becoming increasingly difficult. Example triglycerides: Tripalmitin was delisted in 2020, it is no longer available like the listed triolein.

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.