

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: Joint Research Centre, JRC, European Commission

JCTLM Member status: National and Regional Member

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Period covered: 2022 – 2023

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

The JRC has developed and released a CRM for immunoglobulin G antibodies against β 2-glycoprotein I (anti- β 2GPI IgG) in human serum in collaboration with MHRA (also called NIBSC in the past). The batch of this material was split into two parts called NIBSC 21/266 and ERM@-DA477/IFCC. NIBSC 21/266 was endorsed as the first WHO International Standard for Anti- β 2GPI immunoglobulin G by the WHO Expert Committee on Biological Standardization (ECBS). The assigned value of NIBSC 21/266 in International Units (IU) was directly transferred to ERM@-DA477/IFCC.

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

In the upcoming years, the JRC will continue the development of CRMs for biomarkers in various clinical fields:

a. Autoimmune disorders

The JRC has developed a candidate RM for antibodies targeting tissue transglutaminase (anti-tTG IgG and IgA) in human serum in collaboration with MHRA. The candidate RM was produced in a large batch, which is also split into two parts. The first part is intended to become international standard (IS) with arbitrary values in IU/ml approved by the WHO and distributed by MHRA. The second part will be the CRM EURM-487 with an assigned value directly transferred from the WHO IS.

The production of a CRM for IgG autoantibodies targeting glomerular basement membrane (anti-GBM) has started. An initial commutability study was performed and the most suitable starting material has been selected.

b. Apolipoproteins

The JRC supports the development of a reference measurement system (RMS) for a panel of clinically relevant serum apolipoproteins (apo) A-I, B, C-I, C-II, C-III, E and apo (a) which is done within the IFCC working group on Apolipoproteins by Mass Spectrometry. The RMS will be based on a LC-MS/MS reference measurement procedure (RMP) and commutable serum-based RM.

c. HbA2

The JRC has developed two CRMs for haemoglobin A2 (low and high level) in collaboration with the members of the IFCC working group on standardisation of haemoglobin A2 (WG-HbA2). For each CRM a large batch has been processed and these batches have been tested for homogeneity, stability and

commutability. The materials will be certified using a MS-based RMP calibrated with recombinant hemoglobins.

d.Enzymes

The current CRM ERM-AD457/IFCC for the catalytic activity of aspartate aminotransferase (AST) will be replaced within 2 years. A commutability study with four pilot batches has been performed and based on these results a candidate RM for AST in an artificial matrix was selected. The batch has been produced and the certification studies are planned for 2024.

JRC has also started the production of a new CRM for the catalytic activity of alkaline phosphatase (ALP). First three pilot batches have been produced and they have been evaluated in a commutability study. Based on the results the most suitable material will be selected.

F. Estradiol in human serum

The sales stocks of the CRMs BCR-576-578 are almost exhausted. These materials will be replaced with new batches, which will be tested for their commutability with several IVD MPs. These new materials should become the study materials in the upcoming CCQM key comparison on estradiol in 2024-2025.

3. Promoting traceability in laboratory medicine

Staff members of the JRC have contributed to the drafting and review for important international standards like the CLSI EP30 ed 2 “Characterization and Qualification of Commutable Reference Materials for Laboratory Medicine“ and the ISO15194 within the ISO TC212/WG2.

During the past years, the JRC continued the distribution of the established CRMs in the field of laboratory medicine to laboratories and IVD manufacturers all over the world. Around 6000 units of IVD –CRM are distributed every year.

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

a. Collaborations with IFCC

A staff member of the JRC is an observer in the Executive Committee of the Scientific Division of the IFCC.

Several staff members of the JRC are members in the following IFCC working groups:

- Standardisation of Hemoglobin A2 (WG-HbA2)
- Commutability in Metrological Traceability (WG-CMT)
- Apolipoproteins by Mass Spectrometry (WG-APO MS)
- Fecal Immunochemical Testing (WG-FIT)
- Standardization of Fetal Haemoglobin (WG-HbF)

In addition, the JRC supports the IFCC Scientific Division Committee on Harmonization of Autoimmune Tests (C-HAT), and the working group on Pancreatic Enzymes (WG-PE) by the production of CRMs as mention before.

b. Collaboration Euramet’s European metrology networks (EMN) and projects

The JRC has joined the EMN for Traceability in Laboratory Medicine (TraceLabMed).

The JRC has joined the NeuroBioStand project on the Standardisation of measurements of neurodegenerative disease biomarkers

5. Open questions and suggestions to be addressed by JCTLM

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 authorize 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.