

Draft template for 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: Japanese Committee for Clinical Laboratory Standards (JCCLS)

JCTLM Member status:

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Period covered: 2015 – 2017

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.)

JCCLS established the following activities in support of standardization in laboratory medicine during 2015-2017

AACC started ICHCLR (International Consortium for Harmonization of Clinical Laboratory Results) to standardize and proposed the working standards taking place of reference materials since 2010. Therefore, JCCLS developed panel serum collaborated with USA and European countries and proposed its use for the daily clinical practice based on the ISO/TC212.

Two working standards (MaCRM-001 and CRM-002 (ChE)) were newly distributed from JCCLS during 2015-2017.

(A) MaCRM-001

1. JCCLS developed, manufactured and distributed a panel serum named MacRM-001 (Multianalyte Conventional Reference Material) since July 2015 and is now expanding the distribution activity under the direction of Executive Committee of JCCLS. The current MacRM is a frozen type product with 30 items available to standardize which reserved under -70°C frozen using the left-over serum donated from Japan Red Cross.

2. The manuscript on the panel serum (MacRM) from JCCLS was accepted and reported in Clinical Chemistry 2016; 62; 392. JCCLS joins the HOG program at ICHCLR and proposed the use of MacRM panel serum for standardization of diagnosis. For the supply internationally, the panel serum needs to be freeze dry product, however the current product is frozen product (-70°). JCCLS is planing to develop the freeze dry product for interbationally available to use.

3. Registration of MaCRM-001 to JCTLM

JCCLS is planning to register MacRM to JCTLM 2018.

Working group of MaCRM-001 registration is as follows :

Members; Drs. Naotaka Hanasaki, Masato Maekawa, Shigemi Hosogaya, Katsuyuki Shinohara.

Application item; Among 30 items of MacRM-001, top 13 items of the reference materials and reference methods will be registered to JCTLM.

4. The panel serum for the use of international standardization
JCCLS panel serum (MacRM) was approved as Class I by MHLW and used and distributed by the Japanese diagnostic companies
5. Japan collaborates with USA and will propose the reference method for international standardization using panel serum at ISO/TC212 at ICHCLR next year 2018.

B) CRM-002 (ChE)

1. The manufacturing schedule of the next lot of CRM-002 (ChE) was approved by Executive Committee of JCCLS on August 2016
2. The manufacturing schedule of next lot of CRM-002 (ChE) was discussed at Accreditation Committee on September 4th and approved by Executive Committee of JCCLS.
3. Public offering as a common reference standard of ChE CRM-002d

The public offering of manufacturing of ChE CRM-002d was announced on October 21, 2016. Asahi-Kasei Pharma, a member of JACRI applied and approved on November 16. The manufacturing process and schedule was reported by Asahi-Kasei and approved by Executive Committee of JCCLS.

4. The maintain examination of reference material producers.

The Japan Accreditation Board (JAB) announced the second surveillance of reference material producers of CRM-001c (commonly used enzyme) on November 30 2016.

5. Progress of ChE CRM-002d manufacturing

The manufacture of ChE CRM-002d is delayed at Asahi-Kasei Pharma, but the distribution schedule from JCCLS will not change 2018.

6. The report on the common reference standard of ChE CRM-002d valued by Accreditation Committee. As the number of reference laboratories which can value the reference materials decreases, Japanese Association of Medical Technologists started to offer the training course of the manual procedures.
7. The distribution of common reference standard ChE CRM-002d. The organization of distribution is approved by JCCLS and ReCCS
8. Distribution of new lot of CRM-002d
The new lot distribution started September 12 by JCCLS and ReCCS.

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.)

JCCLS is planning to register MacRM to JCTLM 2018. Working group of MacRM-001 registration is as follows :

Members; Drs. Naotaka Hanasaki, Masato Maekawa, Shigemi Hosogaya, Katsuyuki Shinohara.

Application item; Among 30 items of MacRM-001, top 13 items of the reference materials and reference methods will be registered to JCTLM.

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) The manuscript on the panel serum (MacRM) from JCCLS was accepted and reported in Clinical Chemistry 2016; 62; 392.
- 2) JCCLS invited Dr. Gary Myers of new JCTLM chairman and Dr. Greg Miller of HOG chairman of ICHCLR project at the JCCLS annual symposium on September 2016 and gave their lectures for the members of Japanese IVD companies.

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.)

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)

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.