

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: Korean Association of External Quality Assessment Service

JCTLM Member status: Stakeholder member status

Author(s): Sail Chun, Yoon Hwan Chang

Author(s) email(s): keqas@keqas.org, keqas5@keqas.org

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.)

The Korean Association of External Quality Assessment Service (KEQAS) has its own proficiency testing scheme based on academic classifications, test areas, types of proficiency testing materials and the convenience of participating laboratories. In 2015, there were 10 programs which covered 179 test items in KEQAS's PT scheme. There were 46 programs and 287 test items in 2016. Currently, KEQAS' EQA program is composed of 54 programs covering 326 test items and 1,605 clinical laboratories are participating.

There are three accuracy-based PT programs for HbA1c, creatinine, and lipid during 3 years. Commutable PT materials for accuracy-based PT programs are shipped twice a year with three samples in each mailing. In 2017, 383 clinical laboratories participated in HbA1c program, 153 clinical laboratories participated in creatinine program, and 172 clinical laboratories participated in lipid program.

All target values of PT materials are obtained with the cooperation of the Reference Material Institute for Clinical Chemistry Standards (ReCCS) in Japan, CEQAL in Canada, and the Korean Centers for Disease Control and Prevention (KCDC) reference laboratory which is approved laboratory for the IFCC HbA1c Network and a member of Cholesterol Reference Method Laboratory Network for total cholesterol and triglyceride certified by CDC.

In August 2015, the KEQAS was certified for the ISO 17043 to meet the global standards. After then, ISO committee selects two tests items and runs PT programs annually. In 2016, PT programs for creatinine and

human immunodeficiency virus (HIV) RNA were carried out. In 2017, creatinine and human cytomegalovirus were chosen. For the creatinine PT program, three commutable frozen sera were shipped and were tested three times a day for two days at each participating institute.

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.)

Korean Centers for Disease Control and Prevention (KCDC) are developing the reference methods for glucose, gamma-glutamyl transferase (GGT), and aspartate aminotransferase (AST). KEQAS will choose one or two items with developed reference methods and conduct new accuracy-based PT programs or ISO PT programs.

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)

The Journal of Laboratory Medicine and Quality Assurance (J Lab Med Qual Assur) is the official journal of KEQAS, published quarterly (last day of March, June, September, and December). Based on the data obtained from the external quality assessment of HbA1c from 2009 to 2014, the article "Six Years' Experience of Accuracy-Based Proficiency Testing for HbA1c in Korea" (*J Lab Med Qual Assur* 2015;37: 92-100) was published.

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.)

To continue the standardization effort in Korea, KEQAS will support KCDC and the Korean Society for Laboratory Medicine (KSLM) in various ways.

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.