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): Hyung-Doo Park |
| Author(s) email(s): keqas@keqas.org, keqas1@keqas.org |
| Period covered: 2018 – 2019 |

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 2018, there were 64 programs which covered 318 test items in KEQAS’s PT scheme. This year (2019), KEQAS’ EQA program is composed of 65 programs covering 326 test items and 1,818 clinical laboratories are participating.

There are three accuracy-based PT programs for HbA1c, creatinine, and lipid. Commutable PT materials for accuracy-based PT programs are shipped twice a year with three samples in each mailing. The HbA1c PT does not use the QC materials, but proceeds in the accuracy-based PT format. In 2018, 544 clinical laboratories participated in HbA1c program, 201 clinical laboratories participated in creatinine program, and 230 clinical laboratories participated in lipid program. This year (2019), 565 clinical laboratories participated in HbA1c program, 241 clinical laboratories participated in creatinine program, and 241 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 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. PT programs for total cholesterol and EGFR mutation were carried out in 2018. And, EGFR mutation was chosen in 2019.

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.)

Korea 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. Until 2019, the creatinine PT was operated in two types: PT using QC materials and accuracy-based PT. And accuracy-based creatinine PT was a voluntary participation program by institutions. After 2020, all institutions will be required to participate in the accuracy-based creatinine PT.

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 creatinine from 2011 to 2017, the article “Accuracy-Based Proficiency Testing of Creatinine Measurement: 7 Years’ Experience in Korea” (J Lab Med Qual Assur 2019;41:13-23) 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.