HSA biennial activity report

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: Health Sciences Authority, Singapore |
| JCTLM Member status: National and Regional 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.)

- **Accuracy-Based External Quality Assessment (EQA) Programmes**

  HSA continues to organise accuracy-based EQA programmes for local clinical laboratories and medical clinics in Singapore, where metrologically traceable assigned (target) values determined by the Chemical Metrology Laboratory (CML) are used to evaluate the results of the participating laboratories/clinics. Starting from 2019, a dedicated EQA programme on HbA1c Testing is launched along with the regular EQA programme.

  **The HSA EQA Programme on HbA1c Testing**

  In March 2019, Singapore’s Ministry of Health mandated all licensed hospitals, medical clinics and clinical laboratories intending to offer HbA1c as an alternative screening test (other test being fasting plasma glucose) for diabetes mellitus to participate in the HSA EQA programme. The use of HbA1c as a screening tool offers the ability to diagnose patients with diabetes mellitus even with non-fasted blood samples. With the potential for increased use of HbA1c testing, HSA offers the EQA programme as a continuous quality assurance programme to assist laboratories/clinics in tightening the accuracy of their HbA1c test results, and reducing the possibilities of misclassification of diabetes mellitus. This programme is amenable to both mainframe analysers and portable devices as fresh human whole blood samples are provided for testing. The programme usually comprises three cycles, where two blood samples with different HbA1c levels are provided per cycle. In 2020, only one cycle was organised due to COVID-19 pandemic. In 2021, all three cycles were successfully organised. Close to 60 clinical laboratories and medical clinics participated in each cycle of the EQA Programme.

  **Regular HSA EQA Programme on Clinical Chemistry**

  The regular HSA EQA programme for clinical laboratories is an on-going programme launched since 2011. The programme is intended to focus on chronic diseases (other than diabetes) affecting majority of the...
Singapore population. 17 Analytes (including a new analyte, total protein introduced from 2020) are offered in this programme. The analytes include:

(a) creatinine, glucose, total cholesterol, triglycerides (as ‘total glycerides’), urea, uric acid, LDL-cholesterol, HDL-cholesterol, total protein, calcium, sodium, potassium, magnesium, iron, and chloride in human serum; and
(b) albumin and creatinine in human urine.

In 2020, only one cycle was organised due to COVID-19 pandemic. In 2021, the usual two cycles were successfully organised. Close to 40 clinical laboratories, including all public and almost all private laboratories in Singapore participated in each cycle of the regular HSA EQA programme in both years.

### Clinical Certified Reference Materials (CRMs) Maintained / Produced / Under Development

HSA continues to maintain the following clinical CRMs through regular stability testing:

(a) HRM-3002B: Creatinine, glucose, total cholesterol, HDL-cholesterol, LDL-cholesterol, total glycerides, free glycerol, urea and uric acid in human serum
(b) HRM-3003B: Haemoglobin A1c in human blood
(c) HRM-3004A: Albumin and creatinine in human urine
(d) HRM-2002A: Calcium, potassium and sodium in human serum
(e) HRM-2005A: Calcium, iron, potassium, magnesium, sodium and chloride in human serum
(f) HRM-2011A: Sodium, chloride, copper, selenium and phosphorus in human serum
(g) HRM-3005A: Cortisol in human serum

HSA has produced the following clinical CRM between 2020 - 2021:

(a) HRM-3006A: Testosterone in human serum

Certification of the following clinical CRMs is in progress:

(a) HRM-3007A: Creatinine, glucose, urea and uric acid in human serum
(b) HRM-3008A: Total cholesterol, triglycerides, HDL-cholesterol, and LDL-cholesterol in human serum

Commutability studies on these clinical CRMs commenced in 2021. The studies involve HSA, three clinical laboratories within public hospitals and a major private clinical laboratory in Singapore.

### Reference Measurement Methods Developed / in Development

(a) Spectrophotometry method for total protein in human serum
(b) LC-IDMS/MS method for amino acids in human serum
(c) LC-IDMS/MS method for determination of SARS-CoV-2 antibody concentration
(d) LC-IDMS/MS method for 17β-estradiol in human serum (in progress)
(e) LC-IDMS/MS method for procalcitonin in human serum (in progress)
(f) High resolution IDMS method for human growth hormone in human serum (in progress)

### CCQM Comparisons Related to Healthcare Co-organised / Participated

HSA co-organised the following comparisons:

(a) CCQM-K115.c Key comparison on peptide purity: HbA1c glycated hexa-peptide, GE (in progress)
(b) CCQM-K115.2018 Key comparison on peptide purity: HbA1c hexa-peptide, VE (in progress)
(c) CCQM-P219 Pilot study on determination of the amount-of-substance fraction of $[\text{Hb}1c/(\text{Hb}1c+\text{Hb}A0)]$ in human hemolysate (in progress)

HSA participated in the following comparisons:

(a) CCQM-K159 Key comparison on determination of free amino acids in plasma
(b) CCQM-P216 pilot study on quantification of SARS-CoV-2 monoclonal antibody
(c) 2021 IFCC RELA on HbA1c in human haemolysate
Other Activities


(b) Conducted a collaborative investigation with US Centers for Disease Control and Prevention (CDC) on the impact of ultra-centrifugation procedure in beta-quantification procedure for the measurement of HDL-cholesterol and LDL-cholesterol.

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.)

Development of Clinical CRMs

(a) Human albumin solution calibration standard

(b) SARS-CoV-2 antibody solution CRMs

(c) Vitamin D metabolites in human serum

(d) Steroid hormones (progesterone and estradiol) in human serum

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)

Publications Related to Healthcare

(a) Determination of purity values of amino acid reference materials by mass balance method: an approach to the quantification of related structure impurities


(b) Measurement of urine albumin by liquid chromatography-isotope dilution tandem mass spectrometry and its application to value assignment of external quality assessment samples and certification of reference materials


(c) Improving the accuracy of chloride measurements through participation in regular external quality assessment programme


(d) Impact of heterozygous hemoglobin E on six routine HbA1c laboratory methods


Presentations/Seminars Related to Healthcare

(a) A Sharing on the results of 2020 HSA EQA Programme on HbA1c testing by Sharon Yong via video presentation to participating clinical laboratories and medical clinics in January 2021.
(b) A Sharing on the results of the 2020 HSA EQA Programme by Liu Qinde via video presentation to participating clinical laboratories in April 2021.

(c) Video presentation titled “Metrology Traceability in Clinical Measurement” by Liu Qinde at 2021 World Metrology Day celebration in Singapore in May 2021.


(e) Online oral presentation titled “Metrological Traceability in Clinical Measurement and HSA EQA Programmes” by Liu Qinde for Singapore Association of Clinical Biochemists Education Programme in October 2021.

- Courses for Healthcare Sector
  (a) Training course on “Measurement Uncertainty for Clinical Laboratories” for clinical laboratories in Singapore in February 2021.

  (b) Self-directed online course via Moodle platform on “Measurement Uncertainty for Clinical Laboratories” for local and overseas clinical laboratories in September & November 2021.

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.)

- Two HSA staff members are currently serving in the JCTLM Database Working Group:
  (a) Dr Qinde Liu
     Vice-Chair of Analyte Group 1
     Team Leader of Non-Peptides Hormones Review Team
     Member of Metabolites and Substrates Review Team
  (b) Dr Richard Shin
     Member of Non-Electrolyte Metals Review Team

- IFCC Standardization of Procalcitonin Assay (WG-PCT)
  As a member of International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Working Group on Standardization of Procalcitonin assays (WG-PCT), HSA continues to collaborate with Laboratoire National de Métrie de l'Essai (LNE, France) to develop a LC-IDMS/MS reference method for the measurement of procalcitonin in human serum and to determine the purity of procalcitonin calibration standard. The target is to establish an IDMS-based reference method for procalcitonin in human serum, and to develop procalcitonin calibration standard and human serum CRM for the standardisation of procalcitonin assay. A bilateral comparison between LNE and HSA is ongoing.

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)