JCTLM REPORT 2015

CHEMICAL METROLOGY LABORATORY
APPLIED SCIENCES GROUP
HEALTH SCIENCES AUTHORITY
SINGAPORE

Health Sciences Authority (HSA)

HSA is a Statutory Board of the Ministry of Health, Singapore. HSA took on the role of a Designated Institute for chemical metrology in 2008. The Chemical Metrology Laboratory (CML) was established to develop the capabilities and undertake the relevant chemical metrology programme in HSA. A major focus of the HSA's chemical metrology programme is on healthcare.

Involvement in the Chemical Metrology Community

HSA attends the plenary meeting of the Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology (CCQM) since 2008, and participates actively in the activities of three of its working groups (Bioanalysis WG, Inorganic Analysis WG and Organic Analysis WG). In November 2014, HSA was granted membership to the CCQM by the International Committee for Weights and Measures (CIPM). HSA is also a full member of the Asia-Pacific Metrology Programme (APMP) since 2008, and participates in the activities of two of its technical committees (TC for Amount of Substance and TC on Quality Systems).

HSA is a member of the Joint Committee for Traceability in Laboratory Medicine (JCTLM) since 2013. Two CML staff are currently serving as members of the following review teams of Work Group 1:

Dr Liu Qinde: Member of review team for Metabolites and Substrates
Member of review team for Non-Peptide Hormones

Dr Richard Shin: Member of review team for Non-Electrolyte Metals

Healthcare-Related Metrological Services

External Quality Assessment (EQA) Programme

HSA organises an EQA programme for the local clinical laboratories since 2011. The EQA programme is an accuracy-based programme where the assigned (target) values are independently determined by CML using high accuracy methods, either isotope dilution mass spectrometry (IDMS) or standard addition method. The assigned values are traceable to the SI, each being accompanied by a measurement uncertainty. The main objective of the programme is to provide metrologically traceable assigned values to evaluate the results of the participating clinical laboratories.

The HSA EQA programme started with three analytes (creatinine, glucose and total cholesterol) in 2011. In the 2015 programme, a total of 15 analytes are offered. These include:

(1) creatinine, glucose, total cholesterol, triglycerides (as 'total glycerides'), urea, uric acid, LDL-cholesterol, HDL-cholesterol, calcium, sodium, potassium, magnesium, iron, and chloride in human serum
(2) glycated haemoglobin (HbA1c) in human blood

The 2015 EQA programme is participated by all the public and private hospital laboratories and the major commercial laboratories in Singapore.

Certified Reference Materials (CRMs)

HSA has produced the following clinical CRMs:

(1) HRM-2002A: Calcium, potassium and sodium in frozen human serum (also listed in the JCTLM database)
(2) HRM-3002A: Creatinine, glucose, total cholesterol, total glycerides, urea and uric acid in frozen human serum (also listed in the JCTLM database, without total glycerides)
(3) HRM-2005A: Calcium, potassium, sodium, magnesium, iron and chloride in human serum

HSA is currently working on developing CRMs for HbA1c in human blood, and HDL-cholesterol and LDL-cholesterol in human serum. These CRMs are expected to be ready in early 2016.

Quality System and Peer Reviews

HSA CML completed its second on-site peer review in May 2014 based on ISO/IEC 17025 and ISO Guide 34. The quality system was also reviewed by a quality system expert from the Singapore Accreditation Council (SAC), the national accreditation body of Singapore.

HSA CML is also accredited by SAC as a PT/EQA provider in accordance with the requirements of ISO/IEC 17043:2010 since August 2013.

Participation in CCQM/RMO Comparisons and IFCC Ring Trials (RELAs)

Participation in Comparisons & RELAs

Since 2008, HSA has participated in over 30 CCQM/RMO comparisons. Comparisons related to clinical measurements are given below:

(1) EURAMET.QM-K12 Determination of the mass fraction of creatinine in human serum
(2) CCQM-K6.2 Determination of total cholesterol in human serum
(3) CCQM-K11.2 Determination of glucose in human serum
(4) CCQM-K12.2 Determination of creatinine in human serum
(5) CCQM-K107 Elements (K, Ca, Mg, Fe) in human serum
(6) CCQM-K115 Peptide purity: synthetic human C-peptide (in progress)
(7) CCQM-K132 Low polarity analytes in a biological matrix: vitamin D metabolites in human serum (in progress)

HSA has also participated in the following RELAs:

(1) RELA 2010 for creatinine
(2) RELA 2013 for HbA1c
(3) RELA 2014 for HbA1c

Organisation of CCQM Comparisons

HSA will be organising the following CCQM comparisons related to clinical measurements:

(1) CCQM-K109 & CCQM-P148 High polarity analytes in biological matrix: determination of urea and uric acid in human serum (in progress)
(2) CCQM-K139 & CCQM-P173 Elements in human serum (planned for 2017)

R&D Activities

HSA CML officers have published the following papers related to clinical measurements:

(1) High accuracy analysis of glucose in human serum by isotope dilution liquid chromatography-tandem mass spectrometry
Yizhao Chen, Qinde Liu, Sharon Yong and Tong Kooi Lee. *Clinica Chimica Acta*, **413**, 2012, 808-813.

(2) Determination of total thyroxine in human serum by hollow fiber liquid-phase microextraction and liquid chromatography-tandem mass spectrometry
Sharon Yong, Yizhao Chen, Tong Kooi Lee and Hian Kee Lee. *Talanta*, **126**, 2014, 63-169.

(3) An improved reference measurement procedure for triglycerides and total glycerides in human serum by isotope dilution gas chromatography–mass spectrometry
Yizhao Chen, Qinde Liu, Sharon Yong, Hui Ling Teo and Tong Kooi Lee. *Clinica Chimica Acta*, **428**, 2014, 20-25.

(4) Improved reference measurement method for hemoglobin A1c by use of liquid chromatography–isotope dilution–tandem mass spectrometry

Lingkai Wong, Hong Liu, Sharon Yong, Qinde Liu, Tong Kooi Lee. *Clinical Chemistry*, **61(2)**, 2015, 435-436.

(5) Developing a reference measurement procedure for free glycerol in human serum by two-step gas chromatography–isotope dilution mass spectrometry

Yizhao Chen, Hui Ling Teo, Qinde Liu, Tong Kooi Lee. *Clinical Biochemistry*, **48**, 2015, 897-903.

(6) Achieving comparability with IFCC reference method for the measurement of hemoglobin A_{1c} by use of an improved isotope dilution mass spectrometry method

Hong Liu, Lingkai Wong, Sharon Yong, Qinde Liu, Tong Kooi Lee. *Anal. Bioanal. Chem*., **407**, 2015, 7579-7587.

Participation in Conferences Related to Laboratory Medicine

(1) The 4th Congress of Asia Association of Medical Laboratory Scientists (AAMLS) & the 24th Annual Scientific Meeting of Singapore Association for Medical Laboratory Sciences (SAMLS), October 2013

(a) “Measurement of triglycerides and total glycerides in human serum by gas chromatography-isotope dilution mass spectrometry”, oral presentation, Yizhao Chen

(b) “Establishing the metrological traceability of glycated haemoglobin (HbA1c) measurement”, oral presentation, Lingkai Wong

(c) “Developing an accuracy-based proficiency testing programme in clinical chemistry”, oral presentation, Tong Kooi Lee

(2) The 25th Annual Scientific Meeting of SAMLS, October 2014

(a) “Impact of metrology on quality”, oral presentation, Tang Lin Teo

(b) “Providing an Accuracy-Based EQA Programme: The HSA Experience”, oral presentation, Qinde Liu

(3) The 15th ASEAN Conference for Clinical Laboratory Sciences, June 2015

“Certified reference materials for clinical measurements”, oral presentation, Tang Lin Teo

(4) EuroMedLab Paris 2015, 21st IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine, June 2015

“Achieving SI Traceability in HbA1c Measurements Through Peptide Quantification”, poster presentation, Liu Hong, Sharon Yong, Lingkai Wong, Qinde Liu, Tang Lin Teo, Tong Kooi Lee