HSA's Activities in Support of Traceability in Laboratory Medicine

JCTLM Members' and Stakeholders' Meeting

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Outline

- Health Sciences Authority (HSA) & Chemical Metrology
- Involvement in Chemical Metrology Community
- Involvement in JCTLM
- Healthcare-related Metrological Services
- Healthcare-related R&D Activities
- Participation in Conferences Related to Laboratory Medicine

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HSA and Chemical Metrology

- HSA is a Designed Institute responsible for developing the chemical metrology programme to enhance the accuracy of chemical measurements in Singapore. Our areas of focus are healthcare, food, pharmaceuticals & health products.
- The Chemical Metrology Laboratory (CML) was established in 2008 to develop the relevant capabilities and undertake the chemical metrology programme in HSA.

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The Chemical Metrology Laboratory

Quality system

- ISO/IEC 17025 and ISO Guide 34:
  - 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.
- ISO/IEC17043 :
  - HSA CML is accredited by SAC as a PT/EQA provider in accordance with the requirements of ISO/IEC 17043:2010 since August 2013.

Chemical metrology activities

Since 2008, the laboratory participates actively in regional/international chemical metrology activities including over 30 relevant regional/international comparisons.

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Involvement in Chemical Metrology Community

- Member of the Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology (CCQM)
  - Inorganic Analysis Working Group
  - Organic Analysis Working Group
  - Protein Analysis Working Group

- Member of Asia Pacific Metrology Programme (APMP)
  - Technical Committee for Amount of Substance
  - Technical Committee on Quality Systems

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Participation in CCQM/RMO Comparisons

Comparisons related to clinical measurements:

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

HSA will be organising two CCQM comparisons related to clinical measurements:

- CCQM-K109 & CCQM-P148: High polarity analytes in biological matrix: determination of urea and uric acid in human serum (samples will be dispatched in February 2016)
- CCQM-K139 & CCQM-P173: Elements in human serum (planned for 2017)

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Involvement in JCTLM

- 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
- Two Certified Reference Materials (CRMs) are listed in JCTLM reference material database.
- Participated in RELA:
  - RELA 2010 for Creatinine (related to EURAMET.QM-K12)
  - RELA 2013 for HbA1c
  - RELA 2014 for HbA1c

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Healthcare-Related Metrological Services – CRMs

CRMs available:

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

CRMs under development:

- HbA1c in human blood
- HDL-Cholesterol and LDL-Cholesterol in human serum

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Healthcare-Related Metrological Services – External Quality Assessment (EQA) Programme

- HSA organises an accuracy-based EQA programme for the local clinical laboratories since 2011.
- The main objective of the programme is to provide metrologically traceable assigned values to evaluate the results of the participating clinical laboratories.
- The programme focuses on key biomarkers of chronic disorders.
- All assigned (target) values are independently determined by HSA using high accuracy methods (IDMS or standard addition methods)
- The assigned values are traceable to the SI, each being accompanied by a measurement uncertainty.

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Analytes in HSA EQA Programme

Year of EQA Programme	Creatinine	Glucose	Total Cholesterol	Triglycerides	Urea	Uric Acid	Calcium	Potassium	Sodium	Magnesium	Iron	HbA1c	Chloride	HDL-Cholesterol	LDL-Cholesterol	Total
2011	√	√	√													3
2012	√	√	√	√	√	√	√	√	√							9
2013	√	√	√	√	√	√	√	√	√	√	√	√				12
2014	√	√	√	√	√	√	√	√	√	√	√	√	√			13
2015	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	15

New analytes planned for 2016 HSA EQA Programme:

Urine albumin and creatinine

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Healthcare-Related R&D Activities

Publications related to clinical measurements:

(1) High accuracy analysis of glucose in human serum by isotope dilution liquid chromatography-tandem mass spectrometry, *Clin Chim 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, *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, *Clin Chim Acta*, **428**, 2014, 20-25.

(4) Improved reference measurement method for hemoglobin A1c by use of liquid chromatography–isotope dilution–tandem mass spectrometry, *Clin Chem*, **61**, 2015, 435-436.

(5) Developing a reference measurement procedure for free glycerol in human serum by two-step gas chromatography–isotope dilution mass spectrometry, *Clin Biochem*, **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, *Anal Bioanal Chem*, **407**, 2015, 7579-7587.

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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

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

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

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

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Future Plan

- Developing new measurement capabilities:
  - Steroid hormones in human serum
  - Human growth hormones in serum
  - Albumin in human serum/urine
  - Purity assessment of peptides/proteins
- Expanding the scope of metrological services to local clinical laboratories.

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Thank you

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