Joint Committee for Traceability in Laboratory Medicine

JCTLM Report for 2017

CCQM Meeting, 19-20 April 2018
Outline

1. Status of JCTLM Membership
2. Database WG review activity
   Materials, methods & services nominations
3. TEP WG progress report
   Traceability Education & Promotion
JCTLM Membership

JCTLM Member designations

Executive Committee Member Organizations
BIPM, IFCC, ILAC

Executive Committee
(Meets once per year)
Attended By:
Representatives of Executive Comm.
Member Organizations and WG and Task Force Chairs

National and Regional Members
Organizations that Adhere to and/or contribute to the activities of EC Member

Stakeholder Members
Properly constituted “non-profit” and “for-profit” organizations working to reduce the between method variability in laboratory medicine measurement
New organizations approved:

1. Canadian Society of Clinical Chemists / Société Canadienne de Clinico-Chimistes (CSCC/SCCC)
2. All-Russian Scientific Research Institute for Metrological Service, (VNIIMS)
3. All-Russian Scientific Research Institute for Optical and Physical Measurements, Rosstandart (VNIIOFI)
4. D.I. Mendeleyev Institute for Metrology (VNIIM)
JCTLM Membership

New organizations approved:
1. Maccura Biotechnology Co., Ltd., China
2. MedicalSystem Biotechnology Co., Ltd, China
3. Fujirebio Europe NV, Belgium
4. Bio-Rad Laboratories, United States
5. Roche Diagnostics, United States
6. Siemens Healthcare Diagnostics, United States
7. Institute for Quality Management in Healthcare, Centre for Proficiency Testing, Canada
8. Shanghai Center for Clinical Laboratory (SCCL), China
9. UK National External Quality Assessment Scheme for Leucocyte Immunophenotyping (UK NEQAS LI)
10. Vitamin D External Quality Assessment Scheme (DEQAS), UK
11. Birmingham Quality / UK National External Quality Assessment Scheme (BQ / UK NEQAS)
12. National Center for Clinical laboratories (NCCL), China
13. Association for Quality Management in Laboratory Medicine (AQMLM)
14. R B Diagnostic Private Limited (RBDiagnostic), India
JCTLM Membership

54 JCTLM Members (April 2018)

- National Accreditation Body
- National Laboratory Medicine Society
- NMI
- EQAS provider
- IVD Manufacturer
- National & Regional organization
- Other
- Private Laboratory Organization
- Writing standards body
Global reach of JCTLM Membership

19 countries

Number of Members

<table>
<thead>
<tr>
<th>Country</th>
<th>Members</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>1</td>
</tr>
<tr>
<td>Australia</td>
<td>2</td>
</tr>
<tr>
<td>Belgium</td>
<td>3</td>
</tr>
<tr>
<td>Canada</td>
<td>2</td>
</tr>
<tr>
<td>China</td>
<td>8</td>
</tr>
<tr>
<td>Colombia</td>
<td>1</td>
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<tr>
<td>France</td>
<td>1</td>
</tr>
<tr>
<td>Germany</td>
<td>6</td>
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<tr>
<td>India</td>
<td>1</td>
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<tr>
<td>Italy</td>
<td>1</td>
</tr>
<tr>
<td>Japan</td>
<td>4</td>
</tr>
<tr>
<td>Korea</td>
<td>4</td>
</tr>
<tr>
<td>Netherlands</td>
<td>3</td>
</tr>
<tr>
<td>Russian Federation</td>
<td>3</td>
</tr>
<tr>
<td>Singapore</td>
<td>1</td>
</tr>
<tr>
<td>Switzerland</td>
<td>1</td>
</tr>
<tr>
<td>Turkey</td>
<td>1</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>7</td>
</tr>
<tr>
<td>United States</td>
<td>8</td>
</tr>
</tbody>
</table>
JCTLM Membership

Progress in expanding JCTLM Executive Member organizations to include other disciplines in laboratory medicine

- Engaged discussion with the International Council for Standardization in Haematology (ICSH)

- ICSH/JCTLM Meeting planned in May 2018 at BIPM to discuss technical issues in the field
### 2017 JCTLM New nominations

Cycle 14 (Materials & Methods) and Cycle 12 (Services)

<table>
<thead>
<tr>
<th>Analyte category</th>
<th>Materials # submissions in 2017</th>
<th>Methods # submissions in 2017</th>
<th>Services # submissions in 2017</th>
<th>All # submissions in 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs</td>
<td>1</td>
<td>1</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Electrolytes</td>
<td>18</td>
<td>5</td>
<td>3</td>
<td>26</td>
</tr>
<tr>
<td>Enzymes</td>
<td>7</td>
<td></td>
<td>14</td>
<td>21</td>
</tr>
<tr>
<td>Metabolites &amp; Substrates</td>
<td>10</td>
<td>2</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>Non-Peptide Hormones</td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Non-electrolyte Metals</td>
<td></td>
<td></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Proteins</td>
<td>7</td>
<td>2</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Vitamins</td>
<td>2</td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td><strong>Total:</strong></td>
<td><strong>8</strong></td>
<td><strong>46</strong></td>
<td><strong>11</strong></td>
<td><strong>79</strong></td>
</tr>
</tbody>
</table>
2018 JCTLM Database Publication

+ 3 CRMs
LGC (UK) : Tacrolimus
UME (TR): 25-hydroxyVitamin D2 & D3 /serum

296 CRMs in the database
12 producers including 11 NMIs/DIs

95 % CRMs listed from NMIs/DIs
2018 JCTLM Database Publication

+ 8 RMPs

Roche Diagnostics, Germany
An LC-MS/MS based candidate reference method for the quantification of carbamazepine in human serum

RMIT University, Australia
Quantitation of sweat chloride by ICP-MS.

National Center for Clinical laboratories (NCCL), China
ICP-MS reference measurement procedures for serum Calcium, Potassium, Magnesium, and Sodium in serum

CDC, US
Evaluation of an isotope dilution HPLC tandem mass spectrometry candidate reference measurement procedure for total 17-β Estradiol in human

NMIA, Australia
Accurate analysis of Testosterone in human serum using a heart-cutting 2D-UPLC MS/MS procedure
2018 JCTLM Database Publication

Distribution of methods by organizations

194 RMPs in the database
## 2018 JCTLM Database Publication

Cycle 14 (Materials & Methods) and Cycle 12 (Services)

+ 15 reference measurement services

<table>
<thead>
<tr>
<th>Analyte Category</th>
<th>Analyte</th>
<th>Location of Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrolytes</td>
<td>Potassium</td>
<td>China</td>
</tr>
<tr>
<td></td>
<td>Magnesium</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Calcium</td>
<td></td>
</tr>
<tr>
<td>Enzymes</td>
<td>Alanine aminotransferase (ALT)</td>
<td>China</td>
</tr>
<tr>
<td></td>
<td>Aspartate aminotransferase (AST)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Creatine kinase (CK)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lactate dehydrogenase (LDH)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gamma-glutamyltransferase (GGT)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alpha-amylase</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alkaline phosphatase (ALP)</td>
<td></td>
</tr>
<tr>
<td>Metabolites and substrates</td>
<td>Creatinine</td>
<td>China</td>
</tr>
<tr>
<td></td>
<td>Uric acid</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Glucose</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bilirubin (total)</td>
<td></td>
</tr>
<tr>
<td>Proteins</td>
<td>HbA1c</td>
<td>China</td>
</tr>
</tbody>
</table>
2018 JCTLM Database Publication

176 reference measurement services in the database

18 services providers including 2 NMIs

Distribution RMS providers by country of origin:
- China: 39%
- Germany: 36%
- Japan: 2%
- Belgium: 5%
- France: 3%
- United Kingdom: 7%
- Spain: 4%
- Italy: 4%
2018 JCTLM Database WG review outcomes

1. Large number of nominations for RMs and RMPs rejected
   Need to provide adequate guidance/training to the JCTLM stakeholders with regards to the ISO 15194 and 15193 for clarifying key requirements and how to implement certain concepts such as commutability study, method validation, extent of equivalence demonstration.

   • DB WG’s session will be held at the next PPTD-2018 conference in Chengdu
     - ISO 15194 (K. Phinney, NIST)
     - ISO 15193 (A. Kessler, RfB)
     - ISO 15195 (M. Pantheghini, CIRME)

   • Suitable examples for CRM and RMP nominations will be developed

2. Large number of submissions
   Review team Leaders requested additional experts to help for the review
Other issues raised

1. **possibility to produce the documentation partly or fully in English?**
   Certified Reference Material Certificates and Certification Reports
   JCTLM will conduct an opinion survey amongst NMIs having CRM listed in the JCTLM Database

2. **possibility to streamline the nomination process?**

   2.1 Nomination of replacement materials
   JCTLM will conduct a survey among NMIs with CRMs in the JCTLM Database in compliance with ISO 17034/ISO 15194 in order to identify critical criteria for renewing batches of the certified reference materials that would be produced under the same procedures.

   2.2 Nomination of materials listed in KCDB
   JCTLM will conduct a comparison study of the CIPM MRA review process against the JCTLM review acceptance criteria
JCTLM TEP WG Report

Organizes the JCTLM Members & Stakeholders Meeting

‘Accurate Results for Patient Care Workshop 2017’
4-5 December 2017, BIPM
117 participants from 27 countries
Medical researchers; NMI; EQAS, Laboratory medicine specialists,
Organizes the JCTLM Members & Stakeholders Meeting

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Day 1 - Traceability in Action
• Update from JCTLM
• Why traceability matters to patients
• Traceability in external quality assessment
• Why traceability matters to manufacturers

Day 2 - Traceability into the future
• Clinical challenge - biomarkers in neurodegenerative disease
• Developments in traceability in infectious diseases
• Recent advances in traceability - a global perspective
• Responding to the future of traceability
Organised sessions on traceability at conferences

15 sessions
14 countries
Maintains Website – www.jctlm.org

- Extensive and growing list of resources:
- All resources are freely available for use
- Regular news updates
- Forms to apply for JCTLM membership and JCTLM auspices
- Direct access to JCTLM database
1. Glossary of terms and definitions
   14 terms with Everyday easy to understand definitions and a formal definition (VIM 3 source)

2. Webinars of scientific concepts
   1. Basics of traceability applied to laboratory medicine. Anja Kessler (RfB).
   4. Examples of reference measurement procedures Jeanita Pritchett (NIST).
   8. The pillars of standardization. Elvar Theodorsson (Eurachem).
   10. All results are made and interpreted by comparison. Elvar Theodorsson (Eurachem).

3. Webinars produced to assist trainees in laboratory medicine.
4. Review article on Global Significance of TML
published in Clin Chem Lab Med with permission to translate into other languages and submit to national journals

DE GROOTHER

Opinion Paper

Graham H. Beastall*, Nannette Brouwer, Silvia Quiroga and Gary L. Myers, prepared on behalf of the Joint Committee for Traceability in Laboratory Medicine

**Traceability in laboratory medicine: a global driver for accurate results for patient care**

DOI 10.1515/cclm-2017-0060
Received January 20, 2017; accepted March 15, 2017

**Keywords:** action plan; commutability; standardization; traceability.
5. Library of scientific publications
   • ~100 References for publications both general and analyte specific
   • Other references:
     ISO references; Publications from JCTLM

6. Annual JCTLM Newsletter
JCTLM Announcements

Call for materials, methods and services nominations
Closing date 30 May 2018

Future meetings under JCTLM Auspices

10 - 12 October 2018
Protein and Peptide Therapeutics and Diagnostics Workshop (PPTD-2018), Chengdu (China), Workshop website: http://pptd.ncrm.org.cn/

29 November 2018  “Every day is patient safety day",
12th International Scientific Meeting of the Centre of Metrological Traceability in Laboratory Medicine (CIRME) Milan (Italy), Programme of the meeting

Future JCTLM Members’ and Stakeholders meeting
2 - 3 December 2019, BIPM