

The JCTLM had a busy and productive year in 2017 with an important increase in the membership, and a successful Members and Stakeholders Meeting in December 2017. We are also pleased to report on new entries in the JCTLM database resulting from the 2017 review cycle; highlights from the 2017 Executive meetings; the activity of the Traceability, Education and Promotion WG; the announcement of the 2018 call for materials, methods and services nominations, and plans for 2018 JCTLM Meetings.

1 Report on the 'Accurate Results for Patient Care Workshop 2017'

A 'full house' of 117 delegates from 27 countries attended the biennial meeting of the Joint Committee for Traceability in Laboratory Medicine (JCTLM), which was held on 4-5 December 2017 at the Bureau International des Poids et Mesures (BIPM).

The two-day programme for the meeting included presentations and informed discussion on:

- Why traceability matters to patients
- Traceability in external quality assessment
- Traceability and the IVD industry: the manufacturers role
- Traceability in the investigation of infectious diseases
- Traceability: a global perspective
- JCTLM update

The final element of the programme focused on the clinical challenge of neurodegenerative disease with contributions on the requirements for and development of high-quality biomarker assays for the investigation of Alzheimer's disease, Parkinson's disease and other debilitating conditions. The presentations from the workshop are available to download.

An evaluation of the workshop by its participants revealed a high level of satisfaction with the programme and its relevance to current practice. The inclusion of posters was praised and there was a special mention for the excellent catering provided by the BIPM.

There is growing recognition of the importance of metrological traceability as a driver for accurate results for patient care through facilitating reduced between-method variability in laboratory medicine. Medical researchers; national metrology institutes; manufacturers of in vitro diagnostic systems; and laboratory medicine specialists are equal partners in delivering improved clinical laboratory methods and all were well represented at the workshop.

Plans are being developed for the next workshop in December 2019 and ideas for programme content are invited – contact jctlm@bipm.org



2 Commutability explained

Commutability is an essential property of a certified reference material (CRM) when it is used as a calibrator in the calibration hierarchy of an *in vitro* diagnostics medical device (IVD-MD) as described in ISO 17511. The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Working Group on Commutability (WGC) recently published recommendations for assessing commutability of reference materials. An overview of the recommendations from the IFCC WGC is presented in this edition of the Newsletter and should be of interest to all parties involved in laboratory medicine and clinical chemistry: clinical laboratory specialists, IVD industry, reference material providers, and EQA organizations. Download the [Special report on commutability of certified reference materials](#), by G. Miller and N. Greenberg, April 2018, 3 pp.

3 New entries in the JCTLM database

The JCTLM review process conducted in 2017 resulted in four new entries in the JCTLM Database for available higher-order certified reference materials, as well as eight new published reference measurement methods and 15 new measurement services delivered by reference laboratories. The new entries are listed below. The JCTLM Database can be found at : www.bipm.org/jctlm/

New entries for available Certified Reference Materials

Analyte Category	Analyte*	Material / Matrix
Drugs	Tacrolimus	High-purity material
Metabolites and substrates	L-Arginine	High-purity material
Vitamins and micronutrients	25-Hydroxyvitamin D₂ 25-Hydroxyvitamin D₃	Lyophilized serum

*Complete information for each certified reference Material entry can be retrieved by clicking on the Analyte name.

New entries for Reference Measurement Methods

Analyte Category	Reference Measurement Method (<i>JCTLM Identification Number</i>)
Drugs	An LC-MS/MS based candidate reference method for the quantification of Carbamazepine in human serum (JCTLM C14RMP5). Taibon J. et al, <i>Clin. Chim. Acta</i> , 2017, 475 , 35-40
Non-peptide hormones	Evaluation of an isotope dilution HPLC tandem mass spectrometry candidate reference measurement procedure for total 17-β Estradiol in human serum (JCTLM C12RMP4R) Botelho J.C. et al., <i>Anal. Chem.</i> , 2016, 88 (22), 11123-11129
Non-peptide hormones	Accurate analysis of Testosterone in human serum using a heart-cutting 2D-UPLC MS/MS procedure (JCTLM C13RMP6). Vamathevan V. et al., <i>J. Chromatogr. B</i> , 2016, 1038 , 49-56
Electrolytes	A candidate reference method using ICP-MS for sweat Chloride quantification (JCTLM C13RMP3R). Collie J. et al., <i>Clin. Chem. Lab. Med.</i> , 2015, 54 (4), 561-567
Electrolytes	A candidate reference method for serum Calcium measurement by inductively coupled plasma mass spectrometry (JCTLM C14RMP6). Yan Y. et al., <i>Clin. Chim. Acta</i> , 2016, 461 , 141-145
Electrolytes	A candidate reference method for serum Potassium measurement by inductively coupled plasma mass spectrometry (JCTLM C14RMP7) Yan Y. et al., <i>Clin. Chem. Lab. Med.</i> , 2017, 55 (10), 1517-1522
Electrolytes	Measurement of serum Sodium and Magnesium by inductively coupled plasma mass spectrometry with aluminum as internal standard, (JCTLM C14RMP8 for Magnesium, for C14RMP9 Sodium). Yan Y. et al., <i>Clin. Lab.</i> , 2016, 62 , 719-725

Complete information for each method entry can be retrieved by clicking on the JCTLM identification number.

New entries for Reference Measurement Laboratory Services

Analyte Category	Analyte	Location of Laboratory
Electrolytes	Potassium, Magnesium, Calcium	China
Enzymes	Alanine aminotransferase (ALT) Aspartate aminotransferase (AST) Creatine kinase (CK) Lactate dehydrogenase (LDH) Gamma-glutamyltransferase (GGT) Alpha-amylase Alkaline phosphatase (ALP)	China
Metabolites and Substrates	Creatinine, Uric acid, Glucose, Bilirubin (total)	China
Proteins	HbA1c	China

Complete information for each entry can be retrieved from the [Analyte keyword search results](#) for the reference measurement services.

4 JCTLM Members' activity reports 2017

The JCTLM convenes a meeting of members and stakeholders once every two years at the BIPM in Sèvres, France. The most recent meeting was held on 4-5 December 2017. Participation in the JCTLM enables organizations, which are authorities in their fields of professional and technical competence, to express the views of their members and to play an appropriate role in providing a world-wide platform to promote and give guidance on the importance of traceability in laboratory medicine. All members of the JCTLM are invited to attend the Members and Stakeholders Meeting and submit a report of their activities in support of traceability in laboratory medicine during the past two years and plans for the next two years.

In response to the call for activity reports for the 2017 Members and Stakeholders meeting 28 organizations submitted reports to the JCTLM Executive Committee. This represented 60% of the JCTLM members at the time of the meeting. Specific organizations submitting activity reports included the following members:

National and Regional Members:

- American Association for Clinical Chemistry (AACC)
- China Accreditation Service for Conformity Assessment (CNAS)
- Health Sciences Authority, Singapore (HSA)
- Korean Society of Clinical Chemistry (KSCC)
- National Institute of Metrology, China (NIM)
- National Metrology Institute of Japan (NMIJ/AIST)
- Physikalisch-Technische-Bundesanstalt (PTB)
- National Metrology Institute of Turkey (TUBITAK -UME)

Stakeholder Members:

- Beijing Aerospace General Hospital
- Research Centre for Metrological Traceability in Laboratory Medicine (CIRME)
- ECAT Foundation
- European Organisation For External Quality Assurance Providers in Laboratory Medicine (EQALM)
- Guangdong Provincial Hospital of Chinese Medicine
- Institution for Standardisation and Documentation in the Medical Laboratory (INSTAND e.V.)
- Japan Association of Clinical Reagents Industries (JACRI)
- Japanese Committee for Clinical Laboratory Standards (JCCLS)

- Korean Association of External Quality Assessment Services (KEQAS)
- Maccura Biotechnology Co., LTD
- Medical System Biotechnology Co., LTD
- Paul-Ehrlich-Institute
- Buenos Aires External Quality Assessment Scheme [ProgBA]
- Quik S.A.S
- R B Diagnostic Private Limited
- Ref4U – Laboratory for Toxicology - Ghent University
- Reference Institute for Bioanalytics (RfB)
- Shanghai Center for Clinical laboratory (SCCL)
- Siemens Healthcare Diagnostics
- Wales External Quality and Assessment Scheme (Weqas), UK

Most members reported on activities to develop reference materials and/or reference measurement procedures. A copy of each member's activity report is available to [download](#).

The activities of two members are mentioned here to highlight activities and to promote traceability in laboratory medicine.

The AACC has been working to educate the US Congress on the importance of harmonization and traceability of test results to improve patient care. A major thrust of this effort has been to push for increased federal funding for the Centers for Disease Control and Prevention's Clinical Chemistry Standardization Branch so that it has sufficient resources to fully engage in the development of needed reference measurement procedures, which will serve as the basis for its global standardization efforts to improve the comparability of laboratory test results.

Quik S.A.S. Colombia has developed a tool (app) in Excel for smartphones that use Apple and Android platforms. The app has been created to allow the checking of metrological traceability in clinical laboratories, as well as checking information on the reference material, the methods of reference and the reference laboratories implicated in the metrological traceability. Laboratories can access the analytes and see, for example, the reference material approved by the JCTLM.

The JCTLM Executive Committee thanks its members for submitting reports of their important activities that continue to advance traceability in laboratory medicine. We encourage our readers to review the reports posted on the [JCTLM Members' webpage](#).

5 Survey of member support services

The number of JCTLM Member organizations increased substantially during 2017. We were pleased to welcome new members from the *in vitro* diagnostic industry, from EQA provider organizations and from regional / national professional societies. This shift towards the user end of the traceability chain is a positive move.

With an increasing and varied membership, the time is right to conduct a survey of member support services. We want to know what services you value, how they may be improved, and what new services you would like to see introduced. Accordingly, we have produced a short online survey that will take about five minutes to complete. The survey is being distributed together with this newsletter. It may also be accessed directly at: <https://www.surveymonkey.com/r/JCTLMservices>.

Your input is requested to improve the support that JCTLM offers its members. Please respond by Monday 14 May 2018.

6 Traceability, Education & Promotion (TEP): What has been achieved?

In the 2017 JCTLM Newsletter we announced the launch of a new portal for information and free educational support materials to help with the understanding and promotion of traceability in laboratory medicine. What has been achieved in the last year?

Website:

The www.jctlm.org website is widely viewed, with >10,000 visits since its launch.

News:

Regular news updates appear on www.jctlm.org. They appear on the home page before being archived in the Latest News section. News items include the latest publications; new resource materials; information about meetings; and other developments in the world of improving the quality of laboratory medicine methods.

Publications:

A library of relevant publications is held in the Publications section of www.jctlm.org. The library is updated as new publications appear. Wherever possible a direct link is provided to the relevant publication. The JCTLM is keen to receive information about relevant publications that may be added to the library – contact jctlm@bipm.org with suggestions.

Resources:

A series of ten webinars have been produced by the TEP team. These address all aspects of traceability in laboratory medicine. The webinars are archived on the IFCC e-academy and are available for viewing free of charge. Information on the webinars

may be found in the Resources section of www.jctlm.org. These webinars have been translated into Spanish and information on their archiving will be available shortly. A glossary of terms used in traceability, together with every day explanations is also available on this section of the website.

Meetings:

During the past two years 15 meetings, symposia and individual lectures on traceability in laboratory medicine have been held in 15 different countries. The presentations from some of these are available on the Meetings section of www.jctlm.org. Several of these sessions were held under the auspices of the JCTLM. Details of how to organize a session under the umbrella of the JCTLM can be found at the bottom of the Meetings section of www.jctlm.org. The last JCTLM Members and Stakeholders meeting was held in December 2017 and a report appears elsewhere in this newsletter.

Citations about traceability:

During 2017 the number of Google Scholar citations about traceability in laboratory medicine exceeded 300 for the first time, in 13 different languages.

The future:

- A project has been launched to refresh the www.jctlm.org home page
- The importance of traceability and EQA is being developed
- Efforts are being made to promote traceability in laboratory medicine as part of the curricula for postgraduate training in laboratory medicine.

7 Current call for nominations for materials, methods and services

Every year the JCTLM launches a call for nominations within its Framework for the identification and international recognition of available higher-order reference materials, reference measurement procedures and reference measurement laboratories for laboratory medicine.

All interested parties, including producers of materials, authors of method publications, and calibration laboratories that provide reference measurement services are invited to submit nominations for possible inclusion in the [JCTLM database](#).

Nominations are being solicited for the following categories of measurand: [drugs](#), [metabolites and substrates](#); [non-peptide hormones](#); [blood cell counting and typing](#); [coagulation factors](#); [enzymes](#); [infectious diseases](#); [nucleic acids](#); [proteins](#); [electrolytes and blood gases](#); [non-electrolyte metals](#); and [vitamins and micronutrients](#).

Nominations should be made by 30 May 2018 using the [procedures and forms available on the website](#).

8 Future meetings

Meetings held under the auspices of the JCTLM

- 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: 12th International Scientific Meeting of the Centre of Metrological Traceability in Laboratory Medicine (CIRME) "Every day is patient safety day", Milan (Italy). See [Meeting programme](#)

Future JCTLM meetings

- 5 December 2018: JCTLM Database Working Group meeting, BIPM, Sèvres
- 6-7 December 2018: 20th meeting of the JCTLM Executive Committee, BIPM, Sèvres
- 2-3 December 2019: JCTLM Members and Stakeholders Meeting, BIPM, Sèvres

9 Highlights from 2017 JCTLM Executive Meetings

The 18th and 19th meetings of the Executive Committee of the JCTLM took place under the Chairmanship of Dr Gary Myers in Athens (Greece) on 11 June 2017 and at the BIPM on 6-7 December 2017. The reports of the meetings are available to download from the [JCTLM webpages](#).



Changes in the JCTLM Executive representatives

Dr Anja Kessler (RfB) was appointed as the new representative from the IFCC to the JCTLM Executive Committee in June 2017, replacing Prof. Siekmann

Ms Regina Robertson (National Association of Testing Authorities) informed the Executive Committee that she will no longer serve as one of the two ILAC liaisons to the JCTLM Executive. The Committee warmly thanked Ms Robertson for her important contributions to the JCTLM and support over the years. Ms Martina Bednarova (Czech Accreditation Institute) was appointed in December 2017 to replace her.

Changes in the JCTLM Database WG leadership

Dr Heinz Schimmel (JRC) resigned in September 2017 from his JCTLM positions as vice-Chair of the Database WG for Analyte Group 2, and leader of the JCTLM Review Teams for Non-Peptide Hormones and Proteins. The Committee thanked Dr Schimmel for his important contribution as one of the founding members of the JCTLM WG, and for his continued participation as a leader and member of the JCTLM Review Teams.

The Executive appointed Prof. Mauro Pantheghini (CIRME, Italy) as new vice-Chair of the Database WG responsible for AG2 composed of the Coagulation Factors, Enzymes, Proteins, Nucleic Acid, Infectious diseases, Blood Grouping and Cell typing, and Blood cell counting Review teams. Dr Quinde Liu (HSA) was appointed as the new lead of the Non-Peptide Hormones review team, and Dr Milena Quaglia (LGC) as the new lead of the Protein review team.

JCTLM Quality Manual Modifications

The JCTLM process requires nominators of methods to provide extent-of-equivalence information in order to comply with the method validation requirements of ISO 15193. This process is documented in the procedure JCTLM DBWG P04B which was modified to clarify the case where two methods showed different measurement results.

See [JCTLM DBWG P04B](#), Multiple reference method/procedure comparison process.

New JCTLM Member Organizations

The Committee welcomed eighteen new JCTLM Members as follows:

Regional and National Membership

- Canadian Society of Clinical Chemists / Soci t  Canadienne de Clinico-Chimistes [CSCC/SCCC)
- All-Russian Scientific Research Institute for Metrological Service, (VNIIMS)
- All-Russian Scientific Research Institute for Optical and Physical Measurements, Rosstandart (VNIIOFI)
- D.I. Mendeleev Institute for Metrology (VNIIM).

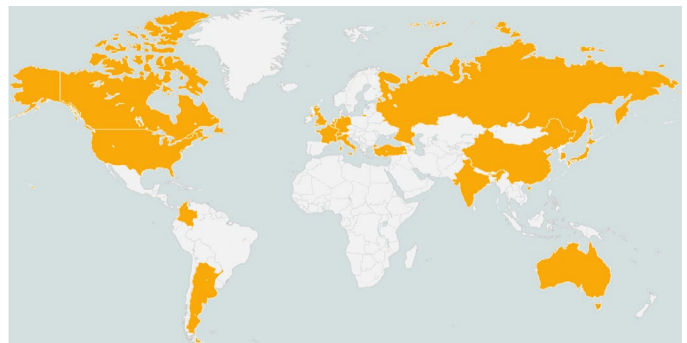
Stakeholder Membership

- Association for Quality Management in Laboratory Medicine (AQMLM), UK
- Birmingham Quality/UK National External Quality Assessment Scheme (BQ /UK NEQAS)
- Bio-Rad Laboratories, United States
- Fujirebio Europe NV, Belgium
- Institute for Quality Management in Healthcare, Centre for Proficiency Testing (IQMH), Canada
- Maccura Biotechnology Co., Ltd., China
- MedicalSystem Biotechnology Co., Ltd., China
- National Center for Clinical laboratories (NCCL), China
- R B Diagnostic Private Limited, India
- Roche Diagnostics, United States
- Shanghai Center for Clinical Laboratory (SCCL), China

- Siemens Healthcare Diagnostics (Siemens DX), United States
- UK National External Quality Assessment Scheme for Leucocyte Immunophenotyping (UK NEQAS LI)
- Vitamin D External Quality Assessment Scheme (DEQAS), UK

See the full list of [JCTLM Member organizations](#)

To apply for membership of the JCTLM click here: [How to join](#)



World-wide reach of the JCTLM Membership continued to grow in 2017