JCTLM
Accurate results for patient care

Database Newsletter

https://www.jctlmdb.org

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In this issue we report on highlights from the last Executive meeting; new entries in the database; the activities of the Task Force on Reference Measurement System Implementation, Working Group for Traceability, Education and Promotion, and Task Force on Knowledge transfer; and JCTLM meetings in 2025. We also welcome the new JCTLM Chair.

The BIPM celebrates 150 years since the signing of the Metre Convention

The year 2025 marks the 150th Anniversary of the signing of the Metre Convention. This led to the establishment of the International Bureau of Weights and Measures (BIPM), the international organization through which Member States work together on matters related to metrology. The BIPM is the home of the International System of Units (SI) and the international reference time scale (UTC) and it works with Members States' National Metrology Institutes (NMIs), Regional Metrology Organizations (RMOs) and strategic partners world-wide to promote and advance the global comparability and traceability of measurements.

The 150th Anniversary will be celebrated from 20-22 May 2025 in Paris and Versailles. For further details follow this link

https://www.bipm.org/en/-/2024-07-24-save-the-date

BIPM 150
1875 – 2025

The BIPM is one of the founding members of the Joint Committee for Traceability in Laboratory Medicine (JCTLM), which was established in 2002 through a declaration of cooperation with the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), and the International Laboratory Accreditation Cooperation (ILAC) in response to the implementation of the European Community Directive 98.79/EC on *in vitro* medical devices. The JCTLM now includes the International Council for Standardization in Haematology (ICSH) as an Executive Committee Member Organization.

The aim of JCTLM is to support world-wide equivalence and comparability of measurement results in laboratory medicine, for the purpose of improving health care, and facilitating national and international trade in *in vitro* diagnostic (IVD) medical devices.

To mark the 150th Anniversary of the signing of the Metre Convention, a Special Report on the successes and challenges delivering higher order references for laboratory medicine has been produced.

Download the JCTLM Special Report 2025

New Chair of the JCTLM Appointed

Prof. Mauro Panteghini was elected as the Chair of the Joint Committee for Traceability in Laboratory Medicine (JCTLM) by its Executive Committee during the JCTLM Annual Meeting held on 4 December 2024. The appointment acknowledges his long-standing contributions to the field of standardization in laboratory medicine and the work of the JCTLM. Prof. Panteghini succeeds Dr Greg Miller, whose four-year tenure concluded at the end of 2024.

Under Dr Miller's leadership, the JCTLM achieved significant milestones, including the development of new committee websites, the introduction of a machine-readable database, and the successful hosting of a stakeholder meeting that addressed critical challenges and outlined the committee's future direction. As the JCTLM welcomes Prof. Panteghini, the Executive Committee also expresses its deepest gratitude to Dr Miller for his invaluable service and dedication.

Prof. Panteghini (left) and Dr Miller (right)

Dynamic updates in the JCTLM Database: Keeping pace with innovation

Author: Anja Keßler, RfB SPMD, Germany

The JCTLM database is designed to support the introduction of reference systems and to represent transparently the current state-of-the-art for all listed components, including certified reference materials (CRM), reference measurement procedures (RMP), reference measurement services (RMS). To fulfill its purpose, the database must be publicly accessible and up to date. This ensures that parties interested in establishing traceable values for calibration materials and control materials can find laboratories offering suitable services.

How do we guarantee that the database remains up to date? The system is dynamic, and changes to the listed procedures must be reflected accordingly. Support from the laboratories responsible for the entries is required for this. For example, if the measurement principle of a system has changed from gas chromatography-mass spectrometry (GC-MS) to liquid chromatography- mass spectrometry (LC-MS), or if modifications need to be made to a method published by colleagues, these changes have to be reported.

What constitutes a relevant change and how can these changes be reported? Any changes in the procedures used should be reported to keep the information current and to maintain the database service at the highest level in the long term. Reference measurement service providers should inform the JCTLM when they use a procedure that is different from the one originally submitted and resubmit their entry if major changes have been made to the procedure.

The JCTLM Executive Committee has agreed that changes will be evaluated using a risk-based analysis of their impact. Additionally, the JCTLM will assist the community in identifying journals that are open to publishing modified reference measurement procedures as reported in the next article.

JCTLM Members' and Stakeholders' meeting and Workshop on 'Result harmonization in medical laboratories: accomplishments and challenges'

The JCTLM Members and Stakeholders Meeting and Workshop for 2025 will be held on 1-2 December at the BIPM headquarters. The theme of this year's meeting is 'Result harmonization in medical laboratories: accomplishments and challenges' and will focus on the importance of result harmonization and progress in this area.

The biennial meeting of the Members and Stakeholders will start with a JCTLM update, followed by the Workshop.

There will be fifteen presentations with five discussion sessions to ensure maximum input from the audience and to allow learning opportunities.

Key topics to be presented are:

- Patients' expectations of laboratory results
- Realizing the benefits of metrological traceability
- Why doesn't harmonization always work
- Reference Materials, Procedures and Services
- The role of professional bodies: IFCC projects with an immediate effect on clinical practice
- The role of EQA providers and the challenges for IVD manufacturers in meeting different regulatory requirements for traceability in the international market
- The Comet project
- Challenges in maintaining and adopting new standards.

CLICK HERE FOR THE AGENDA AND REGISTRATION FORM

2025 Call for nominations for materials, methods and services

The JCTLM invites producers of materials, authors of method publications, and calibration laboratories that provide reference measurement services in laboratory medicine to submit nominations for review and possible inclusion in the JCTLM database.

Submissions should be sent to jctlm(a)bipm.org no later than 31 May 2025 using the procedures and form available at:

DATABASE SUBMISSIONS

Call for nominations for JCTLM Review Team experts

The JCTLM maintains a database of available certified reference materials, reference measurement methods and services that relate to the *in vitro* diagnostic area (www.jctlmdb.org). This database relies on the important contributions from individuals/experts who volunteered to participate in the activity of the JCTLM Review Teams, and in identifying and evaluating nominations against agreed criteria.

The JCTLM is seeking additional experts to contribute to the review teams for: blood cell counting; drugs; enzymes; haemostasis; non-peptide hormones; proteins; and vitamins. These additional experts are required to help with the increasing number of nominations that are submitted in these measurement fields.

Submissions via the nomination/application form (DBWG-P-06-F-01) for JCTLM Review Team Membership can be made at any time to the JCTLM Secretariat (jctlm(a)bipm.org).

JCTLM Task Force on Reference Measurement System Implementation (TF-RMSI) report

Mauro Panteghini, TF-RMSI Chair

To aid IVD manufacturers in meeting ISO 17511:2020* requirements the identification of available reference measurement systems by exploiting all the traceability hierarchy components may be very helpful. In 2019, the JCTLM created the TF-RMSI, aiming to integrate the information historically provided in its database and to provide practical guidance on metrological traceability implementation to the IVD community. The TF-RMSI proposed a procedural approach combining a critical review of what is available in the JCTLM database with a comparison of this information against analytical performance specifications for measurement uncertainty (MU) [1].

Published results offered an overview of where we are and what is still missing in the practical application of the metrological traceability concept for 30 common biochemical tests employed in laboratory medicine [2,3]. In particular, the analysis showed that for 28 out of 30 measurands, conditions exist to correctly implement metrological traceability to the SI and fulfil at least the maximum allowable MU of minimum quality level. For two measurands (serum albumin and serum chloride) further improvements in the performance of high-order references would be necessary. The TF-RMSI work has shown for the first time the important practical impact and the value added by the information provided by the JCTLM through its database, which therefore represents a suitable practical tool on which the IVD manufacturers should rely on to fulfil the requirements for implementation of metrological traceability and work with MU relevant for clinical applications.

Future planned activities of the TF-RMSI will be related to an analysis of the performance of the JCTLM-listed reference measurement services (RMS) in the RELA EQAS (https://www.dgkl-rfb.de/). This analysis will cover the same 30 common measurands that were studied to investigate whether significant deviations from the MU of the employed reference measurement procedure (RMP) are observed when compared with that listed in the JCTLM database. The practical aim of this analysis would be to look at the impact for users (for example, IVD manufacturers and EQAS organizers) of RMS performance, highlighting and discussing the source of a potentially dangerous significant bias, if any, in the provided services for the same measurand (see the total bilirubin example in ref. 4).

*Note: this standard is now referenced as harmonized standards of the European Union IVD Regulation, see: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022D0015&from=EN)

References

1. Panteghini M., Braga F. Implementation of metrological traceability in laboratory medicine: where we are and what is missing. *Clin Chem Lab Med* 2020;**58**:1200-1204.
2. Panteghini M., Braga F., Camara J.E., et al. Optimizing available tools for achieving result standardization: value added by Joint Committee on Traceability in Laboratory Medicine (JCTLM). *Clin Chem* 2021;**67**:1590-1605.
3. Panteghini M., Camara J.E., Delatour V., et al. Feasibility of metrological traceability implementation using the Joint Committee on Traceability in Laboratory Medicine database entries including the fulfillment of "fit-for-purpose" maximum allowable measurement uncertainty. *Clin Chem* 2024;**70**:1321-1333.
4. Panteghini M., Miller W.G., Wielgosz R. Time to refresh and integrate the JCTLM database entries for total bilirubin: the way forward. *Clin Chem Lab Med* 2025;**63**:e73-75

New entries in the JCTLM database - www.jctlmdb.org

The JCTLM review process conducted in 2024 resulted in four new entries in the JCTLM Database for available higher-order certified reference materials, eleven newly published reference measurement method, and 47 new measurement services delivered by reference laboratories. The new entries are listed below:

New entries for available Certified Reference Materials

Analyte Category	Analyte*	Matrix/Material
Drugs	Sibutramine hydrochloride monohydrate (certified as sibutramine free base)	High-purity material
Metabolites and substrates	Creatinine	Human urine
Proteins	Albumin	Human urine
Proteins	Amyloid beta 40	Standard solution of Aβ40

*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 *(JCTLM Identification Number*)*
Non-peptide hormones	Reference measurement procedure for quantification of aldosterone in human plasma by ID-LC/MS(JCTLM RMP ID: C20RMP4)
Nucleic acid	Reference measurement procedure for *KRAS* G12A fractional abundance by digital PCR (JCTLM RMP ID: C18RMP5) Reference measurement procedure for *KRAS* G12D fractional abundance by digital PCR (JCTLM RMP ID: C18RMP6) Reference measurement procedure for *KRAS* G12R fractional abundance by digital PCR (JCTLM RMP ID: C18RMP7) Reference measurement procedure for *KRAS* G12C fractional abundance by digital PCR (JCTLM RMP ID: C18RMP8) Reference measurement procedure for *KRAS* G12S fractional abundance by digital PCR (JCTLM RMP ID: C18RMP9) Reference measurement procedure for *KRAS* G12V fractional abundance by digital PCR (JCTLM RMP ID: C18RMP10) Reference measurement procedure for *KRAS* G13D fractional abundance by digital PCR (JCTLM RMP ID: C18RMP11) Reference measurement procedure for *HER*2 copy number variation by digital PCR (JCTLM RMP ID: C21RMP8) Reference method for human immunodeficiency virus type 1 (HIV-1) quantification by RT-dPCR (JCTLM RMP ID: C20RMP3)
Proteins	Reference measurement method for urine albumin quantification by ID-LC-MS/MS (JCTLM RMP ID: C21RMP9)

*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 Service Providers
Enzymes	Alanine aminotransferase (ALT) Aspartate aminotransferase (AST) Creatine kinase (CK) Lactate dehydrogenase (LDH) Gamma-glutamyltransferase(GGT) Alpha-amylase (AMY) Alkaline phosphatase (ALP)	China
Metabolites and substrates	Urea Glucose Creatinine Total Bilirubin Total cholesterol	China
Non-peptide hormones	17-hydroprogesterone total 3,3',5-Triiodothyronine Estriol Progesterone Testosterone	China
Proteins	HbA1c Total haemoglobin Total Protein	China
Vitamins	25-hydroxyvitamin D_3	China

*Complete information for each reference measurement service can be retrieved from www.jctlmdb.org.

JCTLM Task Group for Knowledge Transfer (TG-KT) report

The TG-KT was launched in 2023 to develop educational materials to improve the number of nominations to the database that are successful on the first submission. The first product was a checklist of frequently observed major non-conformances with suggestions for a successful submission to the JCTLM. The checklist, JCTLM-DBWG/P-02-I-02, is available on the JCTLM database procedures webpage

The first version was made available in January 2024 and covered certified reference material (CRM) and reference measurement procedure (RMP) submissions for the 2024 nomination cycle. Suggestions for reference measurement service (RMS) submissions were added in September 2024.

During 2024, the TG-KT prepared four educational videos, each lasting 8-10 minutes, covering the following topics:

- Overview of the JCTLM nomination and review process
- CRM submissions
- RMP submissions
- RMS submissions

The videos lead a submitter through the JCTLM database procedures web pages to identify the specific ISO and JCTLM documents and forms needed, to provide guidance on completing the forms and what supporting documentation is needed for a successful nomination.

The educational videos are available on the BIPM e-learning plaform and will also be available on the IFCC eAcademy for use in the 2025 nomination cycle.

Guidance for creating a user account on the BIPM e-learning platform is available from HERE.

Progress with the Promotion Task Group in the JCTLM WG TEP

Tony Badrick, JCTLM Working Group for Traceability, Education and Promotion (JCTLM WG TEP) Chair

It is important to raise awareness of the JCTLM's role and value in establishing metrological traceability of clinical laboratory measurement procedure results. The key stakeholders are the IVD industry, reference material and measurement procedure developers, and regulatory agencies responsible for approving IVD medical devices for use in clinical laboratories.

The JCTLM-WGTEP has developed a Marketing Review Plan with an outline of the activities for an initial promotion campaign for the JCTLM to facilitate this objective. The IFCC has agreed to actively support to the promotion of the JCTLM using their communication channels, including mass mailing via their corporate and associate members, publication division, e-Newsletter and an invitation for the JCTLM to participate at the IFCC General Conference.

A Task Team consisting of R. Wielgosz, C. Cobbaert, T. Fawcett and T. Badrick, and a representative from IFCC CDP was formed to progress the activities of a future Task Group on Promotion in collaboration with the IFCC Communication and Publication Division.

Future meetings and events

Please note that all the meetings listed will be held as hybrid meetings at the BIPM headquarters in Sèvres, France

1-2 December 2025
JCTLM Members' and Stakeholders' Meeting with Workshop on "Result harmonization in medical laboratories: accomplishments and challenges."

3 December 2025
Meeting of the JCTLM TEP WG
Review Meeting of the JCTLM Database Working Group.

4-5 December 2025
27th Meeting of the JCTLM Executive Committee.