JCTLM
Accurate results for patient care

Database Newsletter

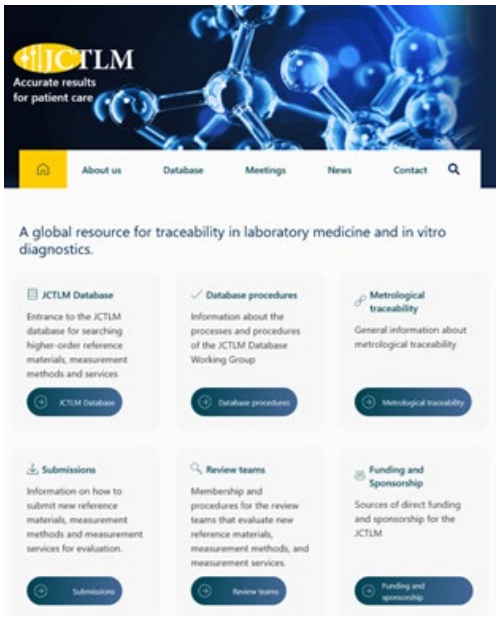
https://www.jctlmdb.org

Issue 10 | October 2023

1 A new version of JCTLM.ORG

The JCTLM has recently published a new edition of its website jctlm.org which provides traceability-related information and brings together materials from its parent organizations, especially the International Bureau of Weights and Measures (BIPM), the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), the International Laboratory Accreditation Cooperation (ILAC) and the International Council for Standardization in Hematology (ICSH). The website provides a resource of information on the international standardization of laboratory medicine and provides information on the principles of metrological traceability and the importance of standardization in laboratory medicine. It also lists the JCTLM member organizations and provides information on the JCTLM database of higher-order reference materials, measurement procedures and measurement services. The JCTLM website is a useful resource for laboratory professionals, researchers, regulators and policymakers who are engaged in international standardization and metrological traceability.

The new version of the website is optimized for desktop browsers, mobile phones and tablets.



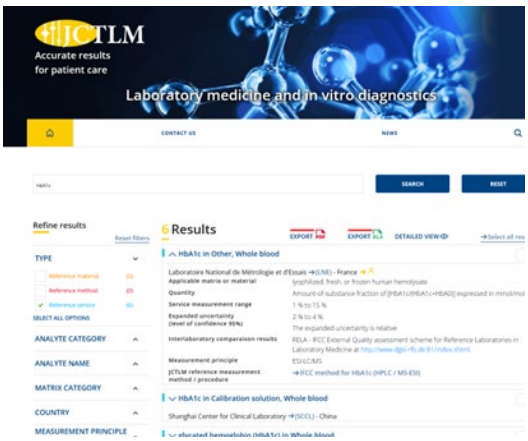
2 A new JCTLM Database website and an API for machine readable data

A new version of the JCTLM database website - www.jctlmdb.org - has recently been published and provides an improved keyword search and advanced search facility for accessing information on higher-order reference materials, measurement methods and services to be used in calibration hierarchies for value-assigning calibrators and trueness control materials for quantities measured by i*n vitro* diagnostic medical devices.

In addition, an application programming interface (API) has been developed for enabling machine-readable data - via JSON and XML formats - accessible to other software, databases or applications. The API JCTLM provides the data in response to search queries on certified reference materials, measurement method/procedures and services.

The API JCTLM is accessible at:

https://www.jctlmdb.org/backend/swagger/index.html



Search for HbA1c service provider for – human-readable data

3 JCTLM 2023 Survey on services and processes

The JCTLM Strategy Task Group has developed a questionnaire to gather stakeholder opinions and to inform the Committee on the needs of stakeholders regarding the JCTLM Database of Reference Materials, Methods and Services for *in vitro* diagnostics (www.jctlmdb.org). We invite you to take a few minutes to complete the online questionnaire, which will provide us with feedback to help ensure the JCTLM continues to provide services that are aligned to stakeholder needs.

The on-line questionnaire can be found at: https://www.surveymonkey.com/r/JCTLMSurvey

The deadline for completing the on-line questionnaire is extended to **20 October 2023**.

If you have any difficulties completing the questionnaire, please send queries to jctlm@bipm.org

4 Outcome from the C-reactive protein JCTLM Workshop

The JCTLM held a workshop in December 2022 on the developments in reference measurement systems for C-reactive protein and the importance of maintaining currently used clinical decision-making criteria. This workshop was triggered from the review of new C-reactive protein (CRP) candidate reference materials (cRMs) nominated in the recent JCTLM review cycles. While characterization of the cRMs were thoroughly carried out, the JCTLM was concerned about the impact of the materials for the laboratory medicine community that the JCTLM database serves.

A consensus summary and reviews from the Worshop on Implementing metrological traceability of C-reactive protein measurements have recently been published in:
Clin. Chem. Lab. Med. (CCLM) **61**(9) 2023.

Implementing metrological traceability of C-reactive protein measurements: consensus summary from the Joint Committee for Traceability in Laboratory Medicine Workshop.
W. Greg Miller *et al*.
DOI: 10.1515/cclm-2023-0498

Developments in reference measurement systems for C-reactive protein and the importance of maintaining currently used clinical decision-making criteria.
Mauro Panteghini
DOI : 10.1515/cclm-2023-0558

Why C-reactive protein is one of the most requested tests in clinical laboratories?
Mario Plebani
DOI: 10.1515/cclm-2023-0086

C-reactive protein and clinical outcome in COVID-19 patients: the importance of harmonized measurements.
Elena Aloisio *et al*.
DOI : 10.1515/cclm-2023-0276

Current performance of C-reactive protein determination and derivation of quality specifications for its measurement uncertainty.
Francesca Borrillo *et al.*
DOI : 10.1515/cclm-2023-0069

5 2021 JCTLM-ICHCLR-IFCC Workshop Report and Recommendations

The report has been published of the consensus discussion and recommendations from the workshop, which was held in December 2021. It addressed the challenges associated with the availability and use of CRMs and with meeting regulatory requirements in many countries when recalibration to achieve standardized results is desirable. The workshop was organized by the Scientific Division of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), the International Consortium for Harmonization of Clinical Laboratory Results (ICHCLR), and the JCTLM. The workshop had approximately 400 participants from 65 countries. The meeting agenda, speakers, and organizing committee are included in the supplementary material that accompanies this report of the consensus discussion and recommendations from the workshop.

Overcoming challenges regarding reference materials and regulations that influence global standardization of medical laboratory testing results.
W. Greg Miller *et al.*
Clin.Chem. Lab. Med. (CCLM), **61**(1) 2023 48-54.
DOI : 10.1515/cclm-2022-0943

6 Recent publication from the JCTLM TF-RMSI review

The JCTLM Task Force on Reference Measurement System Implementation (TF-RMSI) produced a synopsis of JCTLM listed higher-order certified reference materials (CRMs) and reference measurement procedures (RMPs) for thirteen selected measurands, including their main characteristics for implementing traceability and fulfilling (or not) the analytical performance specifications (APS) for suitable measurement uncertainty. Results showed that traceability to higher-order references can be established by IVD manufacturers within the defined APS for most of the thirteen selected measurands. However, some measurands do not yet have suitable CRMs for use as common calibrators. For these measurands, splitting clinical samples with a laboratory performing the RMP may provide a practical alternative for establishing a calibration hierarchy. This review work has recently been published.

Optimizing Available Tools for Achieving Result Standardization: Value Added by Joint Committee on Traceability in Laboratory Medicine (JCTLM)
Mario Panteghini *et al.*
Clin.Chem. **67**(12) 2021 1590–1605
DOI : 10.1093/clinchem/hvab178

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

The JCTLM review process conducted in 2022 resulted in 29 new entries in the JCTLM Database for available higher-order certified reference materials, one newly published reference measurement method, and 29 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
Enzymes	Gamma-glutamyltransferase (GGT) Alkaline phosphatase (ALP)	blood serum
Metabolites and substrates	Creatinine, Glucose, Urea and Uric acid	blood serum
Metabolites and substrates	Total Cholesterol, HDL-Cholesterol, LDL-Cholesterol and Total Glycerides	blood serum
Nucleic acids	KRAS (G12A, G12D, G12R, G12C, G12S, G12V or G13D) Mutation KRAS (G12A, G12D, G12R, G12C, G12S, G12V and G13D) Mutation	buffer solution
Nucleic acids	Human DNA	blood serum
Nucleic acids	In vitro transcribed SARS-CoV-2 RNA (E, ORF1ab or N gene) (high and low concentration)blood serum	high-purity material
Nucleic acids	BRAF V600E mutation	buffer solution
Non-electrolyte metals	Cobalt	whole blood

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

New entry for Reference Measurement Methods

Analyte Category	Reference Measurement Method *(JCTLM Identification Number*)*
Non-peptide hormones	Reference measurement method/procedure for 17α-hydroxyprogesterone in human plasma (JCTLM C17RMP6R)

*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
Electrolytes	Calcium Magnesium Potassium Sodium	China
Metabolites and substrates	Glucose Urea Total cholesterol Homocysteine	China
Non-peptide hormones	Cortisol 17β-Estradiol total 3,3',5-Triiodothyronine	China

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

8 Experts' participation in JCTLM Review Teams' activities – submit an application/nomination

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 results and relies on the important contribution 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 following review teams: Drugs, Electrolytes and blood gases, Enzymes and Vitamins and micronutrients, with the increasing numbers of nominations that are submitted in these measurement fields.

Submission of 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@bipm.org).

9 2023 JCTLM Members and Stakeholders Meeting and Workshop

The JCTLM Members and Stakeholders Meeting along with a Workshop on '*EQA schemes elucidating the clinical suitability of laboratory results*' will be held as a hybrid meeting hosted at the BIPM Headquarters on Monday 4 and Tuesday 5 December 2023.

The morning session of the biennial meeting of the Members and Stakeholders will start with a JCTLM update and Executive report and will be followed by a Workshop to explore the relationship between proficiency testing/external quality assurance (EQA) and traceability.
Sessions at the workshop will include:

- Current status of and responsibility for traceability in laboratory medicine
- EQA principles, practice and practical use
- The role of EQA in quality systems
- The driving forces of traceability in laboratory medicine and in EQA.

CLICK HERE FOR THE PROGRAMME

The meeting is open to all individuals and groups with an interest in traceability and method standardization or harmonization. This includes laboratory medicine specialists, EQA providers, IVD manufacturers and national metrology institutes.

CLICK HERE TO REGISTER

10 Future meetings and events

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

4-5 December 2023
JCTLM Members' and Stakeholders' Meeting with Workshop on '*EQA schemes elucidating the clinical suitability of laboratory results*'.

6 December 2023
Review Meeting of the JCTLM Database Working Group.

7-8 December 2023
25th Meeting of the JCTLM Executive Committee.

11 2022 JCTLM Executive Committee meeting report

The 24th meeting of the Executive Committee (EC) of the Joint Committee for Traceability in Laboratory Medicine (JCTLM) was held at the BIPM on 6-7 December 2022. The report of the meeting is available for download from the JCTLM report webpage.