



## Meeting requirements for metrological traceability in laboratory medicine and clinical chemistry

The JCTLM database comprises lists of higher-order reference materials, measurement methods, and services that have been reviewed against appropriate metrological criteria and judged to be compliant with applicable ISO standards.

In this issue of the JCTLM Newsletter, we report on highlights from the last Executive meeting; the new entries in the database following the 2014 review cycle; a summary of current entries in the database; changes to JCTLM procedures; the announcement of the 2015 call for reference material, method and service nominations; and plans for the next JCTLM Members' and Stakeholders' meeting in 2015.

### 1 Highlights from the 13th Executive Committee meeting

The 13th meeting of the Executive Committee of the Joint Committee for Traceability in Laboratory Medicine (JCTLM) took place at the BIPM on 4-5 December 2014. The [Executive Committee](#) convened for the last time under the Chairmanship of Prof. Mathias Müller whose term ended in December, and thanked him for his important contribution in support of the JCTLM.

#### Changes in the JCTLM Executive representatives

Prof. Linda Thienpont resigned from the Chairmanship of Working Group 2, and the Committee thanked her for her important contribution and great work in support of the JCTLM since it started. The JCTLM Executive approved the Chairmanship of Dr Gary Myers, and the BIPM's continued role as the Secretariat for the JCTLM.

#### Establishment of an *ad hoc* Working Group on JCTLM Governance

The Executive established an *ad hoc* Working Group on JCTLM Governance which would be tasked to revise JCTLM procedures, and propose the most appropriate structure and assignment of duties to the JCTLM Executive, Working Group Chairs and the Secretariat.

#### Establishment of a new JCTLM Working Group on Education and Promotion on Traceability

The Executive decided to form a new JCTLM Working Group on Education and Promotion on Traceability in order to increase the level and recognition and acknowledgement of the JCTLM and the database that it produces.

#### New JCTLM Member organization

The JCTLM Executive approved the JCTLM membership of China National Accreditation Service for Conformity Assessment (CNAS) from Beijing. As of 13 February 2015, there are 28 JCTLM Member organizations.

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

#### Traceability Statements – References to JCTLM – for IVD Manufacturers

The Executive finalized the guidance document on Traceability Statements, which provides advice to manufacturers and others on the appropriate manner to make reference to JCTLM-listing of reference materials, methods and services in any documentation in which information on metrological traceability is included.

The [Traceability Statement document](#) is available from the [JCTLM website](#).

See the full text of the [2014 JCTLM Executive Meeting report](#).

## 2 New entries in the JCTLM database

The JCTLM nomination and review process completed in 2014 has resulted in eight new entries in the JCTLM Database for available higher-order certified reference materials, as well as three new published reference measurement methods, and 23 new measurement services delivered by reference laboratories.

The new entries are listed below. Full information on the reference materials and their producers, methods, measurement services and reference laboratories can be found by searching the database at <http://www.bipm.org/jctlm/>

### New entries for available Certified Reference Materials

Analyte Category	Analyte*	Material/Matrix
Metabolites & Substrates	L-tyrosine, L-threonine, L-serine, L-methionine, L-histidine, L-cystine	High-purity material
Proteins	HbA1c	Whole Blood

\*Complete information for each entry can be retrieved from the [Analyte keyword search results](#) for the reference materials, e.g. Name and Contact of the producer of the reference material, Name of the reference material, Range of certified value, and Range of expanded uncertainty value, as well as Reference(s) on commutability, certification, or inter-laboratory comparability studies if available.

### New entries for Reference Measurement Methods

Analyte Category	Reference Measurement Method (JCTLM Identification Number)
Drugs	<u>Quantification of vancomycin in human serum by LC-MS/MS</u> (JCTLM C10RMP1) König K et al., <i>Clin. Chem. Lab. Med.</i> , 2013, 51(9), 1761
Drugs	<u>Simultaneous quantification of acetaminophen and structurally related compounds in human serum and plasma</u> (JCTLM C11RMP8) Bylda C et al., <i>Drug Test Anal.</i> , 2014, 6(5), 451-460
Proteins	<u>Human C-peptide quantitation by LC-MS Isotope-Dilution assay in serum or urine samples</u> (JCTLM C10RMP12_C-Peptide) Stoyanov AV et al., <i>J. Chromat. Separation Techniq.</i> , 2013, 4, 172

Complete information for each entry can be retrieved from the [Analyte /JCTLM ID keyword search results](#) for the reference methods, e.g. Name of the reference method, Applicable measurement range, and expected uncertainty value, as well as Reference(s) of peer-reviewed publication for method description and validation.

### New entries for Reference Measurement Laboratory Services

Analyte Category	Analyte	Location of Laboratory
Enzymes	Alanine aminotransferase	China
	Alkaline phosphatase	
	Alpha-amylase	
	Aspartate aminotransferase	
	Creatine kinase	
	Gamma-glutamyltransferase	
	Lactate dehydrogenase	
	Alkaline phosphatase	
Metabolites & Substrates	Glucose	Spain
	Glucose	Italy
	Urea	China
	Total glycerol	Germany
Non Peptide Hormones	Uric acid	Germany
	Thyroxine	
Proteins	Testosterone	Germany
	HbA1c	
Proteins	Total protein	France
		China

Complete information for each entry can be retrieved from the [Analyte keyword search results](#) for the reference measurement services, e.g. Contact for Reference Laboratory, Scope of the service offered and a link to the results for the inter-laboratory comparison.

### 3 2015 JCTLM call for nominations now open

The 2015 call for nominations of available higher-order certified reference materials, measurement methods, and services for laboratory medicine and *in vitro* Diagnostic measurement systems is currently being made, and the closing date for submissions is 30 May 2015. Certified Reference Material Producers, authors of publications of Reference Methods, and Laboratories providing Reference Measurement Services for laboratory medicine and clinical

chemistry, are invited to submit nominations for review and possible publication in the database using the procedures and forms available at:

[JCTLM WG1 Cycle 12 \(2015\): Call for Material and Method nominations and](#)

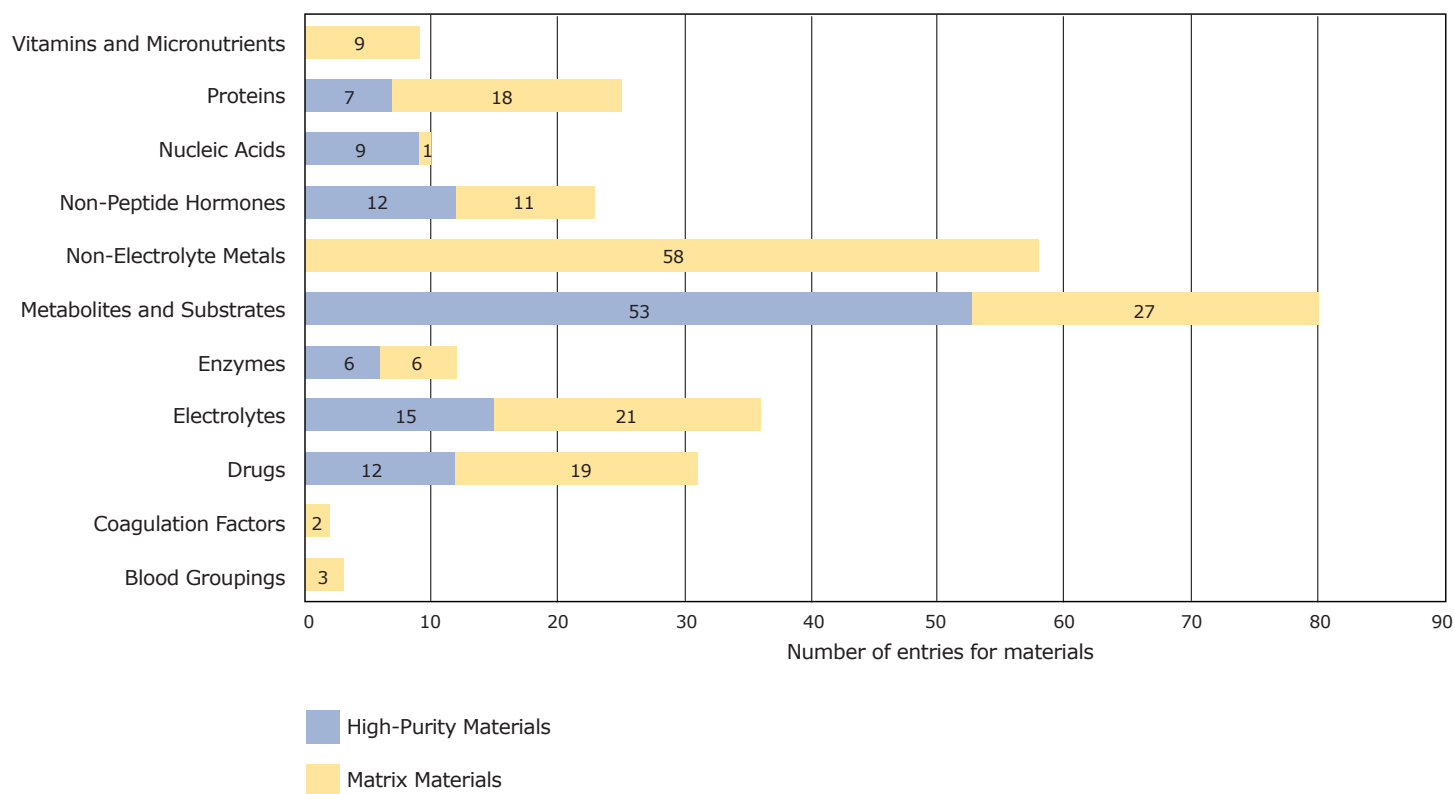
[JCTLM WG2 Cycle 10 \(2015\): Call for Laboratory Measurement Service nominations](#)

### 4 Content of the JCTLM Database

As of February 2015 the [JCTLM Database](#) contains:

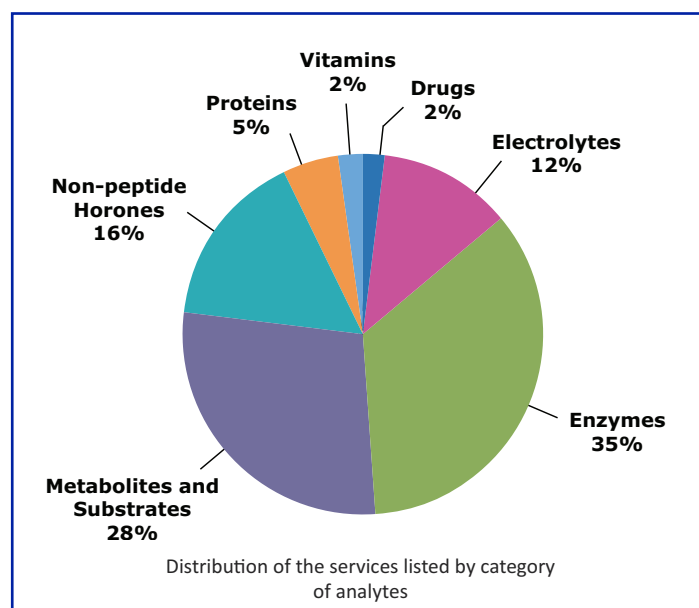
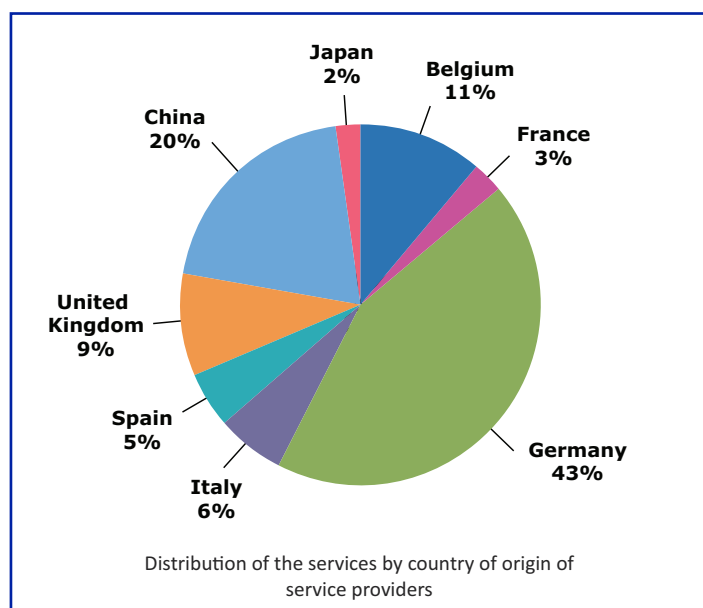
- 289 available certified reference materials covering eleven categories of analytes. The bar chart below shows the distribution of the total number of entries published for certified reference materials evaluated as being of a higher metrological order for each type of analyte.
- 170 reference measurement methods or procedures that represent about 80 different analytes in nine categories of analytes;
- 128 reference measurement services, delivered by fourteen reference laboratories and two national metrology institutes in eight countries and which cover seven categories of analytes. The pie charts on page 4 show the distribution of the services listed by region of origin of the service provider and by type of analyte.

#### JCTLM Database entries for available certified materials as of February 2015



continued on page 4...

## JCTLM Database entries for reference measurement services provided by reference laboratories worldwide as of February 2015



## 5 JCTLM Quality Manual modifications

The following changes have been introduced into the JCTLM Quality Manual for 2015:

- Publication of validation report for improved method:**  
JCTLM WG2 Procedure Manual was modified to include the new acceptance criteria for listing a reference measurement service of a provider using a listed reference measurement method that has been modified with the provision that the basic principle of measurement was maintained, and the validation report is made available to and approved by the review team, and published in the database.
- Re-review of listed reference measurement services:**  
The laboratory having a reference measurement service listed in the database must provide evidence that its status for accreditation for compliance with ISO/IEC 17025 and ISO 15195 is up-to-date, and that its

participation in appropriate EQAS Schemes for Reference Measurement Laboratories fulfill the two following JCTLM requirements;

- The laboratory must participate every year for at least one measurand in a group of analyte for which a service is listed, and,
- The laboratory must participate for each listed measurand at least once in a time period of three years.

[WG2-P-02](#), *Nomination of measurement services from Reference Laboratories*

[WG2-P-03 A](#), *Review of measurement services from National Metrology Institutes*,

[WG2-P-03 B](#), *Review of measurement services from accredited laboratories*

## 6 Future JCTLM Meetings

JCTLM Symposium to be held at the international conference of [EuroMedLab in Paris](#) on 24 June 2015

JCTLM Technical Workshop to be held at the BIPM on 30 November 2015, with a session on High Impact Measurands, and a session on Gap Analysis

JCTLM Members' and Stakeholders' Meeting to be held at the BIPM on 01 December 2015

JCTLM Working Groups' meeting to be held at the BIPM on 02 December 2015

JCTLM Executive meeting to be held at the BIPM on 03 and 04 December 2015