

Reference Materials, Measurement Methods and Services for *In Vitro* Diagnostics

JCTLM Database Newsletter

<http://www.bipm.org/jctlm/>

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. The easily searchable database can be accessed at <http://www.bipm.org/jctlm/> and is for use by persons and companies involved in laboratory medicine. The database is freely available, and provides the necessary information to aid manufacturers of medical diagnostic test kits to be compliant with European and international regulations and written standards that require metrological traceability to be established for test kit calibrators and/or metrologically traceable measurement results.

In this first issue of the JCTLM Newsletter, we report on new entries in the database following the 2013 review cycle; a summary of current entries in the database; changes to JCTLM procedures; a call for experts to participate in the JCTLM review process; and announcement of the 2014 call for reference material, method and service nominations.



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New entries in the JCTLM database

The 2013 JCTLM nomination and review process has resulted in 20 new entries in the [JCTLM Database](http://www.bipm.org/jctlm/) for available higher-order certified reference materials, as well as six new published reference measurement methods, and 13 measurement services delivered by reference laboratories.

The new entries are listed on the next page. 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
Drugs	Sodium diclofenac	High-purity material
Nucleic acids	BCR-ABL b3a2 transcript (for 6 copy number concentrations)	Plasmid solutions
Nucleic acids	HIV molecular marker	Blood plasma
Vitamins & Micronutrients	Total retinol, Gamma-tocopherol, Alpha-tocopherol, Total lutein, Total zeaxanthin, Total beta-cryptoxanthin, Total beta-carotene	Frozen human serum
Metabolites & Substrates	Creatinine, Glucose, Total Cholesterol, Urea, Uric Acid	Frozen human serum

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

New entries for Reference Measurement Methods

Analyte Category	Reference Measurement Method (JCTLM Identification Number)*
Metabolites & Substrates	Isotope dilution liquid chromatography tandem mass spectrometry (ID-LC-MS/MS) reference measurement procedure for Cholesterol in serum (JCTLM C10RMP9) Clin. Chem. Lab. Med., 2011, 49(4), 669-676
Metabolites & Substrates	High Performance Liquid Chromatography (HPLC) reference measurement procedure for Cholesterol in serum (JCTLM C10RMP10) J. Chromatogr. B, 2007, 858, 239-246
Drugs	Isotope dilution liquid chromatography tandem mass spectrometry (ID-LC-MS/MS) reference measurement method for antiepileptic drugs ¹ in human serum (JCTLM C10RMP5, C10RMP6, C10RMP7, C10RMP8) ¹ the analytes being measured are phenytoin, phenobarbital, lamotrigine, and topiramate Anal. Bioanal. Chem., 2011, 40, 1915

*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, Measurand, Applicable measurement range, and expected uncertainty value, as well as Reference(s) of peer-reviewed publication for method description and validation.

New entries for Measurement Laboratory Services

Analyte Category	Analyte	Location of laboratory
Enzymes	Alanine aminotransferase, Alpha-amylase, Aspartate aminotransferase, Creatine kinase, Gamma-glutamyltransferase, Lactate dehydrogenase, Alkaline phosphatase	China
Enzymes	Alkaline phosphatase	Germany
Metabolites & Substrates	Bilirubin	China
	Glucose	China
	Urea	China
Vitamins & Micronutrients	25-hydroxyvitamin D2 25-hydroxyvitamin D3	Belgium

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

JCTLM call for nominations now open

The 2014 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 2014. 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:

http://www.bipm.org/en/committees/jc/jctlm/jctlm-wg1/wg1_call.html

http://www.bipm.org/en/committees/jc/jctlm/jctlm-wg2/wg2_call.html

Call for experts' participation in the activity of the JCTLM Review Teams

The JCTLM is currently seeking additional experts to contribute to the following review teams: Drugs, Non-electrolyte metals, Non-peptide hormones, Proteins and Vitamins.

Submission of the nomination/application forms for JCTLM Review Team Membership can be made at any time to the JCTLM Secretariat (jctlm@bipm.org).

The procedure document for the application/nomination for [Membership of JCTLM WGs Review Teams](#) and the application/nomination form ([WG1-P-06-F-01](#)) can be found on the JCTLM WG1 Quality Manual Webpage.

JCTLM Quality Manual modifications

The following changes have been introduced into the JCTLM Quality Manual for 2014:

a) **Compliance demonstration required for nominations:**

Nomination forms for reference materials and methods ([JCTLM WG1-P-02](#)) were revised in January 2014 to include a Compliance demonstration spreadsheet that must be completed by the nominating organization to describe how compliance has been met for all requirements listed in ISO 15194:2009 for Reference Materials and 15193:2009 for Reference Measurement Methods.

[WG1-P-02-F-01](#): Reference material template, Version 9, January 2014

[WG1-P-02-F-02](#): Reference measurement method template, Version 9, January 2014

[WG1-P-02-I-01](#): Instructions for completing nomination templates, January 2014

b) **Extension for submitting supporting documentation:**

The procedure document WG1-P-02, *Reference material and procedure nomination requests*, retains a nomination submission deadline for 30 May for reference method nominations, but now allows submission of the final version (non-changeable format) of its supporting documentation or publication by 30 September.

c) **Reference measurement services based on modified methods:**

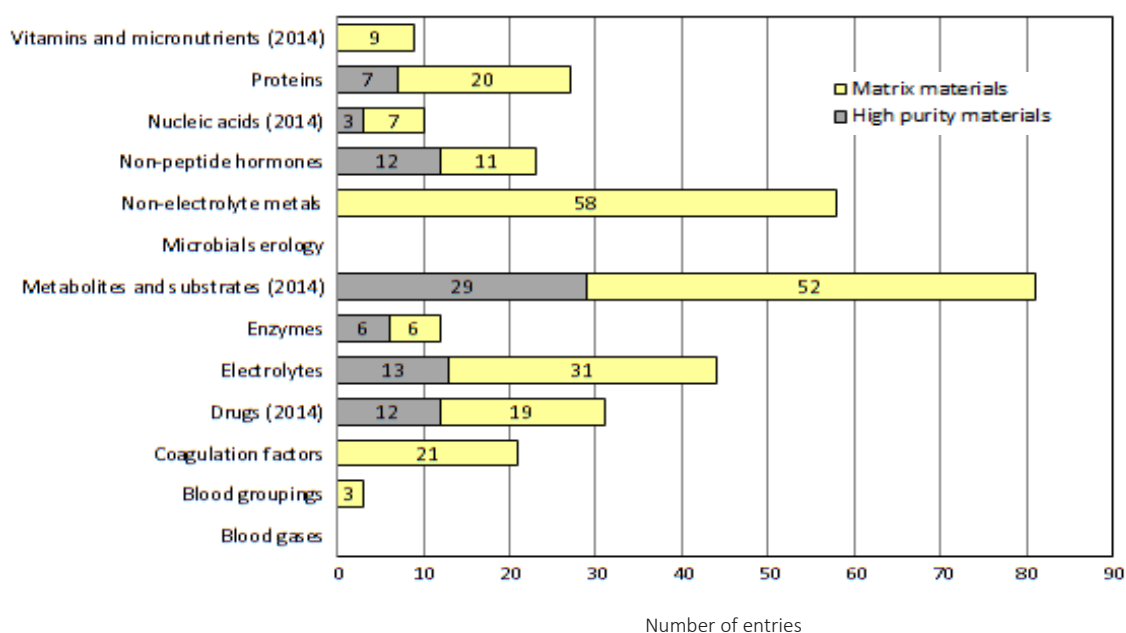
The procedure document JCTLM [WG2-P-03 B](#), *Review of measurement services from accredited laboratories*, was revised to permit publication of measurement services based on modified listed reference measurement procedure without need for JCTLM listing of another publication of the modified method, provided that the basic principle of the measurement procedure (e.g. IDMS) is maintained, and that the modified procedure is approved by the accreditation body.

Content of the JCTLM Database

As of March 2014 the [JCTLM Database](#) contains:

- 319 available certified reference materials covering 11 categories of analytes. The figure 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.
- 162 reference measurement methods or procedures that represent about 80 different analytes in eight categories of analytes;
- 115 reference measurement services, delivered by ten reference laboratories and two national metrology institutes in five countries and which cover seven categories of analytes.

JCTLM Database entries for available certified materials as of March 2014



JCTLM Database Entries for Reference Measurement Services provided by Reference Laboratories Worldwide as of March 2014

Analyte categories	No. of services listed	No. of analytes	Analytes	No. of Reference Laboratories	Country
Drugs	3	3	digoxin, digitoxin, theophylline	2	Germany
Electrolytes	15	6	Li, K, Na, Cl, Mg, Ca	4	Germany, UK
Enzymes	31	7	ALP, ALT, AST, CK, GGT, alpha-amylase, LDH	5	China, Germany, Italy, Spain, UK
Metabolites and substrates	31	6	creatinine, glucose, cholesterol (total), glycerides (total), urea, uric acid	9	Belgium, China, France, Germany, Japan, UK
Non-peptide hormones	19	10	17 beta-estradiol, 17-hydroxyprogesterone, aldosterone, cortisol, estriol (non-conjugated), progesterone, testosterone, free thyroxine, total thyroxine (TT4), total triiodothyronine (TT3)	4	Belgium, Germany, UK
Proteins	4	2	HbA1c, total protein	4	Germany, Italy, Japan
Vitamins and micronutrients	2	2	25-hydroxyvitamin D2, 25-hydroxyvitamin D3	1	Belgium
Total	105	36			