

Joint Committee for Traceability in Laboratory Medicine

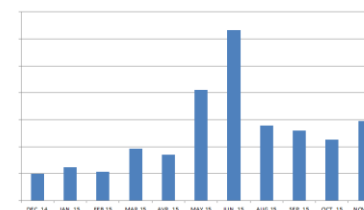
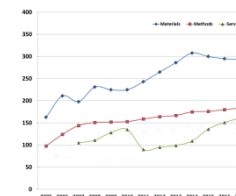
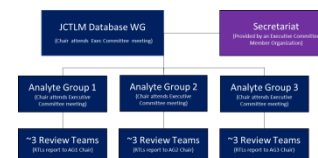
JCTLM Database Update 2017

R. Wielgosz and S. Maniguet

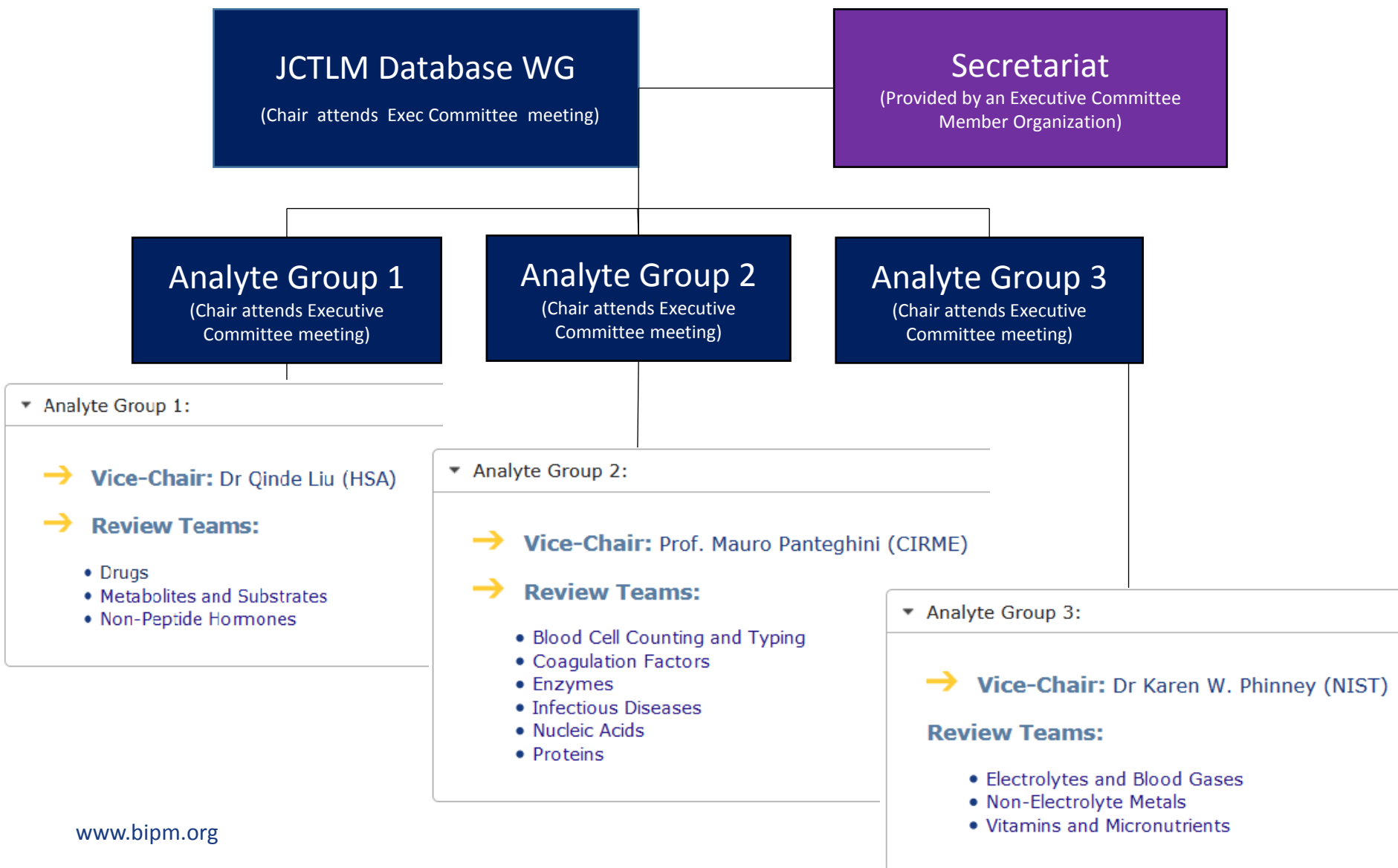


Summary of JCTLM Database Activities in 2017

1. JCTLM Database WG
2. Nomination and review process
3. Update of the content of the database
4. External Communication and Visits
5. Issues arising/resolved



JCTLM Database Working Group



Annual Schedule for JCTLM Nomination and review process

Approximate dates: (final dates may vary slightly)

- | | |
|--|------------|
| ◆ Launch of the call for nominations: | 1 February |
| ◆ Deadline for the submission of nominations: | 30 May |
| ◆ Distribution of nominations to the review teams: | 15 July |
| ◆ Deadline for the submission of the review teams' reports: | 31 October |
| ◆ Review of review teams' recommendations (meeting): | 6 December |
| ◆ Communication of results to the nominating organizations: | 31 January |
| ◆ Publication of approved nominations in the JCTLM database: | 31 January |

Documented JCTLM Nomination and review process

Materials & Methods Process
Services Process
JCTLM Secretariat
JCTLM Executive Committee

→ Download as a zipped file, or select an individual section from the list of contents below.

JCTLM-DBWG Quality Manual:
Reference Materials and Reference Procedures


		Title	File type	Last update
⌵		Preamble		2017/01/27
⌵	DBWG-P-00	Quality Policy of the Database Working Group		2017/01/27
⌵	DBWG-P-01A	Outline of JCTLM procedures for material and method nomination review		2017/01/27
⌵	DBWG-P-02A	Reference material and procedure nomination requests		2017/01/27
⌵	DBWG-P-02A-F-01	Reference material template		2017/01/27
⌵	DBWG-P-02A-F-02	Reference measurement procedure template		2017/01/27
⌵	DBWG-P-02A-I-01	Instructions for completing nomination templates		2017/01/27
⌵	DBWG-P-03A	Review and approval of nominations for materials and methods		2017/01/27
⌵	DBWG-P-03A-F-03	Review report form for material and method nomination		2017/01/27
⌵	DBWG-P-04A	Multiple CRM comparison process		2017/01/27
⌵	DBWG-P-04B	Multiple reference method/procedure comparison process		2017/01/27
⌵	DBWG-P-05	Consensus review and communication of recommendations		2017/01/27
⌵	DBWG-P-06	Membership of JCTLM DBWG Review Teams		2017/01/27
⌵	DBWG-P-06-F-01	Review Team membership form		2017/01/27
⌵	DBWG-P-07	Process for changing the DBWG Quality System procedures		2017/01/27
⌵	DBWG-P-07-F-01	Procedure change request form		2017/01/27
⌵	DBWG-P-08	Process for changing WG Review Teams		2017/01/27
⌵	DBWG-P-09	Appeals process		2017/01/27

Relevant ISO Standards for higher order RMs and RMPs

- ◆ **ISO 17511:2003** In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
- ◆ **ISO 18153:2003** Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials
- ◆ **ISO 15193:2009** Requirements for content and presentation of reference measurement procedures
- ◆ **ISO 15194:2009** Requirements for certified reference materials and the content of supporting documentation
- ◆ **ISO 15195:2003 and ISO 17025:2005** Reference Measurement Laboratories

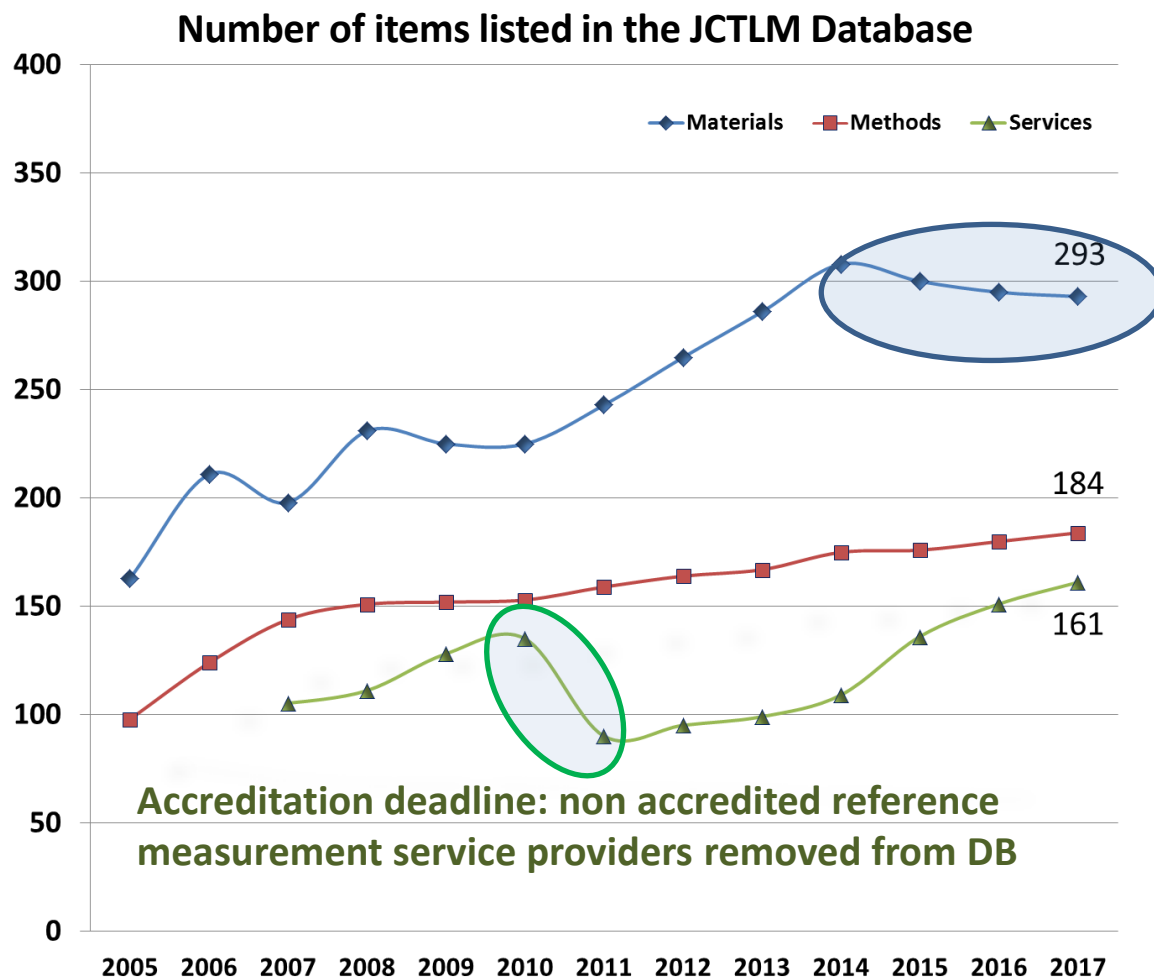
JCTLM Database

Content update in 2017

Publication of New Materials, Methods and Services approved by EC

Review Cycle 13 (2016) for materials and methods: + 2 materials, + 5 methods

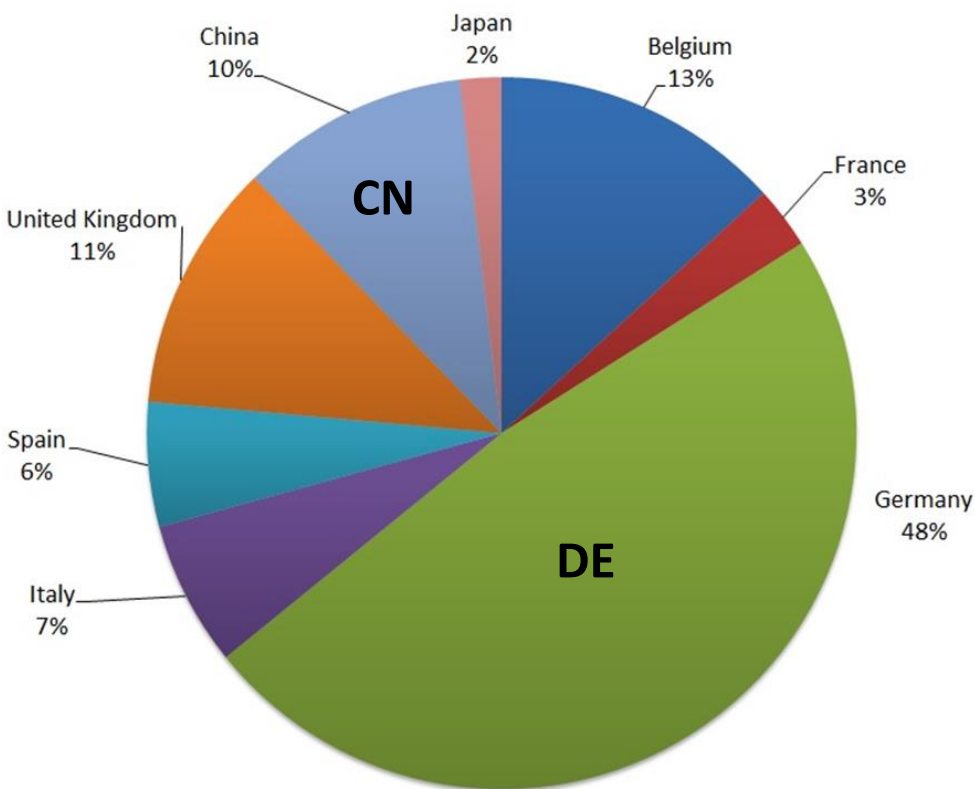
Review Cycle 11 (2016) for services: + 15 services



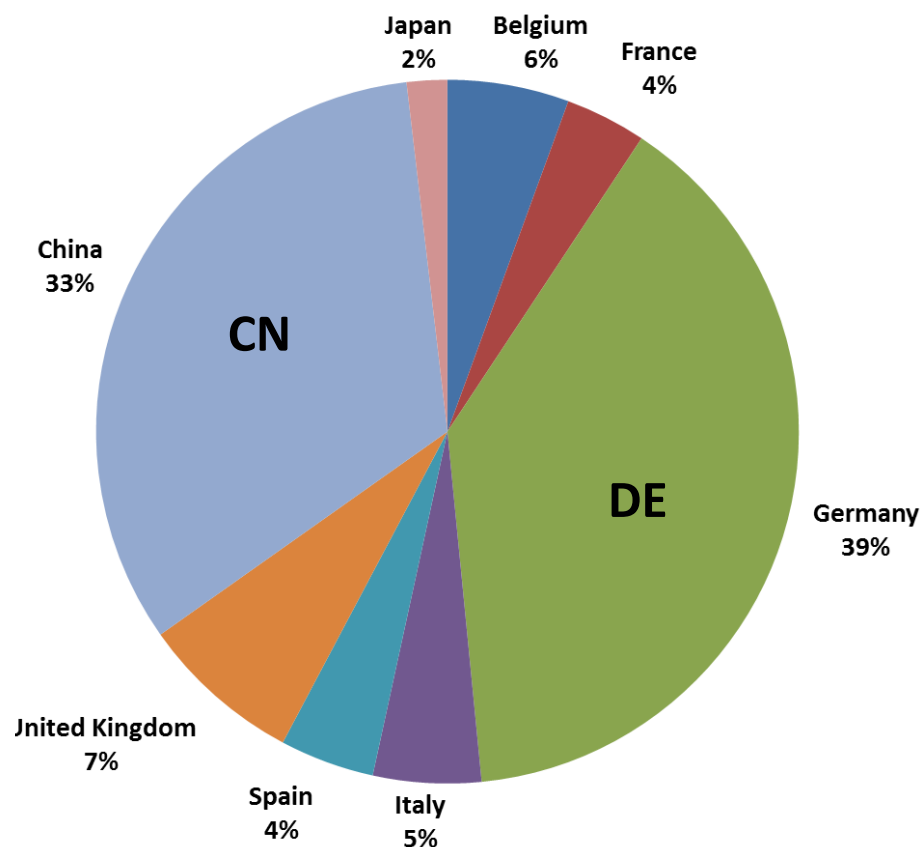
JCTLM Database

Content status in 2017 vs. 2014

Distribution of reference measurement service providers by country of origin



2014

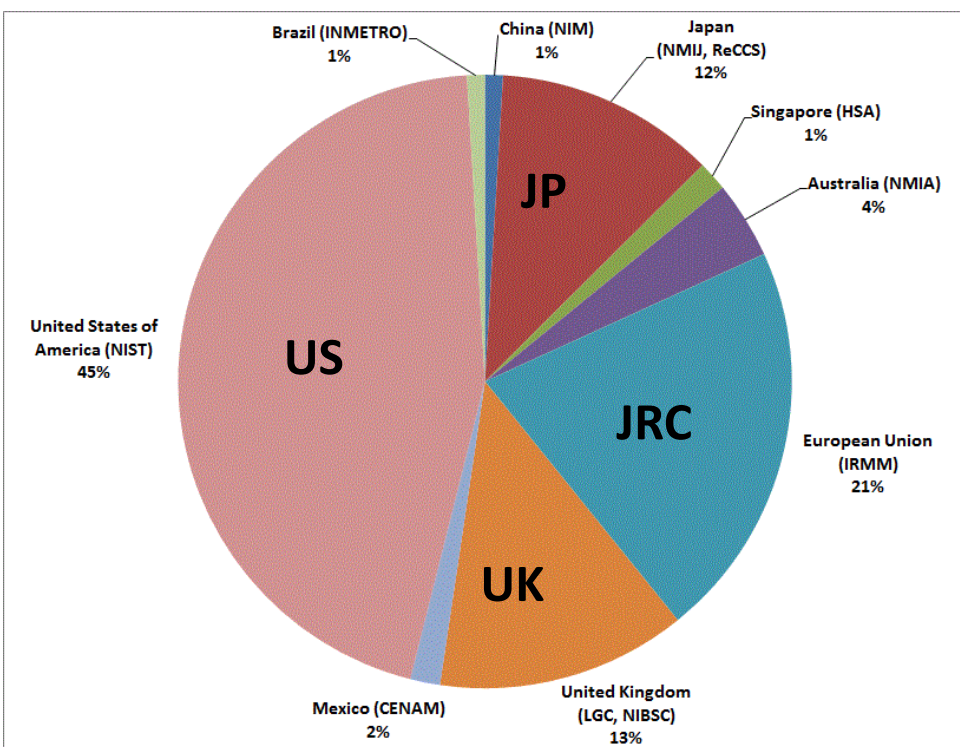


2017

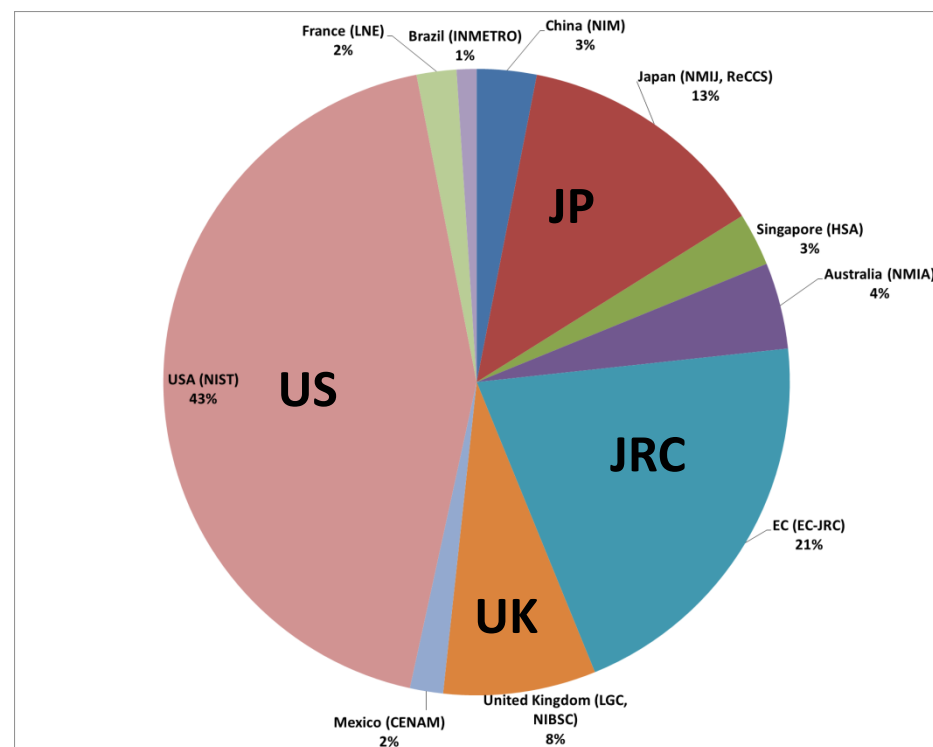
JCTLM Database

Content status in 2017 vs. 2014

CRMs by country of origin



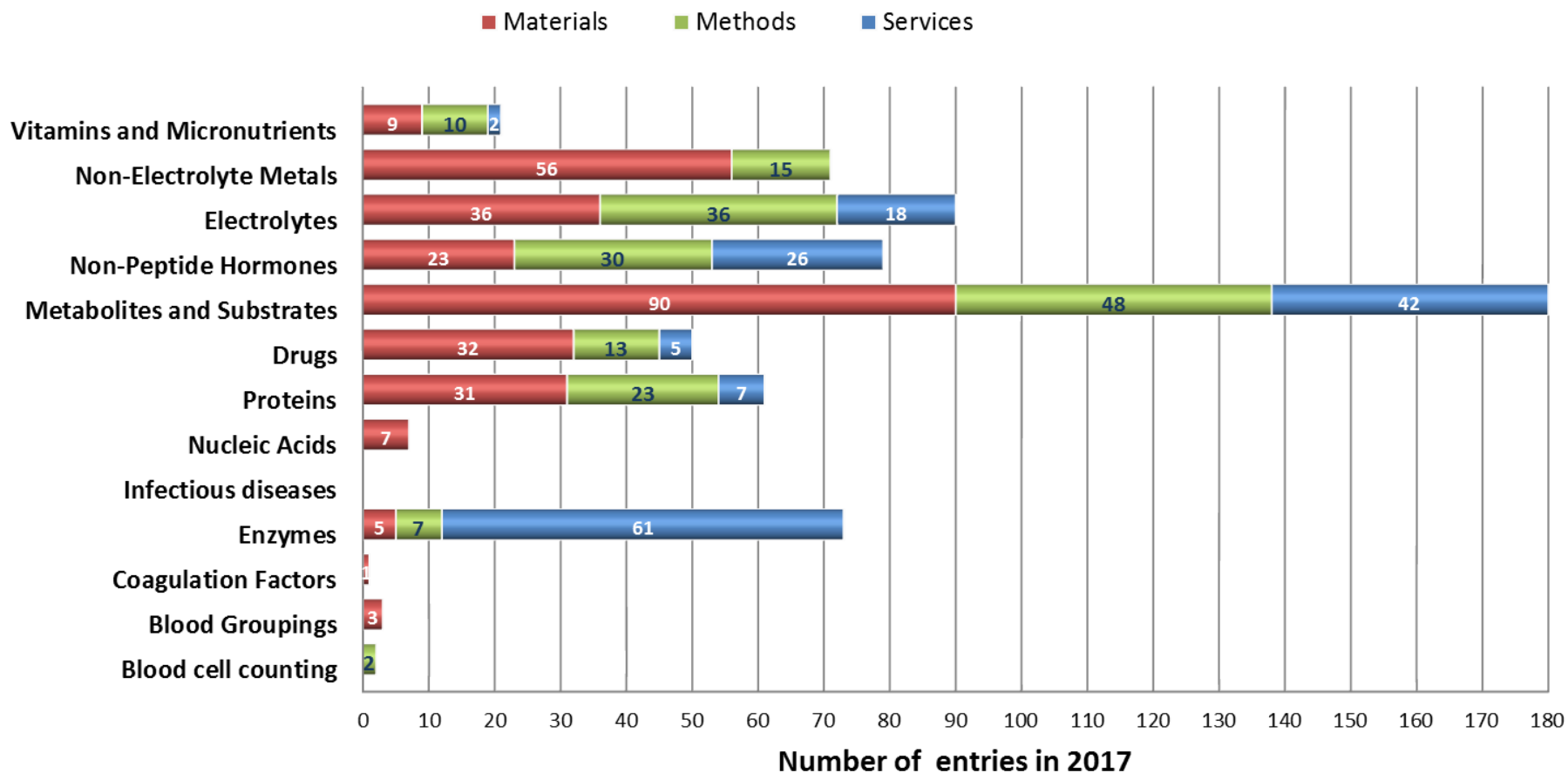
2014



2017

JCTLM Database

Content status in 2017



JCTLM Database

Content update in 2017

New entries in the JCTLM Database : Materials

Producer	Analyte Group	CRM Identifier
IRMM	Proteins	ERM-AD500/IFCC; Haemoglobin in buffer
NMIJ	Metabolites & Substrates	NMIJ CRM 6017-b; L-arginine

Materials delisted in September as no longer available

JRC-EC BCR-410 : prostatic acid phosphatase

NMIJ CRM 6201-b: C-reactive protein (CRP)

JCTLM Database

Content update in 2017

New entries for Reference Measurement Laboratory Services

Analyte Category	Analyte	Location of Laboratory
Drugs	Digoxin Digitoxin	Germany
Enzymes	Alanine aminotransferase Alkaline phosphatase Alpha-amylase Aspartate aminotransferase Creatine kinase Gamma-glutamyltransferase Lactate dehydrogenase	China
Metabolites & Substrates	Glucose Creatinine	Germany Japan
Non Peptide Hormones	Total thyroxine (TT4) Progesterone 17Beta-estradiol	China Germany
Non peptide Hormones	Estriol (non-conjugated)	China

JCTLM Database

External communication

Distribution of Issue 4 of the Database Newsletter



1. A new portal for Traceability in Laboratory Medicine - www.jctlm.org
2. Latest publications and educational support from TEP WG
3. JCTLM 2017 call for nominations announcement
4. New entries in the JCTLM database and its status
5. The JCTLM database – Gap analysis March 2017 ([Newsletter Special report](#))
6. Highlights from 2016 JCTLM Executive meetings
7. New JCTLM Member Organizations
8. JCTLM Members' and Stakeholders' meeting December 2017

JCTLM DB: Issues arising/solved

1. Certified Reference Material Certificates and Certification Reports: Language
2. Nomination of replacement materials: Streamlined process for replacements?
3. **BIPM Key comparison database (KCDB) and JCTLM Database listing of CRMs?**
4. **Publication of Reference Methods prior to availability of comparison data of Reference Measurement Services?**

CMC – ‘Capability’

Calibration and Measurement Capabilities Chemistry (not including pH and electrolytic conductivity) Service details



Biological fluids and materials, Blood serum

United Kingdom, LGC (Laboratory of the Government Chemist)

[Complete CMCs in Chemistry for Biological fluids and materials for United Kingdom \(.pdf file\)](#)

Matrix or material	Analyte or component	Dissemination range of measurement capability		Range of certified values in reference materials	
		Mass fraction in mg/kg	Relative expanded uncertainty in %	Mass fraction in mg/kg	Absolute expanded uncertainty in mg/kg
serum	creatinine	3 to 50	0.3 to 0.5	3.1 to 50	0.5 to 3

Mechanism(s) for measurement service delivery: Calibration and ERM-DA250 to DA253

Expanded uncertainty for certified values estimated with $k = \sim 2$ (level of confidence 95%)

Uncertainty convention 1.

Approved on 06 December 2011

Internal NMI service identifier: LGC/Org-019

BIPM KCDB: Calibration and Measurement Capability (CMC)

CCQM-K80

Results

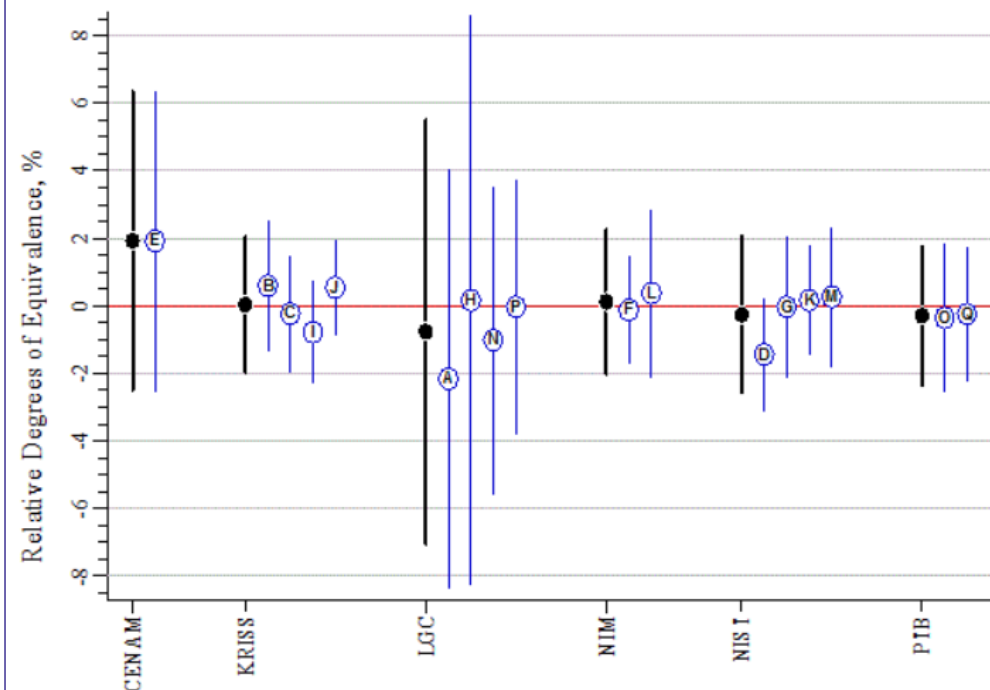
Laboratory individual measurements	Equivalence statements	Degrees of equivalence	Graph(s) of equivalence
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MEASURAND : Mass fraction of creatinine in human serum

NOMINAL RANGE : 3 mg/kg to 57 mg/kg

Degrees of equivalence D_i and expanded uncertainty U_i (95 % level of confidence) for laboratory i expressed in %

Degrees of equivalence D_j and expanded uncertainty U_j (95 % level of confidence) for submitted CRM j expressed in %



Operational Quality Management System

ISO 17025

ISO Guide 34 (ISO 17034)

Accreditation/Peer Review/ Self Declaration

Intra and Inter-regional review and acceptance of claim by peers

Available CRMs

List of higher-order reference materials



creatinine in human serum

LGC Limited (LGC), United Kingdom

Phone : +44 (0)20 8943 8480

Fax : +44 (0)20 8943 7554

Email : uksales@lgcstandards.com

Web : <http://www.lgc.co.uk>

Name of the reference material	ERM-DA252a
Quantity	Mass concentration
Analyte certified/assigned value	3.1 mg/kg
Expanded uncertainty (level of confidence 95 %)	0.2 mg/kg
Other relevant publication(s)	Stokes P and O Connor G, <i>Journal of Chromatography B</i> , 2003,1,125-136
Traceability	SI
CRM listing	List I

This (Certified) Reference Material has been reviewed for compliance with ISO 15194:2003 but not been reviewed against ISO 15194:2009

JCTLM BD Review of a CRM: Compliance with ISO 15194

4. Systematic format of properties in the supporting documentation of a CRM

ISO 31

5. Properties, production and characterization of a CRM

ISO Guide 34

ISO Guide 35

ISO 17511

ISO 18153

GUM

6. Content of supporting documentation

6.2 Label

6.3 Certificate

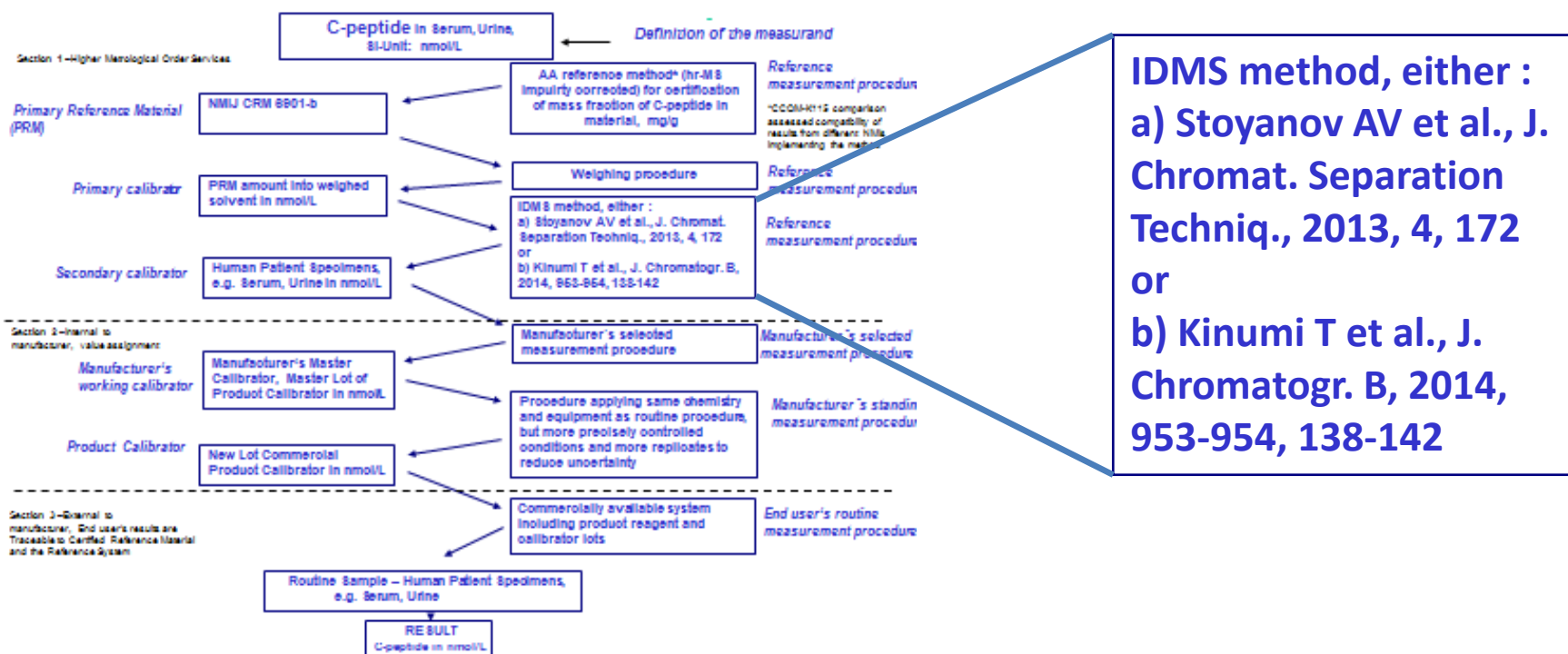
6.4 Certification Report

ISO Guide 31

ISO 15194:2009

Publication of Newly Developed Reference Methods

C-peptide measurements in serum

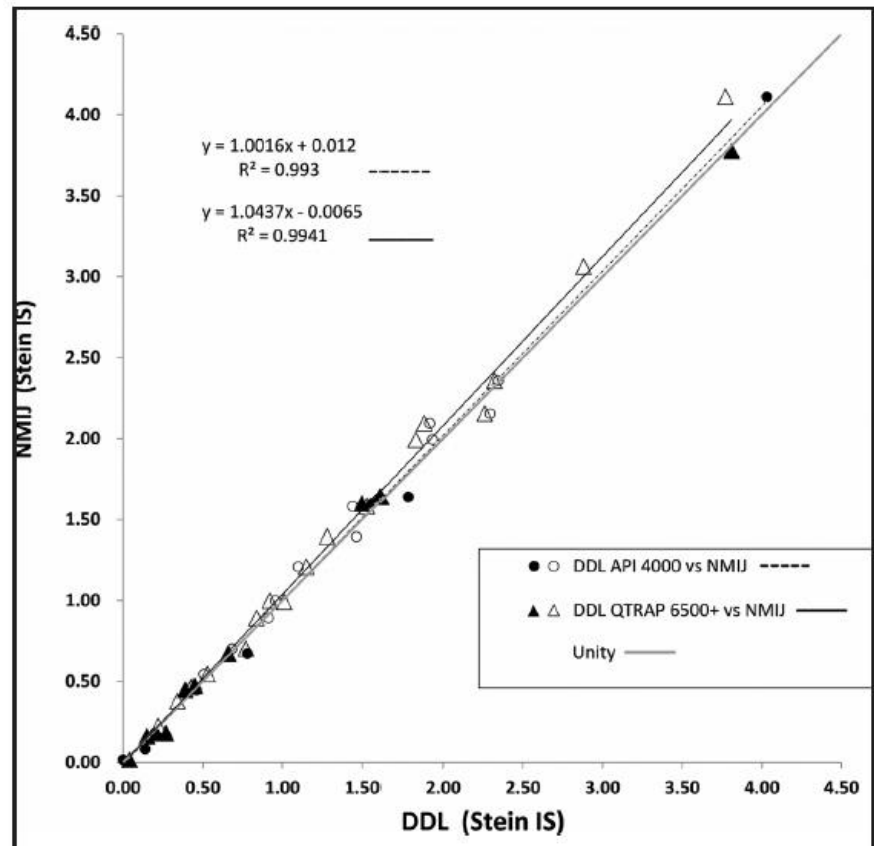


Publication of Newly Developed Reference Methods

Reference methods shown to agree after further collaboration between groups

Solving initial problem which had reported a disagreement between methods

Little R.R., Wielgosz R.I., Josephs R., Kinumi T., Takatsu A., Li H., Stein D., Burns C., Implementing a reference measurement system for C-peptide: Successes and lessons learned, Clin. Chem., 2017, 63(10), 1447-1456



Publication of Newly Developed Reference Methods

Modification of JCTLM procedure DBWG P04B:

Demonstrating the extent-of-equivalence of reference measurement methods/procedures (RMM/Ps) for the same measurand

6.1. The process for demonstrating the extent-of-equivalence of RMM/Ps will be initiated by the RMM/P nominator which submits a method for inclusion in the Database whenever one or more RMM/Ps that are nominally fit for the same purpose are identified in the JCTLM database. The extent-of-equivalence demonstration process should be completed by the time the laboratory submits a RMM/P nomination for evaluation by DB WG RT.

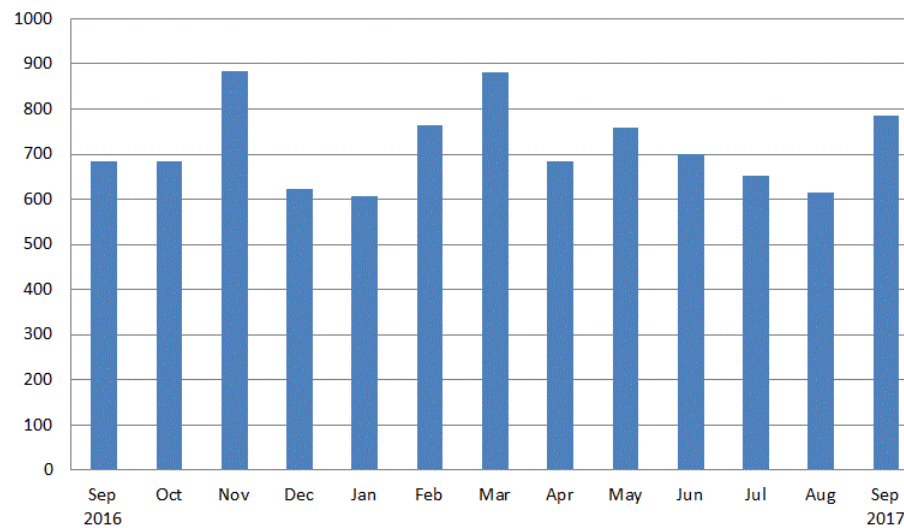
6.1.2. In the case where there is no higher-order method that are published by JCTLM to allow for an extent-of-equivalence study, the RMM/P nominator will seek to address the JCTLM requirement for method validation data by conducting a comparison study of its newly evaluated method with an existing method used by routine measurement laboratory.

6.1.2.1. Where subsequently obtained comparison results show suitable methods comparability and ascertain that there will be no adverse impact on the patient measurement results when implementing the newly evaluated method, this will constitute sufficient validation information for listing the method in the database until a new method becomes available for further compatibility assessment.

JCTLM Database

Visits 2017

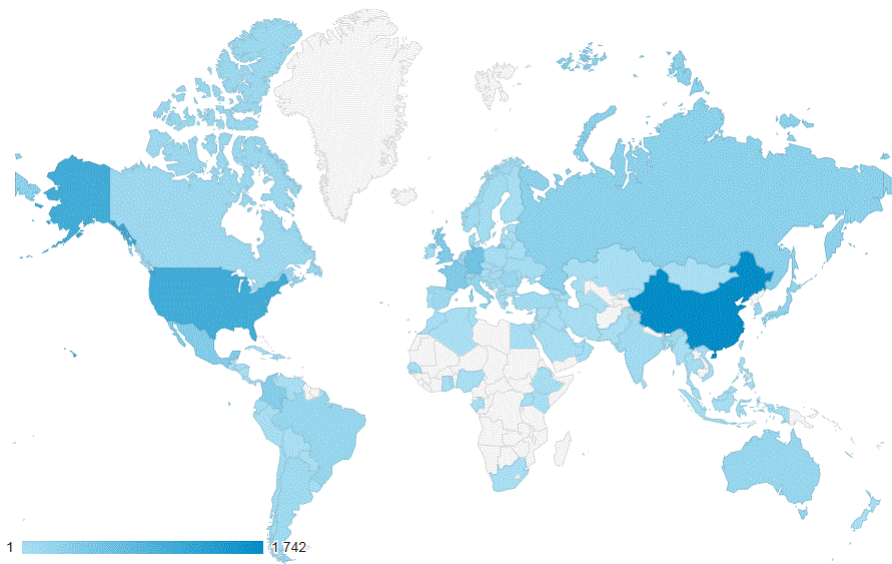
Visits per month













JCTLM Database

Visits 2017

Visits per country



	China	18,68 %
	United States	11,55 %
	Germany	6,23 %
	France	4,49 %
	United Kingdom	4,39 %
	Mexico	4,38 %
	Colombia	4,10 %
	Russia	3,28 %
	Japan	2,82 %
	Italy	2,51 %

Sep 2016 – Sep 2017

2017 JCTLM New nominations (Reviewed later this week)

Cycle 14 (Materials & Methods) and Cycle 12 (Services)

	Materials	Methods	Services	
Analyte category	# nominations submitted in 2017	# nominations submitted in 2017	# nominations submitted in 2017	
Drugs	1	1		
Electrolytes	18	5	3	
Enzymes	7		14	
Metabolites & Substrates	10	2	4	
Non-Peptide Hormones	1			
Non-electrolyte Metals		1		
Proteins	7	2	1	
Vitamins	2			
Total	46	11	22	79