

# “Accurate Results for Patient Care” The Role of Traceability in Laboratory Medicine



Accurate results  
for patient care

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## Abstract

Clinical laboratories require global metrological standardization to produce equivalent patient test results across space and time. Standardization is required to use evidence based laboratory medicine (EBLM) practice guidelines and eliminate the need for local or method-specific reference intervals/decision cut-offs with the goal of improving e-healthcare and patient safety.

Healthcare providers and patients take for granted all test results are accurate, comparable and interchangeable, and clinical practice guidelines assume results are independent of assay methodology. Due to lack of standardization, currently all results are not equivalent and assay method-specific reference intervals and medical decision points are required. The European Union's In Vitro Diagnostics Directive (IVDD) mandates metrological traceability for calibrators and trueness controls to promote assay standardization.

The Joint Committee for Traceability in Laboratory Medicine (JCTLM), formed in 2002, promotes standardization in the clinical laboratory. It was founded by the BIPM (Bureau International des Poids et Mesures), the IFCC (International Federation for Clinical Biochemistry and Laboratory Medicine), and ILAC (International Laboratory Accreditation Cooperation). JCTLM now has 28 member organizations, including AACC that are committed to traceability in laboratory medicine. JCTLM promotes the use of proven metrological principles to support equivalence of measurements in the clinical laboratory through metrological traceability to appropriate reference materials and methods.

Standardization is achieved when all routine assay results for test are traceable, with an unbroken metrological chain of comparisons, to reference materials and methods of a “higher order,” with a sufficiently small uncertainty such that results may be validly compared.

**Results:** The JCTLM has developed a database of such higher order reference materials and methods and reference measurement services (<http://www.bipm.org/jctlm/>). Entry in the database is determined by review by experts using ISO standards and approval by the JCTLM Database Working Group and Executive Committee. In 2015 the database contained listings for 295 materials for 162 measurands, 70 methods for 79 analytes and 130 reference measurement services for 39 analytes.

Implementation of traceability requires action by many bodies: national measurement institutes and other organizations that prepare materials and develop methods; reference measurement service laboratories; IVD manufacturers that prepare calibrators/trueness controls for field assays following appropriate traceability chains and provide traceability information to users; clinical laboratories that select and use traceable assays; EQA/PT providers that confirm claimed traceability; and guideline committees that base recommendations on traceable results.

To promote these activities the JCTLM formed a Working Group on Traceability: Education and Promotion (WG-TEP) in 2015 to produce and use educational materials demonstrating the value of traceability in laboratory medicine. Its sixteen members represent the JCTLM Executive Committee, the wider international membership, and individuals with skills and experience in creating educational materials. WG-TEP provides key traceability educational material at professional society meetings and maintains a traceability website containing information and resource materials about traceability and standardization in laboratory medicine and links to the JCTLM database and member organizations. WG-TEP also provides the clinical laboratory industry with recommendations for calibration traceability statements and supporting documentation that provides metrologically appropriate and clear assay standardization descriptions which are the responsibility of IVD manufacturers.

## Introduction

It is vital that medical laboratory results are stable over time and place. This can be achieved by having all results traceable to high quality reference materials or methods by appropriate traceability chains (Fig 1). This has not yet been achieved and results for the same measurand often vary between laboratories and can also vary over time.

The Joint Committee for Traceability in Laboratory Medicine (JCTLM) was formed to support the world-wide comparability, reliability, and equivalence of measurement results in laboratory medicine, for the purpose of improving health care and facilitating national and international trade for *in vitro* diagnostic devices.

A key activity is the listing of appropriate reference materials (RM) reference measurement procedures (RMP) and reference Measurement Services (RMS) on the JCTLM database.

The JCTLM also aims to promote the concept of traceability. A working group, “Traceability, education and promotion” (WG-TEP) was formed in 2015 to support this goal.

## Aim

To outline the functions of the JCTLM including the database and WG-TEP.

## Database

The JCTLM database ([www.bipm.org/jctlm](http://www.bipm.org/jctlm)) is a freely available list of certified RM, RMP and RMS (table & figure 2).

Submissions for inclusion in the database are assessed against ISO standards and publicly available procedures (see [www.bipm.org/jctlm](http://www.bipm.org/jctlm)).

The database provides a reference source for manufacturers, laboratories and other parties seeking the appropriate top of the traceability chain for an analyte (Figure 2).

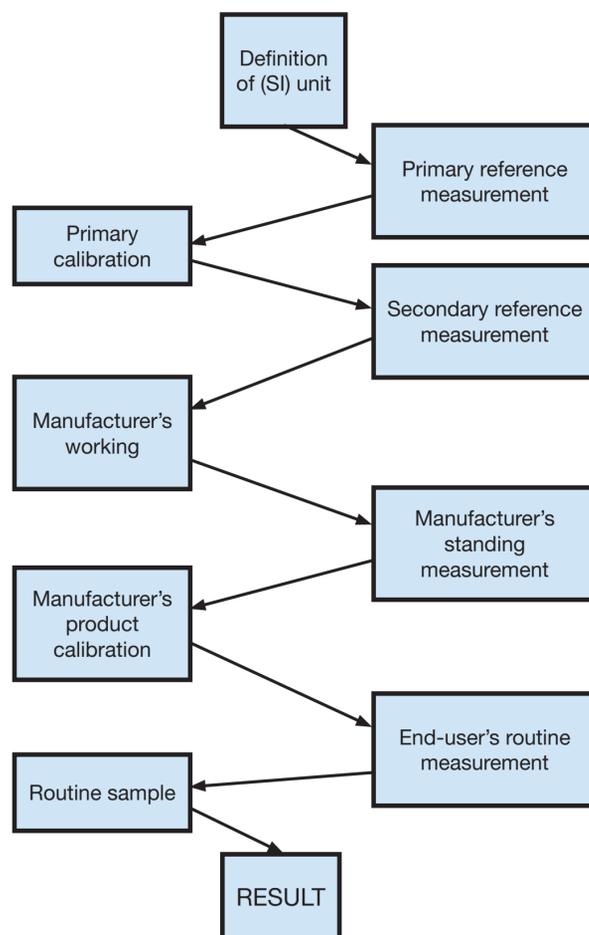
The database can be used to identify “higher order” materials and methods to meet the needs of the European Union In-Vitro Diagnostics Directive which requires traceability of laboratory medicine tests.

The JCTLM database currently lists:

- 298 RM for 175 measurands
- 180 RMP for 80 measurands
- 146 RMS for 39 measurands.

The number of current listings on the JCTLM database in each category are shown in the table.

## Figure 1. Example Traceability Chain



## References

1. Jones GRD, Jackson C. *The Joint Committee for Traceability in Medicine (JCTLM)- Its history and operation.* Clin Chim Acta 2016;453:86-94.
2. Morris HA. *The clinical value of assay standardization and traceability.* Newsletter of the Asian Pacific Federation of Clinical Biochemistry and Laboratory Medicine 2016; 58-59.
3. Armbruster D, Miller RR. *The Joint Committee on Traceability in Laboratory Medicine (JCTLM): A global approach to promote the standardisation of clinical laboratory test results.* Clin Biochem Rev 2007;28:105-113.
4. Armbruster D, Donnelly J. *Harmonization of clinical laboratory test results: The role of the IVD industry.* eJIFCC 2016;27:37-47.

Table 1. JCTLM Database Listings - 2016

Analyte Category	Reference Materials		Reference Methods		Reference Measurement Services	
	Number of entries	Number of Analytes	Number of entries	Number of Analytes	Number of entries	Number of Analytes
Blood cell counting			2	1		
Blood gases						
Blood groupings	3	3				
Coagulation factors	1	1				
Drugs	32	24	13	9	3	3
Electrolytes	36	6	36	7	18	6
Enzymes	10	7	7	7	54	7
Metabolites & Substrates	91	52	47	13	40	9
Microbial serology						
Non Electrolyte Metals	56	31	15	7		
Non-peptide Hormones	23	11	30	13	22	10
Nucleic acids	7	2				
Proteins	30	29	21	18	7	2
Vitamins	9	9	9	5	2	2
<b>Totals</b>	<b>298</b>	<b>175</b>	<b>180</b>	<b>80</b>	<b>146</b>	<b>39</b>

Figure 2. Example Database Search (Creatinine RM) ([www.bipm.org/jctlm](http://www.bipm.org/jctlm))

## Search Screen

## Results of a Search

Results of the search

Your search criteria produced 7 summary results. Select one or several higher-order reference material summary descriptions amongst the following list and click on 'View' to access more information.

Select all items from the list

Sort by:  Analyte  Matrix/Material  Organization

Select	Analyte	Analyte category	Matrix/Material	Organization
<input type="checkbox"/>	creatinine	metabolites and substrates	creatinine crystalline material	NIST
<input type="checkbox"/>	creatinine	metabolites and substrates	creatinine crystalline material	NMIJ
<input type="checkbox"/>	creatinine	metabolites and substrates	frozen human serum	CENAM
<input type="checkbox"/>	creatinine	metabolites and substrates	frozen human serum	NIST
<input type="checkbox"/>	creatinine	metabolites and substrates	human serum	IRMM
<input type="checkbox"/>	creatinine	metabolites and substrates	human serum	LGC
<input type="checkbox"/>	creatinine	metabolites and substrates	human serum	NIST

## Details of Database Entry

Results of the search

creatinine in creatinine crystalline material

National Metrology Institute of Japan (NMIJ), Japan

Phone: +81 29 861 4346 Email: keiryuu-counselors@m.aist.go.jp  
Fax: +81 29 861 4240 Web: <http://www.nmi.jp/>

Name of the reference material	Quantity
NMIJ CRM 6005-a, creatinine	Mass fraction
Analyte certified/assigned value	0.999 kg/kg
Expanded uncertainty (level of confidence 95%)	0.002 kg/kg

Comment(s) This certified reference material has been reviewed for compliance with ISO 15194:2003. It has been resubmitted for review cycle 9(2012) and is currently being reviewed against ISO 15194:2009.

Traceability SI  
CRM listing [List I](#)

## WG-TEP

### The Mission of the WG-TEP Includes:

- Organization of the two-yearly JCTLM Members Meetings
- Organization of JCTLM scientific and educational meetings, symposia and conferences
- Assessment of applications for meetings to be held with JCTLM auspices
- Production of educational materials to promote the value of traceability in laboratory medicine
- In conjunction with the JCTLM Secretariat, production of the annual JCTLM e-newsletter
- Production and maintenance of a “traceability” website, which contains information, resource material and regular news items about the role of traceability in laboratory medicine. This website will link to the JCTLM database and will be available to link to the websites of all JCTLM members
- Website: <http://www.bipm.org/en/committees/cc/wg/jctlm-wg-tep.html>

## Conclusions

- The JCTLM database now provides important information for manufacturers and laboratories to establish and confirm traceability for routine methods.
- This work needs to be ongoing to ensure a wider coverage of all the measurands used in laboratory medicine. For example blood gases and serology tests are not currently represented in the database (table 1).
- The JCTLM is continuing with the work of promoting traceability in laboratory medicine.