"Accurate Results for Patient Care" The Role of Traceability in Laboratory Medicine

JCTLM Accurate results for patient care

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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 in 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 gaol.

Aim

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

Database

- The JCTLM database 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).
- 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.

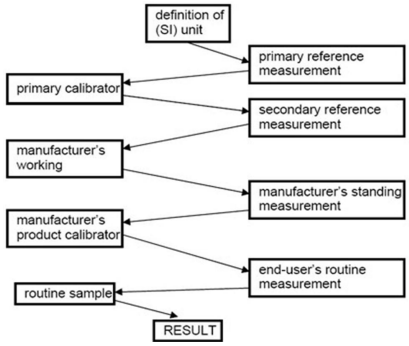

Figure 1. Example traceability chain

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 Electroyte 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
Totals	298	175	180	80	146	39

Table 1. JCTLM database listings - 2016

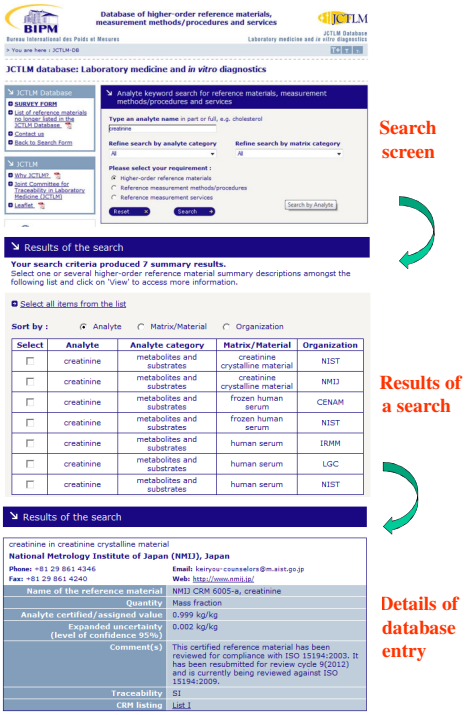

Figure 2. Example database search (creatinine RM) (www.bipm.org/jctlm)

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

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 JCLTM is continuing with the work of promoting traceability in laboratory medicine.

Abstract

"Accurate Results for Patient Care": The Role of Traceability in Laboratory Medicine

Graham Jones, Dave Armbruster, For the JCTLM Working Group for Traceability: Education and Promotion (WG-TEP)

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.

AACC Annual Scientific Meeting, 2016