JCTLM
Introduction
A global approach to improve reference systems

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JCTLM
Joint Committee of Traceability in Laboratory Medicine

• Reference Measurement Procedures
• Certified Reference Materials
• Reference Laboratories
• Reference Ranges

A joint venture of professionals, metrology institutes, regulators and ivd-industry
Inadequate or incorrect analytical performance has consequences for practical medicine and the health care system:

- incorrect interpretation of results by the physician
  - wrong diagnosis and treatment
  - additional diagnostic procedures
  - impairment of the patient’s situation and behavior
- increase in health care expenses
  - wrong political decisions
ANALYTICAL BIAS

- ± 2SD
- Reference Method
- All Routine Methods
- One Routine Method

Number of Measurements

Quantity - Result

R. DYBKAER 1975
provides certified reference values with demonstrated traceability for chemical measurements, independent of participants results

enables result-oriented evaluation of performance
demonstrates degree of equivalence of measurement results on the international scene

International Comparison

IMEP-17: Trace and minor constituents in human serum
Certified value: 140.36 ± 0.95 mmol·L⁻¹ [U=k·u_c (k=2)]

Results from all participants (992 laboratories)
Amylase Comparison

**Difference in field methods**

**Patient results not comparable**

Need for Harmonisation and Standardisation

**Nordic Countries**

AT, BE, DK, FL, DE, IT, PT, SP, SE, NL, UK

**North America**

Results from participants from North America; Canada and USA

IMEP-17: Trace and minor constituents in human serum
Certified value: 56.8 ± 2.6 U·L⁻¹ \( [U=k·u_c \ (k=2)] \)

Results from participants from Nordic Countries; Denmark, Finland, Iceland, Norway and Sweden

IMEP-17: Trace and minor constituents in human serum
Certified value: 56.8 ± 2.6 U·L⁻¹ \( [U=k·u_c \ (k=2)] \)

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Effect of Uniform Calibration on Various Methods

Amylase (U/L) - 37°C

Before: CV=45%
After: CV=3%

AP (U/L) - 37°C

Before: CV=42%
After: CV=3%

G. FERARD, J. M. LESSINGER 1998
EQUAS Results
Clinical Guidelines for Decisions

NEED FOR INTERNATIONAL STANDARDISATION

• Characterisation of Analyte
• Clinical Needs
• Reference Procedure
• Reference Material
• Reference Laboratories
• Reference Ranges
IVD-Directive 98/79

The traceability of values assigned to calibrators and or control materials must be assured through reference measurement procedures and reference materials of a higher order.

ISO Standards

*In vitro* diagnostic medical devices - Measurements of quantities in biological samples

- **ISO 17511** – Metrological traceability assigned to calibrators and control materials.
- **ISO 18153** – Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials.
ISO/EN 17511
Measurement of quantities in samples of biological origin – Metrological traceability of values assigned to calibrators and control materials
EU Lex: Directive 98/79 EC application on in vitro diagnostic medical reagents

**TRACEABILITY**

Property of the result related to national or international standards through an unbroken chain of comparisons all having stated uncertainties.

A: traceable to SI
B: non-traceable to SI

- Int’l Reference measurement procedure and int’l calibrator
- Int’l Reference measurement procedure but no int’l calibrator
- Int’l calibrator but no int’l reference measurement procedure
- Manufacturer's measurement procedure but neither int’l reference measurement procedure nor int’l calibrator
# FORMATION of JCTLM

| 1999 | Informal Meetings at the Netherlands Metrology Institute  
AACC, BIPM, DGKC, IFCC, IRMM, NIST  
Abbott, Beckman, Dade Behring, Roche  
IVD Associations from Europe, Japan, USA |
|------|---------------------------------------------------------------|
| 2001 | Declaration of Cooperation between BIPM, IFCC, and ILAC  
“The goal of the JCTLM is to provide a worldwide platform to promote  
and give guidance on internationally recognized and accepted  
equivalence of measurements in Laboratory Medicine and traceability to  
appropriate measurement standards.” |
| 2002 | Building the Structure of JCTLM  
Members: WG chairs, Representtives of BIPM, IFCC, ILAC |
| 2003 | Forming Workinggroups 1 and 2 |
| 2006 | Publication of Web-based Database |
JCTLM

Working Groups

1. Reference Materials and Reference Methods
   Chair: H. Schimmel (IRMM), K. W. Phinney (NIST)
   Compilation of existing data (Lists)

2. Reference Laboratories - Networks
   Chair: L. Siekmann (IFCC), L. Thienpont (IFCC)
   Guidelines for reference laboratories
   EQUAS for Reference Laboratories

http://www.bipm.org/enus/2_Committees/JCTLM.shtml
Objective:

• establishing a process for identifying, and reviewing against agreed upon criteria “higher order” Certified Reference Materials and Reference Measurement Procedures required for IVD industry compliance with the EC IVD Directive regarding in vitro diagnostic medical devices.

• publishing Lists of “higher order” Certified Reference Materials and Reference Measurement Procedures required for IVD industry compliance with the EC IVD Directive regarding in vitro diagnostic medical devices.
Worldwide representation from Lab Accreditation Organizations, NMIs, Professional Societies, and IVD Industry

Blood Cell Counting
L. Wang, NIST
Blood Grouping
S. Thorpe, NIBSC
Coagulation Factors
E. Gray, NIBSC
Drugs
A. Hendrion, PTB
Electrolytes
B. Tousaint, IRMM
Enzymes
M. Panteghini, IFCC
Metabolites and Substrates
X. Bei, NIM
Microbiology Serology
C. Giroud, Bio-Rad Lab.
Non-Electrolyte Metals
L. Yu, NIST
Non-Peptide Hormones
H. Schimmel, IRMM
Nucleic Acids
H. Parkes, LGC Ltd.
Proteins
D. Bunk, NIST
Quality System
C. Jackson, Hartwell Foundation
Vitamines
D. Wiebe, Univ. Wisconsin
Objectives:

• Collecting information on existing and candidate reference measurement laboratories (RMLs)

• Encouraging and facilitating the formation of networks of RMLs for different groups of measurable quantities (concerning electrolytes, substrates/metabolites, enzymes, HbA1c, low molecular hormones, etc.)

• Establishing a procedure for the approval of RMLs on the basis of their metrological level according to ISO 15195, 17025 and their performance as demonstrated in inter-laboratory comparisons linked to an NMI or to RELA trials organized by the C-TLM (IFCC).
IMPACT of Traceability on Laboratory Medicine

- Harmonisation and better comparability of field methods
- Change of numeric results
- Change of reference ranges
- Impact on clinical decisions and classification of patients