JCTLM

Introduction

A global approach to improve reference systems

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JCTLM

Joint Committee of Traceability in Laboratory Medicine

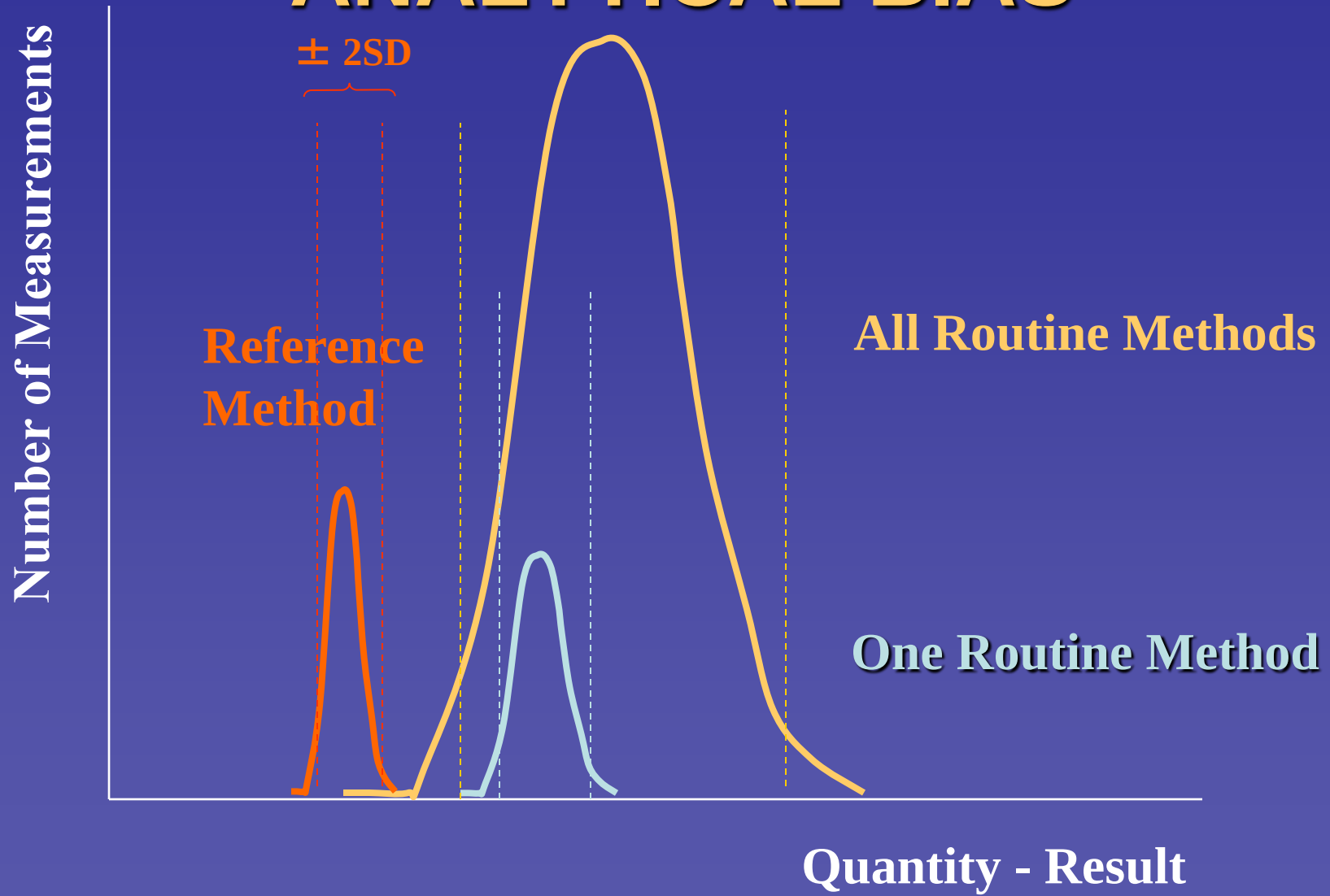
- **Reference Measurement Procedures**
- **Certified Reference Materials**
- **Reference Laboratories**
- **Reference Ranges**

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

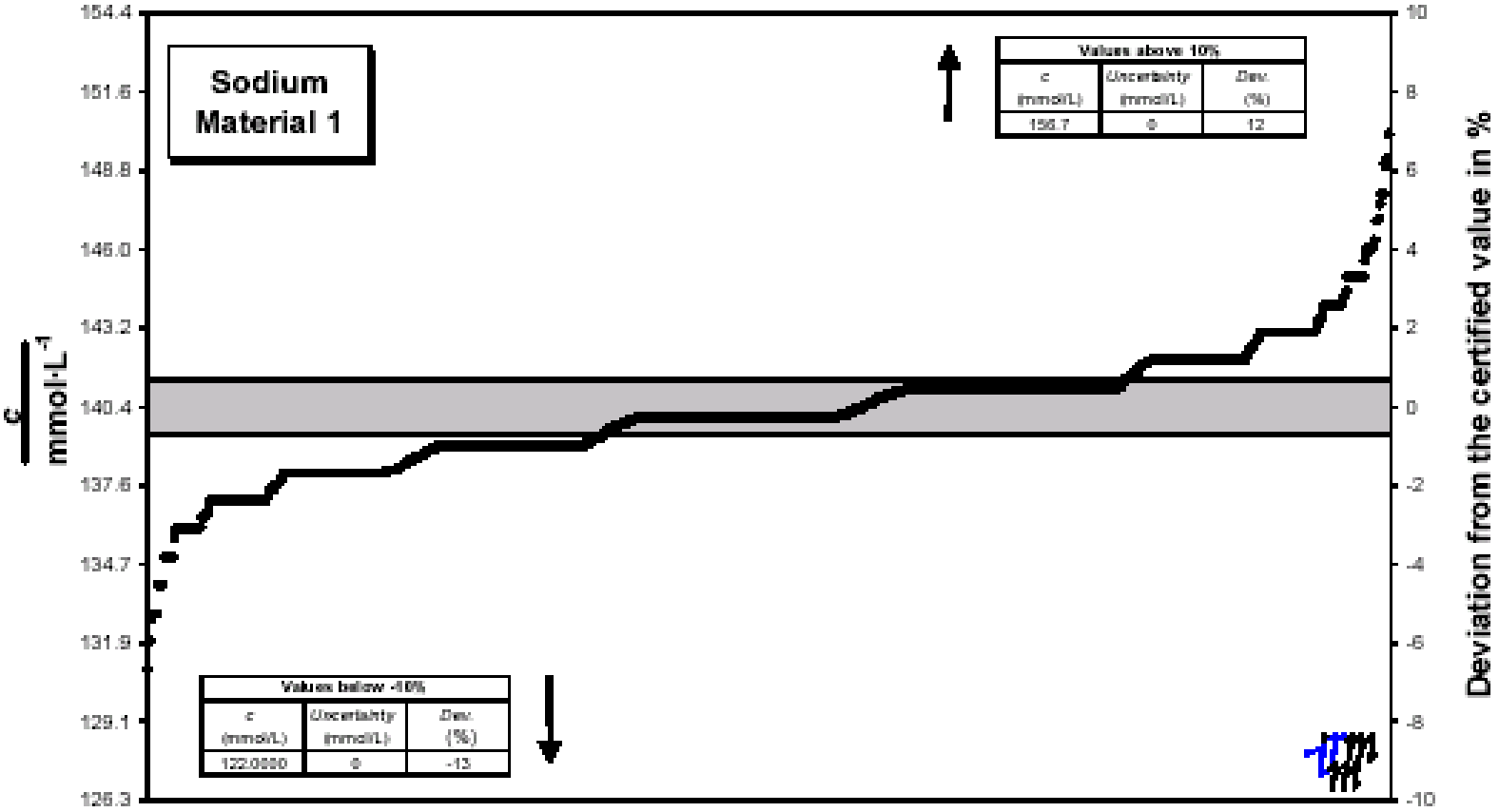


R. DYBKAER 1975

International Comparison

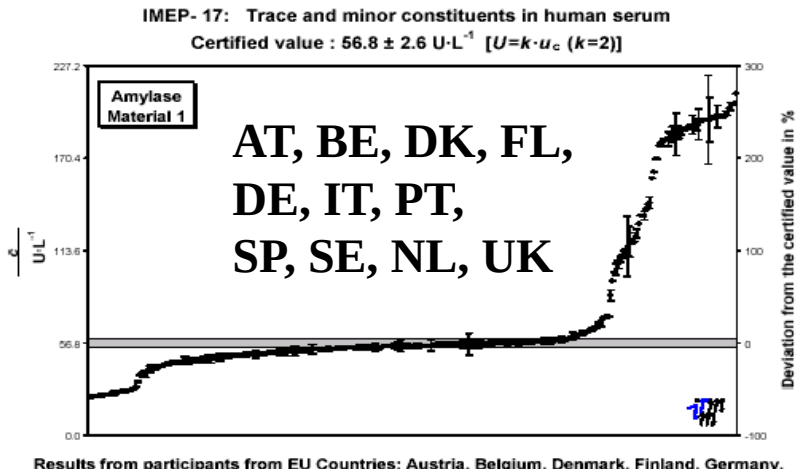
IMEP- 17: Trace and minor constituents in human serum

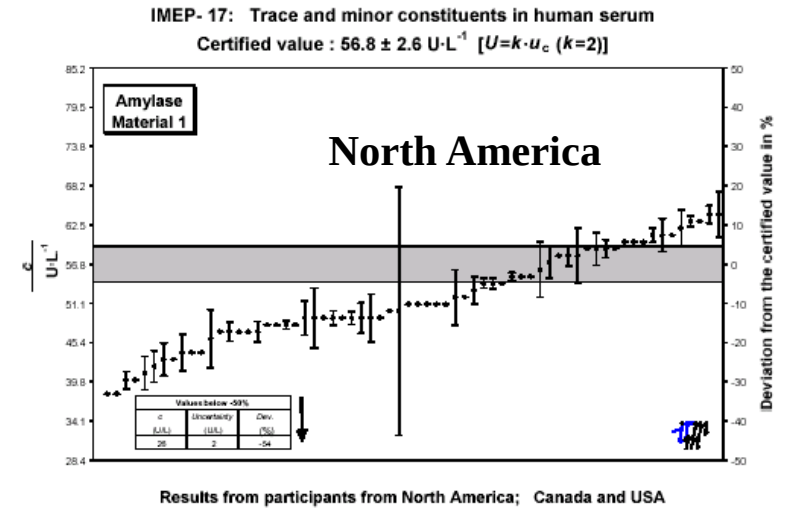
Certified value : 140.36 ± 0.95 mmol·L^{-1} [$U = k \cdot u_c$ ($k = 2$)]

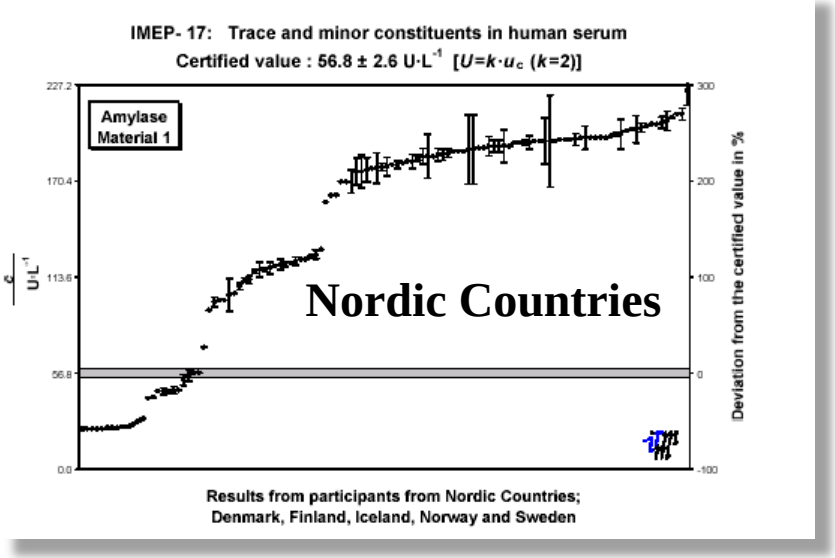


Results from all participants (992 laboratories)

Amylase Comparison







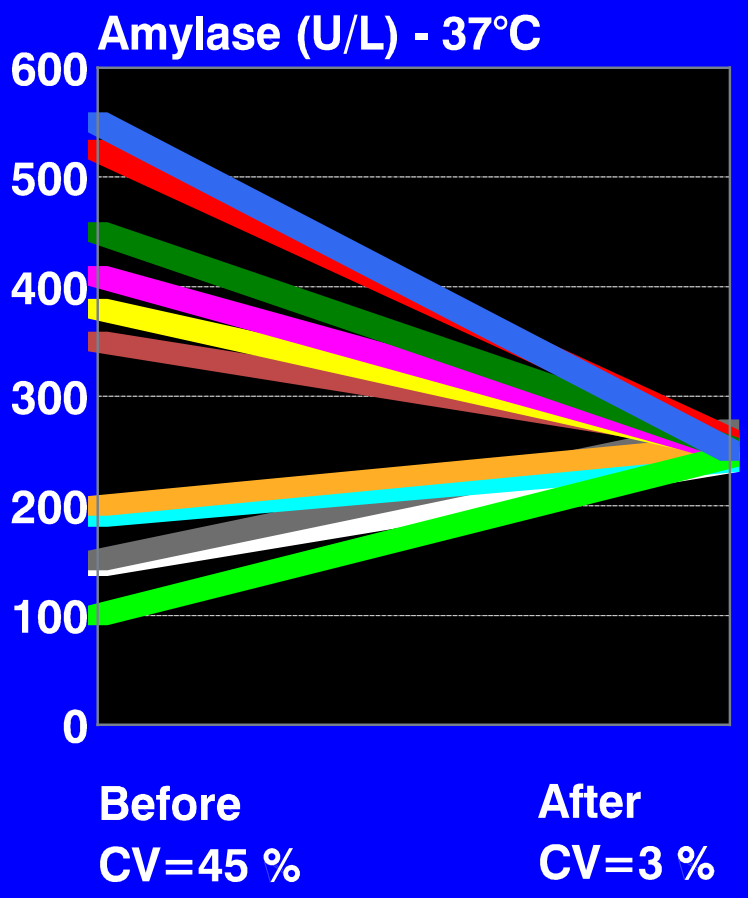
- **Difference in field methods**
- **Patient results not comparable**

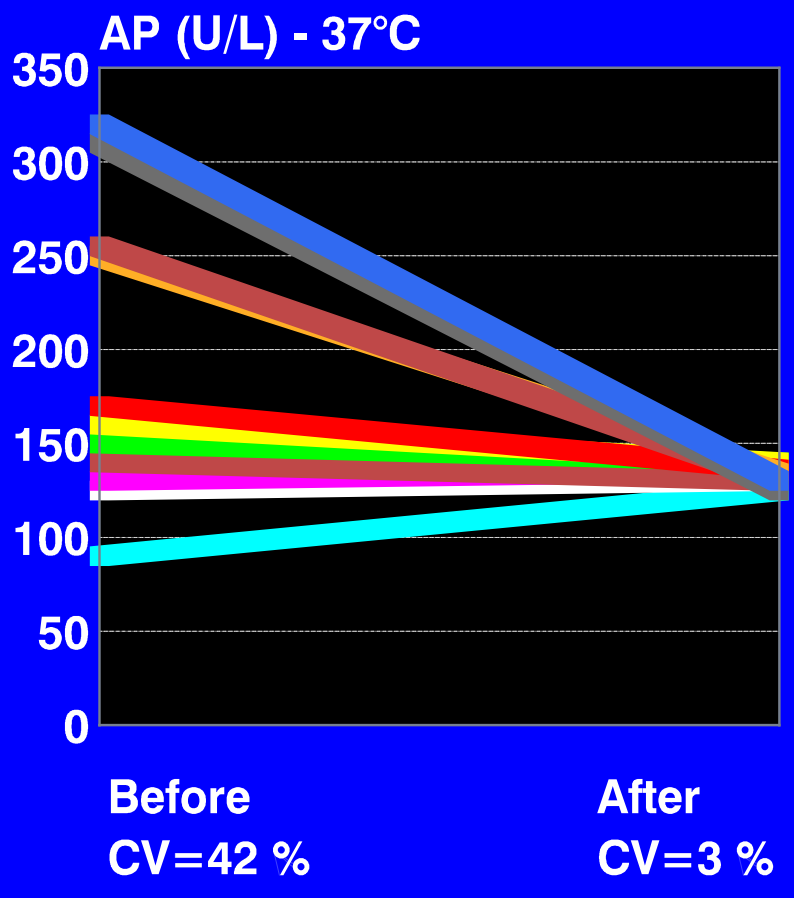
Need for Harmonisation and Standardisation

ifcc SD

WG-CALIBRATORS IN CLINICAL ENZYMOLOGY (WG-CCE)

Effect of Uniform Calibration on Various Methods





G. FERARD, J. M. LESSINGER 1998

EQUAS Results
Clinical Guidelines for Decisions

NEED FOR INTERNATIONAL STANDARDISATION

REFERENCE SYSTEM

- **Characterisation of Analyte**
- **Clinical Needs**
- **Reference Procedure**
- **Reference Material**
- **Reference Laboratories**
- **Reference Ranges**

IVD-Directive 98/79

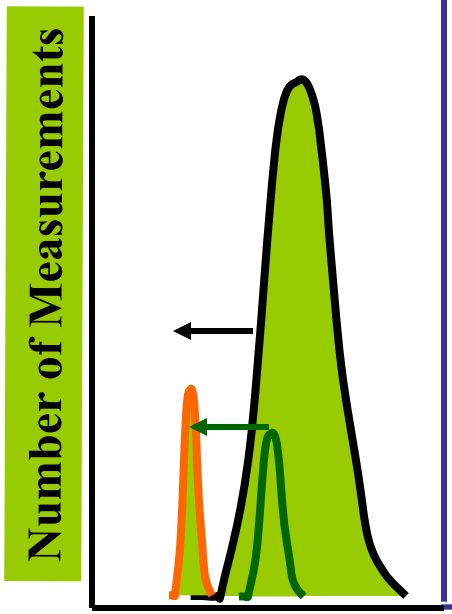
The **traceability** of values assigned to calibrators and or control materials must be assured through **reference measurement procedures and reference materials** of a higher order

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.

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 Rreference 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** **Executive (IFCC): J. Thijssen (2002-2005), J. C. Forest (2006 – 2009), M. M. Müller (2010 -)** **Secretary (BIPM): A. E. Sammel (2002 – 2003), R. Wielgosz (2004 -)** **Members: WG chairs, Representtives of BIPM, IFCC, ILAC**
2003 **2006**	**Forming Workingroups 1 and 2** **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

WG 1

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.

WG1, 2 REVIEW TEAMS

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**

WG 2

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**