



The work of the JCTLM to overcome challenges to the global standardization of clinical laboratory testing

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A decorative graphic on the right side of the slide, consisting of multiple overlapping, concentric arcs in various colors (red, orange, yellow, green, blue, purple, pink). The arcs are arranged in a way that they appear to be part of a larger, circular pattern, creating a sense of movement and depth.

Working together to promote and advance the global comparability of measurements

Joint committee sponsored by four organizations

Established in 2002 in response to regulatory requirements of the EU IVDD, now IVDR, that are relevant globally.



- Financial support



Accurate results
for patient care



- Secretariate
- Review Teams
- Database
- Financial support



Summary:

- Laboratory medicine measures bio-molecules in body fluids to inform medical decisions
- Equivalent testing results are important for health care
- Metrological traceability enables equivalent results
- JCTLM supports the *in-vitro* diagnostic industry
- Achieving globally standardized medical laboratory results has challenges
- People in all countries are the beneficiaries of the JCTLM's work



Laboratory Medicine

let's get some
blood work to
check your heart



The *in vitro* diagnostics industry



- Develops medical laboratory measuring systems (devices)
- IVD companies market their products globally
- Supports research into new biomarkers for diseases
- Collaborates with medical laboratory professionals to provide laboratory medicine for patient care



Lab test results should be the same everywhere

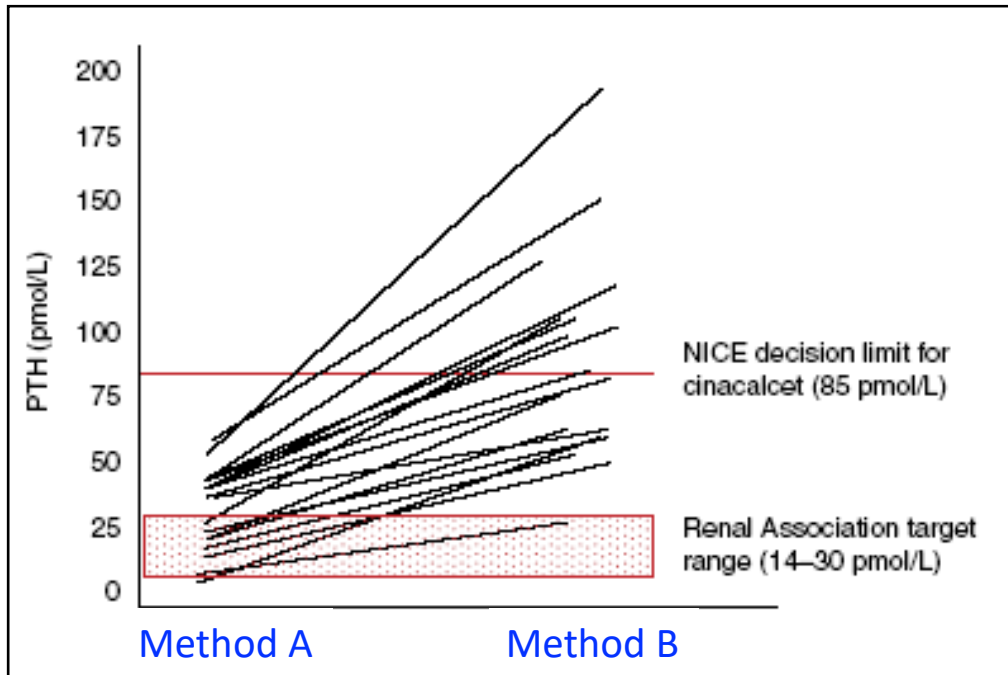


Results are compared to decision values to make a diagnosis or define a therapy

- Glucose >7 mmol/L = diabetes
- Troponin >99 %-tile = heart attack
- $eGFR_{\text{creatinine}} <60$ mL/min/1.73m² = kidney disease



Between method variability causes medical errors



Treatment variation caused by comparing highest and lowest PTH concentrations in 18 patients.

Almond et al. Ann Clin Biochem 2012; 49: 63–67.

**PTH (1-84) Reference System Development
Collaboration by:**



Reference Method Development



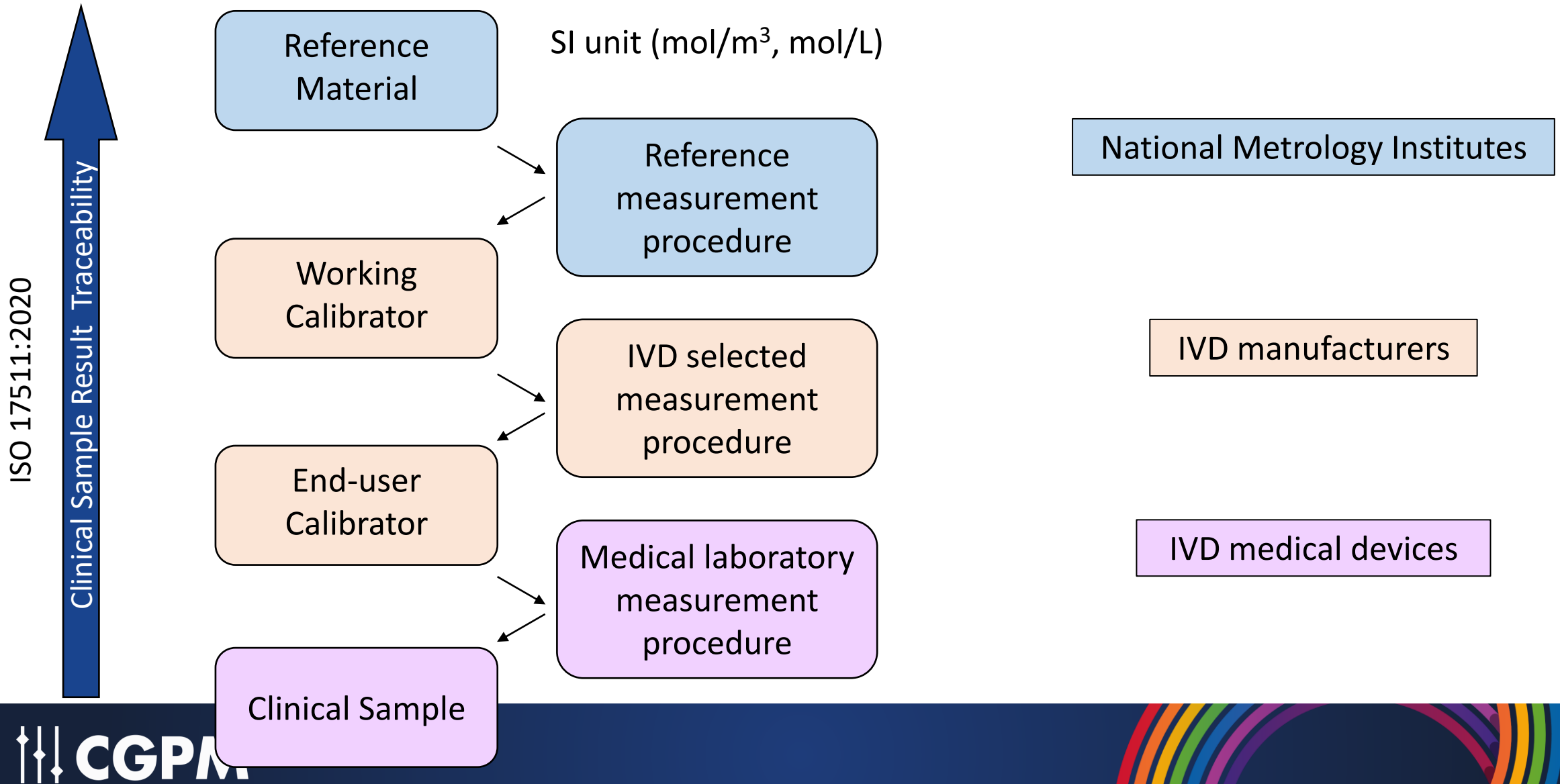
**Primary Reference Material
Comparison (CCQM-K115.d)**



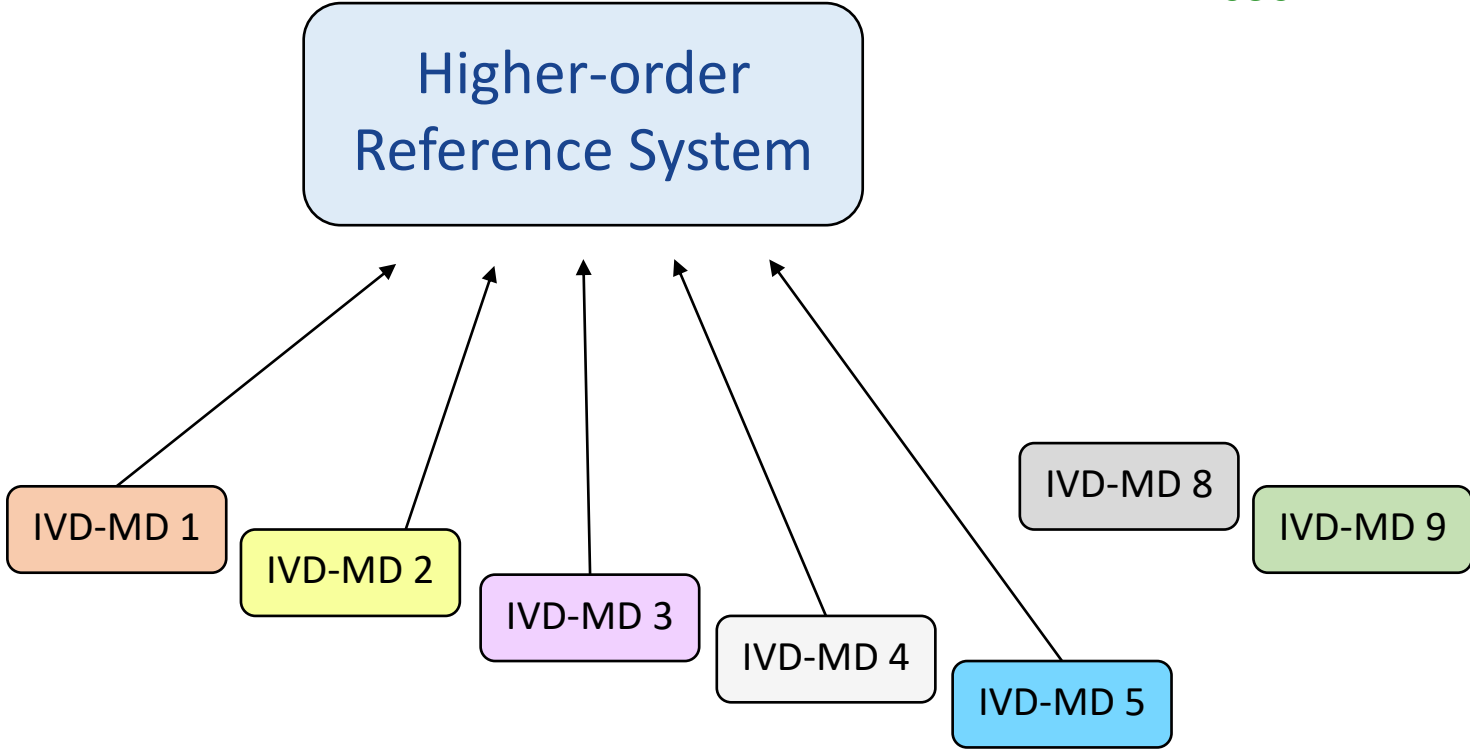
**Commutable Certified
Reference Material**



Metrological traceability enables equivalent results



2023 → 2030 → 2040





International Standards Organization

- 15193:2009 - Requirements for content and presentation of **reference measurement procedures**
- 15194:2009 - Requirements for **certified reference materials** and the content of supporting documentation
- 15195:2018 - Requirements for the competence of **calibration laboratories using reference measurement procedures**





Accurate results
for patient care

Laboratory medicine and in vitro diagnostics



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NEWS



JCTLM Database: higher-order reference materials, methods and services

265

Materials

215

Methods

224

Services

- ✓ Supported by volunteer review teams in all disciplines of laboratory medicine



New JCTLM Database - with Machine Readability

Web-based application to search database

Search database

Please type a key word * SEARCH

[→Advanced search](#)

2 Results

EXPORT PDF EXPORT XLS DETAILED VIEW

IFCC Committee on Plasma Proteins (C-PP) reference method for C-reactive protein

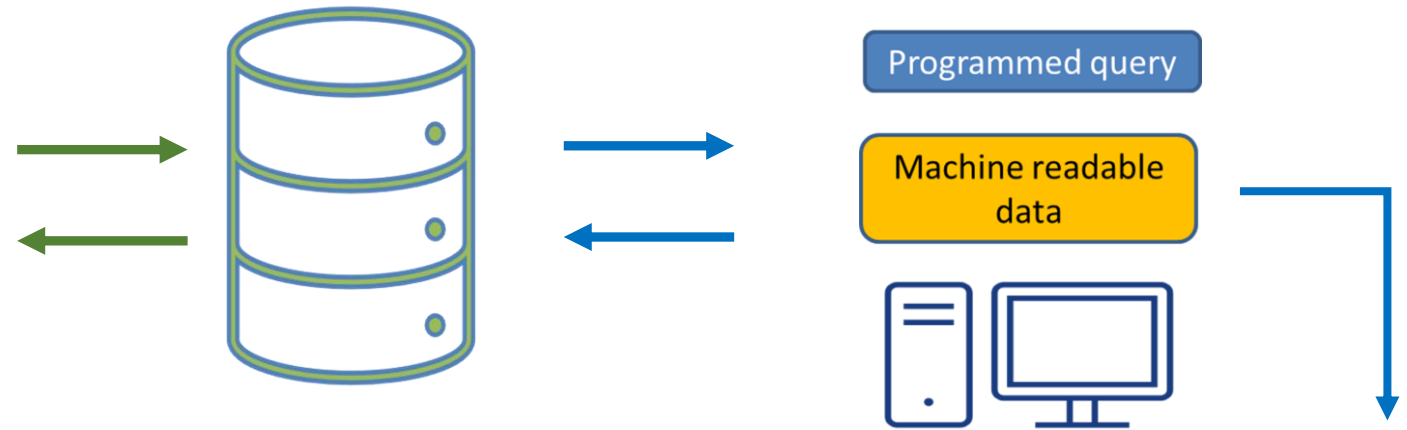
JCTLM DB Identifier	C1RMP_P8
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C-reactive protein (CRP) in processed human serum

European Commission - Joint Research Centre →(EU - JRC) - Belgium

ERM-DA474/IFCC, Human serum

Application and Programming Interface for published reference materials, methods and services



- Supports development of user specific applications
- Avoids time in manually checking and following changes in the JCTLM Database
- JCTLM Data can be added to digital products
- User has up-to-date database information



Laboratory medicine needs equivalent results to use clinical decision values based on health outcomes research

In-vitro diagnostics manufacturers use JCTLM listed references with confidence

- to achieve metrological traceability
- to achieve equivalent results for clinical samples
- to meet regulatory requirements to market products

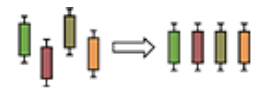




Guidelines and Recommendations

W. Greg Miller*, Gary Myers, Christa M. Cobbaert, Ian S. Young, Elvar Theodorsson, Robert I. Wielgosz, Steven Westwood, Stephanie Maniguet and Philippe Gillery

Overcoming challenges regarding reference materials and regulations that influence global standardization of medical laboratory testing results



International Consortium
for Harmonization of Clinical Lab

Report from a JCTLM/IFCC/ICHCLR workshop hosted by BIPM in December 2021

400 participants from 65 countries (virtual meeting)



Workshop recommendations

(summary)

1. Develop higher order reference system components as early as possible in the life cycle of IVD measurement procedures used by medical laboratories.
2. Coordinate global prioritization of measurands needing standardized measurement results.
3. Coordinate the global supply of certified reference materials.

The preceding 3 recommendations could be considered by the CIPM for health care sector engagement

4. JCTLM should identify reference materials that are useful but do not meet all ISO requirements.
5. Regulatory review is national or regional. Developing globally recognized requirements for regulatory review will improve availability of standardized results.



The work of JCTLM improves healthcare for everyone, everywhere

