



Traceability in laboratory medicine: a driver of accurate results for patients

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Outline

- Laboratory medicine in healthcare
- Traceability in laboratory medicine
- Joint Committee for Traceability in Laboratory Medicine
- Facing the challenge

Some big numbers

Global cost of healthcare \$~8.2 trillion pa

Global cost of laboratory medicine \$~200 billion pa

Global cost of reagents & equipment \$~62 billion pa

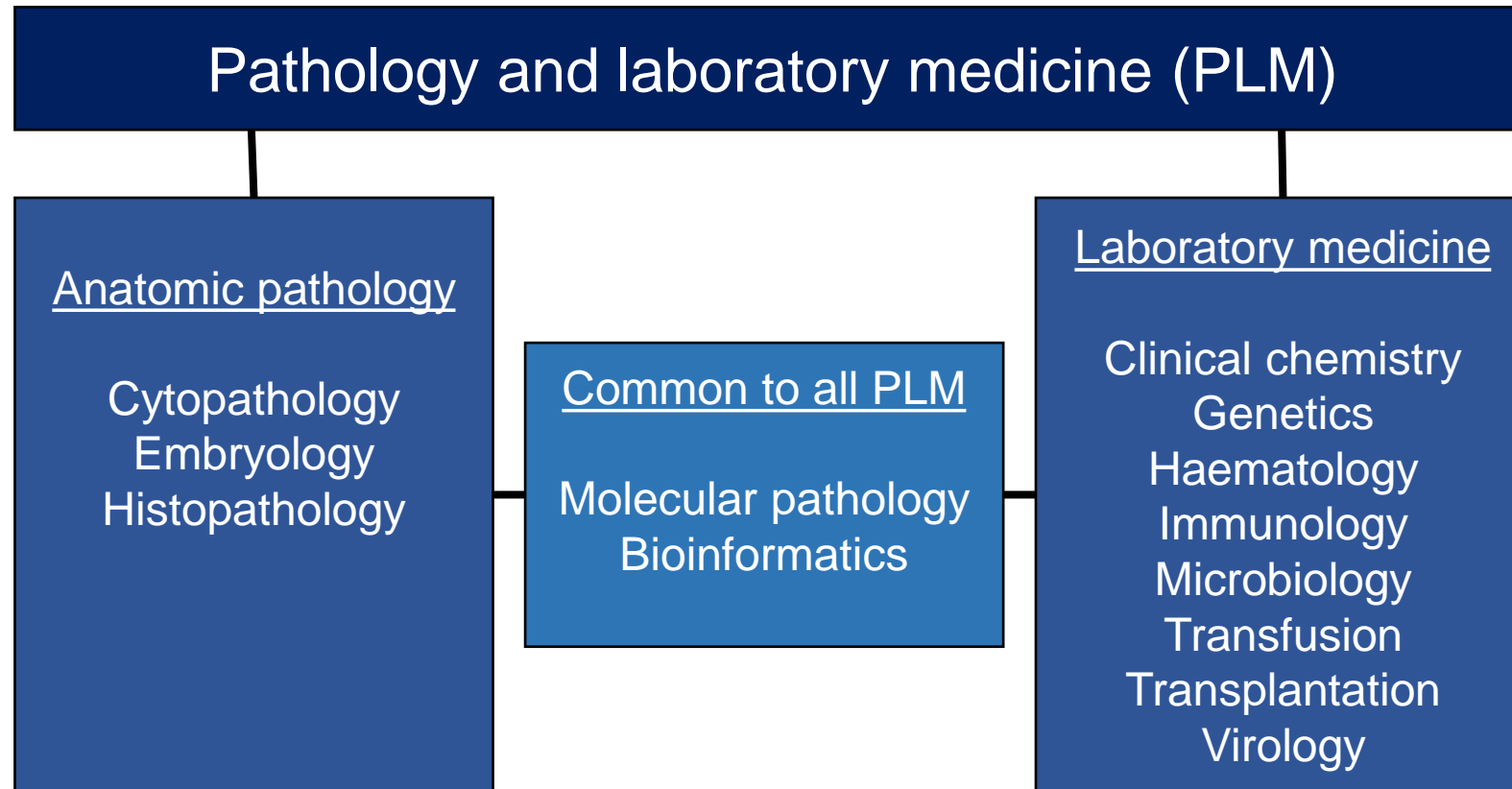
Global cost of staff and overheads \$~138 billion

Global IVD tests ~35 billion pa

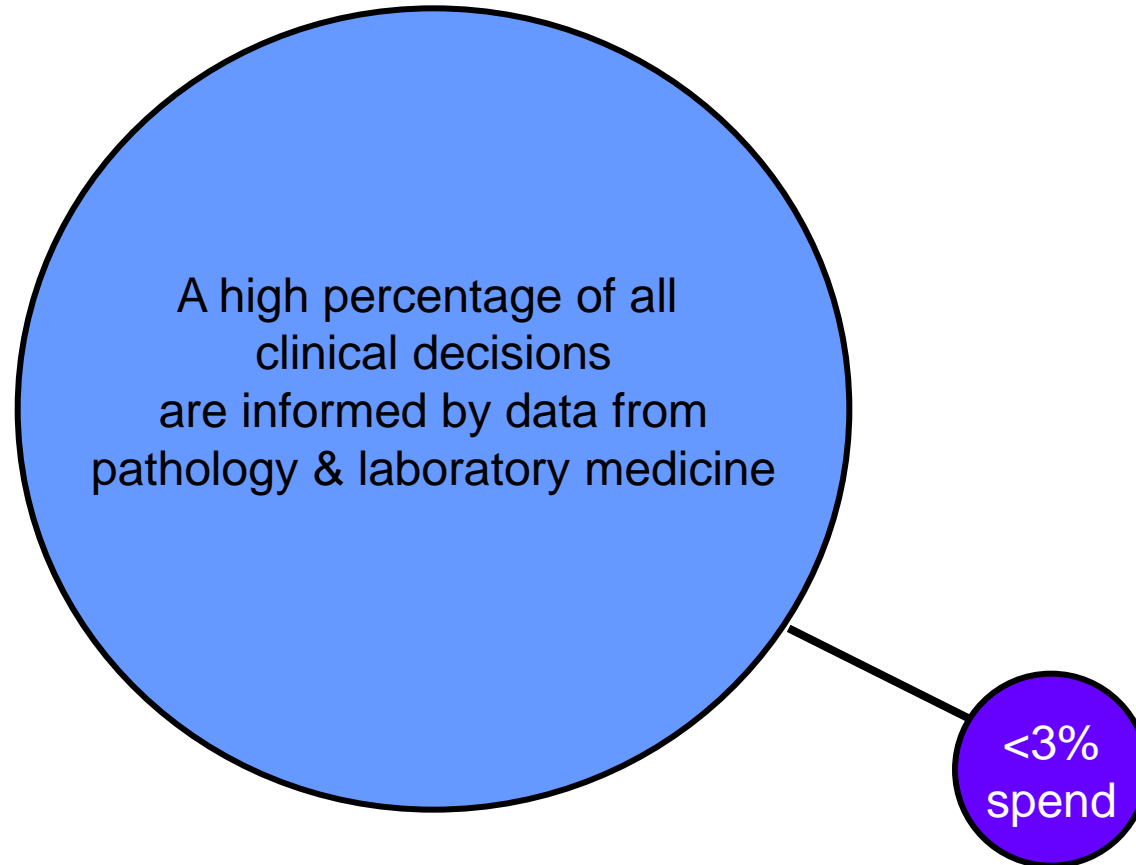
Number of different IVD tests ~ 4000

Annual growth of ~5% for all of above

Pathology and laboratory medicine

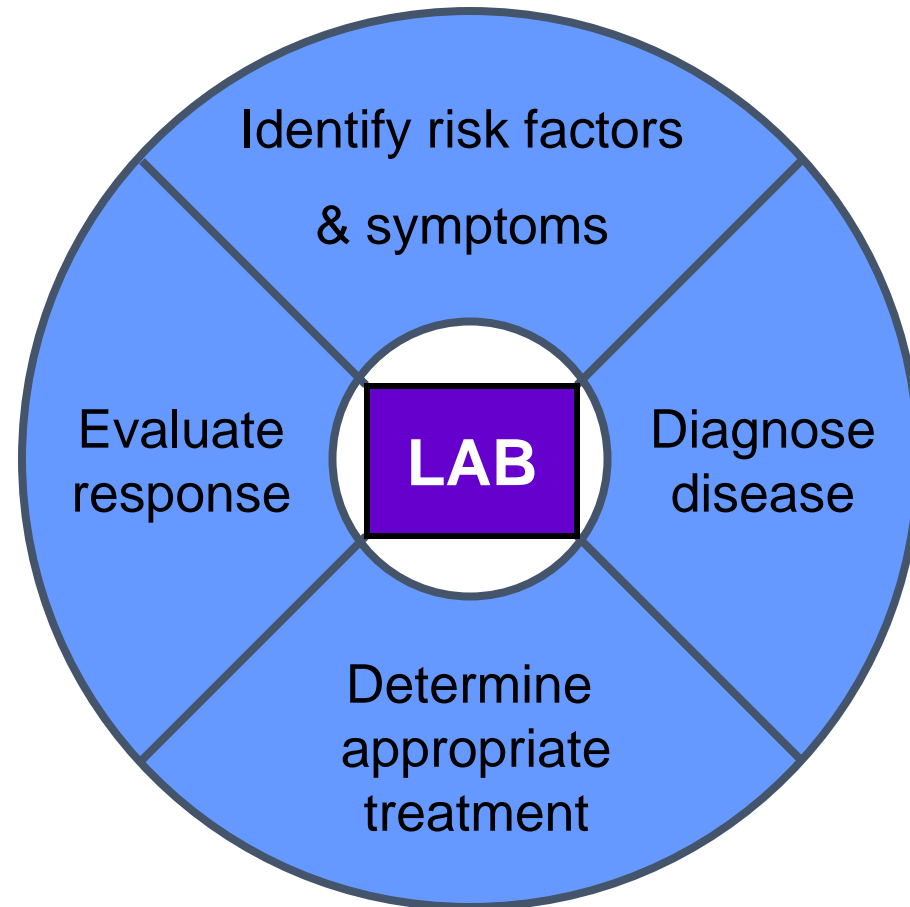


Central role of pathology & laboratory medicine



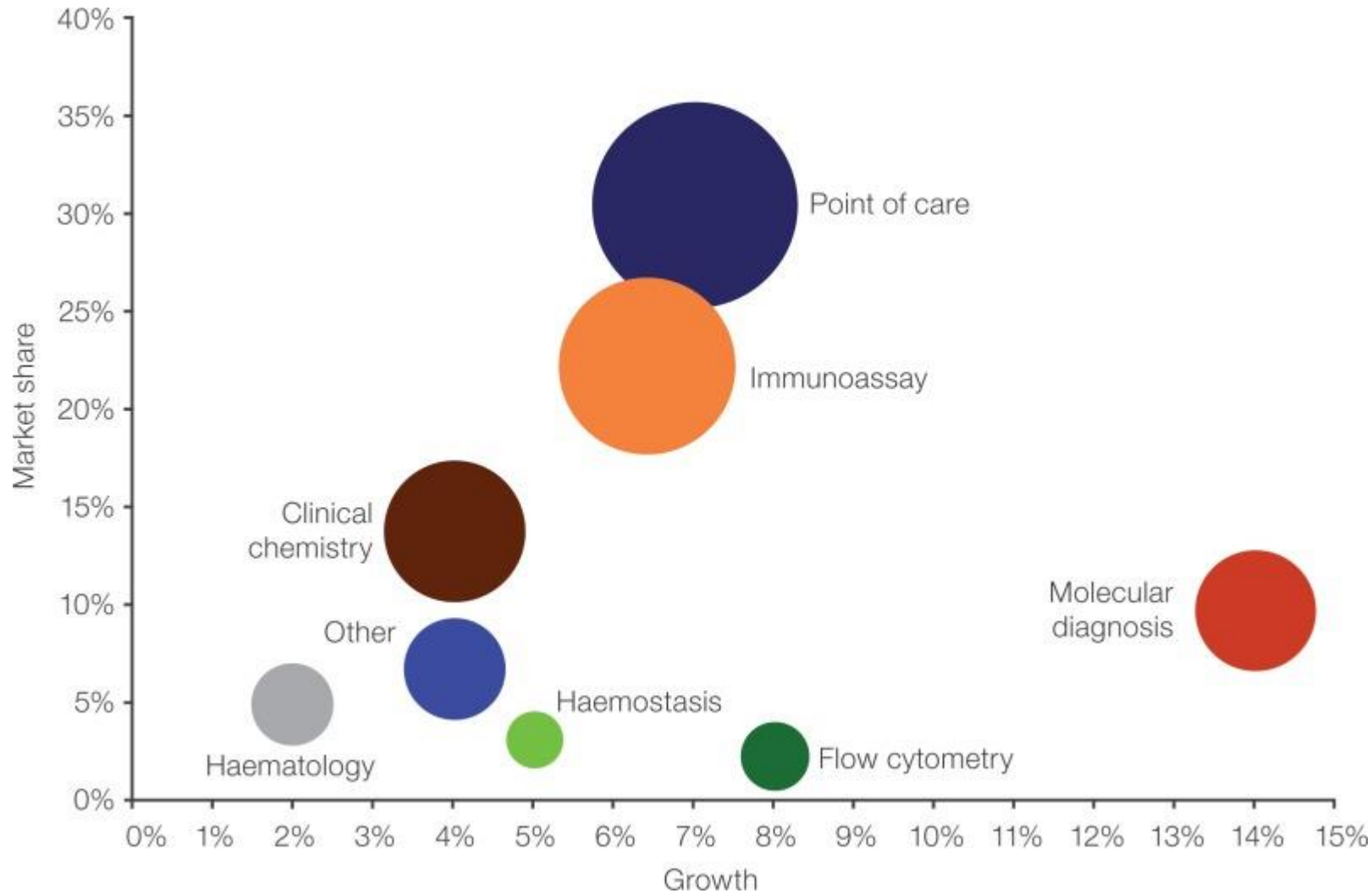
Central role of pathology & laboratory medicine

Pathology & laboratory medicine is part of the multi-disciplinary team at the centre of healthcare



With this influence comes responsibility to deliver a high quality service

Laboratory medicine sectors



Laboratory medicine methods

- Some measurands are structurally simple and available in pure form (e.g. glucose)
- Most measurands are complex, often heterogeneous (e.g. viruses)
- Method calibration is a challenge
- >100 diagnostic companies producing IVDs – using ‘own’ calibrators
- Result is often variability between methods for the same measurand
- The same patient specimen can give different results in different methods!

Variability between methods



Incorrect patient results



Mis-diagnosis / mis-management



Poor clinical outcomes



Impact on patient safety

Current HbA2 EQA performance

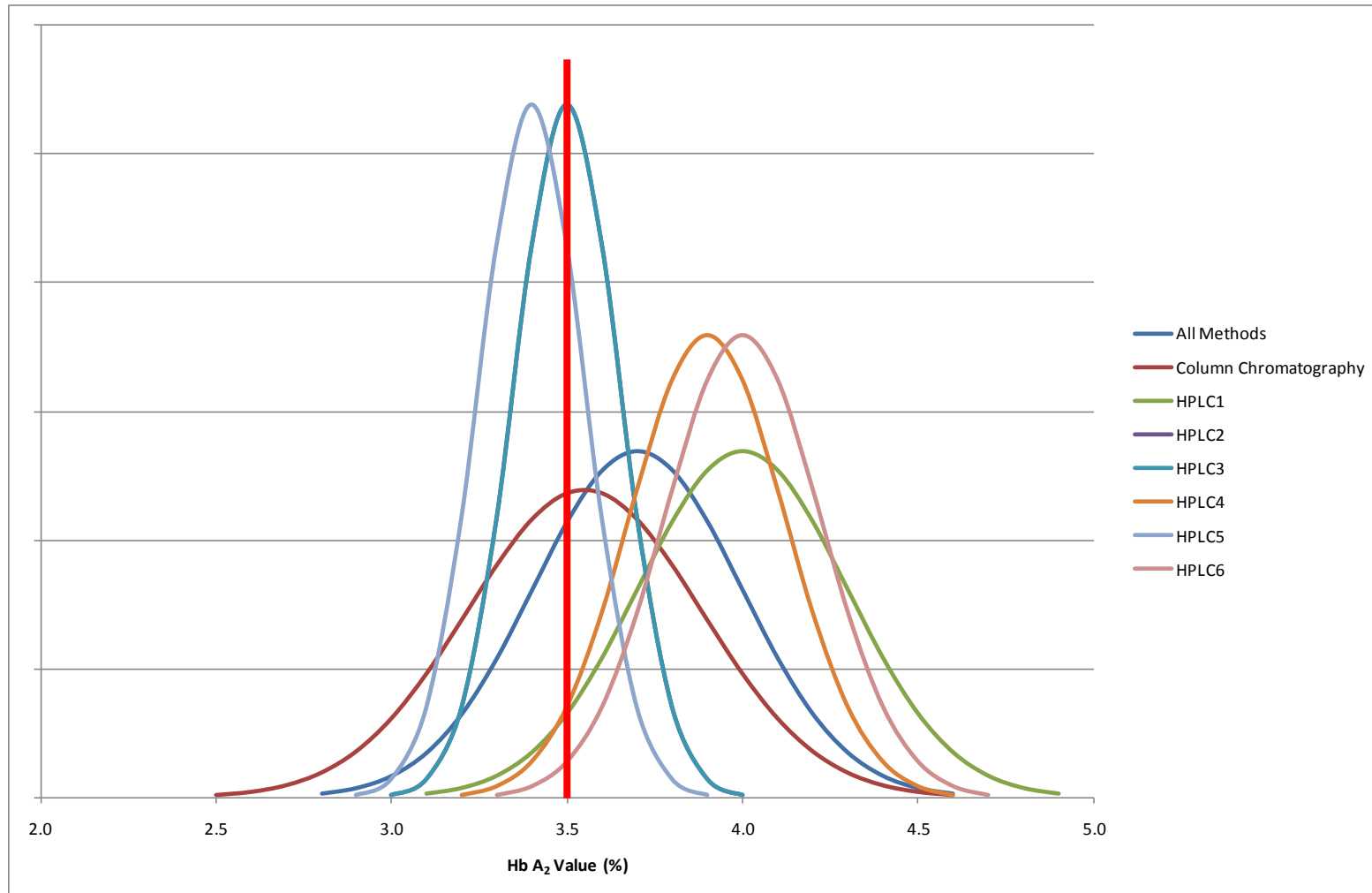


Figure from UK NEQAS with permission

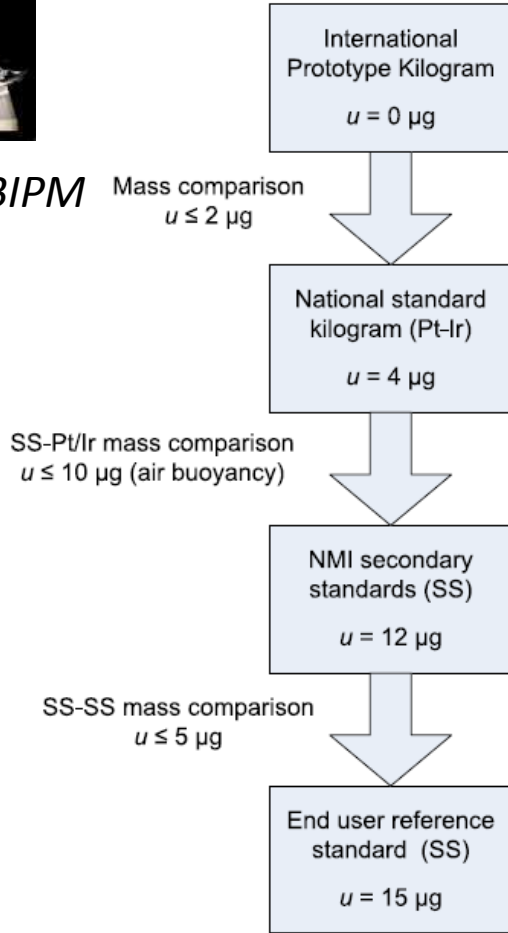
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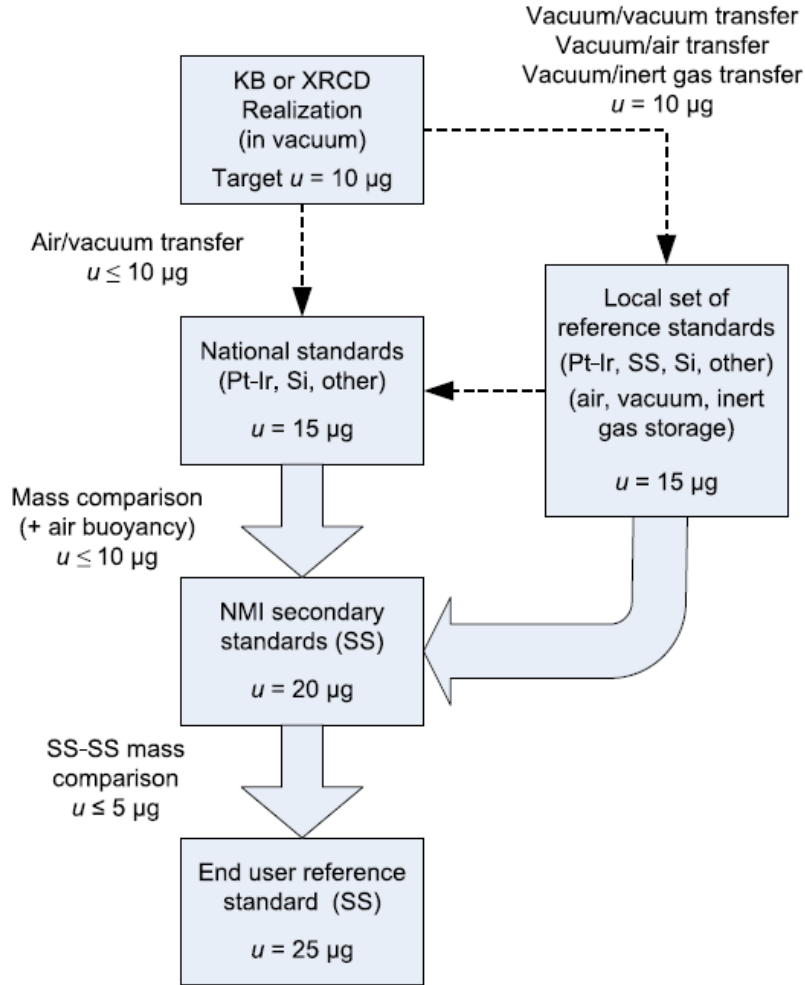


The IPK, at the BIPM

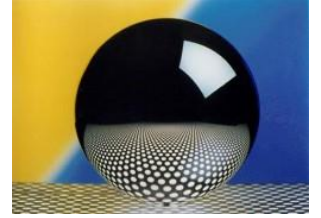
Current Traceability Chain



Proposed Future Traceability Chain



Kibble Balance



XRCD

Traceability chains for mass measurements

Traceable measurement results are compatible

What is traceability in laboratory medicine?

- Metrological traceability is the property of a measurement result, which can be related to a **reference** through a documented unbroken chain of **calibrations**, each contributing to the **measurement uncertainty**
- Traceability requires both (certified) reference materials and the reference measurement procedures (methods) in which they are used
- For structurally simple measurands (analytes) it is possible to get pure substance primary reference materials . For more complex measurands pure substance may not be available
- Primary reference measurement procedures are based on physical methods (e.g. ID-MS)

Reference materials (calibrators)

- Primary reference material (pure substance)
- Primary calibrator (SI traceable)
- Secondary calibrator
- Product calibrator

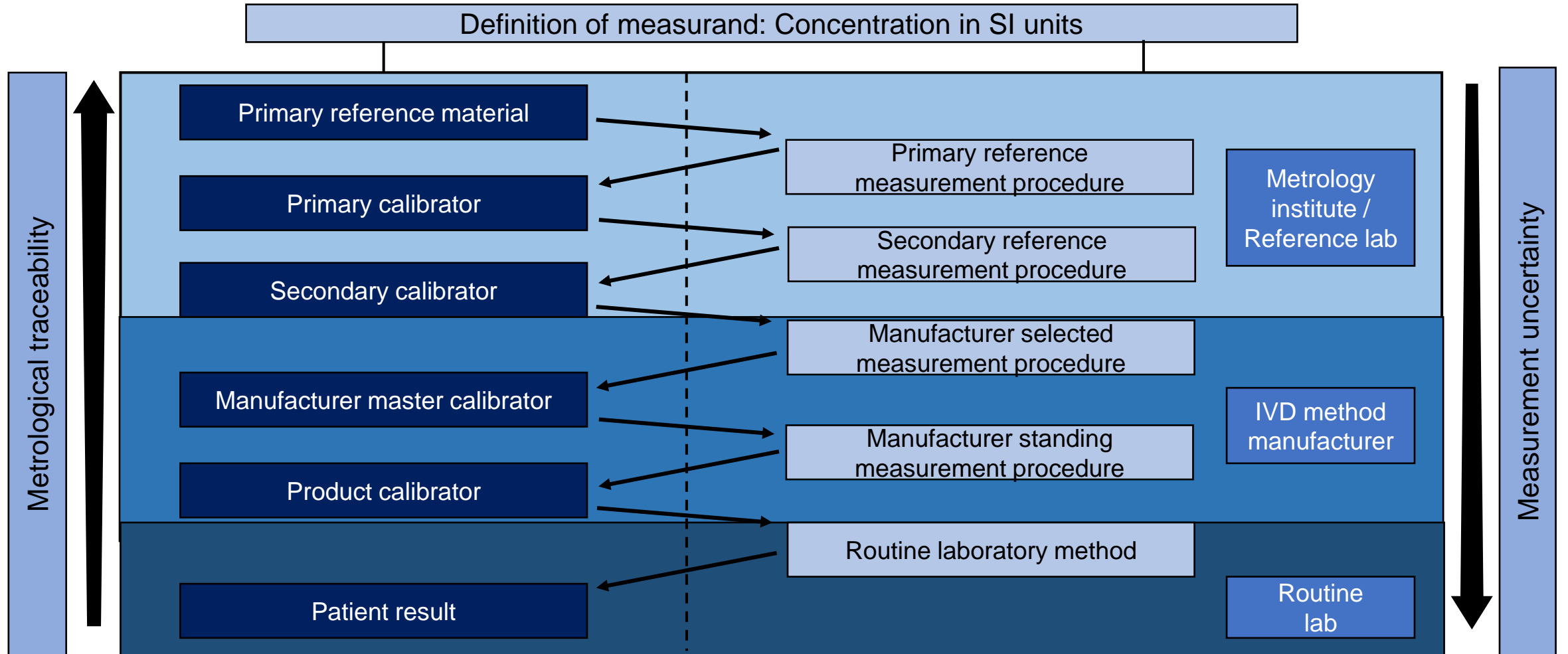


Reference measurement procedures

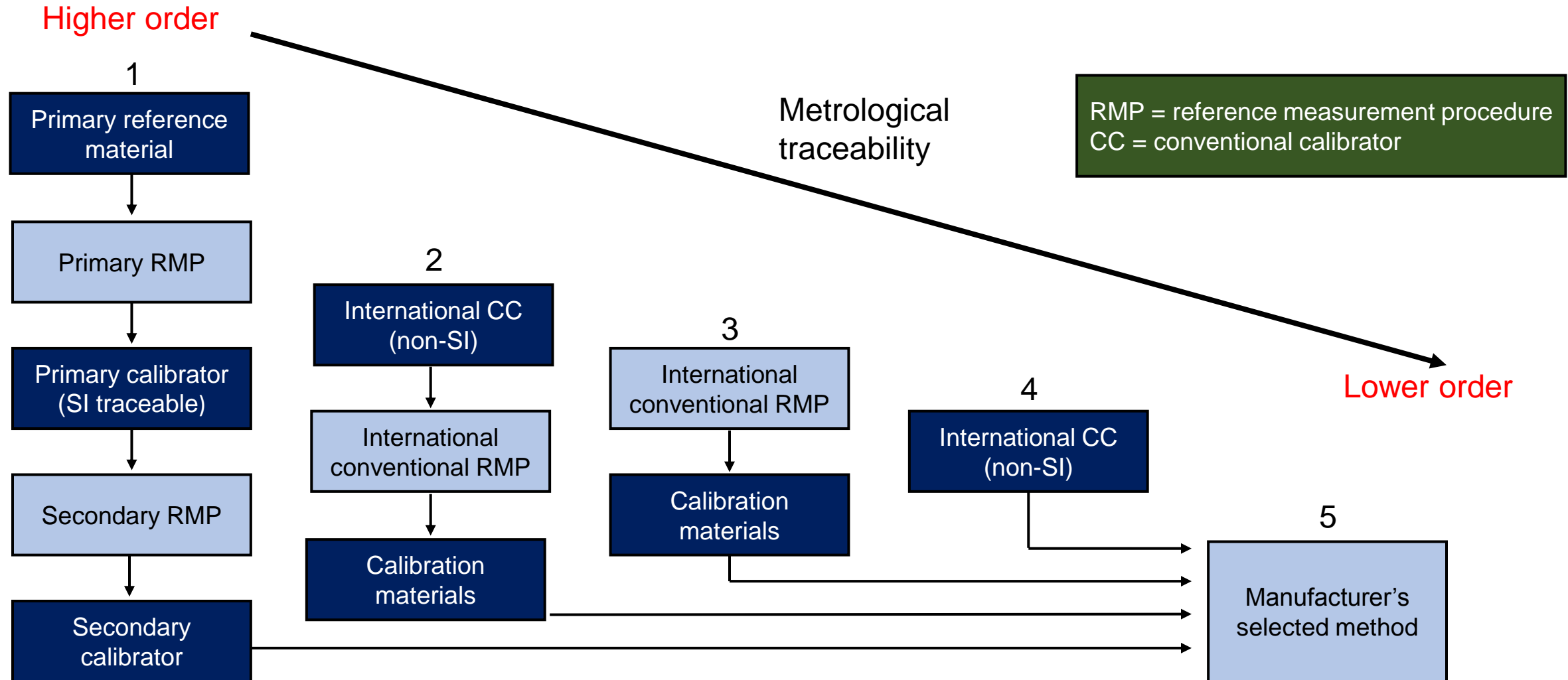
- Primary reference measurement procedure
- Secondary reference measurement procedure
- Manufacturer selected procedure
- Routine laboratory procedure

Hierarchy

The metrological traceability chain



'Higher order' materials and procedures



Requirements for traceability in laboratory medicine

European Union In-Vitro Diagnostic Directive (IVDD): 98/79/EC

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

EU In-Vitro Diagnostic Device Regulation (IVDR): EU/2017/746

“9.3. Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures and/or suitable reference materials of a higher metrological order”.

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Joint Committee for Traceability in Laboratory Medicine

Formed in 2002 to enable a global response to the IVD Directive



Intergovernmental treaty organisation for measurement standards



International NGO for professionals in laboratory medicine



International NGO for accreditation bodies

Now has 49 members from 19 countries
NMIs, EQA providers, professional bodies, IVD manufacturers
BIPM leads on metrology and provides the Secretariat



What does JCTLM do?

Maintains a global database of:

- Reference materials
- Reference methods
- Reference services

www.bipm.org/jctlm

Co-ordinates the nomination and review process for database entries

www.bipm.org/jctlm



Contributes to ISO Working Groups on reference systems, which are responsible for global standards

Provides news and freely available resources on traceability in laboratory medicine:

- Webinars; publication lists

www.jctlm.org

Hosts a biennial scientific meeting

JCTLM Database : www.bipm.org/jctlm/



Bureau International des Poids et Mesures

Database of higher-order reference materials,
measurement methods/procedures and services



JCTLM Database
Laboratory medicine and *in vitro* diagnostics

> You are here : JCTLM-DB



JCTLM database: Laboratory medicine and *in vitro* diagnostics

JCTLM-DB

- [Search Form](#)
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Highlights

- [Extension of the JCTLM-DB](#)
- [Publication of new data](#)

JCTLM

- [General information](#)

Analyte keyword search for reference materials, measurement methods/procedures and services

Type an analyte name in part or full, e.g. cholesterol

Refine search by analyte category

Refine search by matrix category

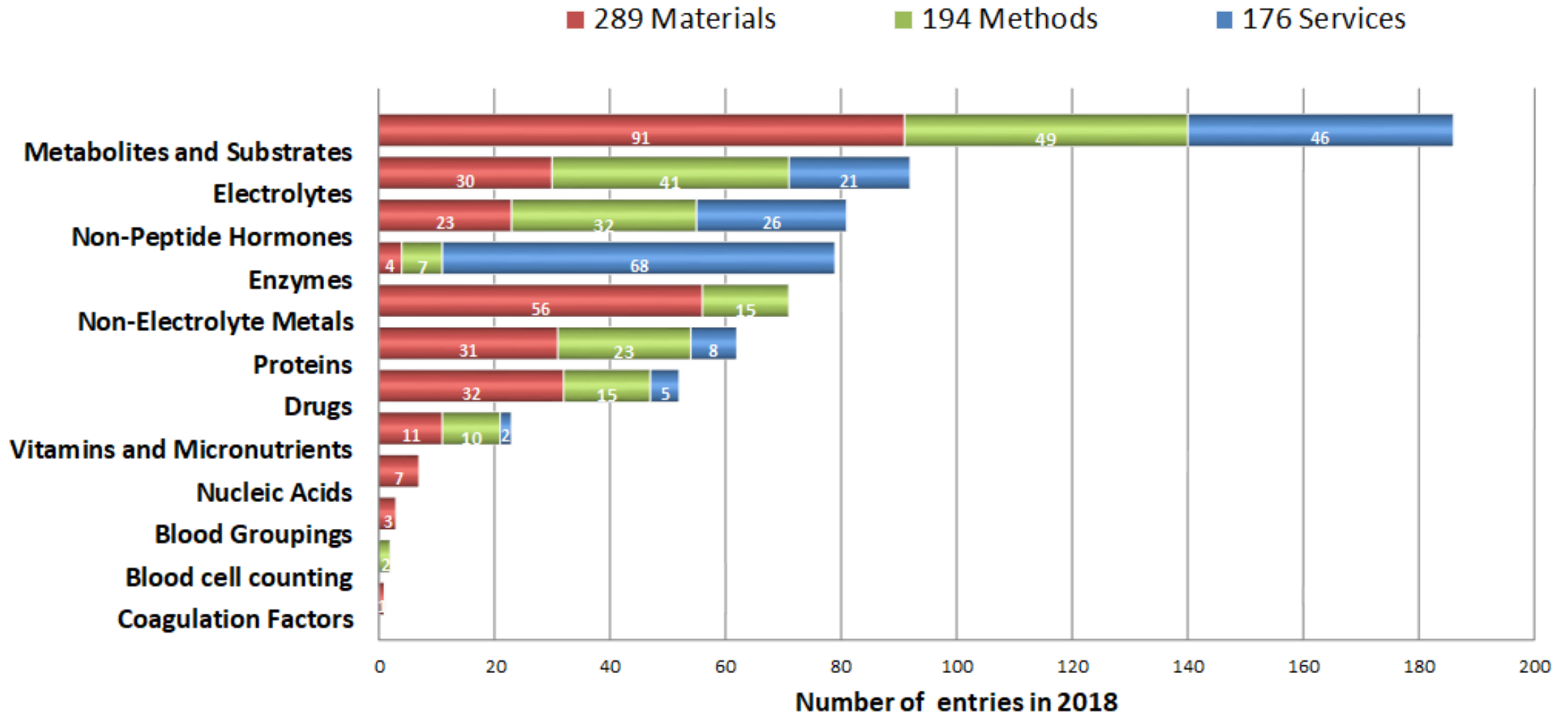
Please select your requirement :

- Higher-order reference materials
- Reference measurement methods/procedures
- Reference measurement services

Reset x

Search →

JCTLM Database: Entries in 2018



289 Certified Reference Materials

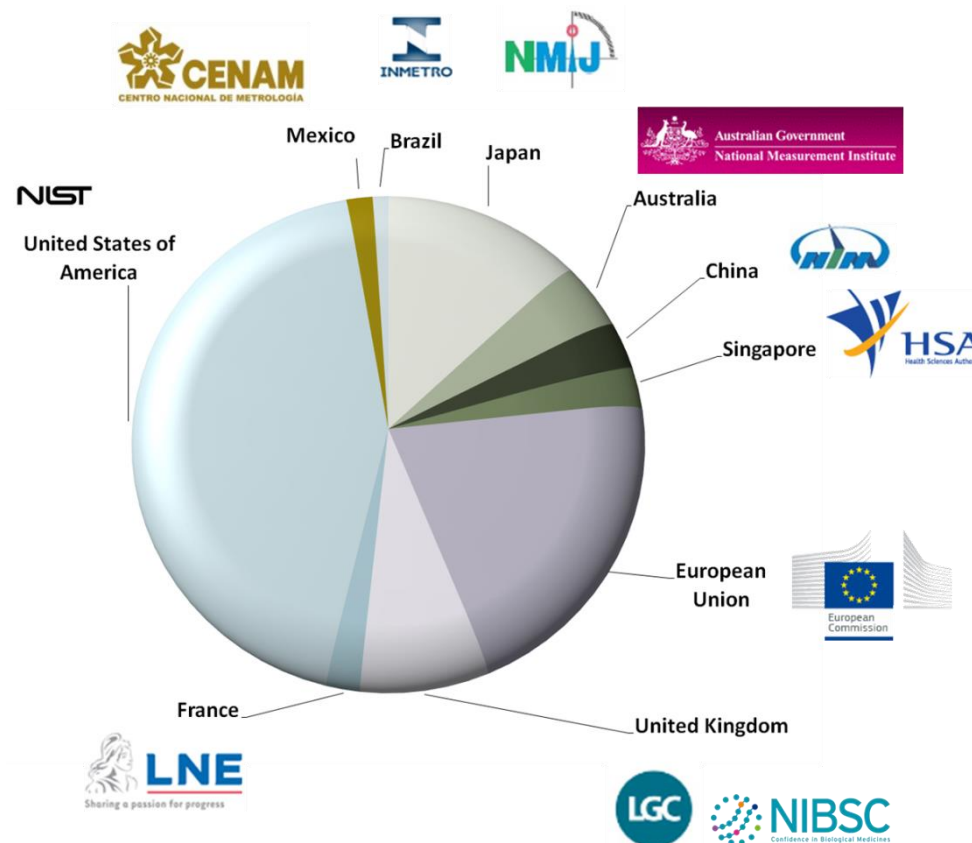
194 RMPs that represent 80 different analytes in 9 categories

176 reference measurement services delivered by 17 reference labs

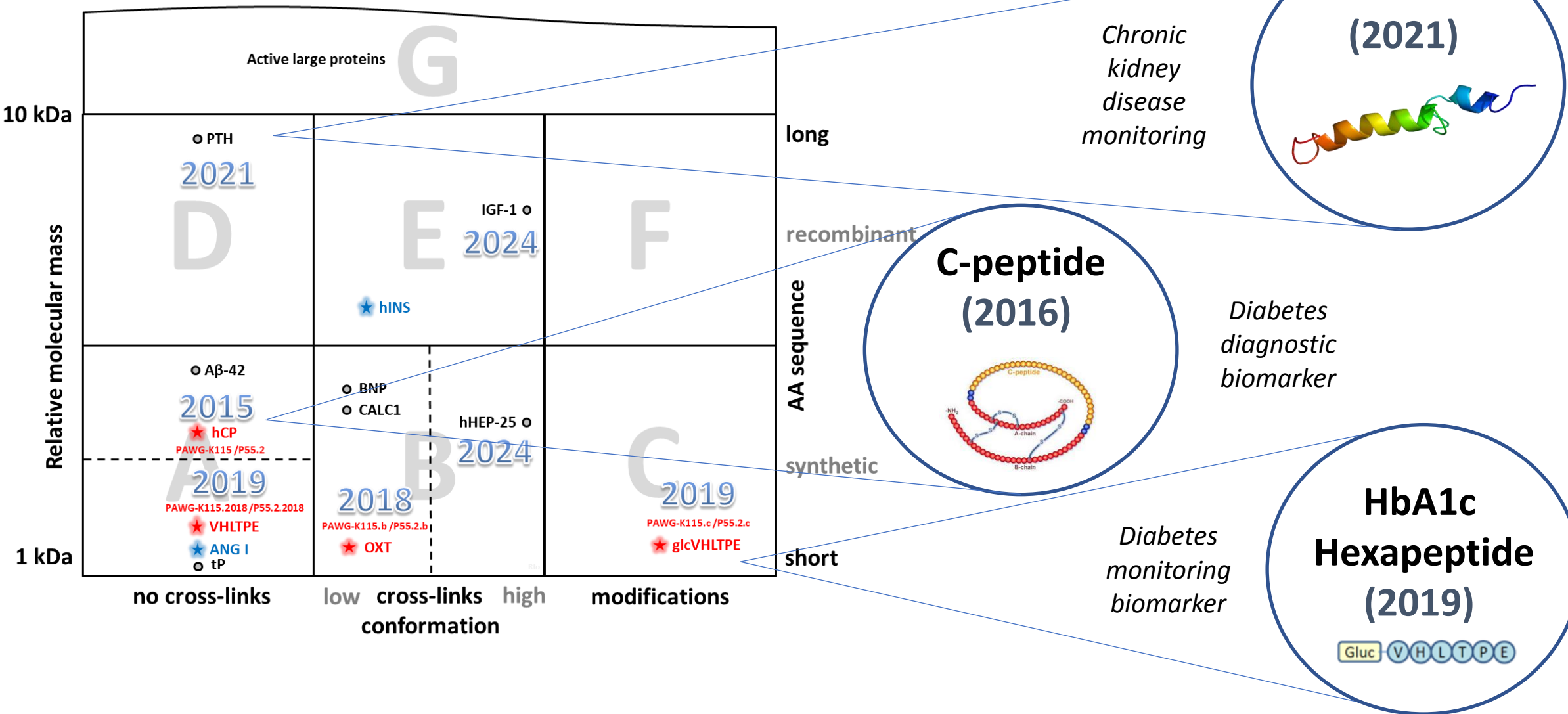
Higher order reference materials

- NMIs provide higher order reference materials (both pure and matrix materials) to support the IVD industry
- Currently 95% of Certified Reference Materials in the JCTLM database come from NMIs

- BIPM functions as an external quality assessment provider for NMIs:
 - Coordinates Key Comparisons
 - Send samples of pure materials for NMIs to value assign and compare
 - Use own labs to value assign the materials independently.



Pure peptide comparisons coordinated by BIPM for the NMIs



CCQM-K115: Peptide Primary Reference Material Comparison Series

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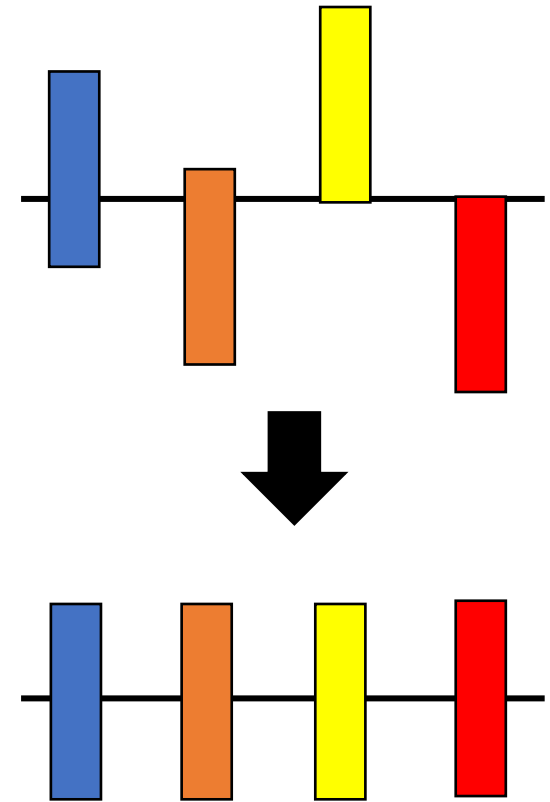
Facing the challenge



The world population of



7.7 billion people



is entitled to believe that all methods will give the same result on their specimen

Stakeholder coordination to address the challenge

