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

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Joint Committee for Traceability in Laboratory Medicine

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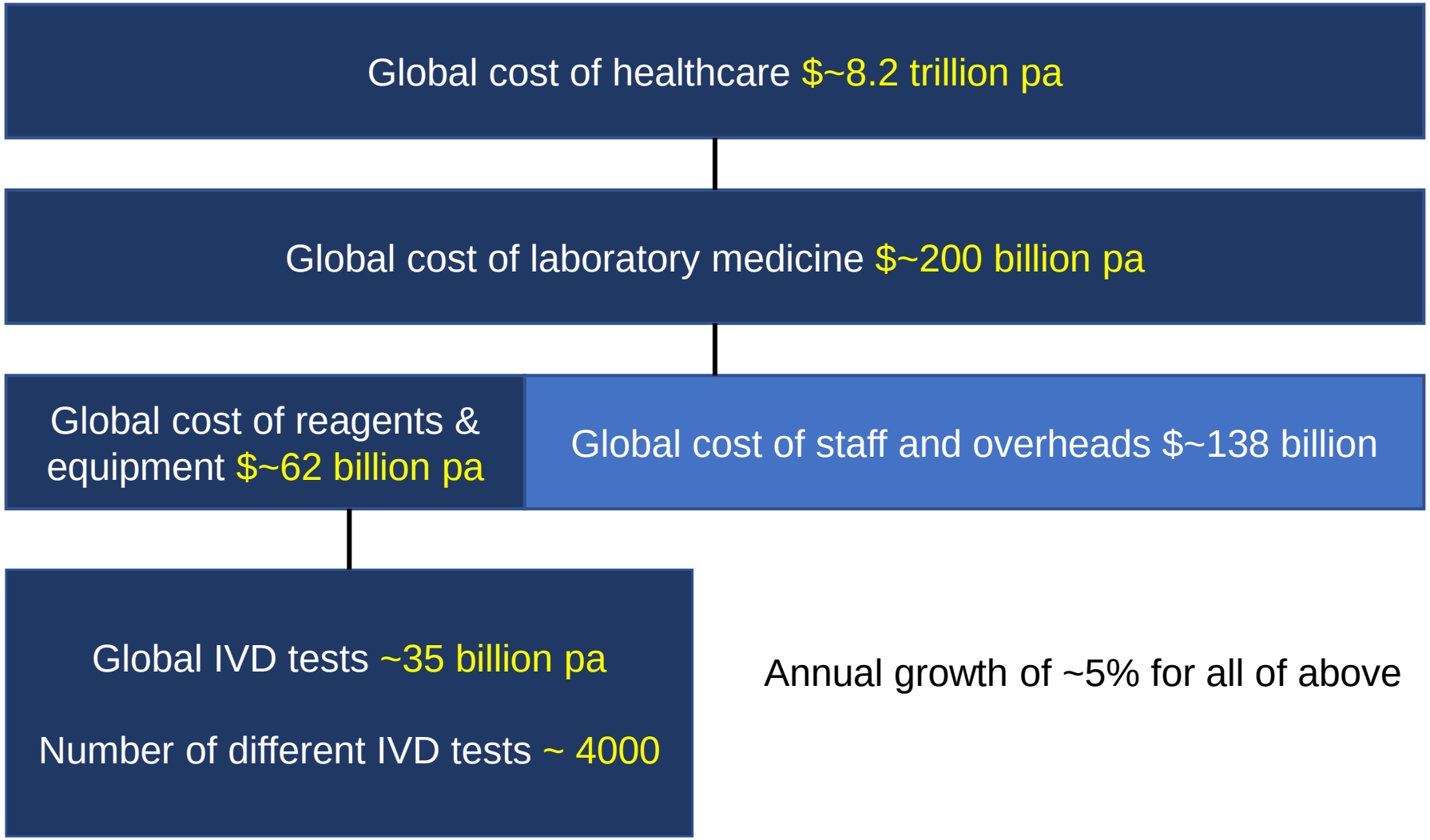
Outline

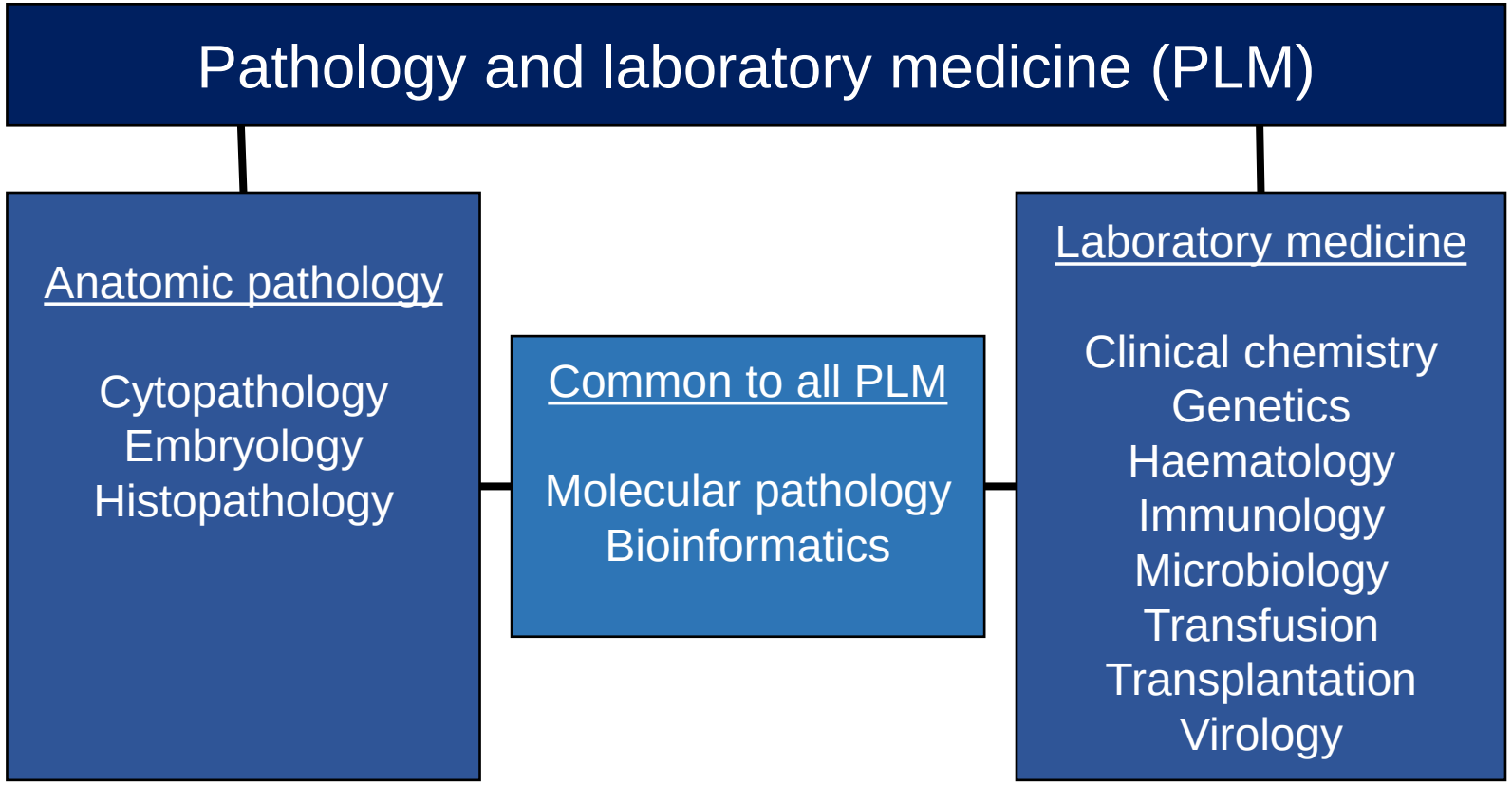
- Laboratory medicine in healthcare
- Traceability in laboratory medicine
- Joint Committee for Traceability in Laboratory Medicine
- Facing the challenge

Some big numbers

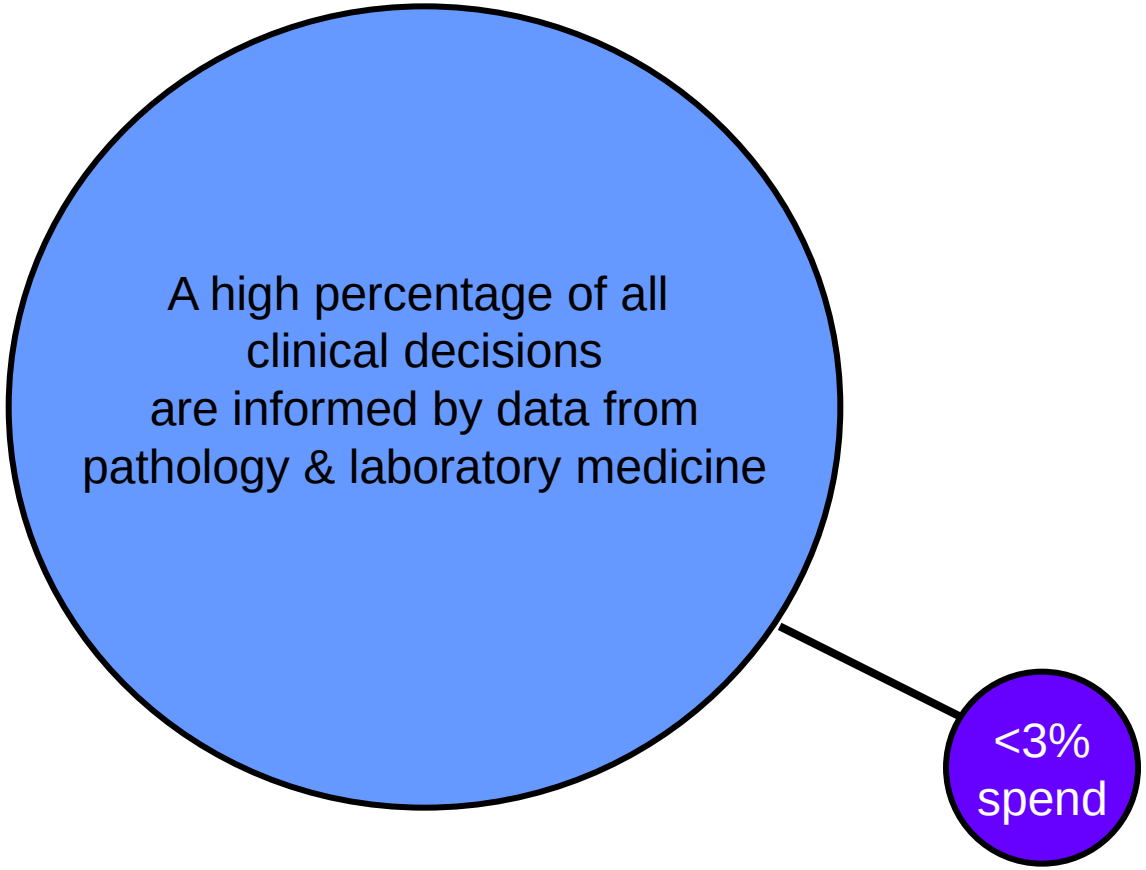


Annual growth of ~5% for all of above

Pathology and laboratory medicine

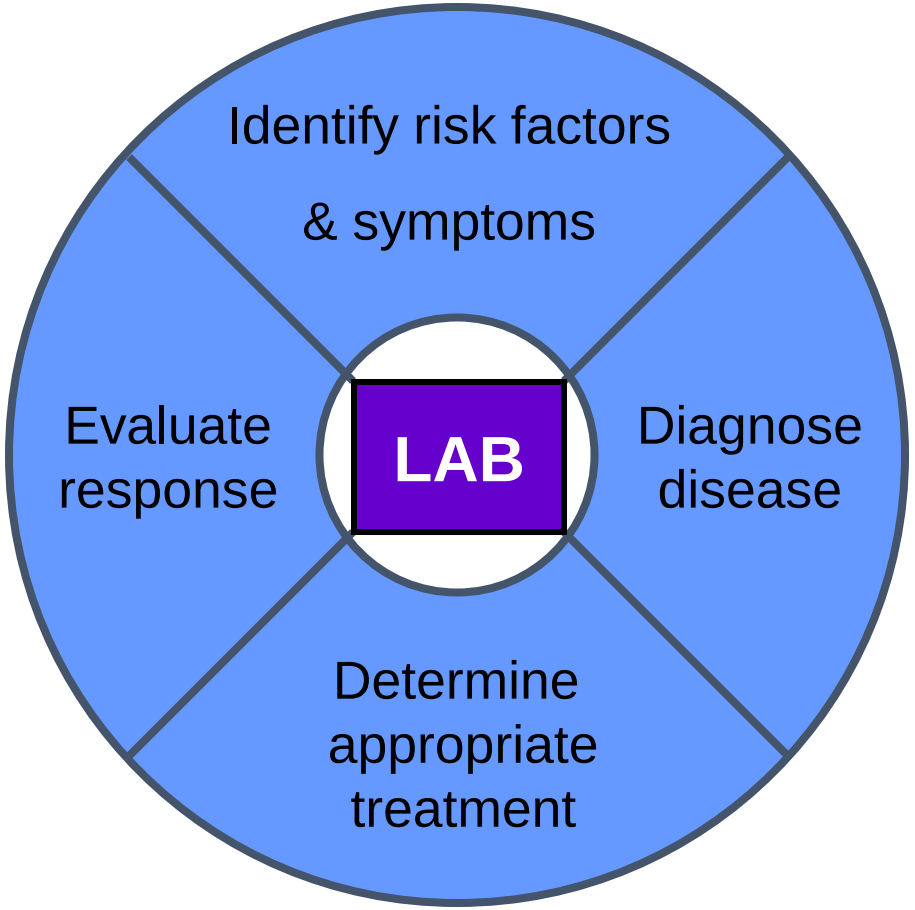


Central role of pathology & laboratory medicine



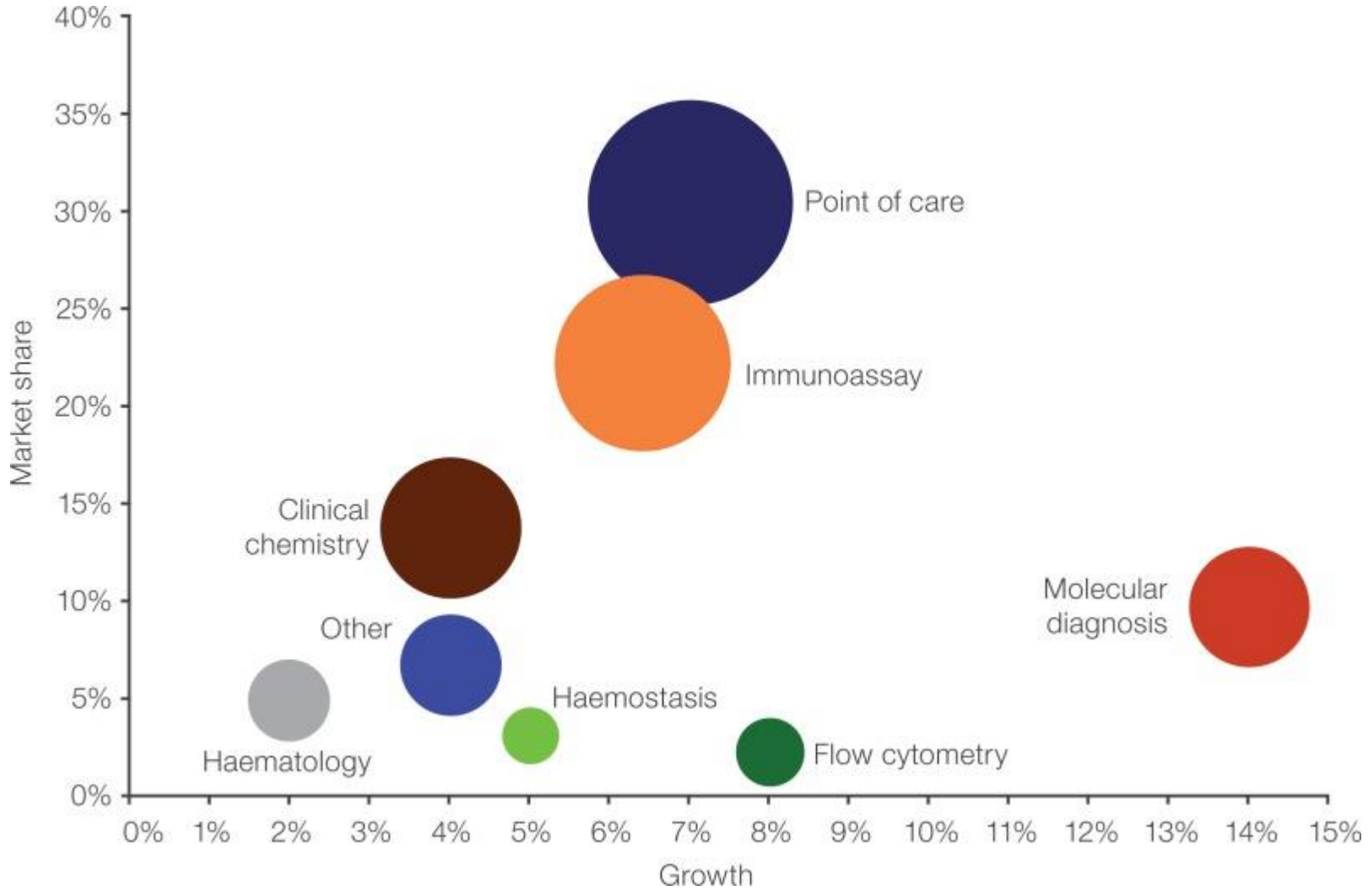
Central role of pathology & laboratory medicine

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



Morgan Stanley Research Estimates

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

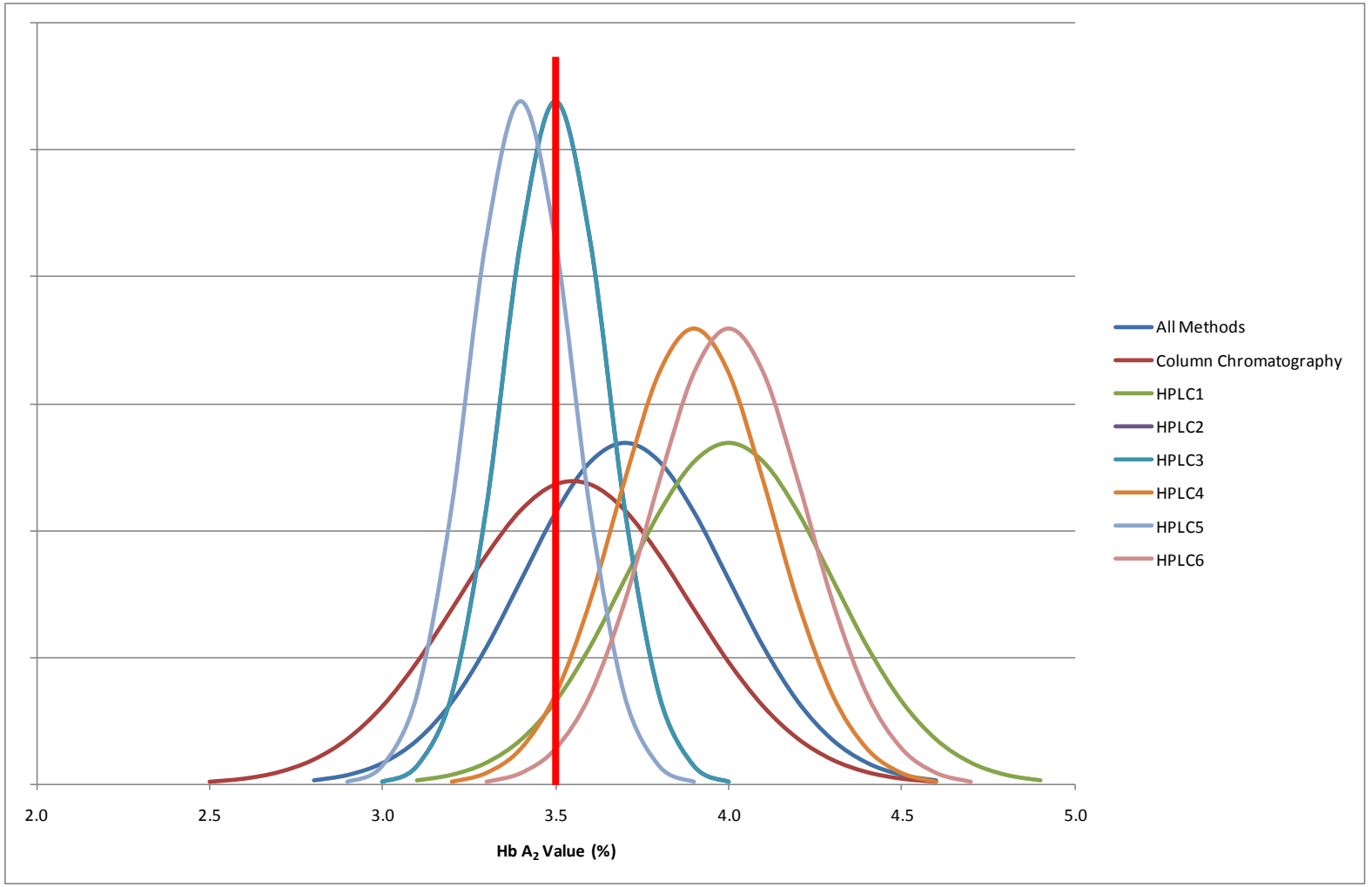


Figure from UK NEQAS with permission

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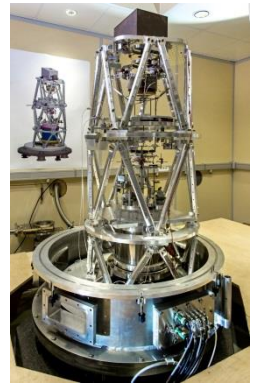
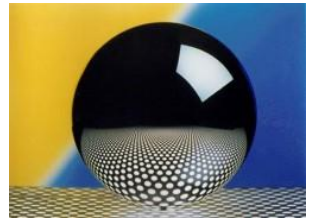
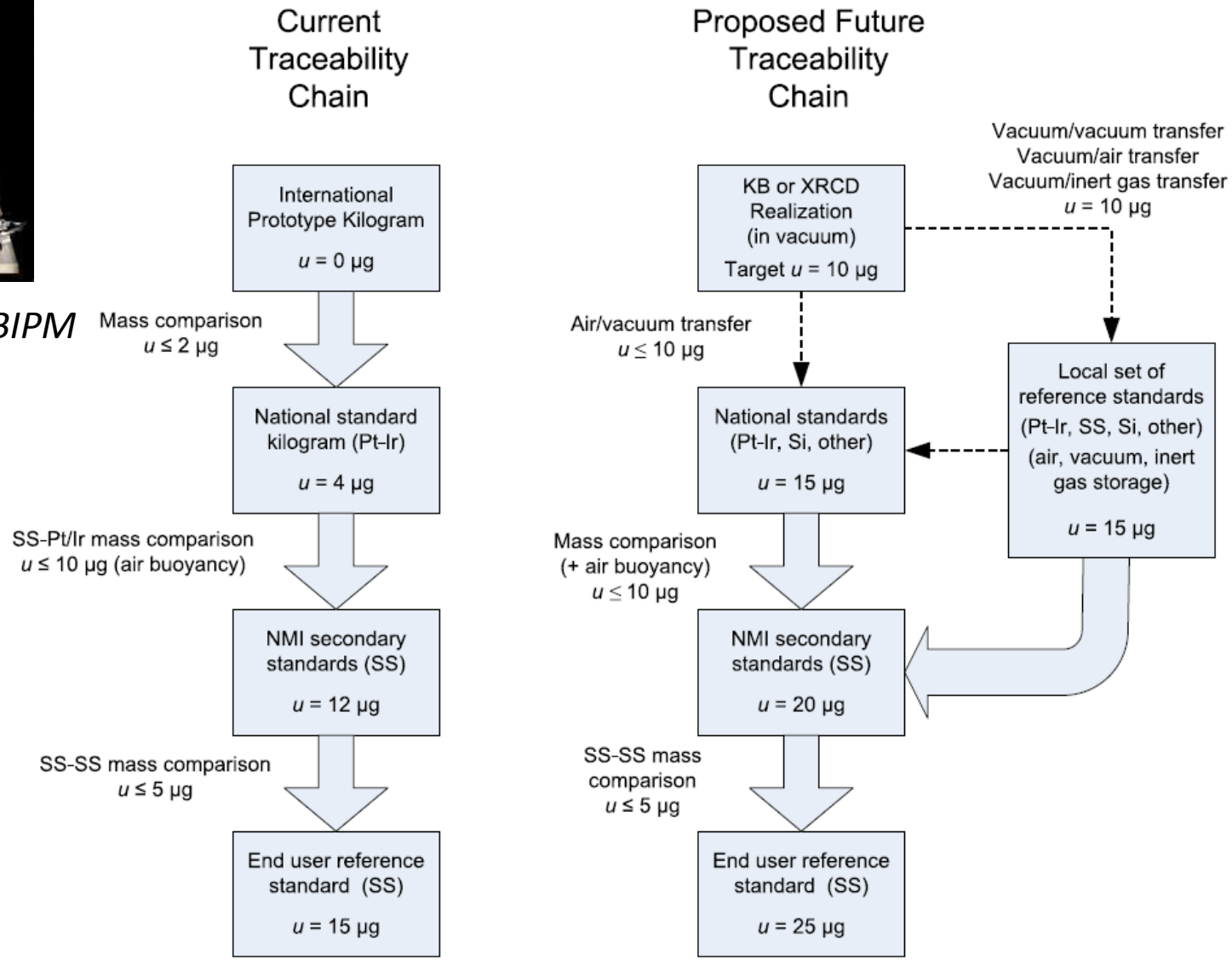
The IPK, at the BIPM



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)

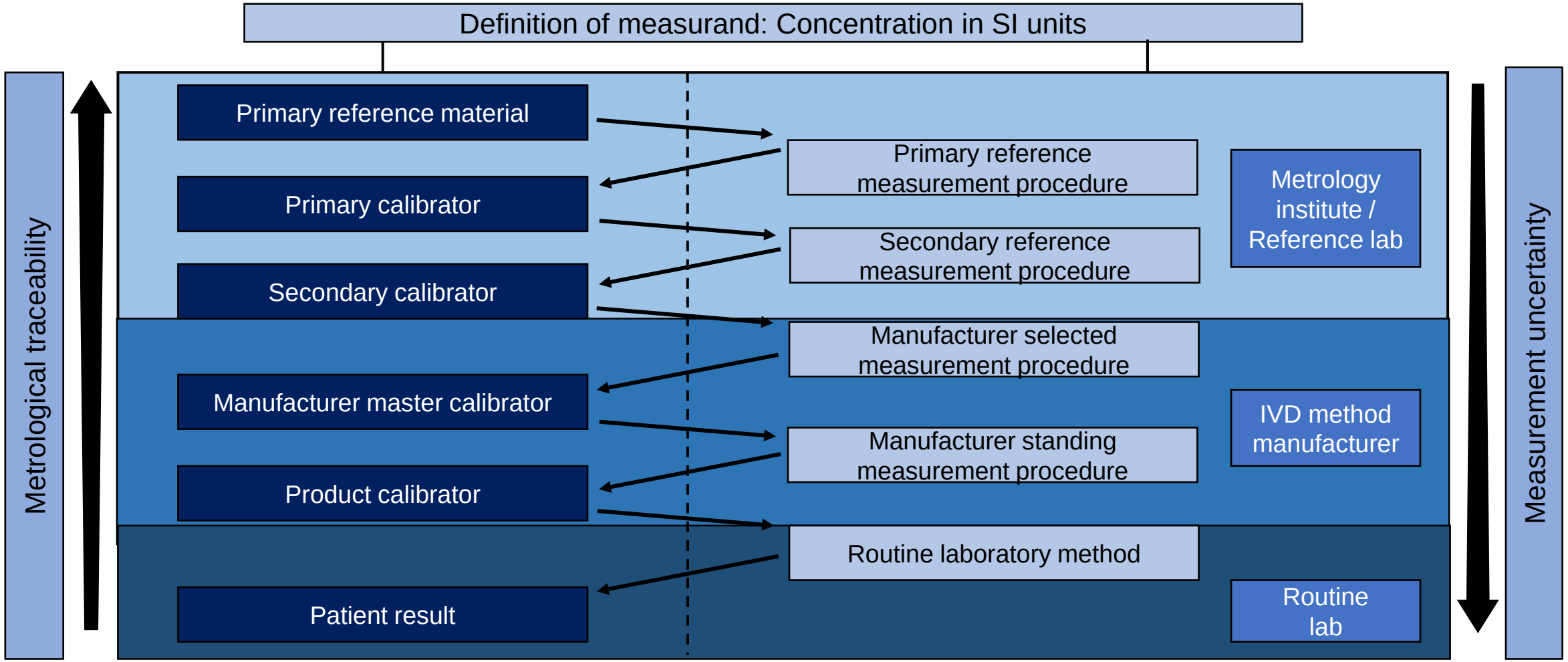
- Primary reference material (pure substance)
- Primary calibrator (SI traceable)
- Secondary calibrator
- Product calibrator

Reference measurement procedures

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

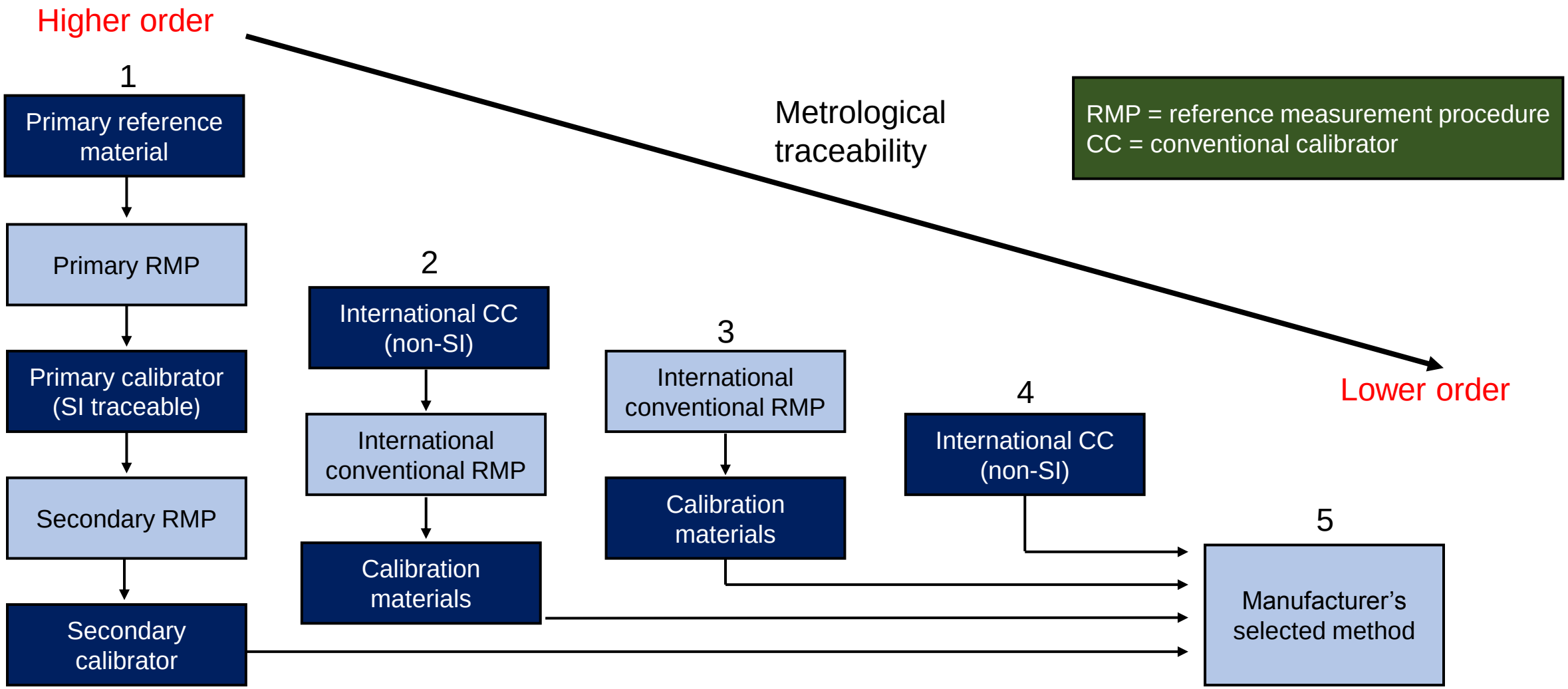
Hierarchy

The metrological traceability chain



Adapted from EN ISO 17511 2003

‘Higher order’ materials and procedures



Adapted from White GH Ann Clin Biochem 2011; 48: 393-408

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

JCTLM
Accurate results for patient care

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

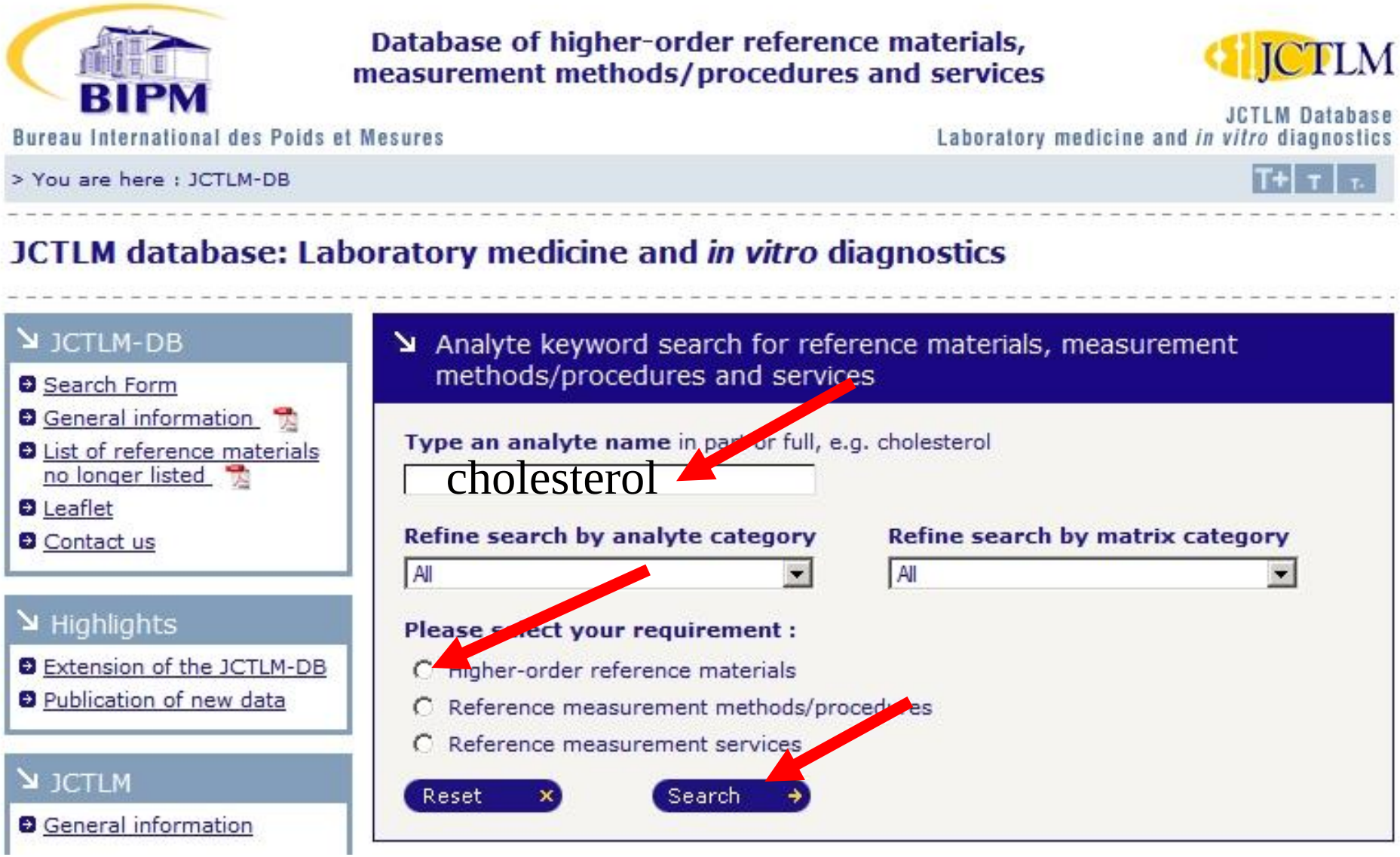
Contributes to ISO Working Groups on reference systems, which are responsible for global standards

Provides news and freely available resources on traceability in laboratory medicine:
- Webinars; publication lists

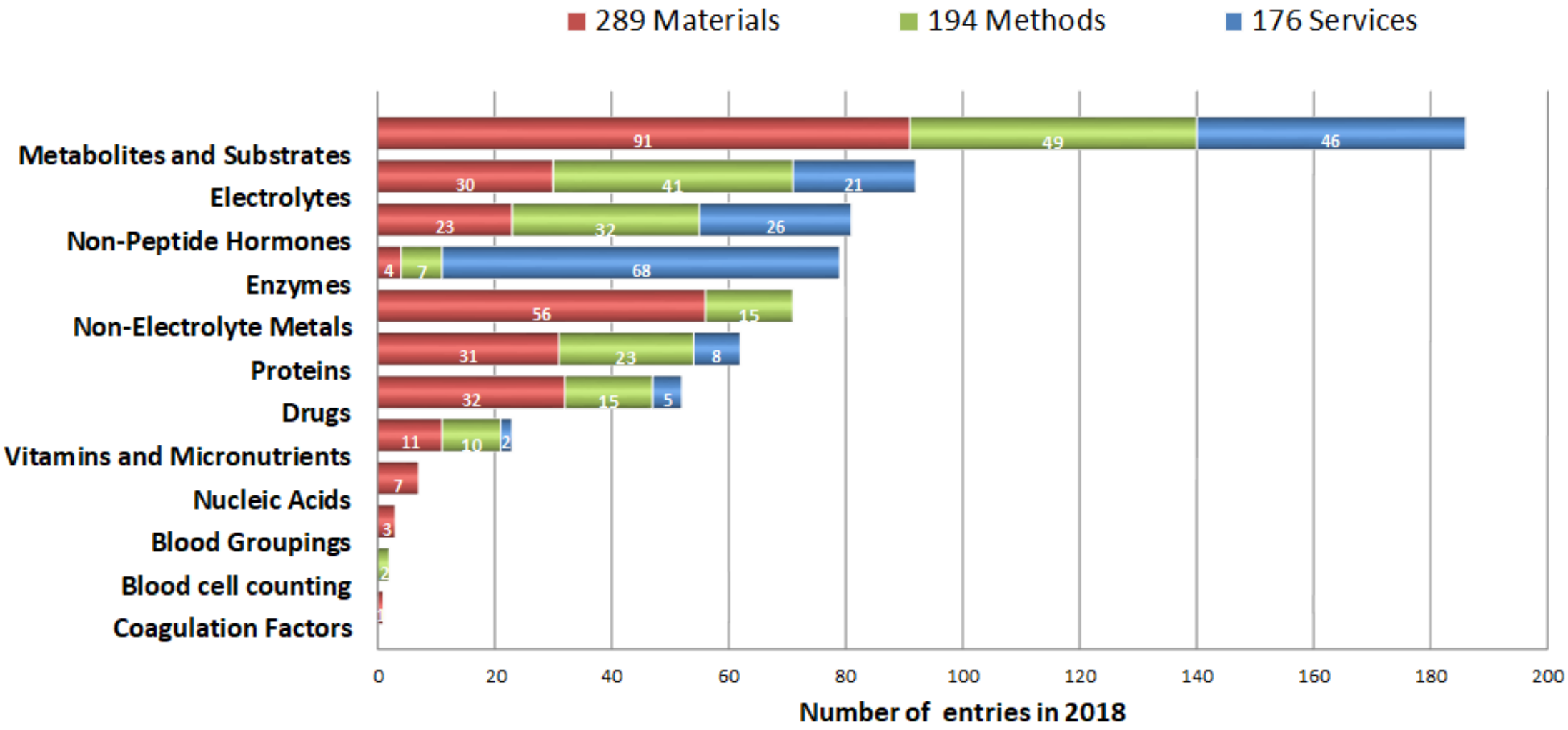
www.jctlm.org

Hosts a biennial scientific meeting

JCTLM Database : www.bipm.org/jctlm/



JCTLM Database: Entries in 2018

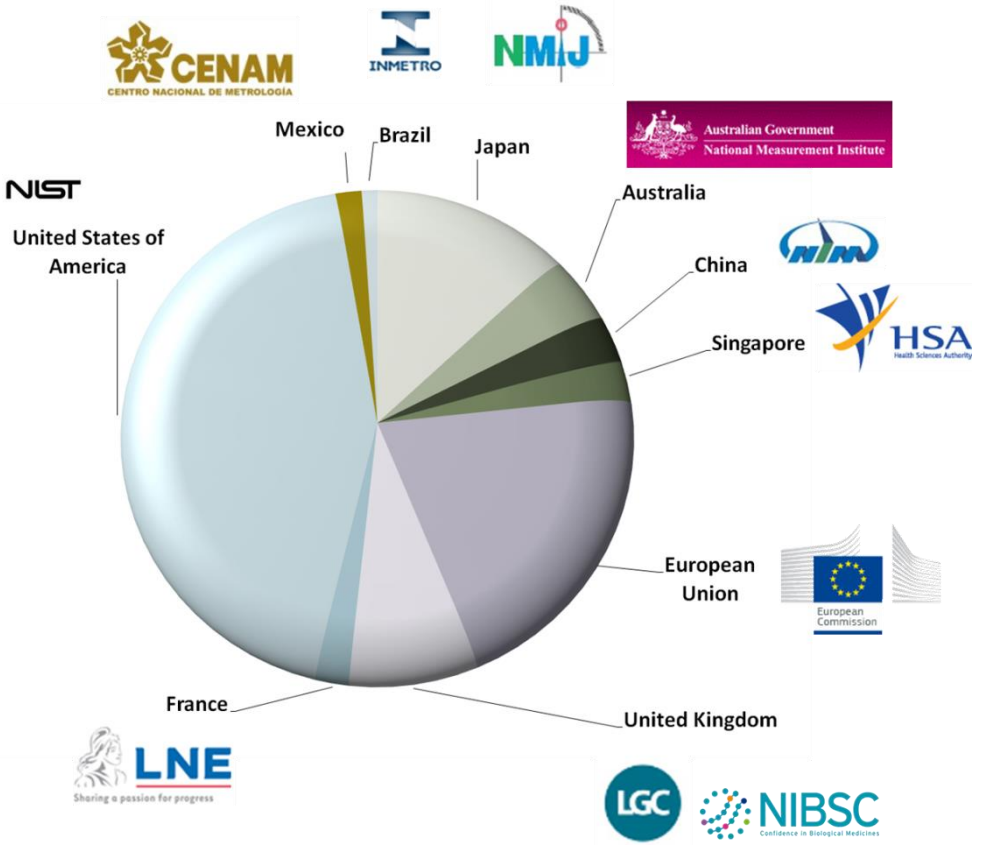


289 Certified Reference Materials
194 RMPs that represent 80 different analytes in 9 categories
176 reference measurement services delivered by 17 reference labs

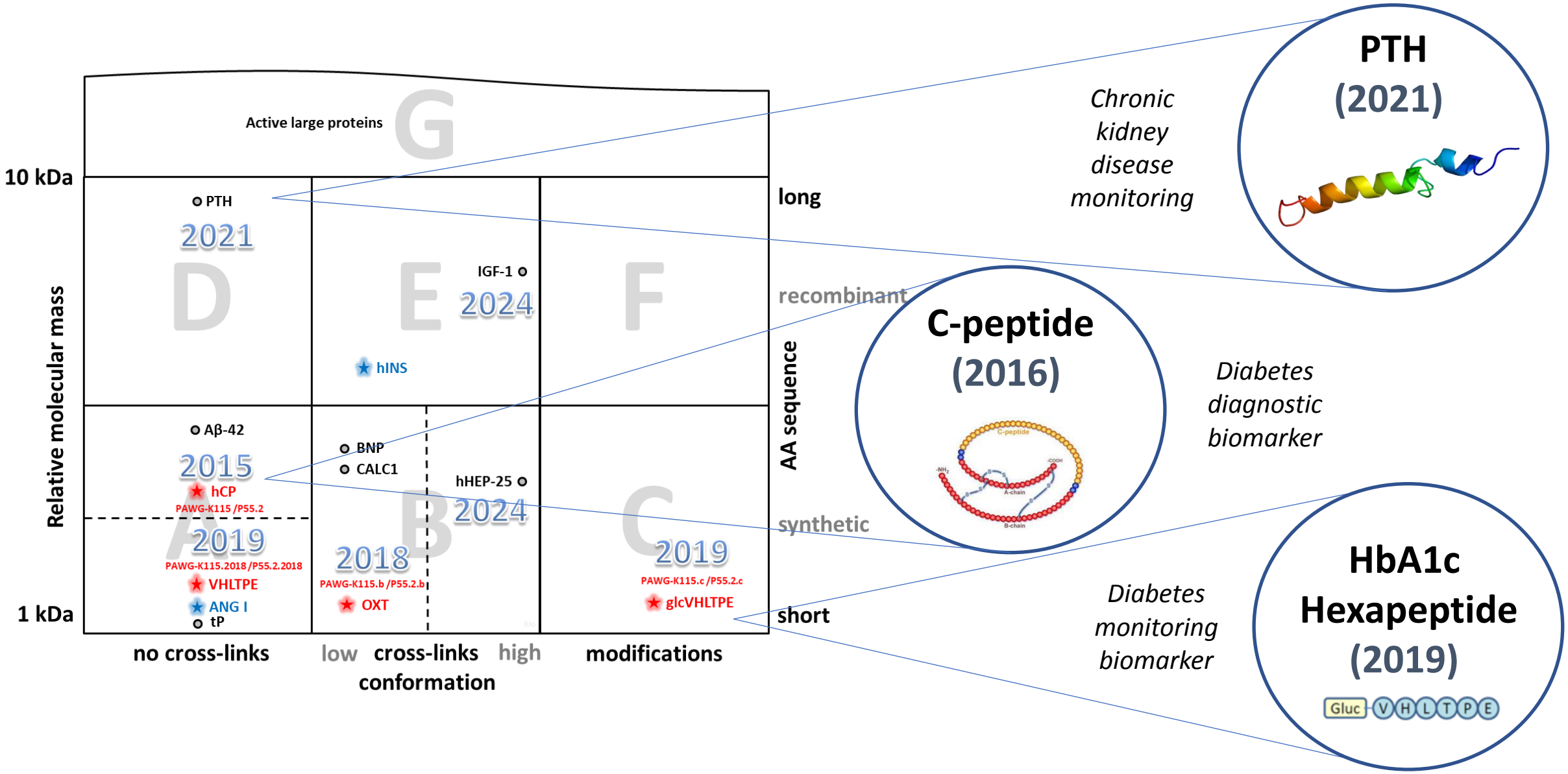
Higher order reference materials

- 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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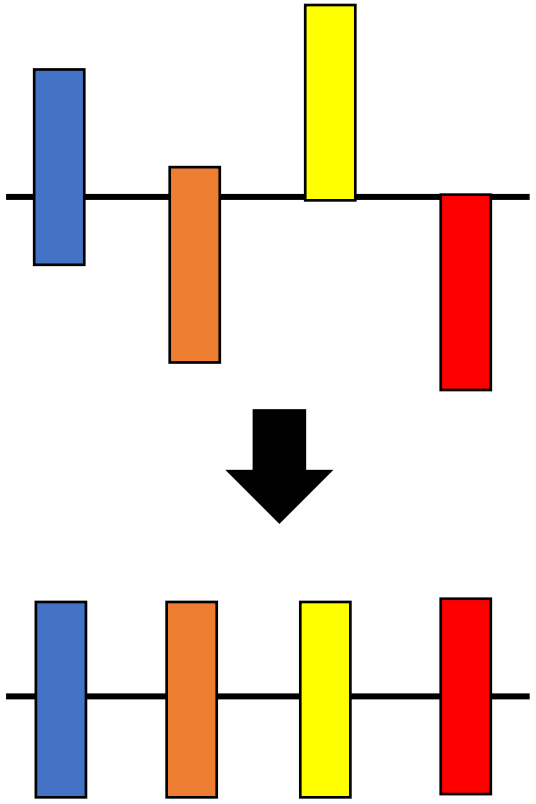
Facing the challenge

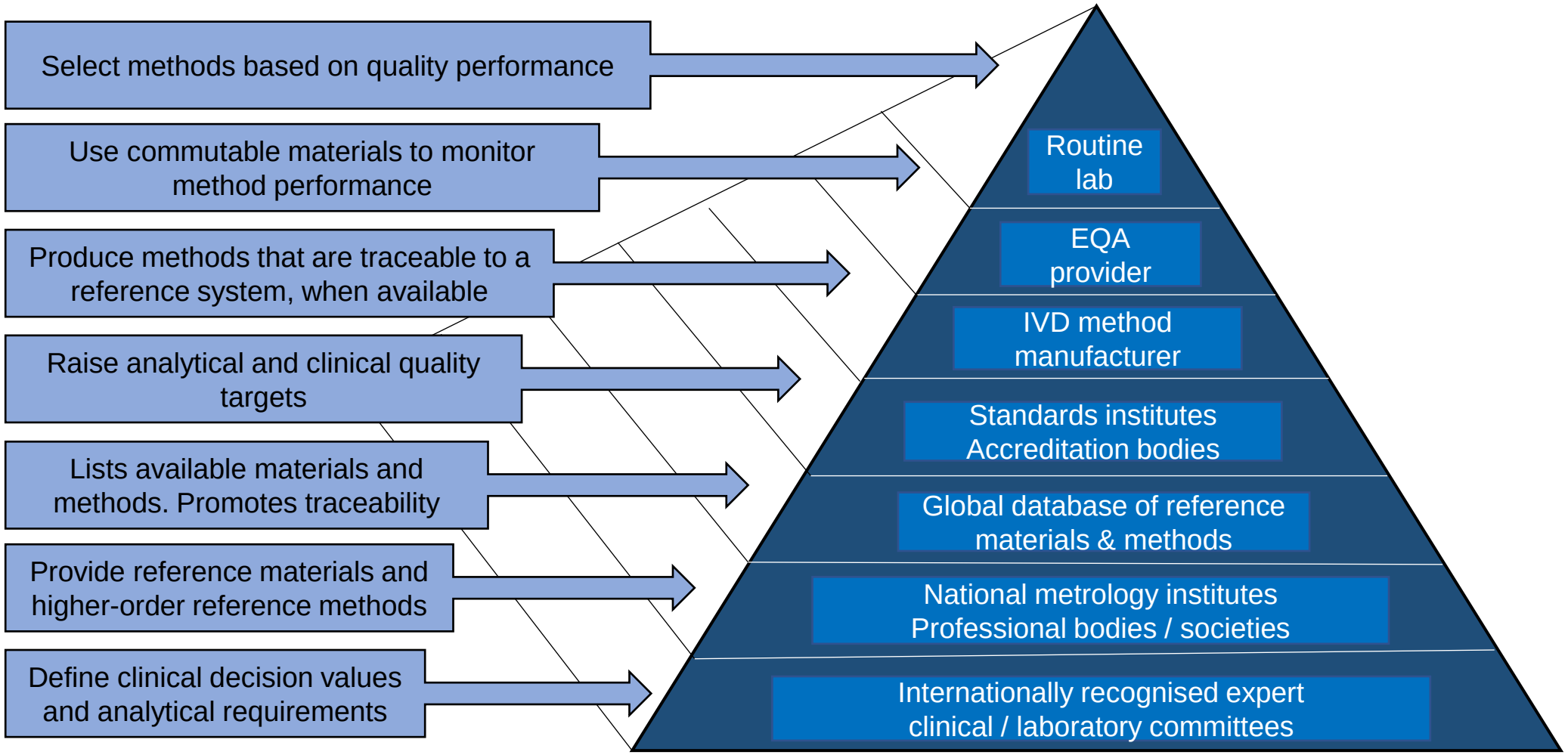
The world population of

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



Beastall et al Clin Chem Lab Med 2017; 55: 1100-1108