



JCTLM Database
Laboratory medicine and *in vitro* diagnostics

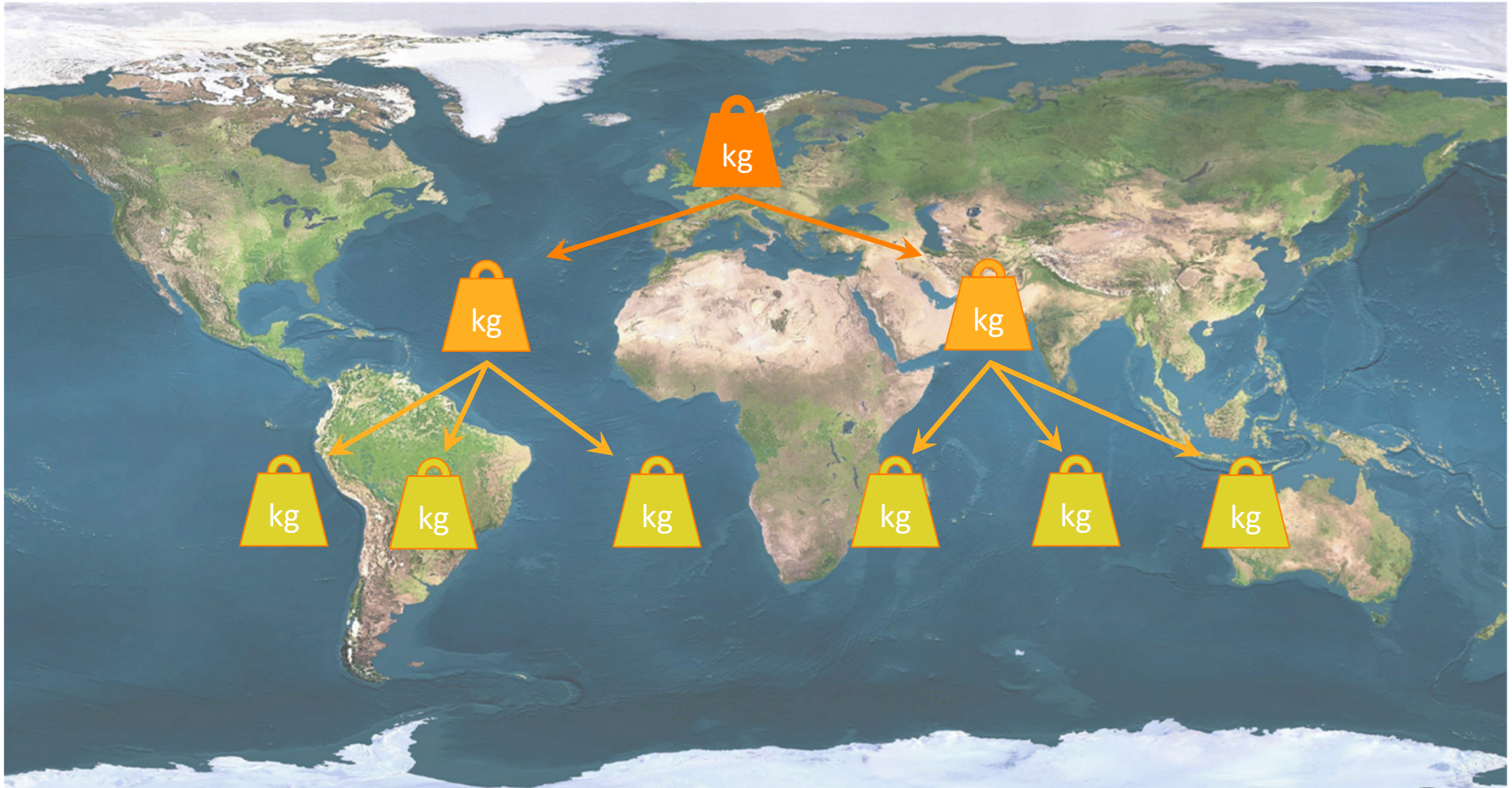
Basics of traceability applied to laboratory medicine

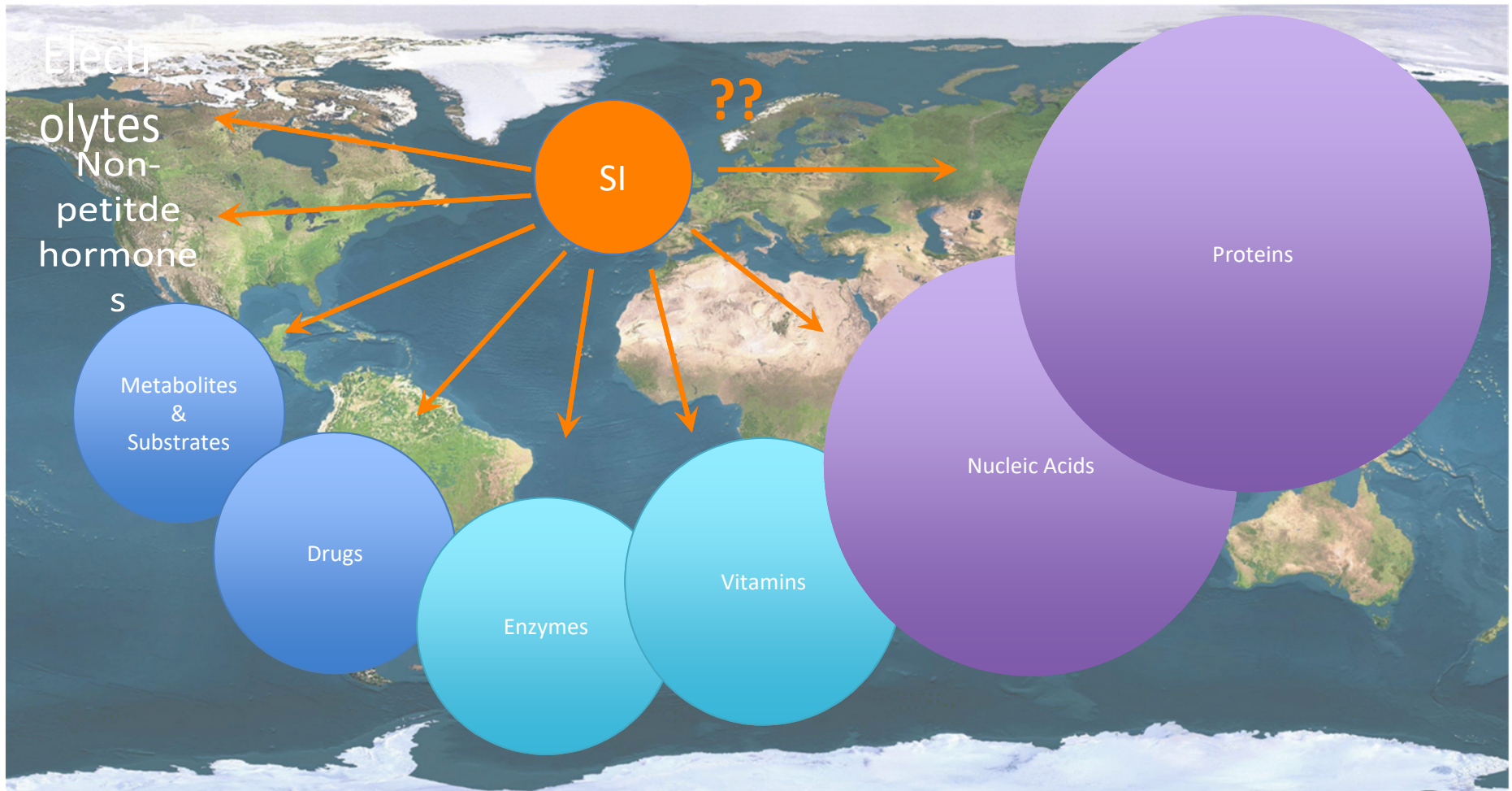
JCTLM Working Group for Traceability: Education and Promotion (WG-TEP)
Area 2: Mini-presentations to explain scientific concepts












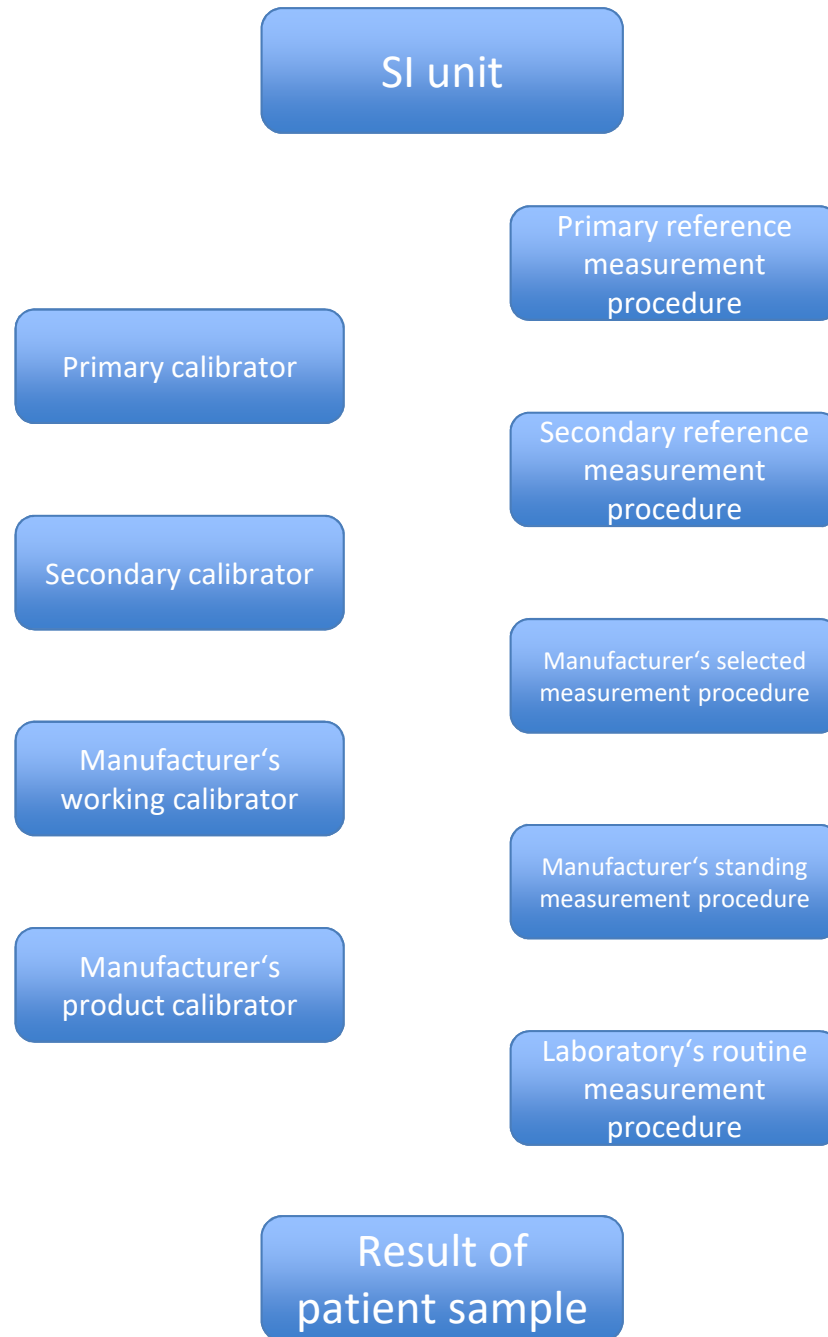


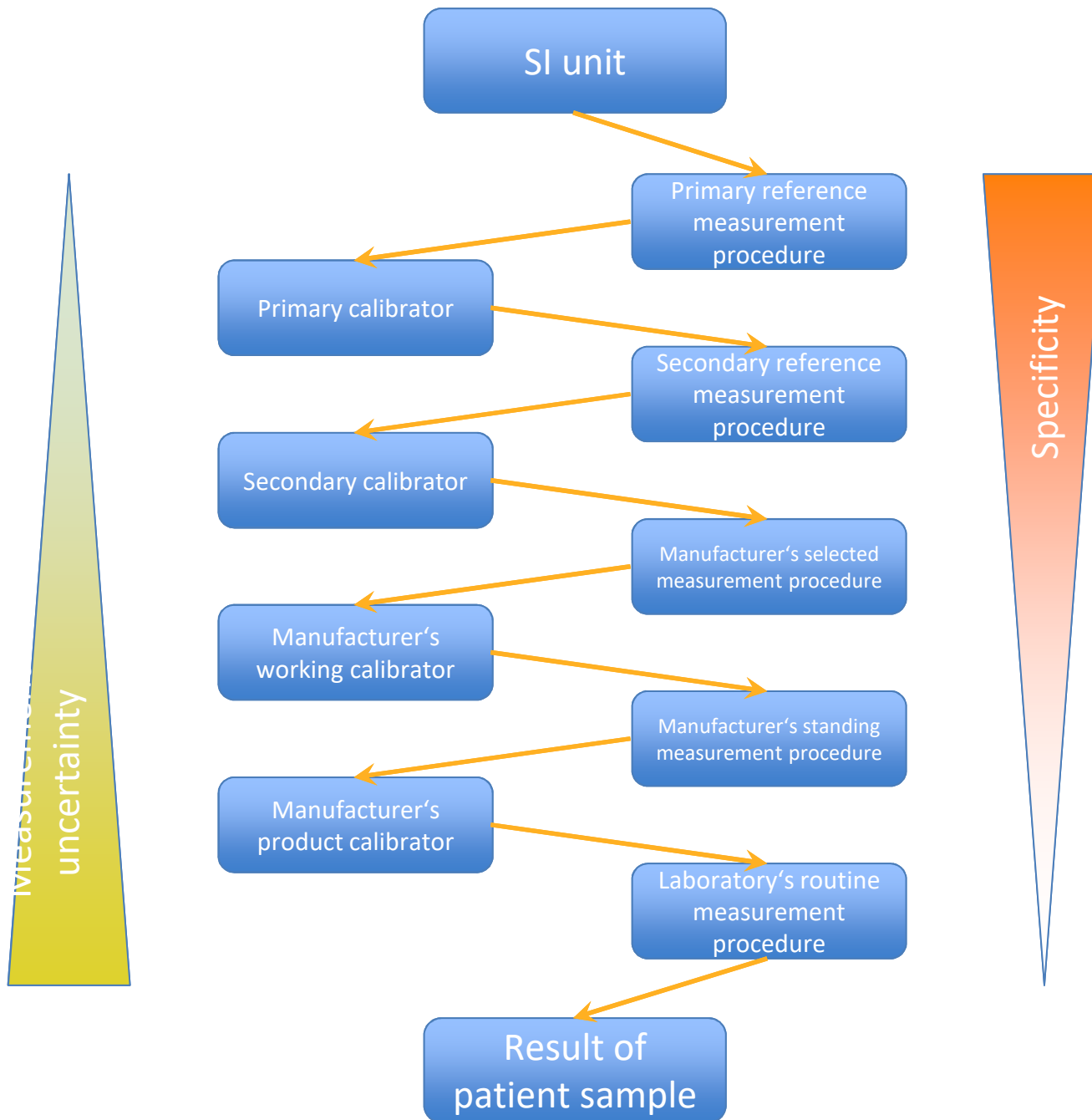
Results of medical laboratories are important for:

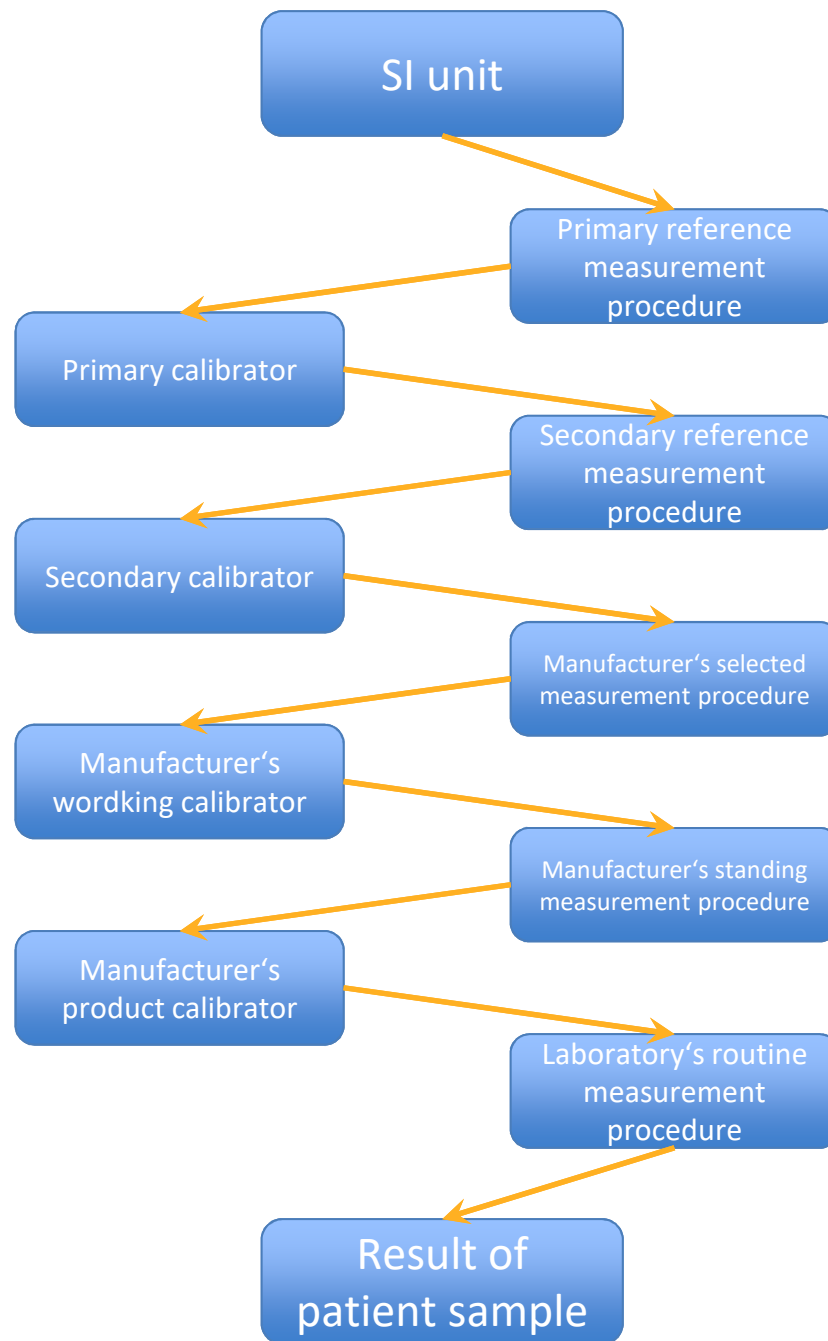
- Diagnosis
- Risk assessment
- Choice of treatment
- Success control

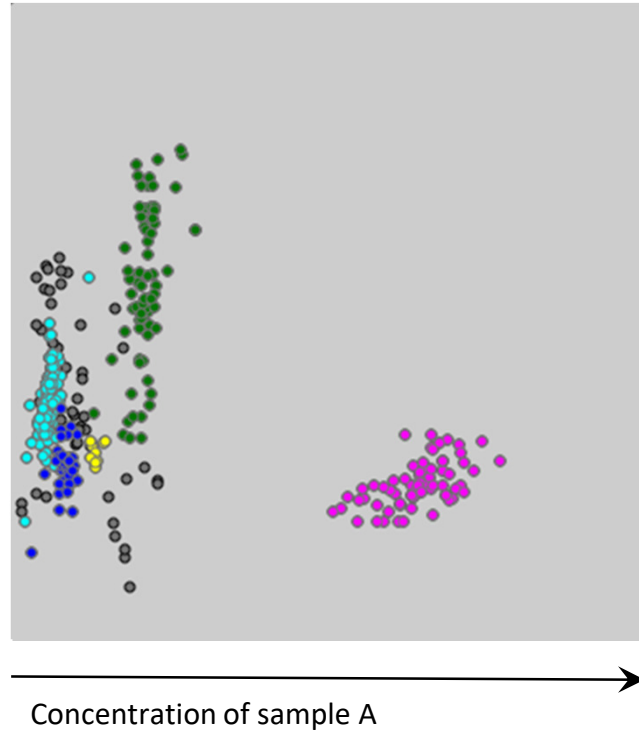
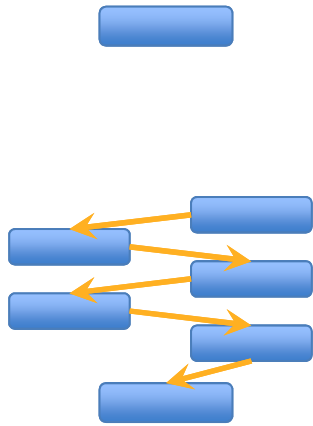
It is the responsibility of the laboratory to provide accurate results considering precision and trueness.











600 laboratories measured the same 2 samples.

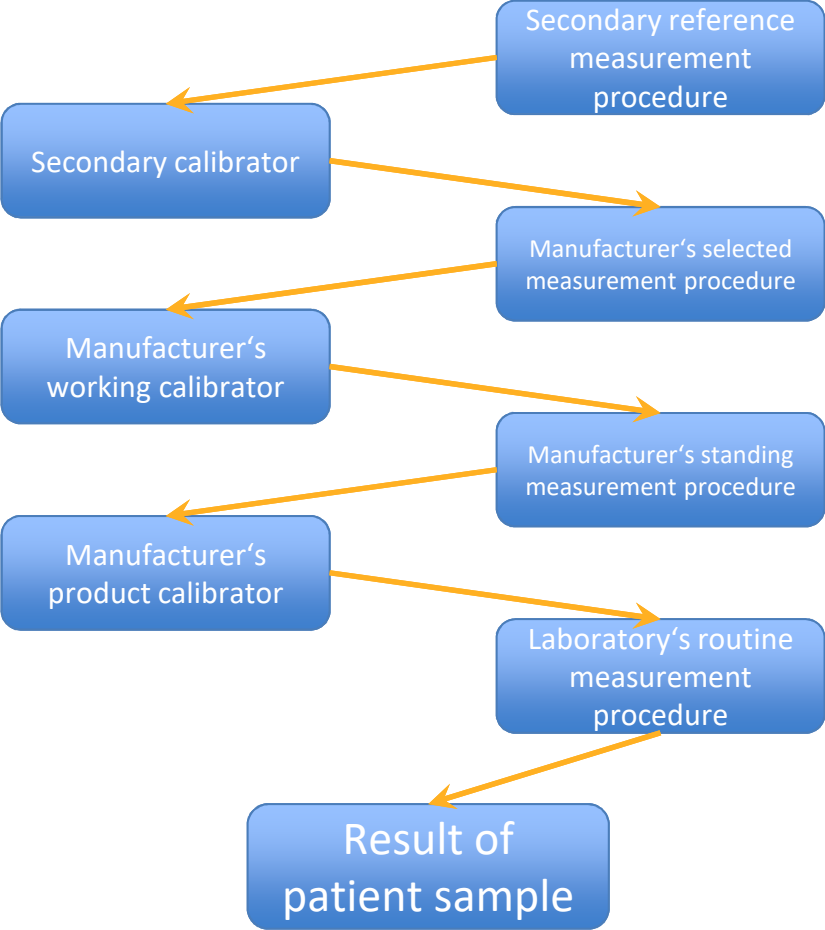
5 different routine measurement procedures are marked in colour.

1. The results of the laboratories using the **same routine measurement procedure** are traceable to the value of the same manufacturer's calibrator and comparable within this group.

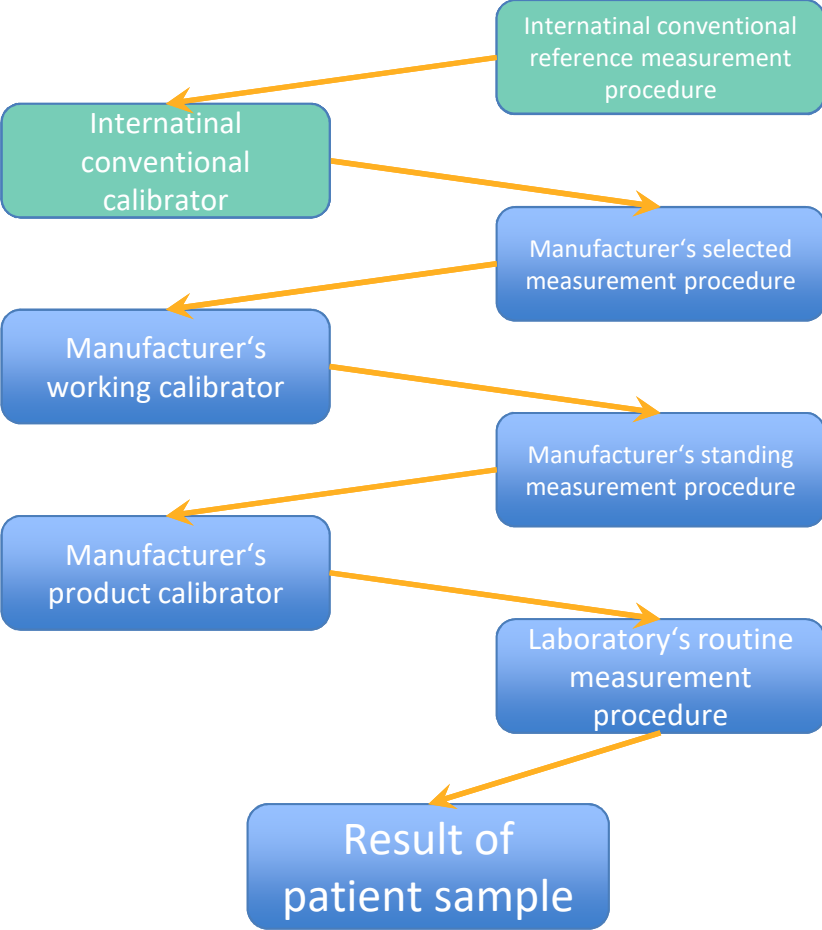
2. The results of **different routine measurement procedures** are not comparable one to the others.

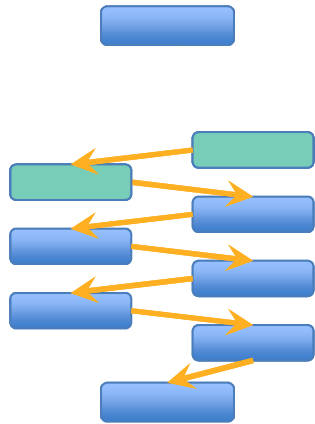


SI unit



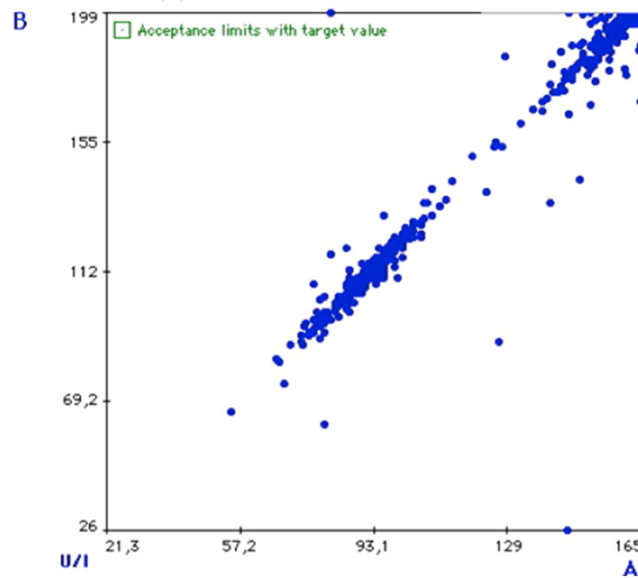
SI unit



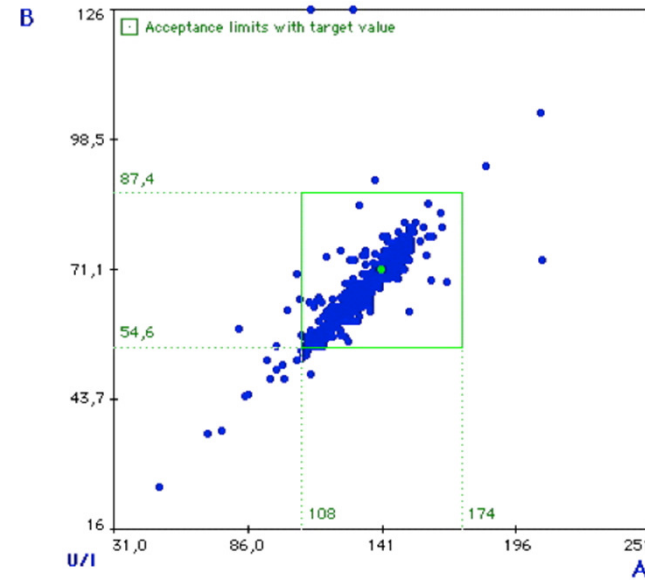


Example: Enzyme “GGT”

Traceability chain with an international convention reference measurement procedure at the top

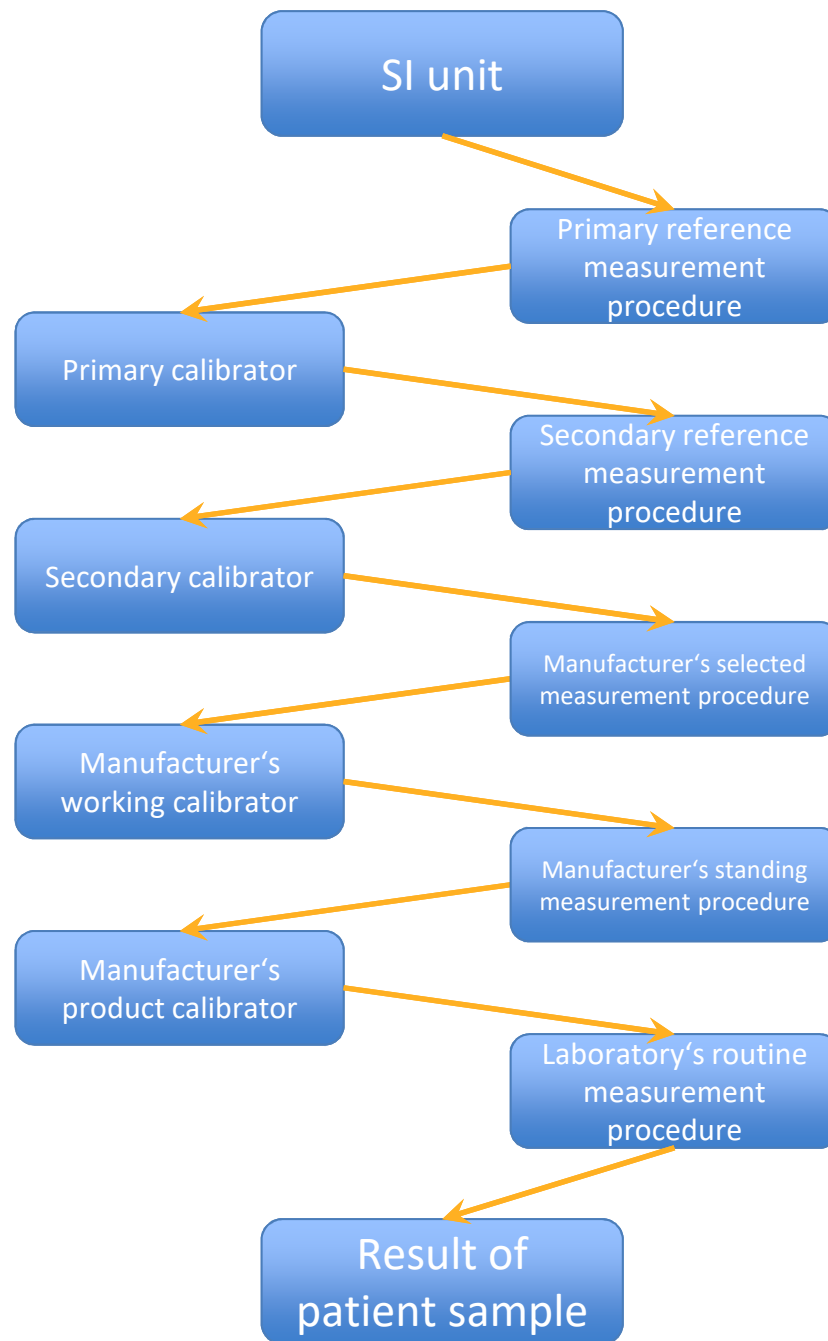


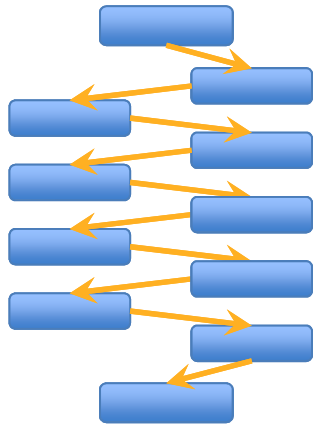
2002 (before the introduction)



2003 (after the introduction)

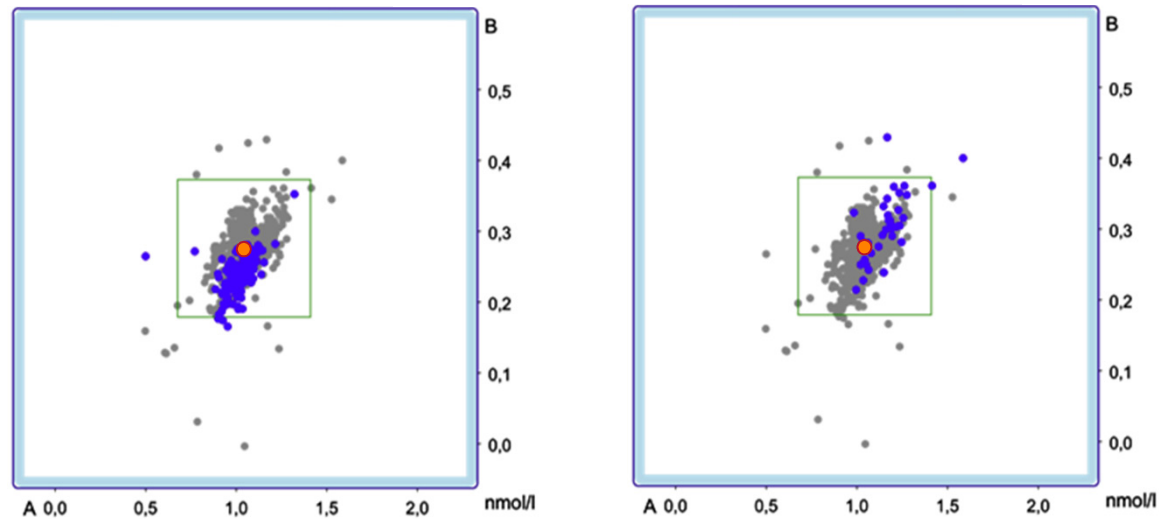






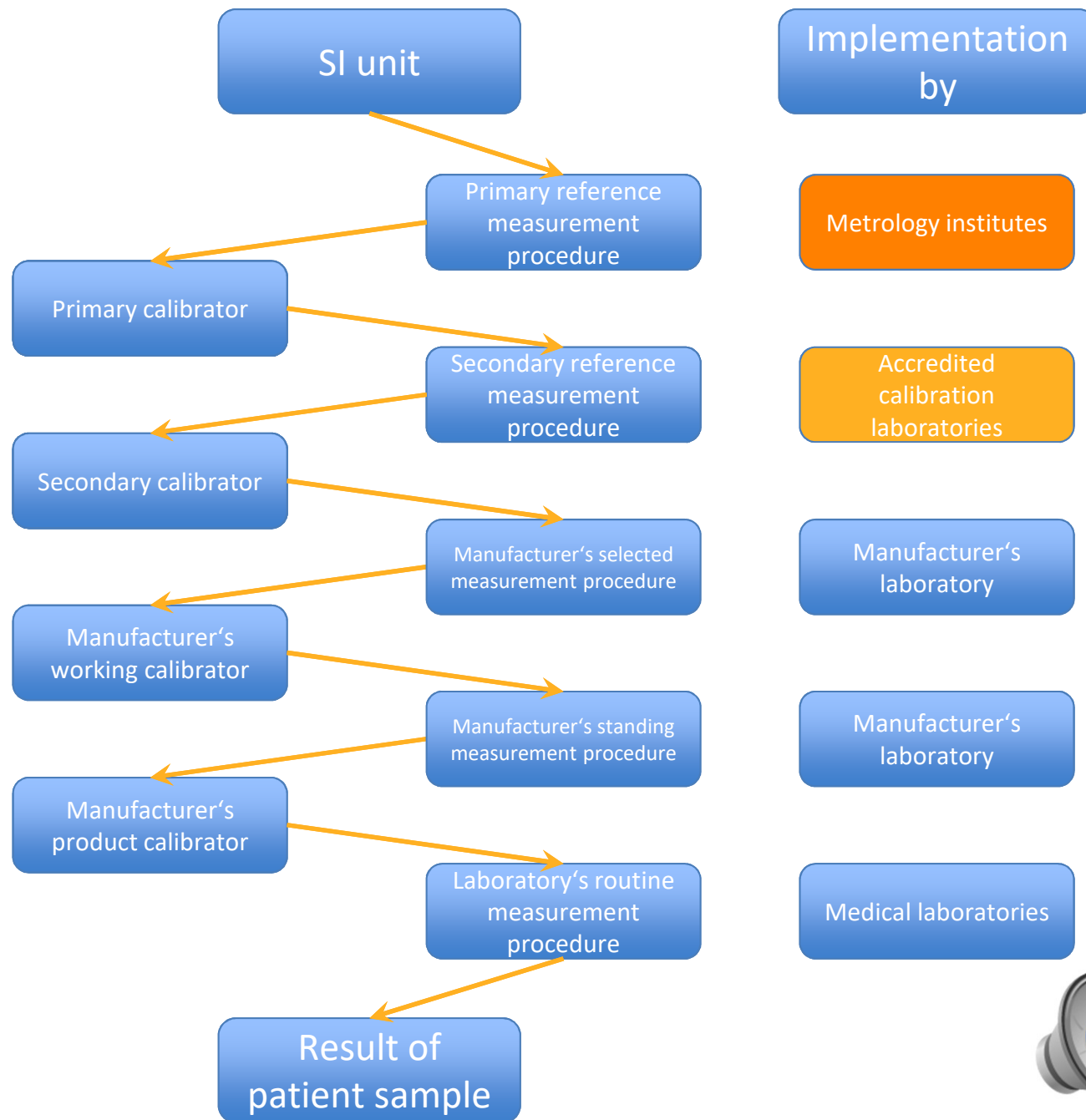
Example: Steroid hormone “17 β -Estradiol”

Traceability chain with a primary reference measurement procedure and the SI-unit at the top



- Comparison study for medical laboratories
- Target values assigned by a primary reference measurement procedure (orange dot)
- The results of the laboratories can be evaluated equally, regardless of the method used.





Reference measurement systems consists of

➤ Reference materials

Primary calibrator

Secondary calibrator

ISO 15194

➤ Reference measurement procedures

Primary reference
measurement
procedure

Secondary reference
measurement
procedure

ISO 15193

➤ Services of reference measurement laboratories

Metrology institutes

Accredited
calibration
laboratories

ISO 17025

ISO 15195

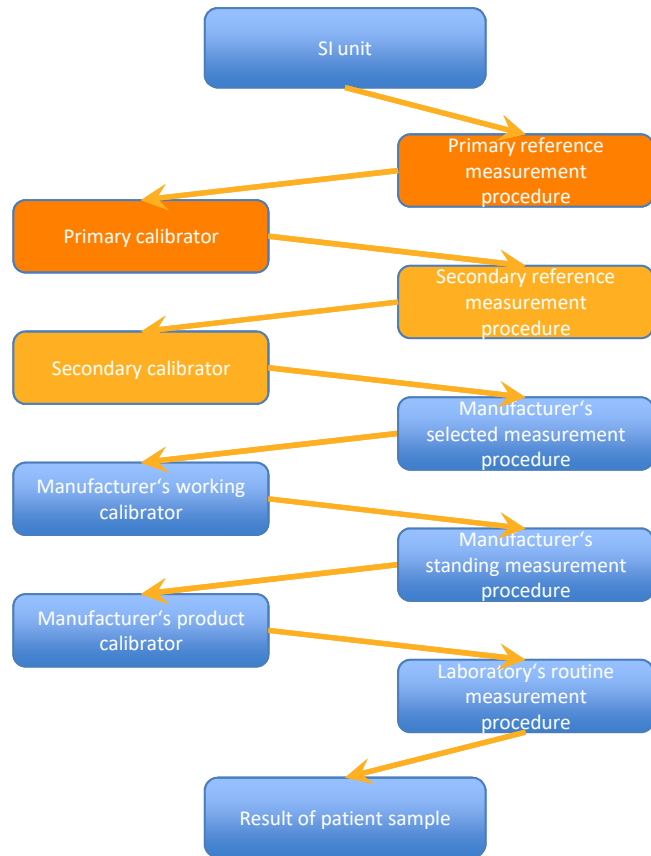
EQAS



The implementation of traceability in laboratory medicine requires the support of

- National Metrology Institutes
- Scientific Societies of Clinical Chemistry and Laboratory Medicine
- Accreditation Bodies
- Suppliers of Certified Reference Materials
- Calibration Laboratories
(also known as: Reference Measurement Laboratories)
- IVD Industry
- External Quality Assessment Organizers
- Legal Authorities
- Medical Laboratories themselves





For many frequently analysed measurands reference measurement systems are available to build up traceability chains up to the SI unit or international conventional reference measurement procedures.

For the majority of measurands the traceability chain is currently terminating at the level of the manufacturer's calibrator and procedure.

Scientific work is necessary to develop reference measurement systems for further measurands in laboratory medicine.

The implementation of traceability in laboratory medicine and the improvement of comparability depend on the contribution of many parties to ultimately optimize results of laboratory medicine.



