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.
SI unit

Primary calibrator

Primary reference measurement procedure

Secondary calibrator

Secondary reference measurement procedure

Manufacturer’s selected measurement procedure

Manufacturer’s working calibrator

Manufacturer’s standing measurement procedure

Manufacturer’s product calibrator

Laboratory’s routine measurement procedure

Result of patient sample
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

- Secondary reference measurement procedure
- Manufacturer's selected measurement procedure
- Manufacturer's standing measurement procedure
- Manufacturer's working calibrator
- Manufacturer's product calibrator
- Laboratory's routine measurement procedure
- Result of patient sample
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 “17ß-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

➢ Reference measurement procedures
   - Primary reference measurement procedure
   - Secondary reference measurement procedure

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

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.