



Traceability in Laboratory Medicine in brief

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According to the International vocabulary of metrology traceability **IS** “a *property of a measurement result* that can be related to a *reference* through a documented unbroken chain of calibrations, each contributing to the *measurement uncertainty*” (1).

In Laboratory Medicine the *reference* must be amongst the following:

1. The *definition of a SI unit*
2. A certified value of a *reference material*
3. The result of a *reference measuring system*
4. The value assigned to an *international conventional reference material*
5. The values assigned to *international harmonization reference materials*

The VIM definition (1) of traceability alone is comprehensive in physics where measurements are direct and the *pillars/fundamentals of traceability* are self-evident and fulfilled, e.g. when measuring mass, length, time or temperature. In contrast, the fundamentals must be detailed when claiming traceability in Laboratory Medicine since measurements in laboratory medicine are usually indirect and influenced by matrix effects. These fundamentals of traceability encompass i.a. the “pillars of traceability” detailed in the literature (2-6).

If the pillars/fundamentals of traceability are not detailed in claims of traceability in laboratory medicine, “traceability”, like beauty, risks being in the eye of the beholder (7).

Pillars/fundamentals of traceability

Measuring systems used by manufacturers and laboratories alike must be *fit for the intended use* through *validation/verification* and appropriate calibration.

The measuring principles used must have been proven *fit for the intended diagnostic use* during both technical- (8, 9) and diagnostic validation (10) in order to establish that a measuring system fulfills appropriate performance specifications (11-14).

The laboratory must have *documented quality management* through basic education and continued education of its staff, documented quality systems, e.g. ISO-17025 or ISO-15189 with regular auditing by relevant authorities. The quality system must include optimal internal- and external quality control schemes.

The *external quality assessment* (EQA) should be trueness-based, using commutable-reference value materials.

There must also be documented procedures for monitoring and maintaining traceability of all traceable measurands over *time* (15, 16) since reference materials in Laboratory Medicine have varying and limited shelf-life which influences the timelines of their traceability.

Traceability **IS NOT** “traceability” to:

1. the producers of the reference materials used for calibrating measuring systems
2. to the internal or external quality control samples used in the measurement
3. to the manufacturers of the reagents and measuring systems used.

Traceability can currently be claimed solely referring to ISO-17511:2020 (17) and ISO-21151:2020 (18). To what extent regulators (19) or accreditation authorities will demand one or more of the fundamentals of traceability for valid claims of traceability as well remains to be seen.

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