# Metrological Traceability of Laboratory Test Results


The primary purpose of metrological traceability is to ensure that laboratories produce meaningful test results that are both comparable and portable.

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# The Complete Traceability Chain

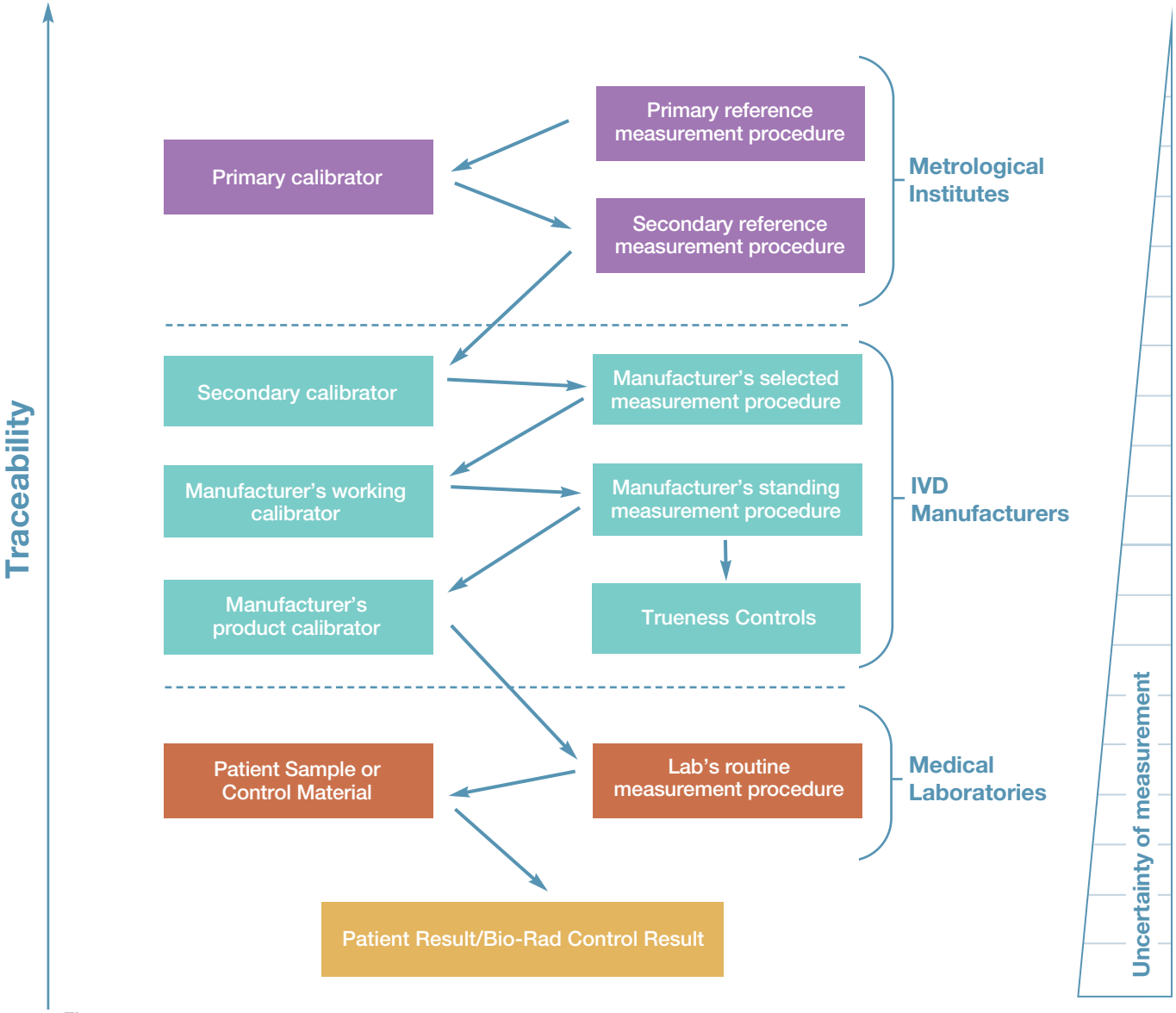


**Fig. 1** Diagram adapted from EN ISO 17511

## Tracing patient results to the origin

# Traceability in Daily Practice

## International Standards and Your Daily Control Materials

The European In Vitro Diagnostics (IVD)[1] directive requires that the traceability of values assigned to calibrators and trueness control materials "must be assured". In theory, traceability means the result of a measurement can be traced back to a primary reference measurement procedure or calibrator through an unbroken chain of comparisons, all having stated measurement uncertainties (Fig. 1). In reality, for the majority of parameters measured in the clinical laboratory, there is no internationally agreed upon reference measurement procedure or reference material available[2]. In this situation, while the principles of traceability still apply, the traceability chain ends with the manufacturer, rather than a metrological institute. International standards, EN/ISO 17511[3] and EN/ISO 18153[4], provide guidance and set requirements for diagnostic manufacturers in assigning values and establishing the traceability chain. The section of the traceability chain that is associated with the manufacturer's product calibrators and measurement procedures is the responsibility of the IVD manufacturer.

EN/ISO 17511 and EN/ISO 18153 apply only to special control materials that are intended to assess "trueness of measurement". Such controls typically have values assigned using the manufacturer's standing measurement procedure and working calibrator. **Daily control materials, such as those manufactured by Bio-Rad Laboratories, are used to verify the consistency over time of routine measurement procedures and reliability of laboratory testing systems. These controls are specifically excluded from EN/ISO 17511 and EN/ISO 18153.**

As an integral part of the traceability chain, manufacturers of kits, methods or calibrators can provide proof of traceability for your laboratory test results.

International Standards EN/ISO 17511 and EN/ISO 18153 apply only to special control materials that are intended to assess "trueness of measurement".

[1] European Parliament and Council Directive 98/79/EC on in vitro diagnostic medical devices.

[2] Refer to Joint Committee on the Traceability of Laboratory Medicine (JCTLM) for a list of higher order reference materials and reference measurement procedures currently available.

[3] EN ISO 17511:2003 In vitro diagnostic medical devices-Measurement of quantities in biological samples-Metrological traceability of values assigned to calibrators and control materials

[4] EN ISO 18153:2003 In vitro diagnostic medical devices-Measurement of quantities in biological samples-Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials

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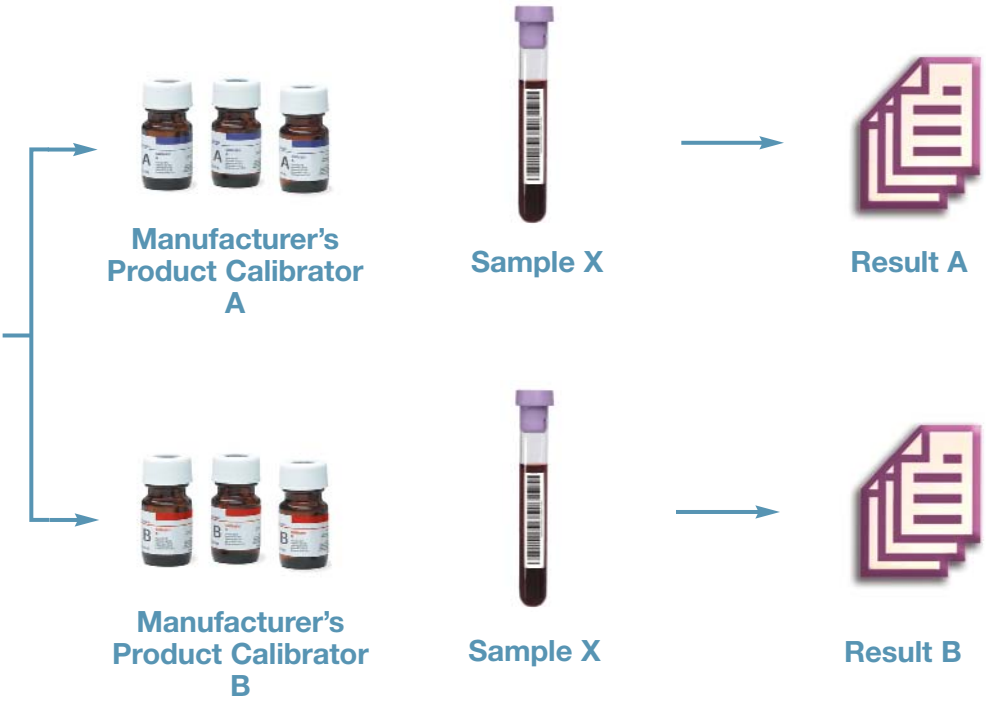
# Traceability for Comparable Results

Without traceability to a reference measurement procedure or calibrator, physicians may receive results for the same patient from different laboratories with little or no information about the comparability of results.

In today's society as patients relocate or change health care plans, the mobility of medical records is increasing. In a monitoring situation, when decisions are made with respect to results previously obtained for the same patient, correct medical interpretation and treatment plans can be dependent on agreement of results between different laboratories and across various measurement procedures.

The solution is to harmonize testing to a reference measurement procedure or calibrator. In the example below, Result A and Result B are comparable because they can both be traced back to a common reference measurement procedure or calibrator.

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