

Traceability in Laboratory Medicine

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Traceability in Laboratory Medicine

Why all the fuss about Traceability?

Traceability is an Essential Requirement of the European Union (EU) Directive on in vitro diagnostic medical devices.



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What is the EU IVD Directive?

- Last of three planned directives for regulating medical devices in the EU
- Intended to harmonize the many national regulations & legal requirements in the EU member states
- IVD Directive formally adopted on Oct 5, 1998
- Key Points:
 - ◆ Harmonization is limited to essential requirements
 - ◆ Only products fulfilling the essential requirements may be placed on the market and put in service



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IVD Directive

Essential Requirement

“ The traceability of values assigned to calibrators and control materials must be assured through available reference measurement procedures and/or available reference materials of a higher order”.

Official Journal of European Communities (1998)



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What is Traceability?

In the context of laboratory medicine, the term *traceability* means metrological traceability.

Definition:

‘property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties’

VIM 1993



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Metrological Traceability

Concept

- ❑ Each calibrator value or test result must come from a calibrated test method
- ❑ Each calibrator must have a value assigned by a calibrated test method



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International Standards

- ☐ Calibration and control materials

ISO 17511

- ☐ Enzyme assays

ISO 18153

- ☐ Medical laboratories

ISO 15189 & ISO 17025



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Traceability Chain

SI UNIT

Calibration Hierarchy

1° Calibrator

2° Calibrator

Working Calibrator

Product Calibrator

Routine Sample

1° Reference MP

2° Reference MP

Selected MP

Standing MP

Routine MP

Measurement Result

Metrological Traceability

Resp.

NMI

NMI

NMI

NMI

MFR

MFR

MFR

MFR

LAB

LAB

LAB



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Traceability in Laboratory Medicine

process ensures
clinical sample result
equivalent to RMP result

Clinical Sample → Result

1° RMP

1° Calibrator

2° RMP

2° Calibrator

MFR RMP

MFR Product Calibrator

Routine MP

Clinical Sample → Result



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Analyte Classification

- **Type A**
 - Well defined compounds
 - Approx. 25-30 analytes (e.g. glucose, electrolytes, urea, cholesterol, steroid hormones)
 - Results are not method dependent
 - Concentrations can be expressed in SI Units
 - Full traceability chain is possible



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Analyte Classification

- **Type B**
 - Not well defined (e.g. heterogeneous)
 - 400-600 analytes (e.g., tumor markers, viral antigens, enzymes, glycoproteins, coagulation factors)
 - Arbitrary or conventional units (e.g., WHO International Units)
 - Full traceability chains not practical



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Traceability is

not accuracy.

a tool to ensure accurate results.

not showing equivalence to a reference standard.

a process that relates measurement values to a reference standard



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Traceability is

not the property of a method.
a property of a test result.

not demonstrated only once.

**maintained through monitoring and correction
over time.**



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Traceability requires.....

- Higher order Reference Measurement Procedures
 - ◆ **ISO 15193**
- Qualified Reference Materials
 - ◆ **ISO 15194**
- Suitable Reference Laboratories
 - ◆ **ISO 15195**



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Joint Committee on Traceability in Laboratory Medicine

- Formed in June 2002
- General mission is to improve quality of healthcare with reduction in costs for governments and IVD industry through promotion of reference examination systems allowing traceability of examination results with improved comparability.
- Four main sponsors
 - ◆ IFCC (professionals in laboratory medicine)
 - ◆ BIPM/CIPM (professionals in metrology)
 - ◆ WHO (professionals in health)
 - ◆ ILAC (professionals in accreditation)



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Joint Committee on Traceability in Laboratory Medicine

- **Three Working Groups formed**
- **Working Group 1 – Reference Materials & Procedures**
 - ◆ Establish criteria for acceptance of materials and procedures and produce lists of such items
- **Working Group 2 – Reference Laboratories**
 - ◆ Establish criteria for accreditation of reference laboratories at the calibration level, establish contacts to form networks , and promote parallel comparisons
- **Working Group 3- Implementation**
 - ◆ Establish plan for long term implementation of JCTLM



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