European Metrology Network

Traceability in Laboratory Medicine



About Us

Laboratory testing is at the heart of modern health care: an estimated 70% of medical decisions depend on in vitro diagnostics (IVDs). Benefits for patients, healthcare providers and the IVD industry are improved when robust and metrologically traceable IVDs are used to provide accurate test results irrespective of the laboratory, the IVD provider, or the instrumentation used for testing. Metrological traceability of IVDs enhances validity of diagnosis, supports further treatment, and lowers the financial burden on healthcare systems by avoiding nonessential testing. Traceability is also an important aspect of regulatory schemes: IVD manufacturers need to comply with legal requirements for traceability to gain and maintain market access. These requirements are defined in the regulation on in vitro diagnostic medical devices EU 2017/746 (IVDR) and include metrological traceability of calibrator and control material values along with testing of high-risk IVDs by EU reference laboratories. The European network on Traceability in Laboratory Medicine (TraceLabMed) was established to build a coordinated metrology-based quality infrastructure in an area that affects almost every European citizen. EURAMET, the European Association of Metrology Institutes is, by forming EMNs, aiming to create sustainable, stakeholder-oriented structures in areas of strategic importance for the future of European metrology.

Our Mission

is to provide a coordinated and service-oriented European metrology infrastructure to enhance metrological traceability of in vitro diagnostics (IVDs). We will contribute to improved patient safety, support the European IVD industry to meet regulatory requirements, and align European activities with global challenges by:

- Connecting with stakeholders to exchange information on needs, experiences and progress in metrology-based data assessment
- Promoting coordinated top down research based on stakeholder requirements
- Building capacities for metrological traceability
- Establishing close links with European reference laboratories

Our Vision

is to become the European gateway for coordination of activities and services concerning the traceability of measurement results based on *in vitro* diagnostics to:

- Justify the public confidence in comparable test results
- Support the European IVD industry
- · Provide the foundation for evidence-based medicine
- Enhance the validity and reliability of electronic health records

Contact us

to **get involved** and ask your questions:

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