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Measurement uncertainty: Friend or foe?

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Abstract

The definition and enforcement of a reference measurement system, based on the implementation of metrological traceability of patients' results to higher order reference methods and materials, together with a clinically acceptable level of measurement uncertainty, are fundamental requirements to produce accurate and equivalent laboratory results. The uncertainty associated with each step of the traceability chain should be governed to obtain a final combined uncertainty on clinical samples fulfilling the requested performance specifications. It is important that end-users (i.e., clinical laboratory) may know and verify how in vitro diagnostics (IVD) manufacturers have implemented the traceability of their calibrators and estimated the corresponding uncertainty. However, full information about traceability and combined uncertainty of calibrators is currently very difficult to obtain. Laboratory professionals should investigate the need to reduce the uncertainty of the higher order metrological references and/or to increase the precision of commercial measuring systems. Accordingly, the measurement uncertainty should not be considered a parameter to be calculated by clinical laboratories just to fulfil the accreditation standards, but it must become a key quality indicator to describe both the performance of an IVD measuring system and the laboratory itself.

Keywords: Analytical performance specifications; Measurement uncertainty; Reference materials.

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