

# Traceability and uncertainty in hematology

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Accreditation of laboratories is currently also extending to laboratories in the health care sector. Since medical laboratories are faced with very specific issues, the International Standardization organization has formulated a set of standards specifically intended for medical laboratories. In particular ISO 15189 is of importance, since it addresses requirements for quality and competence. Medical laboratories seeking accreditation under ISO 15189 are required to document uncertainty and traceability of their analyses.

Measurement uncertainty is a quantitative estimate of the level of confidence that a laboratory has in the analytical precision of test results. Therefore it is an essential component of a laboratory's quality system.

Measurement traceability refers to the property of a measurement result whereby the result can be related to a reference standard or reference material through a documented, unbroken chain of calibrations, each contributing to the measurement uncertainty. If reference standards or qualified reference materials are lacking, higher order reference measurement procedures may be used for metrological traceability. According to ISO15189, laboratories should have documented procedures for calibration procedures with metrological traceability. In this way an individual measurement result can be traced back to a reference material or reference procedure.

Medical laboratories are different from many other disciplines in that they use biological materials as samples, which pose inherent limitations on the metrological traceability of a sample. In addition, many of the analytes are biological substances for which no "absolute" reference standards exist. Hematology laboratories are in an even more challenging position, as some of the commonly measured analytes are living cells, which makes them by definition unsuitable as reference material for standardization and traceability purposes.

This presentation will focus on standardization of measurement procedures in hematology and on the process that is required for making calibration material for end user laboratories traceable to these higher order reference procedures. The measurement uncertainty which is inevitably associated with this process will also be addressed.