



International

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ISO 15194

**In vitro diagnostic medical
devices — Requirements for
certified reference materials
and the content of supporting
documentation**

*Dispositifs médicaux de diagnostic in vitro — Exigences
relatives aux matériaux de référence certifiés et au contenu de la
documentation associée*

**Third edition
2026-06**



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This document was prepared by Technical Committee ISO/TC 212, *Medical laboratories and in vitro diagnostic systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, *In vitro diagnostic medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 15194:2009), which has been technically revised.

The main changes are as follows:

- incorporated requirements, concepts and definitions for consistency with ISO 17511:2020;
- removed [Clause 4](#) of the second edition;
- expanded and clarified the Scope to specify requirements for higher order certified reference materials (CRMs) whose intended use is to underpin routine measurements in laboratory medicine;
- added requirements regarding description of the intended use and commutability of the CRM;
- strengthened the documentation requirements for both the certificate and the certification report accompanying a CRM.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Reference measuring systems are needed to enable the results produced by end user measurement procedures (MPs) to be metrologically traceable to either measurement standards or MPs of the highest metrological level. Such systems exist within a metrological traceability chain/calibration hierarchy as described in ISO 17511. In the context of in vitro diagnostic (IVD) medical devices, metrological traceability to the highest metrological level mitigates the risk of harm to patients by avoiding inconsistent results from different measuring systems.

Reference materials (RMs) are used to establish and maintain metrological traceability of measurement results over time within one location, between different physical locations or with the application of different measurement procedures. Certified reference materials (CRMs) are a category of RMs required at the higher metrological levels of a calibration hierarchy or that underpin the metrological traceability of measurement results.

A given CRM is supported by documentation describing the sources of the material, its processing and production, measurement results, metrological traceability, instructions for use, homogeneity and stability data, commutability data when applicable, and storage conditions, as well as health and safety warnings. When the intended application of the CRM is as a secondary calibrator in the calibration hierarchy of IVD devices, the commutability of the CRM is a critical property to be reported.

This document specifies the quality requirements for such materials and the recommended content of their supporting documentation.

CRMs are used for one of three main purposes:

- a) calibration of quantity values indicated by a measuring system or assigned to another RM;
- b) assessment of measurement trueness of quantity values obtained in a given laboratory, or in a group of laboratories;
- c) assessment of measurement trueness of quantity values obtained using a new MP.

NOTE 1 “Measurement trueness” (ISO 17511:2020, 3.47) is the closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value. It is inversely related to systematic measurement error but is not related to random measurement error.

NOTE 2 “Measurement precision” (ISO 17511:2020, 3.34) is the closeness of agreement between measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions. It is usually expressed numerically by measures of imprecision, such as standard deviation, variance, or coefficient of variation under the conditions of measurement. “Measurement precision” is a measure of random measurement error.

The combined measurement uncertainty of the assigned value of a CRM is the combined measurement uncertainty of the steps above the CRM in the calibration hierarchy and the CRM uncertainties associated with its homogeneity and stability. Suitability of its measurement uncertainty is determined by its intended use in the calibration hierarchy.

Since the proper use of a CRM depends on the provision of detailed information on its production, characterization and intended use, it is important to apply rules for the documentation of CRMs.

[Annex A](#) provides information on CRMs for qualitative nominal properties and ordinal quantities, to provide guidance on important quality attributes for such CRMs, whilst recognizing that they are not within the metrological traceability schemes described in ISO 17511:2020.