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***In vitro* diagnostic medical devices —
Measurement of quantities in samples of
biological origin — Requirements for
certified reference materials and the
content of supporting documentation**

*Dispositifs médicaux de diagnostic in vitro — Mesurage des grandeurs
dans les échantillons d'origine biologique — Exigences relatives aux
matériaux de référence certifiés et au contenu de la documentation
associée*



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15194 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, *In vitro diagnostic medical devices*, in collaboration with Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 15194:2002), which has been technically revised.

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Introduction

Reference measurement systems are needed to produce useful and reliable measurement results, whether in science, technology or routine service, so as to be comparable and ultimately metrologically traceable to measurement standards and/or measurement procedures of the highest metrological level.

Substances or devices that are used to obtain this metrological traceability, through time, distances and different measurement procedures, are reference materials. Certified reference materials are needed at the higher metrological levels of a calibration hierarchy.

A given certified reference material is supported by documentation containing sources of material, descriptions, measurement results, metrological traceability, instructions for use, stability data and storage conditions, as well as health and safety warnings. This International Standard specifies the quality requirements for such materials and the content of their supporting documentation.

Reference materials are used for one of three main purposes:

- a) calibration of quantity values indicated by a measuring system or assigned to another reference material;
- b) validation or control of trueness of measured values in a given laboratory, or in a group of laboratories;

NOTE In ISO terminology "trueness" is related to "bias", "systematic effect" and "systematic error", whereas "accuracy" is related both to "trueness" (with its relations) and "precision", where the latter is related to "standard deviation", "coefficient of variation", "random effect" and "random error".

- c) evaluation of the performance of a new measurement procedure.

The maximum acceptable measurement uncertainty of the assigned value of a reference material depends on the requirements of the measured quantity values obtained by a measurement procedure involving the reference material.

As the proper use of a reference material depends on its description, it is important to apply rules for the documentation of reference materials.

The advantages of having standards available are listed in ISO/IEC Guide 15.

In Clause 3 of this International Standard, concepts are indicated by *italicized text*.