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In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Presentation of reference measurement procedures

Dispositifs médicaux de diagnostic in vitro — Mesure des grandeurs dans des échantillons d'origine biologique — Présentation des modes opératoires de mesure de référence

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.ch
Web www.iso.ch

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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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 15193 was prepared by the European Committee for Standardization (as EN 12286:1998) and was adopted, under a special “fast-track procedure”, by Technical Committee ISO/TC 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*, in parallel with its approval by the ISO member bodies.

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN.

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the European Confederation of Laboratory Medicine (ECLM) have contributed to its preparation.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 1999, and conflicting national standards shall be withdrawn at the latest by May 1999.

This European Standard is based on ISO/DIS 78-2 with special consideration of the requirements for biological materials and for reference measurement procedures. prEN 12287 "In vitro diagnostic medical devices – Measurement of quantities in samples of biological origin – Description of reference materials" specifies requirements of importance to the calibration and quality assurance of reference measurement procedures.

Annexes A and B are for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

Reference measurement systems are needed for producing useful and reliable results of measurement, whether in science, technology, or routine service so as to be comparable and ultimately traceable to measurement standards of the highest metrological level. Analytical reference measurement procedures play a crucial role in this metrological system because they can be used

– in assessing performance characteristics of measuring systems – comprising measuring instruments, auxiliary equipment as well as reagents,

– in demonstrating the functional interchangeability of different routine measurement procedures purporting to measure the same quantity,

– in assigning values to reference materials that are then used for purposes of calibration or control of routine measurement procedures and

– in detecting analytical influence quantities in patient samples.

For clinical laboratory measurements, in particular, it is vitally important to acute and continuous patient care that the results reported to the physicians and patients are adequately comparable, reproducible, and accurate.

In some cases, a reference measurement procedure should be given in the form of a (written) standard, namely when it is related to technical requirements

– specified in standards, technical specifications, or technical regulations, etc.;

– for which values are to be stated by the supplier;

– that have a direct relationship to the performance of a product or process.

The advantages of having such a standard are listed in the ISO/IEC Guide 15.

1 Scope

This European Standard specifies requirements for the drafting of a reference measurement procedure.

NOTE: It is intended that an experienced laboratory worker, following a measurement procedure written in accordance with this European Standard can be expected to produce results with an uncertainty of measurement not exceeding the stipulated range.

This European Standard is applicable to any person, body, or institution, involved in one of the various branches of laboratory medicine, intending to write a document to serve as a reference measurement procedure.

2 Normative references

This European Standard incorporates by dated or undated reference provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to, or revisions of, any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN ISO 3696 Water for analytical laboratory use – Specification and test methods (ISO 3696 : 1987)

ISO 6353-2 Reagents for chemical analysis – Part 2: Specifications – First series

ISO 6353-3 Reagents for chemical analysis – Part 3: Specifications – Second series

ISO/IEC Directives – Part 2 : 1992 Methodology for the development of International Standards

International Vocabulary of Basic and General Terms in Metrology (VIM), 2nd edition, Geneva: ISO, 1993 [1] [2]

Guide to the Expression of Uncertainty in Measurement, 1st edition, Geneva: ISO, 1993 [1]

3 Definitions

For the purposes of this European Standard, the definitions given in "International Vocabulary of Basic and General Terms in Metrology" and in "Guide to the Expression of Uncertainty in Measurement" apply together with the following:

3.1 primary sample: Collection of one or more parts initially taken from a system and intended to provide information about the system or to serve as a basis for a decision about the system.

NOTE: In some cases, the information provided also applies to a larger system or a set of systems of which the sampled system is an element.

3.2 laboratory sample: Primary sample or a subsample of it as prepared for sending to or as received by the laboratory and intended for measurement.

3.3 analytical sample: Sample prepared from the laboratory sample and from which analytical portions may be taken.

NOTE: The analytical sample can be subjected to various treatments before an analytical portion is taken.

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[1]) This document has been prepared by a joint working group consisting of experts appointed by:

BIPM	International Bureau of Weights and Measures
IEC	International Electrotechnical Commission
IFCC	International Federation of Clinical Chemistry and Laboratory Medicine
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
IUPAP	International Union of Pure and Applied Physics
OIML	International Organization of Legal Metrology.

[2]) The abbreviation VIM is used in this standard.