SLOVENSKI STANDARD
SIST EN ISO 15195:2003

01-december-2003

Laboratorijska medicina ï Zahteve za referenļ ne merilne laboratorije (ISO 15195:2003)

Laboratory medicine - Requirements for reference measurement laboratories (ISO 15195:2003)

Laboratoriumsmedizin - Anforderungen an Referenzmesslaboratorien (ISO 15195:2003)

Médecine de laboratoires - Exigences pour les laboratoires réalisant des mesurages de référence (ISO 15195:2003)

Ta slovenski standard je istoveten z: EN ISO 15195:2003

ICS:

11.100.01	Laboratorijska medicina na splošno	Laboratory medicine in general

SIST EN ISO 15195:2003 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15195

October 2003

ICS 11.100

English version

Laboratory medicine - Requirements for reference measurement laboratories (ISO 15195:2003)

Médecine de laboratoires - Exigences pour les laboratoires réalisant des mesurages de référence (ISO 15195:2003)

Laboratoriumsmedizin - Anforderungen an Referenzmesslaboratorien (ISO 15195:2003)

This European Standard was approved by CEN on 24 July 2003.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 15195:2003 E

Foreword

This document (EN ISO 15195:2003) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN.

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 April 2004, and conflicting national standards shall be withdrawn at the latest by April 2004.

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, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 15195:2003 has been approved by CEN as EN ISO 15195:2003 without any modifications.

NOTE Normative references to International Standards are listed in Annex ZA (normative).

Annex ZA
(normative)

Normative references to international publications with their relevant European publications

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 (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN	Year
ISO 17511	2003	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials	EN ISO 17511	2003
ISO 18153	2003	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials	EN ISO 18153	2003

INTERNATIONAL STANDARD

ISO 15195

First edition
2003-10-01

Laboratory medicine — Requirements for reference measurement laboratories

Médecine de laboratoires — Exigences pour les laboratoires réalisant des mesurages de référence

Reference number
ISO 15195:2003(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

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.org
Web www.iso.org

Published in Switzerland

Contents

Page

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 15195 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

Introduction

The general requirements for the competence of calibration laboratories are laid down in ISO/IEC 17025 for testing and calibration laboratories. This International Standard refers to the specific aspects of calibration laboratories in the field of laboratory medicine where such “calibration laboratories” are usually denoted as “reference measurement laboratories.”

The results produced by medical laboratories should be traceable to reference materials and/or reference measurement procedures of higher order, whenever these are available. This is necessary in order to allow transferability of measurement results in patient samples irrespective of the place and time of measurement.

In order to achieve this goal, the first and essential step is to define the quantity to be measured. Once the quantity has been defined, a reference measurement system should be established, consisting of

- reference materials,
- reference measurement procedures, and
- reference measurement laboratories.

The reference measurement laboratories should be embedded in international (global) networks organized under the auspices of, for example, International Federation of Clinical Chemistry and Laboratory Medecine (IFCC) and International Committee of weights and Measures (CIPM).

Reference measurement laboratories must operate with a traceability to the highest metrological level available and with a lower uncertainty than routine laboratories. The metrological level of the results provided by reference measurement laboratories should be appropriate to enable routine laboratories to fulfil medical requirements. The specific requirements of medical laboratories carrying out routine measurements are addressed in ISO 15189.

The presentation of reference measurement procedures and the description of reference materials are the subject of ISO standards (ISO 15193 and ISO 15194, respectively). This International Standard describes the performance characteristics required for reference measurement laboratories in laboratory medicine. These are highly specialized laboratories often attached to or subcontracted by entities such as national metrology institutes, quality assessment/proficiency testing organizations, academic centres, or *in vitro* diagnostic medical device manufacturers.

Reference measurement laboratories should implement reference measurement procedures and produce results of measurement that are accurate and traceable to national or international primary reference materials when such are available. Whenever possible, traceability should be established to a reference material which forms an embodiment of the SI unit (ISO 17511).

In many instances, properties of biological materials cannot be expressed in SI units as the molecular structure of their analytes is not exactly known and may be different in a reference material from that in a native sample of human origin (e.g. state of glycosylation of a protein); then the traceability chain ends at a lower level, e.g., at an arbitrary international unit (int. unit). However, the reference measurement laboratory should provide traceable values on reference materials supplied by customers to the highest available level of reference measurement procedures or reference materials.

Even if the value for a property of a biological material is not traceable to an SI unit, each step of a reference measurement procedure (e.g. gravimetry, volumetry, temperature measurement) should have values that are traceable to the respective SI unit.