



SLOVENSKI STANDARD SIST EN ISO 15189:2013

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Nadomešča:
SIST EN ISO 15189:2007

Medicinski laboratoriji - Zahteve za kakovost in kompetentnost (ISO 15189:2012)

Medical laboratories - Requirements for quality and competence (ISO 15189:2012)

Medizinische Laboratorien - Anforderungen an die Qualität und Kompetenz (ISO 15189:2012)

Laboratoires d'analyses de biologie médicale - Exigences concernant la qualité et la compétence (ISO 15189:2012)

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11.100.01	Laboratorijska medicina na splošno	Laboratory medicine in general

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EUROPEAN STANDARD

EN ISO 15189

NORME EUROPÉENNE

EUROPÄISCHE NORM

November 2012

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Supersedes EN ISO 15189:2007

English Version

Medical laboratories - Requirements for quality and competence (ISO 15189:2012)

Laboratoires de biologie médicale - Exigences concernant
la qualité et la compétence (ISO 15189:2012)

Medizinische Laboratorien - Anforderungen an die Qualität
und Kompetenz (ISO 15189:2012)

This European Standard was approved by CEN on 31 October 2012.

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 CEN-CENELEC 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 15189:2012) 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 May 2013, and conflicting national standards shall be withdrawn at the latest by November 2015.

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

This document supersedes EN ISO 15189:2007.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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Endorsement notice

The text of ISO 15189:2012 has been approved by CEN as a EN ISO 15189:2012 without any modification.

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INTERNATIONAL STANDARD

ISO
15189

Third edition
2012-11-01

Medical laboratories — Requirements for quality and competence

*Laboratoires de biologie médicale — Exigences concernant la qualité et
la compétence*

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ISO 15189:2012(E)

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 15189 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This third edition cancels and replaces the second edition (ISO 15189:2007), which has been technically revised.

A correlation between the second and third editions of this International Standard is provided as Annex B. The third edition continues the alignment established in ISO/IEC 17025:2005.

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Introduction

This International Standard, based upon ISO/IEC 17025 and ISO 9001, specifies requirements for competence and quality that are particular to medical laboratories¹⁾. It is acknowledged that a country could have its own specific regulations or requirements applicable to some or all its professional personnel and their activities and responsibilities in this domain.

Medical laboratory services are essential to patient care and therefore have to be available to meet the needs of all patients and the clinical personnel responsible for the care of those patients. Such services include arrangements for examination requests, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent interpretation, reporting and advice, in addition to the considerations of safety and ethics in medical laboratory work.

Whenever allowed by national, regional or local regulations and requirements, it is desirable that medical laboratory services include the examination of patients in consultation cases, and that those services actively participate in the prevention of disease in addition to diagnosis and patient management. Each laboratory should also provide suitable educational and scientific opportunities for professional staff working with it.

While this International Standard is intended for use throughout the currently recognized disciplines of medical laboratory services, those working in other services and disciplines such as clinical physiology, medical imaging and medical physics could also find it useful and appropriate. In addition, bodies engaged in the recognition of the competence of medical laboratories will be able to use this International Standard as the basis for their activities. If a laboratory seeks accreditation, it should select an accrediting body which operates in accordance with ISO/IEC 17011 and which takes into account the particular requirements of medical laboratories.

This International Standard is not intended to be used for the purposes of certification, however a medical laboratory's fulfilment of the requirements of this International Standard means the laboratory meets both the technical competence requirements and the management system requirements that are necessary for it to consistently deliver technically valid results. The management system requirements in Clause 4 are written in a language relevant to a medical laboratory's operations and meet the principles of ISO 9001:2008, *Quality management systems — Requirements*, and are aligned with its pertinent requirements (Joint IAF-ILAC-ISO Communiqué issued in 2009).

The correlation between the clauses and subclauses of this third edition of ISO 15189 and those of ISO 9001:2008 and of ISO/IEC 17025:2005 is detailed in Annex A of this International Standard.

Environmental issues associated with medical laboratory activity are generally addressed throughout this International Standard, with specific references in 5.2.2, 5.2.6, 5.3, 5.4, 5.5.1.4 and 5.7.

1) In other languages, these laboratories can be designated by the equivalent of the English term "clinical laboratories."

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Medical laboratories — Requirements for quality and competence

1 Scope

This International Standard specifies requirements for quality and competence in medical laboratories.

This International Standard can be used by medical laboratories in developing their quality management systems and assessing their own competence. It can also be used for confirming or recognizing the competence of medical laboratories by laboratory customers, regulating authorities and accreditation bodies.

NOTE International, national or regional regulations or requirements may also apply to specific topics covered in this International Standard.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*

ISO/IEC Guide 2, *Standardization and related activities — General vocabulary*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

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3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC Guide 2 and ISO/IEC Guide 99 and the following apply.

3.1

accreditation

procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks

3.2

alert interval

critical interval

interval of examination results for an alert (critical) test that indicates an immediate risk to the patient of injury or death

NOTE 1 The interval may be open ended, where only a threshold is defined.

NOTE 2 The laboratory determines the appropriate list of alert tests for its patients and users.

3.3

automated selection and reporting of results

process by which patient examination results are sent to the laboratory information system and compared with laboratory-defined acceptance criteria, and in which results that fall within the defined criteria are automatically included in patient report formats without any additional intervention

ISO 15189:2012(E)**3.4****biological reference interval**
reference interval

specified interval of the distribution of values taken from a biological reference population

EXAMPLE The central 95 % biological reference interval for sodium ion concentration values in serum from a population of presumed healthy male and female adults is 135 mmol/l to 145 mmol/l.

NOTE 1 A reference interval is commonly defined as the central 95 % interval. Another size or an asymmetrical location of the reference interval could be more appropriate in particular cases.

NOTE 2 A reference interval can depend upon the type of primary samples and the examination procedure used.

NOTE 3 In some cases, only one biological reference limit is important, for example, an upper limit, x , so that the corresponding biological reference interval would be less than or equal to x .

NOTE 4 Terms such as 'normal range', 'normal values', and 'clinical range' are ambiguous and therefore discouraged.

3.5**competence**

demonstrated ability to apply knowledge and skills

NOTE The concept of competence is defined in a generic sense in this International Standard. The word usage can be more specific in other ISO documents.

[ISO 9000:2005, definition 3.1.6]

3.6**documented procedure**

specified way to carry out an activity or a process that is documented, implemented and maintained

NOTE 1 The requirement for a documented procedure may be addressed in a single document or by more than one document.

NOTE 2 Adapted from ISO 9000:2005, definition 3.4.5.

3.7**examination**

set of operations having the object of determining the value or characteristics of a property

NOTE 1 In some disciplines (e.g. microbiology) an examination is the total activity of a number of tests, observations or measurements.

NOTE 2 Laboratory examinations that determine a value of a property are called quantitative examinations; those that determine the characteristics of a property are called qualitative examinations.

NOTE 3 Laboratory examinations are also often called assays or tests.

3.8**interlaboratory comparison**

organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

[ISO/IEC 17043:2010, definition 3.4]

3.9**laboratory director**

person(s) with responsibility for, and authority over, a laboratory

NOTE 1 For the purposes of this International Standard, the person or persons referred to are designated collectively as *laboratory director*.

NOTE 2 National, regional and local regulations may apply with regard to qualifications and training.

3.10**laboratory management**

person(s) who direct and manage the activities of a laboratory

NOTE The term 'laboratory management' is synonymous with the term 'top management' in ISO 9000:2005.

3.11**medical laboratory****clinical laboratory**

laboratory for the biological, microbiological, immunological, chemical, immuno-haematological, haematological, biophysical, cytological, pathological, genetic or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, management, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation

NOTE These examinations also include procedures for determining, measuring or otherwise describing the presence or absence of various substances or microorganisms.

3.12**nonconformity**

nonfulfillment of a requirement

[ISO 9000:2005, definition 3.6.2].

NOTE Other terms frequently used include: accident, adverse event, error, event, incident, and occurrence.

3.13**point-of-care testing****POCT****near-patient testing**

testing performed near or at the site of a patient, with the result leading to possible change in the care of the patient

[ISO 22870:2006, definition 3.1]

3.14**post-examination processes****postanalytical phase**

processes following the examination including review of results, retention and storage of clinical material, sample (and waste) disposal, and formatting, releasing, reporting and retention of examination results

3.15**pre-examination processes****preanalytical phase**

processes that start, in chronological order, from the clinician's request and include the examination request, preparation and identification of the patient, collection of the primary sample(s), and transportation to and within the laboratory, and end when the analytical examination begins

3.16**primary sample****specimen**

discrete portion of a body fluid, breath, hair or tissue taken for examination, study or analysis of one or more quantities or properties assumed to apply for the whole

NOTE 1 Global Harmonisation Task Force (GHTF) uses the term specimen in its harmonized guidance documents to mean a sample of biological origin intended for examination by a medical laboratory.

NOTE 2 In some ISO and CEN documents, a specimen is defined as "a biological sample derived from the human body".

NOTE 3 In some countries, the term "specimen" is used instead of primary sample (or a subsample of it), which is the sample prepared for sending to, or as received by, the laboratory and which is intended for examination.