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Medicinske laboratorier – Kvalitets- og kompetencekrav

Medical laboratories – Requirements for quality
and competence (ISO 15189:2022)

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EUROPÄISCHE NORM

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Supersedes EN ISO 15189:2012,
EN ISO 22870:2016

English Version

Medical laboratories - Requirements for quality and competence (ISO 15189:2022)

Laboratoires de biologie médicale -
Exigences concernant la qualité et la
compétence (ISO 15189:2022)

Medizinische Laboratorien - Anforderungen an
die Qualität und Kompetenz (ISO 15189:2022)

This European Standard was approved by CEN on 15 November 2022.

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.

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European foreword

This document ([EN ISO 15189:2022](#)) 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of an identical text or by endorsement, at the latest by June 2023, and conflicting national standards shall be withdrawn at the latest by December 2025.

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

This document supersedes [EN ISO 15189:2012](#) and [EN ISO 22870:2016](#).

This document has been prepared under a Standardization Request given to CEN by the European Commission and the European Free Trade Association.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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Endorsement notice

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Fourth edition
2022-12

Medical laboratories — Requirements for quality and competence

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



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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test 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 fourth edition cancels and replaces the third edition ([ISO 15189:2012](http://www.iso.org/iso/15189:2012)), which has been technically revised. It also replaces [ISO 22870:2016](http://www.iso.org/iso/22870:2016).

The main changes are as follows:

- Alignment with [ISO/IEC 17025:2017](http://www.iso.org/iso/17025:2017) resulted in the management requirements now appearing at the end of the document;
- Requirements for point-of-care testing (POCT), previously in [ISO 22870](http://www.iso.org/iso/22870), have been incorporated;
- Increased emphasis on risk management.

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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Introduction

The objective of this document is to promote the welfare of patients and satisfaction of laboratory users through confidence in the quality and competence of medical laboratories.

This document contains requirements for the medical laboratory to plan and implement actions to address risks and opportunities for improvement. Benefits of this approach include: increasing the effectiveness of the management system, decreasing probability of invalid results, and reducing potential harm to patients, laboratory personnel, the public and the environment.

The requirements for risk management are aligned with the principles of [ISO 22367](#).

The requirements for laboratory safety are aligned with the principles of [ISO 15190](#).

The requirements for sample collection and transport are aligned with [ISO 20658](#).¹⁾

This document contains the requirements for point-of-care testing (POCT) and supersedes [ISO 22870](#), which will be withdrawn upon publication of this document.

The format of this document is based on [ISO/IEC 17025:2017](#).

The medical laboratory is essential to patient care; activities are provided within an ethical and governance framework, that recognizes the obligations of healthcare providers to the patient. These activities are undertaken in a timely manner to meet the needs of all patients and the personnel responsible for the care of those patients. Activities include arrangements for examination requests, patient preparation, patient identification, collection of samples, transportation, processing of patient samples, selection of examinations that are fit for intended use, examination of samples, sample storage, as well as subsequent interpretation, result reporting and advice to laboratory users. This may also include the provision of results to the patient, arrangements for urgent testing and the notification of critical results.

While this document is intended for use throughout the currently recognized medical laboratory disciplines, it can effectively be applied to other healthcare services, such as diagnostic imaging, respiratory therapy, physiological sciences, blood banks and transfusion services.

The use of this document facilitates cooperation between medical laboratories and other healthcare services, assists in the exchange of information, and in the harmonization of methods and procedures.

The comparability of patient examination results between medical laboratories, regardless of city or country, is facilitated when medical laboratories conform to this document.

When a laboratory seeks accreditation, it should select an accreditation body which operates in accordance with [ISO/IEC 17011](#), and which takes into account the particular requirements of medical laboratories.

Comparisons between this document, [ISO 9001:2015](#) and [ISO/IEC 17025:2017](#) are in [Annex B](#). The comparison of [ISO 15189:2012](#) to [ISO 15189:2022](#) (this document) is in [Annex C](#).

1) First edition under preparation (previous edition was a Technical Specification). Stage at the time of publication: [ISO/DIS 20658:2022](#).

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Medical laboratories — Requirements for quality and competence

1 Scope

This document specifies requirements for quality and competence in medical laboratories.

This document is applicable to medical laboratories in developing their management systems and assessing their competence. It is also applicable for confirming or recognizing the competence of medical laboratories by laboratory users, regulatory authorities and accreditation bodies.

This document is also applicable to point-of-care testing (POCT).

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 Guide 99:2007](#), *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

NOTE [ISO/IEC Guide 99](#) is also known as the Joint Committee for Guides in Metrology (JCGM) 200.

[ISO/IEC 17000:2020](#), *Conformity assessment — Vocabulary and general principles*

[ISO/IEC 17025:2017](#), *General requirements for the competence of testing and calibration laboratories*