

Patsiendimanused uuringud. Kvaliteedi- ja pädevusnõuded

Point-of-care testing (POCT) - Requirements for quality and competence

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 22870:2006 sisaldab Euroopa standardi EN ISO 22870:2006 ingliskeelset teksti.

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English Version

Point-of-care testing (POCT) - Requirements for quality and
competence (ISO 22870:2006)

Analyses de biologie délocalisées (ADBD) - Exigences
concernant la qualité et la compétence (ISO 22870:2006)

Patientennahe Untersuchungen (point-of-care testing,
POCT) - Anforderungen an Qualität und Kompetenz (ISO
22870:2006)

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 22870:2006) 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of an identical text or by endorsement, at the latest by August 2006, and conflicting national standards shall be withdrawn at the latest by August 2006.

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Endorsement notice

The text of ISO 22870:2006 has been approved by CEN as EN ISO 22870:2006 without any modifications.

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Requirements for quality and competence**

*Analyses de biologie délocalisées (ADBD) — 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.

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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.

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ISO 22870 was prepared by Technical Committee ISO/TC TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

Introduction

Traditional examinations of a patient's body fluids, excreta and tissues are carried out generally in the controlled and regulated environment of a recognized medical laboratory. The introduction of quality management systems and accreditation of these laboratories are gaining increasing interest.

Advances in technology have resulted in compact, easy-to-use *in vitro* diagnostic (IVD) medical devices that make it possible to carry out some examinations at, or close to, the location of the patient. Point-of-care/near-patient testing may benefit the patient as well as healthcare facilities.

Risk to the patient and to the facility can be managed by a well-designed, fully implemented quality management system that facilitates:

- evaluation of new or alternative POCT instruments and systems,
- evaluation and approval of end-user proposals and protocols,
- purchase and installation of equipment,
- maintenance of consumable supplies and reagents,
- training, certification and recertification of POCT system operators,
- quality control and quality assurance.

Bodies that recognise the competence of POCT facilities may use this International Standard as the basis for their activities. If a healthcare facility seeks accreditation for a part or all of its activities, it should select an accreditation body that operates in a manner which takes into account the special requirements of POCT.

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Point-of-care testing (POCT) — Requirements for quality and competence

1 Scope

This International Standard gives specific requirements applicable to point-of-care testing and is intended to be used in conjunction with ISO 15189. The requirements of this International Standard apply when POCT is carried out in hospital, clinic and by a healthcare organization providing ambulatory care. This International Standard can be applied to transcutaneous measurements, the analysis of expired air, and *in vivo* monitoring of physiological parameters.

Patient self-testing in a home or community setting is excluded, but elements of this International Standard can be applicable.

NOTE Local, regional, and national regulations are to be taken into consideration.

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 15189:2003, *Medical laboratories — Particular requirements for quality and competence*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

point-of-care testing

POCT

near-patient testing

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

4 Management requirements

4.1 Organization and management

4.1.1 ISO 15189:2003, 4.1.1, and the following apply.

The management of laboratory services shall plan and develop the processes needed for POCT.

The following shall be considered, as appropriate:

a) quality objectives and requirements for POCT;