SLOVENSKI STANDARD
SIST EN ISO 22870:2006

01-april-2006

Preskušanje ob preiskovancu (POCT) – Zahteve za kakovost in usposobljenost (ISO 22870:2006)

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

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

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

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03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
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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)

This European Standard was approved by CEN on 23 January 2006.

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

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

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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of an identical text or by endorsement, at the latest by August 2006, and conflicting national standards shall be withdrawn at the latest by August 2006.

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

Endorsement notice

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

INTERNATIONAL STANDARD

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

Analyses de biologie délocalisées (ADBD) — Exigences concernant la qualité et la compétence

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

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;

