SLOVENSKI STANDARD
SIST EN ISO 22870:2017

01-februar-2017

Nadomešča:
SIST EN ISO 22870:2006

Testiranje ob pacientu (POCT) - Zahteve za kakovost in kompetentnost (ISO 22870:2016)

Point-of-care testing (POCT) - Requirements for quality and competence (ISO 22870:2016)

Patientennahe Untersuchungen (point-of-care testing, POCT) - Anforderungen an Qualität und Kompetenz (ISO 22870:2016)

Analyse de biologie délocalisée (ADBD) - Exigences en matière de qualité et de compétences (ISO 22870:2016)

Ta slovenski standard je istoveten z: **EN ISO 22870:2016**

ICS:

03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
11.100.01	Laboratorijska medicina na splošno	Laboratory medicine in general

SIST EN ISO 22870:2017 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 22870

November 2016

ICS 03.120.10; 11.100.01

Supersedes EN ISO 22870:2006

English Version

Point-of-care testing (POCT) - Requirements for quality and competence (ISO 22870:2016)

Examens de biologie médicale délocalisée (EBMD) - Exigences concernant la qualité et la compétence (ISO 22870:2016)

Patientennahe Untersuchungen (point-of-care testing, POCT) - Anforderungen an Qualität und Kompetenz (ISO 22870:2016)

This European Standard was approved by CEN on 14 October 2016.

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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 COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 22870:2016) 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of an identical text or by endorsement, at the latest by May 2017, and conflicting national standards shall be withdrawn at the latest by November 2019.

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 22870:2006.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Regulation 765/2008.

According to the CEN-CENELEC Internal Regulations, the national standards organizations 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.

Endorsement notice

The text of ISO 22870:2016 has been approved by CEN as EN ISO 22870:2016 without any modification.

INTERNATIONAL STANDARD

ISO 22870

Second edition
2016-11-01

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

Examens de biologie médicale délocalisée (EBMD) — Exigences concernant la qualité et la compétence

Reference number
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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).

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

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This second edition cancels and replaces the first edition (ISO 22870:2006), of which it constitutes a minor revision.

The changes compared to the previous edition are as follows:

— inclusion of cross-references to the applicable clauses in ISO 15189:2012.

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, installation and maintenance of equipment,

— maintenance of consumable supplies and reagents,

— training, certification and recertification of POCT system operators, and

— quality control and quality assurance.

Bodies that recognize the competence of POCT facilities may use this document 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.