

STN	Vyšetrenia v mieste starostlivosti (VVMS). Požiadavky na kvalitu a kompetentnosť (ISO 22870: 2016).	STN EN ISO 22870 85 5011
------------	--	--

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 04/17

Obsahuje: EN ISO 22870:2016, ISO 22870:2016

Oznámením tejto normy sa od 30.11.2019 ruší
STN EN ISO 22870 (85 5011) z decembra 2006

124441

Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2017
Podľa zákona č. 264/1999 Z. z. o technických požiadavkách na výrobky a o posudzovaní zhody a o zmene a doplnení niektorých zákonov v znení neskorších predpisov sa slovenská technická norma a časti slovenskej technickej normy môžu rozmnožovať alebo rozširovať len so súhlasom slovenského národného normalizačného orgánu.

EUROPEAN STANDARD

EN ISO 22870

NORME EUROPÉENNE

EUROPÄISCHE NORM

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.

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.



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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents	Page
European foreword.....	3

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.

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

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



COPYRIGHT PROTECTED DOCUMENT

© ISO 2016, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Management requirements	1
4.1 Organization and management.....	1
4.2 Quality management system.....	2
4.3 Document control.....	4
4.4 Service agreements.....	4
4.5 Examination by referral laboratories.....	4
4.6 External services and supplies.....	4
4.7 Advisory services.....	4
4.8 Resolution of complaints.....	4
4.9 Identification and control of nonconformities.....	4
4.10 Corrective action.....	5
4.11 Preventive action.....	5
4.12 Continual improvement.....	5
4.13 Quality and technical records.....	5
4.14 Internal audits.....	6
4.15 Management review.....	6
5 Technical requirements	6
5.1 Personnel.....	6
5.2 Accommodation and environmental conditions.....	8
5.3 Equipment.....	8
5.4 Pre-examination procedures.....	8
5.5 Examination procedures.....	8
5.6 Assuring the quality of examination procedures.....	9
5.7 Post-examination procedure.....	9
5.8 Reporting of results.....	10
Bibliography	11

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 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.

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

1 Scope

This document gives specific requirements applicable to point-of-care testing and is intended to be used in conjunction with ISO 15189. The requirements of this document apply when POCT is carried out in a hospital, clinic and by a healthcare organization providing ambulatory care. This document 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 document can be applicable.

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

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 15189:2012, *Medical laboratories — Requirements for quality and competence*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN