

Institut luxembourgeois de la normalisation de l'accréditation, de la sécurité et qualité des produits et services

ILNAS-EN ISO 15189:2022

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)

01011010010 0011010010110100101010101111

National Foreword

This European Standard EN ISO 15189:2022 was adopted as Luxembourgish Standard ILNAS-EN ISO 15189:2022.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

https://portail-qualite.public.lu/fr/normes-normalisation/participer-normalisation.html

THIS PUBLICATION IS COPYRIGHT PROTECTED

Nothing from this publication may be reproduced or utilized in any form or by any mean - electronic, mechanical, photocopying or any other data carries without prior permission!

EUROPEAN STANDARD ILNAS-EN ISO 15189:20 EN ISO 15189

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 2022

ICS 03.120.10; 11.100.01

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.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents	Page
European foreword	3

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.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 15189:2022 has been approved by CEN as EN ISO 15189:2022 without any modification.

IINTERNATIONAL STANDARD

ISO 15189

Fourth edition 2022-12

Medical laboratories — Requirements for quality and competence

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





COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

All rights reserved. Unless otherwise specified, or required in the context of its implementation, 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 CP 401 • Ch. de Blandonnet 8 CH-1214 Vernier, Geneva Phone: +41 22 749 01 11 Email: copyright@iso.org Website: www.iso.org

Published in Switzerland

CO	Contents				
Fore	eword		v i		
Intr	oductio	on	vi i		
1	Scor	0e	1		
2	-	mative references			
3	Terr	Terms and definitions			
4		eral requirements			
	4.1	Impartiality			
	4.2	Confidentiality			
		4.2.1 Management of information			
		4.2.2 Release of information			
	4.3	4.2.3 Personnel responsibility			
5		ctural and governance requirements			
	5.1	Legal entity			
	5.2	Laboratory director			
		5.2.1 Laboratory director competence			
		5.2.3 Delegation of duties			
	5.3	Laboratory activities			
	5.5	5.3.1 General			
		5.3.2 Conformance with requirements			
		5.3.3 Advisory activities			
	5.4	Structure and authority			
		5.4.1 General			
		5.4.2 Quality management	11		
	5.5	Objectives and policies	11		
	5.6	Risk management	12		
6	Reso	ource requirements	12		
	6.1	General			
	6.2	Personnel	12		
		6.2.1 General	12		
		6.2.2 Competence requirements			
		6.2.3 Authorization			
		6.2.4 Continuing education and professional development			
		6.2.5 Personnel records			
	6.3	Facilities and environmental conditions			
		6.3.1 General			
		6.3.2 Facility controls			
		6.3.3 Storage facilities 6.3.4 Personnel facilities			
		6.3.5 Sample collection facilities			
	6.4	Equipment			
	0.1	6.4.1 General			
		6.4.2 Equipment requirements			
		6.4.3 Equipment acceptance procedure			
		6.4.4 Equipment instructions for use			
		6.4.5 Equipment maintenance and repair			
		6.4.6 Equipment adverse incident reporting			
		6.4.7 Equipment records	16		
	6.5	Equipment calibration and metrological traceability	17		
		6.5.1 General			
		6.5.2 Equipment calibration	17		

	6.5.3	Metrological traceability of measurement results	17
6.6	Reage	ents and consumables	18
	6.6.1	General	18
	6.6.2	Reagents and consumables — Receipt and storage	
	6.6.3	Reagents and consumables — Acceptance testing	
	6.6.4	Reagents and consumables — Inventory management	
	6.6.5	Reagents and consumables — Instructions for use	19
	6.6.6	Reagents and consumables — Adverse incident reporting	
	6.6.7	Reagents and consumables — Adverse incident reporting	
6.7		ce agreements	
0.7			
	6.7.1	Agreements with laboratory users	
	6.7.2	Agreements with POCT operators	
6.8		nally provided products and services	
	6.8.1	General	
	6.8.2	Referral laboratories and consultants	
	6.8.3	Review and approval of externally provided products and services	20
Proc	ess rea	uirements	21
7.1		ral	
7.2		xamination processes	
7.2	7.2.1	General	
	7.2.1	Laboratory information for patients and users	
	7.2.3	Requests for providing laboratory examinations	21
	7.2.4	Primary sample collection and handling	22
	7.2.5	Sample transportation	
	7.2.6	Sample receipt	
	7.2.7	Pre-examination handling, preparation, and storage	
7.3		ination processes	
	7.3.1	General	
	7.3.2	Verification of examination methods	25
	7.3.3	Validation of examination methods	25
	7.3.4	Evaluation of measurement uncertainty (MU)	26
	7.3.5	Biological reference intervals and clinical decision limits	26
	7.3.6	Documentation of examination procedures	
	7.3.7	Ensuring the validity of examination results	
7.4		examination processes	30
,,,	7.4.1	Reporting of results	
	7.4.2	Post-examination handling of samples	
7.5		onforming work	
7.6		ol of data and information management	
7.0	7.6.1	General	
	7.6.1		
		Authorities and responsibilities for information management	
	7.6.3	Information systems management	
	7.6.4	Downtime plans	
	7.6.5	Off site management	
7.7	_	laints	
	7.7.1	Process	
	7.7.2	Receipt of complaint	
	7.7.3	Resolution of complaint	
7.8	Conti	nuity and emergency preparedness planning	35
Man	agemen	t system requirements	35
8.1		ral requirements	
0.1	8.1.1	General	
	8.1.2	Fulfilment of management system requirements	
0.2	8.1.3	Management system awareness	
8.2		gement system documentation	
	8.2.1	General	
	8.2.2	Competence and quality	36

8