

STN	Mikrobiológia potravinového reťazca Polymerázová reťazová reakcia (PCR) na dôkaz a kvantifikáciu mikroorganizmov Všeobecné požiadavky a definície (ISO 22174: 2024)	STN EN ISO 22174 56 0110
------------	--	--

Microbiology of the food chain - Polymerase chain reaction (PCR) for the detection and quantification of microorganisms - General requirements and definitions (ISO 22174:2024)

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. 12/24

Rozpracovaná prekladom.

Obsahuje: EN ISO 22174:2024, ISO 22174:2024

Oznámením tejto normy sa ruší
STN EN ISO 22174 (56 0110) z decembra 2005

139433

EUROPEAN STANDARD

EN ISO 22174

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2024

ICS 07.100.30

Supersedes EN ISO 20837:2006, EN ISO 20838:2006,
EN ISO 22119:2011, EN ISO 22174:2005

English Version

Microbiology of the food chain - Polymerase chain reaction
(PCR) for the detection and quantification of
microorganisms - General requirements and definitions
(ISO 22174:2024)

Microbiologie de la chaîne alimentaire - Réaction de
polymérisation en chaîne (PCR) pour la recherche et la
quantification de micro-organismes - Exigences
générales et définitions (ISO 22174:2024)

Mikrobiologie der Lebensmittelkette - Polymerase-
Kettenreaktion (PCR) zum Nachweis von
Mikroorganismen - Allgemeine Anforderungen und
Definitionen (ISO 22174:2024)

This European Standard was approved by CEN on 21 July 2024.

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

EN ISO 22174:2024 (E)

Contents	Page
European foreword.....	3

European foreword

This document (EN ISO 22174:2024) has been prepared by Technical Committee ISO/TC 34 "Food products" in collaboration with Technical Committee CEN/TC 463 "Microbiology of the food chain" the secretariat of which is held by AFNOR.

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 March 2025, and conflicting national standards shall be withdrawn at the latest by March 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 22174:2005, EN ISO 20838:2006, EN ISO 22119:2011, EN ISO 20837:2006.

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 22174:2024 has been approved by CEN as EN ISO 22174:2024 without any modification.



International Standard

ISO 22174

Microbiology of the food chain — Polymerase chain reaction (PCR) for the detection and quantification of microorganisms — General requirements and definitions

*Microbiologie de la chaîne alimentaire — Réaction de
polymérisation en chaîne (PCR) pour la recherche et la
quantification de micro-organismes — Exigences générales et
définitions*

**Second edition
2024-08**

ISO 22174:2024(en)**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2024

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

ISO 22174:2024(en)

Contents

Page

Foreword	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
3.1 General terms.....	2
3.2 Terms related to the extraction and purification of DNA/RNA.....	3
3.3 Terms related to reverse transcription of RNA to DNA.....	4
3.4 Terms related to DNA amplification by PCR/RT-PCR.....	4
3.5 Terms related to controls.....	5
3.6 Terms related to qPCR.....	6
3.7 Terms related to dPCR.....	7
4 Principle	8
4.1 General.....	8
4.2 Laboratory sample.....	9
4.3 Sampling, transport and storage.....	9
4.4 Preparation of test sample.....	9
5 Microbial enrichment and virus concentration	9
5.1 Microbial enrichment.....	9
5.2 Virus concentration.....	9
6 Nucleic acid preparation	10
6.1 General.....	10
6.2 Prevention of amplification of DNA from dead cells.....	10
6.3 Nucleic acid extraction, release and purification.....	10
6.4 Nucleic acid quality and quantity.....	10
7 PCR amplification	11
8 Detection and confirmation of amplicons	11
9 General environmental laboratory requirements	12
9.1 General.....	12
9.2 Laboratory setup.....	12
9.2.1 General.....	12
9.2.2 Control of flows.....	13
9.2.3 Cleaning of laboratory.....	14
9.2.4 Environmental monitoring for nucleic acid contamination.....	14
10 Reagents and consumables	14
11 Equipment	14
12 Procedure	15
12.1 Enrichment and sample treatment.....	15
12.2 Amplification.....	16
12.2.1 General.....	16
12.2.2 Control reaction.....	16
12.2.3 Detection of amplicon.....	18
12.2.4 Data analysis.....	18
12.3 Evaluation.....	19
12.3.1 Qualitative evaluation.....	19
12.3.2 Quantitative evaluation.....	20
12.4 Test report.....	21
13 Performance characteristics of PCR-based methods	21
14 Validation and verification of PCR-based methods	21
14.1 General.....	21

ISO 22174:2024(en)

14.2	Validation	21
14.3	Verification.....	22
Annex A (informative) Fluorescence signals and amplification curve.....		23
Bibliography.....		26

ISO 22174:2024(en)

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of the voluntary nature of standards, 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee TC 34, *Food products*, Subcommittee SC 9, *Microbiology*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 463, *Microbiology of the food chain*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces ISO 22174:2005, ISO 20837:2006, ISO 20838:2006 and ISO 22119:2011, which have been technically revised.

The main changes are as follows:

- inclusion of requirements for the implementation of digital PCR;
- inclusion of requirements for laboratory flows monitoring including environmental monitoring for PCR;
- extension of [12.2.2](#) control reaction with descriptions of the different controls;
- change of [12.3](#) to include quantitative evaluation;
- inclusion of [Clause 14](#) on validation and verification.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Microbiology of the food chain — Polymerase chain reaction (PCR) for the detection and quantification of microorganisms — General requirements and definitions

1 Scope

This document specifies the general requirements for the *in vitro* amplification of nucleic acid sequences (DNA or RNA).

This document is applicable to the testing for microorganisms and viruses from the food chain using the polymerase chain reaction (PCR). This document, or parts of it, is applicable to other fields of PCR diagnostics based on a case-by-case evaluation.

The minimum requirements laid down in this document are intended to ensure that comparable and reproducible results are obtained in different laboratories.

This document has been established for microorganisms from the food chain and is applicable to:

- products intended for human consumption;
- products for feeding animals;
- environmental samples in the area of food and feed production and handling;
- samples from the primary production stage.

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 6887 (all parts), *Microbiology of the food chain — Preparation of test samples, initial suspension and decimal dilutions for microbiological examination*

ISO 7218, *Microbiology of the food chain — General requirements and guidance for microbiological examinations*

ISO 20836, *Microbiology of the food chain — Polymerase chain reaction (PCR) for the detection of microorganisms — Thermal performance testing of thermal cyclers*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN