



BSI Standards Publication

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

National foreword

This British Standard is the UK implementation of EN ISO 22174:2024. It is identical to ISO 22174:2024. It supersedes BS EN ISO 20837:2006, BS EN ISO 20838:2006, BS EN ISO 22119:2011 and BS EN ISO 22174:2005, which are withdrawn.

The UK participation in its preparation was entrusted to Technical Committee AW/9, Microbiology.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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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)

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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of an identical text or by endorsement, at the latest by March 2025, and conflicting national standards shall be withdrawn at the latest by March 2025.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.

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Endorsement notice

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

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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 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).

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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*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1 General terms

3.1.1

laboratory sample

sample as prepared for sending to the laboratory and intended for inspection or testing

[SOURCE: ISO 7002:1986, A.19]

3.1.2

test sample

sample prepared from the *laboratory sample* ([3.1.1](#)) according to the procedure specified in the method of test and from which *test portions* ([3.1.3](#)) are taken

3.1.3

test portion

measured (volume or mass) representative sample taken from the *laboratory sample* ([3.1.1](#))

[SOURCE: ISO 6887-1:2017, 3.5, modified — “for use in the preparation of the initial suspension” and Note 1 to entry deleted.]

3.1.4

reference material

material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process

Note 1 to entry: Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.

[SOURCE: ISO Guide 30:2015, 2.1.1, modified — Notes to entry deleted and a new Note 1 to entry added.]

3.1.5

matrix

all the components of the sample

[SOURCE: ISO 16140-1:2016, 2.38, modified — “(product)” deleted in the term.]

3.1.6

deoxyribonucleic acid

DNA

polymer of deoxyribonucleotides occurring in a double-stranded (dsDNA) or single-stranded (ssDNA) form

3.1.7

deoxyribonuclease

DNase

enzyme which degrades *deoxyribonucleic acid (DNA)* ([3.1.6](#))

3.1.8

amplicon

deoxyribonucleic acid (DNA) ([3.1.6](#)) amplified by *polymerase chain reaction (PCR)* ([3.1.17](#))

3.1.9

ribonucleic acid

RNA

polymer of ribonucleotides occurring in a double-stranded or single-stranded form

3.1.10

ribonuclease

RNase

enzyme which degrades *ribonucleic acid (RNA)* ([3.1.9](#))

3.1.11

nucleic acid

polymer of deoxyribonucleotides or ribonucleotides

3.1.12

target nucleic acid sequence

nucleic acid sequence selected for amplification

3.1.13

endogenous sequence

nucleic acid sequence naturally present in the tested *matrix* ([3.1.5](#))

3.1.14

exogenous sequence

nucleic acid sequence naturally absent in the tested *matrix* ([3.1.5](#))

3.1.15

detection of polymerase chain reaction product

detection of amplicon

process which signals the presence of an *amplicon* ([3.1.8](#))

3.1.16

confirmation of polymerase chain reaction product

confirmation of amplicon

process which demonstrates that the *amplicon* ([3.1.8](#)) originates from the *target nucleic acid sequence* ([3.1.12](#))

3.1.17

polymerase chain reaction

PCR

enzymatic procedure that allows in vitro amplification of *deoxyribonucleic acid (DNA)* ([3.1.6](#))

3.1.18

endpoint polymerase chain reaction

endpoint PCR

procedure using PCR amplification followed by separate detection of *amplicons* ([3.1.8](#)) after the completion of the PCR

3.1.19

real-time polymerase chain reaction

real-time PCR

procedure which combines PCR amplification with the detection and/or quantification of specific *amplicons* ([3.1.8](#)) during the amplification process

3.1.20

multiplex polymerase chain reaction

multiplex PCR

PCR ([3.1.17](#)) allowing the detection of multiple targets simultaneously within a single reaction tube, where more primer pairs (and probes) are used within one *master mix* ([3.4.4](#))

3.2 Terms related to the extraction and purification of DNA/RNA

3.2.1

nucleic acid extraction

sample treatment for the release of *nucleic acids* ([3.1.11](#))

3.2.2

nucleic acid purification

method to reduce the amount of *polymerase chain reaction (PCR)* ([3.1.17](#)) inhibitors in the eluate