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QUESTO DOCUMENTO È UNA PREVIEW. RIPRODUZIONE VIETATA

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.

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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.

QUESTO DOCUMENTO È UNA PREVIEW. RIPRODUZIONE VIETATA

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/>