
**Microbiology of food and animal feeding
stuffs — Polymerase chain reaction
(PCR) for the detection of food-borne
pathogens — Requirements for
amplification and detection for qualitative
methods**

*Microbiologie des aliments — Réaction de polymérisation en chaîne
(PCR) pour la détection des micro-organismes pathogènes dans les
aliments — Exigences relatives à l'amplification et à la détection pour
les méthodes qualitatives*



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Contents

Page

Foreword.....	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions.....	1
4 Principle	1
5 Reagents	2
6 Apparatus and equipment	3
7 Procedure	4
8 Interpretation.....	6
9 Performance	6
10 Test report	6
Bibliography	7

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

ISO 20838 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 275, *Food analysis — Horizontal methods*, in collaboration with Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Introduction

The amplification and detection of target nucleic acid sequences is performed to determine whether certain nucleic acid sequences are present or not in the test portion. This determination is relative to appropriate controls and within the detection limits of the analytical method used and test portion analysed.

This International Standard describes the procedure used to detect food-borne microorganisms, including pathogens, by analysing nucleic acids extracted from foodstuffs, feed and environmental samples, or from cultures or cell suspensions prepared from the foodstuff. Appropriate procedures for sample preparation, culturing of microorganisms and extraction of nucleic acids are described in ISO 20837.

The main focus of this International Standard is on PCR-based amplification methods. However, because of the rapid rate of technological change in this area, other amplification technologies and detection methods may be considered.

This International Standard is related to a series of standards and a Technical Specification under the general title *Microbiology of food and animal feeding stuffs — Polymerase chain reaction (PCR) for the detection of food-borne pathogens*

- *General requirements and definitions* (ISO 22174)
- *Requirements for sample preparation for qualitative detection* (ISO 20837)
- *Performance testing for thermal cyclers* (ISO/TS 20836)
- *Requirements for amplification and detection for qualitative methods* (ISO 20838)

The International Organization for Standardization (ISO) draws attention to the fact that it is claimed that compliance with this document may involve the use of one or more patents concerning the PCR technology.

ISO takes no position concerning the evidence, validity and scope of these patent rights.

ISO has been informed that Applied Biosystems, Roche Molecular Systems, Inc. and F. Hoffman-La Roche Ltd. hold patent rights concerning the PCR technology. The companies have assured ISO that they are willing to negotiate licences under reasonable and non-discriminatory terms and conditions with applicants throughout the world. In this respect, the statements of the holders of these patent rights are registered with ISO. Information may be obtained from:

Licensing Department
Applied Biosystems
850 Lincoln Centre Drive
Foster City, CA 94404
USA

and

Roche Molecular Systems, Inc.
Licensing Department
1145 Atlantic Avenue
Alameda, CA 94501
USA

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Microbiology of food and animal feeding stuffs — Polymerase chain reaction (PCR) for the detection of food-borne pathogens — Requirements for amplification and detection for qualitative methods

WARNING — The use of this standard may involve hazardous materials, operations and equipment. This standard does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

1 Scope

This International Standard provides the overall framework for qualitative methods for the detection of food-borne pathogens using the polymerase chain reaction (PCR).

It covers the general requirements for the specific amplification of target nucleic acid sequences and the detection and confirmation of the identity of the amplified nucleic acid sequence.

Guidelines, minimum requirements and performance characteristics described in this International Standard are intended to ensure that comparable and reproducible results are obtained in different laboratories.

This International Standard has been established for food-borne pathogens in or isolated from food and feed matrices, but can also be applied to other matrices, for example environmental samples, or to the detection of other microorganisms under investigation.

2 Normative references

The following referenced documents are indispensable for the application 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 16140, *Microbiology of food and animal feeding stuffs — Protocol for the validation of alternative methods*

ISO 22174:2005, *Microbiology of food and animal feeding stuffs — Polymerase chain reaction (PCR) for the detection of food-borne pathogens — General requirements and definitions*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 22174 apply.

4 Principle

For the purposes of this International Standard, qualitative analysis consists of screening and/or specific detection of target nucleic acid sequences in the test samples. Specificity can be at genus, species or a lower taxonomic level.