

STN	Mikrobiológia potravinárskeho reťazca Polymerázová reťazová reakcia (PCR) na dôkaz patogénov v potravinách Skúšanie výkonnosti termálneho cykléra (ISO 20836: 2021)	STN EN ISO 20836 56 0152
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Microbiology of the food chain - Polymerase chain reaction (PCR) for the detection of microorganisms - Thermal performance testing of thermal cyclers (ISO 20836:2021)

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. 03/22

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Microbiology of the food chain - Polymerase chain reaction (PCR) for the detection of microorganisms - Thermal performance testing of thermal cyclers (ISO 20836:2021)

Microbiologie de la chaîne alimentaire - Réaction de polymérisation en chaîne (PCR) pour la recherche de micro-organismes - Essais de performance thermique des thermocycleurs (ISO 20836:2021)

Mikrobiologie von Lebensmitteln und Futtermitteln - Polymerase-Kettenreaktion (PCR) zum Nachweis von pathogenen Mikroorganismen in Lebensmitteln - Leistungsprüfung für PCR-Geräte (ISO 20836:2021)

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EN ISO 20836:2021 (E)

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European foreword

This document (EN ISO 20836:2021) 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of an identical text or by endorsement, at the latest by June 2022, and conflicting national standards shall be withdrawn at the latest by June 2022.

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.

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Endorsement notice

The text of ISO 20836:2021 has been approved by CEN as EN ISO 20836:2021 without any modification.

INTERNATIONAL STANDARD

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

Microbiologie de la chaîne alimentaire — Réaction de polymérisation en chaîne (PCR) pour la recherche de micro-organismes — Essais de performance thermique des thermocycleurs



Reference number
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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 documents 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 first edition International Standard cancels and replaces the first edition Technical Specification (ISO/TS 20836:2005), which has been technically revised. The main changes compared with the previous edition are as follows:

- the Scope has been extended to include both thermal cyclers and real-time thermal cyclers;
- the physical performance testing method has been described in more detail, and the biochemical performance testing method has been taken out;
- information for laboratories regarding ISO/IEC 17025 has been included;
- the performance testing method has been aligned with ISO/IEC 17025;
- compliancy testing has been added;
- in [Annex C](#), two procedures to set PCR-method-based specifications have been added.

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.

Introduction

This document is part of a family of International Standards under the general title *Microbiology of the food chain — Polymerase chain reaction (PCR) for the detection of food borne pathogens*:

- ISO 22174, *General requirements and definitions*;
- ISO 20837, *Requirements for sample preparation for qualitative detection*;
- ISO 20836, *Thermal performance testing of thermal cyclers*;
- ISO 20838, *Requirements for amplifications and detection for qualitative methods*.

This document describes a method for performance testing for standard thermal cyclers and real-time thermal cyclers that allows laboratories to evaluate if the thermal cycler used is suitable for the intended use and meets the specifications set by the laboratory.

The described method is based on a physical method that measures directly in the thermal cycler block in block-based thermal cyclers and in tubes in heated-chamber-based thermal cyclers. The described method provides a measurement uncertainty that is sufficiently low to allow meaningful comparison to specifications.

Furthermore, the method does meet the criteria of a metrological traceable calibration method in case it is used by ISO/IEC 17025-compliant laboratories.

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

1 Scope

This document specifies requirements for the installation, maintenance, temperature calibration and temperature performance testing of standard thermal cyclers and real-time thermal cyclers. It is applicable to the detection of microorganisms as well as any other applications in the food chain using polymerase chain reaction (PCR)-based methods.

This document has been established for food testing, but is also applicable to other domains using thermal cyclers (e.g. environmental, human health, animal health, forensic testing).

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/IEC Guide 98-3:2008, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

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