

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 20836:2021 sisaldab Euroopa standardi EN ISO 20836:2021 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 20836:2021 consists of the English text of the European standard EN ISO 20836:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 01.12.2021.	Date of Availability of the European standard is 01.12.2021.
Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 07.100.30

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardimis- ja Akrediteerimiskeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardimis- ja Akrediteerimiskeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autoriõiguse kaitse kohta, võtke palun ühendust Eesti Standardimis- ja Akrediteerimiskeskusega: Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation and Accreditation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation and Accreditation.

If you have any questions about standards copyright protection, please contact the Estonian Centre for Standardisation and Accreditation: Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

English Version

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)

This European Standard was approved by CEN on 19 November 2021.

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, Turkey 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

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.

This document supersedes CEN ISO/TS 20836:2005.

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, Turkey and the United Kingdom.

Endorsement notice

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

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
3.1 Polymerase chain reaction	1
3.2 Thermal cycler	2
3.3 Temperature characteristics	2
3.4 Temperature measurement	5
4 Installation of thermal cyclers	6
5 Maintenance of thermal cyclers	6
6 Performance testing of thermal cyclers	6
6.1 General	6
6.2 Performance testing programme	7
6.3 Metrological traceability	7
6.4 Temperature performance testing method	8
6.4.1 General	8
6.4.2 Principle	8
6.4.3 Equipment	8
6.4.4 Environmental conditions	9
6.4.5 Procedure	9
6.4.6 Performance test results	10
6.4.7 Performance test report	10
6.4.8 Compliancy testing	11
6.5 Optical performance testing method	11
Annex A (informative) Sensor locations	13
Annex B (informative) Universal temperature protocol	18
Annex C (informative) Compliancy testing	19
Annex D (informative) Example of a thermal cycler temperature profile	22
Annex E (informative) Example of performance test and compliancy test	23
Bibliography	27

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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 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)*

3 Terms and definitions

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

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

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

3.1 Polymerase chain reaction

3.1.1

polymerase chain reaction

PCR

enzymatic procedure that allows in vitro amplification of DNA

[SOURCE: ISO 22174:2005, 3.4.1]

3.1.2

PCR method

test method based on the PCR (3.1.1) technique

Note 1 to entry: Examples include, but are not limited to, PCR, quantitative real-time PCR (qPCR), reverse transcription PCR (RT PCR) and reverse transcription quantitative real-time PCR (RT qPCR).