

SLOVENSKI STANDARD

SIST EN ISO 20836:2022

01-februar-2022

Nadomešča:

SIST-TS CEN ISO/TS 20836:2005

Mikrobiologija v prehranski verigi - Polimerazna verižna reakcija (PCR) za ugotavljanje prisotnosti mikroorganizmov - Preskus toplotnega delovanja cikličnih termostatov (ISO 20836:2021)

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

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)

Ta slovenski standard je istoveten z: EN ISO 20836:2021

ICS:

07.100.30

Mikrobiologija živil

Food microbiology

SIST EN ISO 20836:2022

en

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 20836

December 2021

ICS 07.100.30

Supersedes CEN ISO/TS 20836:2005

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

Contents	Page
European foreword.....	3

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 20836:2022

<https://standards.iteh.ai/catalog/standards/sist/23ac4c73-47bc-4939-8cd9-51d36cdb79e7/sist-en-iso-20836-2022>

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.

INTERNATIONAL STANDARD

**ISO
20836**

First edition
2021-11

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*

iTeh STANDARDS (standards.iteh.ai)

SIST EN ISO 20836:2022

<https://standards.iteh.ai/catalog/standards/sist/23ac4c73-47bc-4939-8cd9-51d36cdb79e7/sist-en-iso-20836-2022>



Reference number
ISO 20836:2021(E)

© ISO 2021

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 20836:2022

<https://standards.iteh.ai/catalog/standards/sist/23ac4c73-47bc-4939-8cd9-51d36cdb79e7/sist-en-iso-20836-2022>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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

ISO 20836:2021(E)

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 20836:2022

<https://standards.iteh.ai/catalog/standards/sist/23ac4c73-47bc-4939-8cd9-51d36cdb79e7/sist-en-iso-20836-2022>

