First edition 2005-08-01

Microbiology of food and animal feeding stuffs — Polymerase chain reaction (PCR) for the detection of food-borne pathogens — Performance testing for thermal cyclers

Microbiologie des aliments — Réaction de polymérisation en chaîne (PCR) pour la recherche des micro-organismes pathogènes dans les aliments — Critères de performance pour les thermal cyclers



ISO/TS 20836:2005(E)

This is a preview of "ISO/TS 20836:2005". Click here to purchase the full version from the ANSI store.

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

© ISO 2005

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Co	ontents	Page
Fore	eword	iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Installation of thermal cyclers	2
5	Maintenance of thermal cyclers	2
6 6.1 6.2 6.3	Performance tests General Biochemical performance test Physical performance test	2 2 2
7	Test report and documentation of irregularities	3
	nex A (informative) Biochemical performance test — PCR method for testing the temper accuracy	4
Ann	nex B (informative) Physical performance test	11
Bibli	liography	13

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.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

- an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;
- an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

ISO/TS 20836 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

This Technical Specification is part of a series of International Standards 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 the 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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights other than those identified above. ISO shall not be held responsible for identifying any or all such patent rights.