International Standard

ISO 19045-2

First edition
2024-11

Ophthalmic optics — Contact lens care products —

Part 2: Method for evaluating disinfecting efficacy by contact lens care products using trophozoites of *Acanthamoeba* species as the challenge organisms

Optique ophtalmique — Produits d'entretien de lentilles de contact —

Partie 2: Méthode d'évaluation de l'efficacité désinfectante des produits d'entretien des lentilles de contact utilisant des trophozoïtes de l'espèce Acanthamoeba *comme organismes pour l'épreuve microbienne*

Reference number
ISO 19045-2:2024(en)

© ISO 2024



COPYRIGHT PROTECTED DOCUMENT

© ISO 2024

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**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **1**

4 Principle ... **2**

5 *Acanthamoeba* trophozoite disinfecting test method ... **2**
5.1 Organisms ... 2
5.2 Culture media and reagents ... 2
5.3 Test materials ... 3
5.4 Test samples ... 3
5.5 Culture maintenance ... 3
5.6 Growth and harvest of microbial challenge (trophozoite) ... 3
5.7 Preparation of *Acanthamoeba* stock solution ... 4
5.8 Stand-alone procedure – inoculation ... 4
5.9 Recovery procedures ... 4
5.9.1 Stand-alone procedure – recovery method one (12 well plate method) ... 4
5.9.2 Stand-alone procedure – recovery method two (96 well plate method) ... 5

6 Controls ... **6**
6.1 Inoculum control ... 6
6.2 Recovery medium control ... 6

7 Performance criteria ... **7**

Annex A (normative) **Preparation of *Acanthamoeba* growth medium (Ac#6)** ... **8**

Annex B (normative) **Preparation of ¼ strength Ringer's solution** ... **9**

Annex C (normative) **Maintenance of *Acanthamoeba* trophozoites and preparation for testing** ... **10**

Annex D (normative) **Preparation of non-nutrient agar (NNA)** ... **11**

Annex E (informative) **Preparation of *E. coli* suspension** ... **13**

Annex F (informative) **Preparation of non-nutrient agar (NNA) plates with *E. coli*** ... **14**

Annex G (informative) **Preparation of neutraliser broth for recovery methods** ... **15**

Annex H (normative) **Reed and Muench computation method for calculation of the 50 % endpoint titre** ... **16**

Annex I (normative) **Spearman-Karber computation method for calculation of the 50 % endpoint titre** ... **20**

Annex J (informative) **Micrographs of cultures using the 96 well plate method** ... **22**

Bibliography ... **26**

© ISO 2024 – All rights reserved

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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 ISO/TC 172, *Optics and photonics,* Subcommittee SC 7, *Ophthalmic optics and instruments*.

A list of all parts in the ISO 19045-2 series can be found on the ISO website.

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.

© ISO 2024 – All rights reserved

Ophthalmic optics — Contact lens care products —

Part 2: Method for evaluating disinfecting efficacy by contact lens care products using trophozoites of *Acanthamoeba* species as the challenge organisms

1 Scope

This document specifies a test method to be used in evaluating the antimicrobial activity of products for contact lens disinfection by chemical methods using the trophozoite form of *Acanthamoeba* species as the challenge organism.

This document is not applicable to the evaluation of oxidative systems that require a special lens case for use.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
contact lens disinfection
chemical or physical process to reduce the number of viable microorganisms

Note 1 to entry: This is specified in the performance requirement clauses of ISO 14729 or ISO 18369-1.

3.2
trophozoite
motile, feeding amoeboid form of *Acanthamoeba*

[SOURCE: ISO 19045:2015, 2.1]

3.3
encystment
phase in the life cycle of *Acanthamoeba* where the trophozoite stage transforms into the cyst stage

3.4
mature cyst
dormant form of *Acanthamoeba,* composed of an inner and outer cell wall, typically more resistant to a range of challenges than *trophozoites* (3.2)

Note 1 to entry: Challenges include heat, dehydration, chemical, etc.

© ISO 2024 – All rights reserved