
Ophthalmic optics — Contact lens care products — Method for evaluating Acanthamoeba encystment by contact lens care products

Optique ophtalmique — Produits d'entretien de lentilles de contact — Méthode d'évaluation de l'enkystement de Acanthamoeba au contact des produits d'entretien des lentilles de contact

Sample Document

get full document from standards.iteh.ai



Sample Document

get full document from standards.iteh.ai



COPYRIGHT PROTECTED DOCUMENT

© ISO 2015

All rights reserved. Unless otherwise specified, 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
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

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Terms and definitions	1
3 Principle	2
3.1 General.....	2
3.2 Encystment test.....	2
4 Encystment test method	2
4.1 General.....	2
4.2 Test organism.....	2
4.3 Culture media and reagents.....	2
4.4 Test materials.....	2
4.5 Test samples.....	3
4.6 Culture maintenance.....	3
4.7 Preparation of microbial challenge.....	3
4.8 Encystment procedure.....	4
4.8.1 General.....	4
4.8.2 Control plate.....	4
4.8.3 Test samples.....	5
4.9 Encystment calculation.....	7
5 Controls	7
Annex A (normative) <i>Acanthamoeba</i> growth medium (Ac#6)	9
Annex B (informative) 1/4 strength Ringer's Solution	10
Annex C (informative) Sarkosyl-Calcofluor White solution	11
Annex D (informative) Preparation of encystment control solutions	12
Annex E (informative) Maintenance of <i>Acanthamoeba</i> trophozoites and preparation for testing	14
Bibliography	15

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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: [Foreword — Supplementary Information](#).

The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

get full document from standards.iteh.ai

Introduction

Acanthamoeba is a genus of small free-living amoeba common to most soil and aquatic habitats.[1],[2] The organism is characterized by a life cycle of a feeding and dividing trophozoite which, in response to adversity, can transform into a resistant cyst stage.[1],[2] *Acanthamoeba* cysts have been shown to resist extremes of temperature, pH, desiccation, and most chemical disinfectants at normal concentration for use.[1],[2],[3],[4]

Recently, it has been observed that a contact lens disinfecting solution associated with a significant number of *Acanthamoeba* keratitis cases was able to induce trophozoite encystment.[5],[6],[7] Such a phenomenon is of important concern as *Acanthamoeba* cysts can be resistant to contact lens disinfection systems and this can increase the risk of acquiring *Acanthamoeba* keratitis.[3],[4],[7],[8],[9]

This International Standard provides a methodology for assessing the capability of a contact lens disinfecting solution to induce *Acanthamoeba* trophozoite encystment. This method does not describe methodology to assess the efficacy of a contact lens disinfecting product against *Acanthamoeba* spp.

Sample Document

get full document from standards.iteh.ai

Sample Document

get full document from standards.iteh.ai

Ophthalmic optics — Contact lens care products — Method for evaluating *Acanthamoeba* encystment by contact lens care products

1 Scope

This International Standard specifies a method for evaluating the potential of products for contact lens disinfection to induce encystment of *Acanthamoeba* species. This method excludes the evaluation of oxidative systems that require a special lens case for use. This International Standard does not address the evaluation of disinfection efficacy of contact lens disinfecting products.

2 Terms and definitions

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

2.1

trophozoite

motile, feeding amoeboid form of *Acanthamoeba*

2.2

encystment

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

2.3

mature cyst

dormant form of *Acanthamoeba* composed of an inner and outer cell wall, typically more resistant to a range of challenges than *trophozoites* (2.1)

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

2.4

immature cyst

cyst comprised only of the inner cell wall

2.5

room temperature

temperature defined as 18 °C to 25 °C

2.6

passage

transfer or transplantation of cells, with or without dilution, from one culture vessel to another

Note 1 to entry: It is understood that any time cells are transferred from one vessel to another, a certain portion of the cells may be lost and, therefore, dilution of cells, whether deliberate or not, can occur.

Note 2 to entry: This term is synonymous with the term “subculture”.^[10]

2.7

passage number

number of times cells in the culture have been subcultured or *passaged* (2.6)^[10]