SLOVENSKI STANDARD
oSIST prEN 14476:2024

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Kemična razkužila in antiseptiki - Kvantitativni suspenzijski preskus za vrednotenje virucidnega delovanja v humani medicini - Preskusna metoda in zahteve (faza 2, stopnja 1)

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1)

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Suspensionsversuch zur Bestimmung der viruziden Wirkung im humanmedizinischen Bereich - Prüfverfahren und Anforderungen (Phase 2, Stufe 1)

Antiseptiques et désinfectants chimiques - Essai quantitatif de suspension pour l'évaluation de l'activité virucide dans le domaine médical - Méthode d'essai et prescriptions (Phase 2/Étape 1)

Ta slovenski standard je istoveten z: **prEN 14476**

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English Version

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1)

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This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 216.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (prEN 14476:2024) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN-Enquiry.

This document will supersede EN 14476:2013+A2:2019.

This document was revised to adapt it to the latest state of science, to correct errors and ambiguities, to harmonize the structure and wording with other existing tests of CEN/TC 216 or in preparation and to improve its readability and thereby make it more understandable.

prEN 14476:2024 includes the following significant technical changes with respect to EN 14476:2013+A2:2019:

— the scope was expanded for the following fields of application within the medical area, i.e. products for textile disinfection (including Peracetic Acid as reference);

— for the hygienic handrub and handwash claims, a test for virucidal activity against enveloped viruses with vaccinia virus was added with specific log reduction requirement for handwash products;

— the calculation was shifted to the main text (harmonized with EN 13727);

— the LVP method was shifted to the main text;

— it was clarified that given cell line numbers are only examples;

— spelling errors and incorrect references were corrected.

The changes of this revision have no impact on the test results obtained with reference to the version EN 14476:2013+A2:2019. Those results are still valid with the exception of test reports using gel filtration detoxification, which do not provide a parallel titration of the non-detoxified test mixture.

Other methods to evaluate the efficacy of chemical disinfectants and antiseptics for different applications in the medical area are in preparation.

Introduction

This document specifies a suspension test for establishing whether a chemical disinfectant or an antiseptic has a virucidal activity in the area and fields described in the scope.

This laboratory test takes into account practical conditions of application of the product including contact time, temperature, test organisms and interfering substances, i.e. conditions which can influence its action in practical situations. Each utilization concentration of the chemical disinfectant or antiseptic found by this test corresponds to the chosen experimental conditions.

1 Scope

This document specifies a test method and the minimum requirements for virucidal activity of chemical disinfectant and antiseptic products that form a homogeneous physically stable preparation when diluted with hard water – or in the case of ready-to-use products, i.e, products that are not diluted when applied, – with water. Ready-to-use-products can only be tested at a concentration up to 80 % (97 %, with a modified method for special cases) as some dilution is always produced by adding the test organisms and interfering substance.

This document applies to products that are used in the medical area in the fields of hygienic handrub, hygienic handwash, instrument disinfection by immersion, surface disinfection by wiping, spraying, flooding or other means and textile disinfection.

This document applies to areas and situations where disinfection is medically indicated. Such indications occur in patient care, for example:

— in hospitals, in community medical facilities, and in dental institutions;

— in clinics of schools, of kindergartens, and of nursing homes;

and can occur in the workplace and in the home. It can also include services such as laundries and kitchens supplying products directly for the patient.

NOTE 1 The method described is intended to determine the activity of commercial formulations or active substances under the conditions in which they are used.

NOTE 2 This method corresponds to a phase 2, step 1 test.

NOTE 3 EN 14885 specifies in detail the relationship of the various tests to one another and to “use recommendations”.

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.

EN 12353, *Chemical disinfectants and antiseptics - Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity*

EN 14885, *Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 14885 and the following apply.

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

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

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

3.1
cytotoxicity
morphological alteration of cells and/or their destruction caused by the product

3.2
plaque forming units
PFU
number of infectious virus particles per unit volume (ml)

3.3
reference test for virus inactivation
test with a defined product (e.g. formaldehyde) in parallel with a product under test for the internal control of the test

3.4
$TCID_{50}$
50 % infecting dose of a virus suspension or that dilution of the virus suspension that induce a CPE (3.5) in 50 % of cell culture units

3.5
viral cytopathic effect
CPE
morphological alteration of cells and/or their destruction as a consequence of virus multiplication

3.6
viral plaque
area of lysis formed in a cell monolayer under semisolid medium due to infection by and multiplication of a single infectious virus particle

3.7
virus titre
amount of infectious virus per unit volume present in a cell culture lysate or in a solution

4 Requirements

The product shall demonstrate at least a decimal log (lg) reduction of 4 in virus titre (for hygienic handwash at least a 2 lg reduction) when tested in accordance with Table 1 and Clause 5.

Table 1 — Minimum and additional test conditions

Test Conditions	Hygienic handrub	Hygienic handwash	Instrument disinfection	Surface disinfection	Textile Disinfection
Minimum spectrum of test organisms	**Virucidal activity** poliovirus adenovirus [d] murine norovirus		**Virucidal activity for medical aplications** poliovirus adenovirus murine norovirus **when temperature is 40 °C or higher**: only murine parvovirus	**Virucidal activity for medical aplications** poliovirus adenovirus murine norovirus	**Virucidal activity for medical aplications** murine parvovirus
	Limited spectrum virucidal activity[a] adenovirus [d] murine norovirus			Limited spectrum virucidal activity[a] adenovirus murine norovirus	
	Virucidal activity against enveloped viruses [b] vaccinia virus	**Virucidal activity against enveloped viruses** [b] vaccinia virus	**Virucidal activity against enveloped viruses** [b] (**Pre-cleaning products** with a combined cleaner/ disinfectant**)** vaccinia virus	**Virucidal activity against enveloped viruses** [b] vaccinia virus	**Virucidal activity against enveloped viruses** [b] vaccinia virus
additional	Any relevant test organism				
Test temperature	according to the manufacturer's recommendation, but at / between				
	20 °C (alcohol dis. with adenovirus at 25 °C ± 1°C) [d]	20 °C	20 °C and 70 °C	4 °C and 30 °C	30 °C and 70 °C
Contact time	according to the manufacturer's recommendation				
	but between 30 s and 120 s	but between 30 s and 120 s	but no longer than 60 min	but no longer than 5 min or 60 min [c]	but between 10 min and 20 min
Interfering substance					
clean conditions	0,3 g/l bovine albumin solution (hygienic handrub) [d]	–	0,3 g/l bovine albumin solution **and/or**	0,3 g/l bovine albumin solution **and/or**	0,3 g/l bovine albumin solution (for pre-washed process)

Test Conditions	Hygienic handrub	Hygienic handwash	Instrument disinfection	Surface disinfection	Textile Disinfection
dirty conditions	–	3,0 g/l bovine albumin solution plus 3,0 ml/l erythrocytes (hygienic handwash) [e]	3,0 g/l bovine albumin solution plus 3,0 ml/l erythrocytes	3,0 g/l bovine albumin solution plus 3,0 ml/l erythrocytes	3,0 g/l bovine albumin solution plus 3,0 ml/l erythrocytes (for non-pre-washed process)
Additional conditions	dirty any relevant substance	clean any relevant substance	any relevant substance	any relevant substance	any relevant substance

[a] The test for "limited spectrum virucidal activity" will cover all enveloped viruses (Annex A) and norovirus, rotavirus and adenovirus.

[b] The test for "virucidal activity against enveloped viruses" will cover all enveloped viruses only (Annex A).

[c] The contact times for surface disinfectants stated in this table are chosen on the basis of the practical conditions of the product. The recommended contact time for the use of the product is within the responsibility of the manufacturer. Products intended to disinfect surfaces that are likely to come into contact with the patient and / or the medical staff and surfaces, which are frequently touched by different people, leading to the transmission of microorganisms to the patient, shall be tested with a contact time of maximum 5 min. The same applies where the contact time of the product shall be limited for practical reasons. Products for other surfaces than stated above may be tested with a contact time of maximum 60 min.

[d] For hand rubs, adenovirus shall be tested at (25 ± 1) °C. It has long been known that adenoviruses, unlike other non-enveloped viruses (polio + entero viruses), exhibit a temperature effect in alcoholic formulations [16]. This is most likely due to the special structure with antenna-like fibre proteins, which could cause precipitation of the virus, which then dissolves again at (37 ± 1) °C. The viruses are then released into the solution. Thus, the hand disinfectant appears to be false-negative ineffective, although only a few degrees difference makes the virus s capable of inactivation again in this artificial suspension test. 25 °C is still in the range of the hand skin temperature. [16]

5 Test methods

5.1 Principle

5.1.1 A sample of the product as delivered and/or diluted with hard water (or water for ready to use products) is added to a test virus suspension in a solution of an interfering substance. The mixture is maintained at one of the temperatures and the contact times specified in Clause 4 and 5.5.1.1. At the end of this contact time, an aliquot is taken; the virucidal action in this portion is immediately suppressed by a validated method (dilution of the sample in ice-cold cell maintenance medium). The dilutions are transferred into cell culture units i.e. wells of microtitre plates either using monolayer or cell suspension. Infectivity tests are done either by plaque test or quantal tests. After incubation, the titres of infectivity are calculated according to Spearman and Kärber (quantal tests,5.6.2.2), by plaque counting (plaque test, 5.6.2.3) or large-volume-plating (LVP) method (5.6.2.4) and evaluated. Reduction of virus infectivity is calculated from differences of lg virus titres before (virus control) and after treatment with the product.

NOTE Handwash products are always prediluted with hard water (5.2.2.7). The resulting solution is regarded as a ready-to-use product (5.4.2).

5.1.2 The test is performed using the test organisms as specified in Clause 4, Table 1.

5.1.3 Other contact times and temperatures within the limits specified in Clause 4, Table 1 may be used. Additional interfering substances and test organisms may be used.

5.2 Materials and reagents, including cell cultures

5.2.1 Test viruses

The virucidal activity shall be evaluated using the following strains as test organisms selected according to Clause 4, Table 1[1]. Virus strains shall be obtained from a national or international culture collection:

a) non-enveloped RNA virus[2]:

1) poliovirus type 1, LSc 2ab (Picornavirus);

Regarding poliovirus only virus material that passed the requirements for the production of oral polio vaccine of the competent authority shall be used (Other stocks derived from LSc-2ab cannot be used any longer).

NOTE See the list of vaccines of the World Health Organisation (WHO).

2) murine norovirus, strain S99 Berlin;

b) non-enveloped DNA virus:

1) adenovirus type 5, strain Adenoid 75, ATCC VR-5*;

2) murine parvovirus, minute virus of mice, strain Crawford, ATCC VR-1346;

c) enveloped DNA virus:

1) modified vaccinia virus Ankara (MVA), ATCC VR-1508, or vaccinia virus strain Elstree, ATCC VR-1549.

The required incubation temperature for these test organisms is (36 ± 1) °C or (37 ± 1) °C (5.3.1.3). The same temperature (either 36 °C or 37 °C) shall be used for all incubations performed during a test and its control and validation.

If additional test organisms are used, they shall be kept and used under optimum growth conditions (temperature, time, atmosphere, media, susceptible cell line) noted in the test report. If these additional test organisms (viruses and cell line) are not classified at a reference centre, their identification characteristics shall be stated. In addition, they shall be held by the testing laboratory or national culture collection under a reference for five years.

[1] The ATCC numbers are the collection numbers of strains supplied by these culture collections. This information is given for the convenience of users of this document and does not constitute an endorsement by CEN.

[2] LSc-2ab can be obtained from NIBSC (www.nibsc.ac.uk). Murine norovirus and poliovirus can be obtained from Friedrich-Loeffler-Federal Research Institute for Animal Health, Hauptsitz Insel Riems Südufer 10, 17493 Greifswald-Insel Riems; phone: +49 38351 7-0; fax: +49 38351 7-121. http://www.fli.de/. This information is given for the convenience of users of this document and does not constitute an endorsement by CEN.