

STN	Chemické dezinfekčné a antiseptické prípravky Uchovávanie mikrobiálnych kmeňov používaných na stanovenie bakteriocídnej (vrátane <i>Legionell</i>), mykobakteriocídnej, sporicídnej, fungicídnej a virulocídnej (vrátane bakteriofágov) aktivity	STN EN 12353 85 7018
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Chemical disinfectants and antiseptics - Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/21

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English Version

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

Antiseptiques et désinfectants chimiques - Conservation des micro-organismes d'essai utilisés pour la détermination de l'activité bactéricide (Legionella incluses), mycobactéricide, sporicide, fongicide et virucide (bactériophages inclus)

Chemische Desinfektionsmittel und Antiseptika - Aufbewahrung von Prüforganismen für die Prüfung der bakteriziden (einschließlich Legionella), mykobakteriziden, sporiziden, fungiziden und viruziden (einschließlich Bakteriophagen) Wirkung

This European Standard was approved by CEN on 1 February 2021.

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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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN 12353:2021) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, 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 March 2022, and conflicting national standards shall be withdrawn at the latest by March 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 EN 12353:2013.

The document was revised to adapt it to the latest state of science, to correct errors and ambiguities. The following are the significant technical changes since the last edition:

- the methods of preservation of viruses are described more detailed (5.8);
- MEM is not the only suitable cell culture medium, therefore it was replaced by the general term “cell culture medium” (5.2.2.17 and in the whole text);
- the description of BCYE Agar for *Legionella* was added (5.2.2.24);
- the information on source of strains was added (5.10.2);
- the information of the storage of documentation was added (5.11.6);
- *Clostrioides difficile* (A.3.3) was added;
- the CIP numbers for fungi were deleted (replaced by UMIP numbers) (see A.4);
- the used virus strains are re-drafted (see A.5).

The changes mentioned above have no impact on the test results obtained with reference to the previous version. Those results are still valid.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations 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.

Introduction

Standardized tests for the determination of bactericidal (incl. *Legionella pneumophila*), mycobactericidal, sporicidal, fungicidal and virucidal (incl. bacteriophages) activity of chemical disinfectants and antiseptics necessitate the use of test organisms whose purity and identity have been verified and whose biological behaviour remains stable. Therefore, it is essential to specify the storage requirements.

This document aims to describe methods for preservation of test organisms used for such purposes.

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1 Scope

This document specifies methods for keeping test organisms used and defined in European Standards for the determination of bactericidal (incl. *Legionella pneumophila*), mycobactericidal, sporicidal, fungicidal and virucidal (incl. bacteriophages) activity of chemical disinfectants and antiseptics drawn up by CEN/TC 216. These methods for keeping test organisms can only be carried out in connection with at least one of those standards where a reference to this document is established.

NOTE 1 Annex A (informative) contains a non-exhaustive list of test organisms for which this document can be applied.

NOTE 2 European Standards (EN) where this document is referenced are listed in the Bibliography.

NOTE 3 A specific description on the preservation of bacterial spores could be added once the results of the ongoing ring trials are available.

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 13610, *Chemical disinfectants — Quantitative suspension test for the evaluation of virucidal activity against bacteriophages of chemical disinfectants used in food and industrial areas — Test method and requirements (phase 2, step 1)*

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

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