SLOVENSKI STANDARD
SIST EN 1500:2001

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Kemična razkužila in antiseptiki - Higiensko razkuževanje rok - Preskusna metoda in zahteve (faza 2/stopnja 2)

Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2/step 2)

Chemische Desinfektionsmittel und Antiseptika - Hygienische Händedesinfektion - Prüfverfahren und Anforderungen (Phase 2/Stufe 2)

Antiseptiques et désinfectants chimiques - Traitement hygiénique des mains par frictions - Méthode d'essai et prescriptions (phase 2/étape 2)

Ta slovenski standard je istoveten z: **EN 1500:1997**

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11.080.20	Dezinfektanti in antiseptiki	Disinfectants and antiseptics
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EUROPEAN STANDARD

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Descriptors: Disinfectants, chemical compounds, hygiene, hand (anatomy), tests, contamination, antibacterial activity, neutralizing, counting, micro-organisms

English version

Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2/step 2)

Antiseptiques et désinfectants chimiques - Traitement hygiénique des mains par frictions - Méthode d'essai et prescriptions (phase 2/étape 2)

Chemische Desinfektionsmittel und Antiseptika - Hygienische Händedesinfektion - Prüfverfahren und Anforderungen (Phase 2/Stufe 2)

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Contents

Foreword

This European Standard has been prepared by the 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of an identical text or by endorsement, at the latest by January 1998, and conflicting national standards shall be withdrawn at the latest by January 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Annex A is normative. Annexes B, C, D and E are informative.

NOTE : Attention is drawn to the fact that tests on human volunteers are the subject of legal provisions in certain European countries/regions.

1 Scope

This European Standard specifies a method of test simulating practical conditions for establishing whether a product for hygienic handrub reduces the release of transient flora according to the requirements when rubbed onto the artificially contaminated hands of volunteers.

This European Standard applies to products for hygienic handrub for use in 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 may occur in the workplace and in the home. It may also include services such as laundries and kitchens supplying products directly for the patient.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

prEN 12054 Chemical disinfectants and antiseptics – Products for hygienic and surgical handrub and handwash – Bactericidal activity – Test method and requirements (phase 2/step 1)

3 Definitions

For the purposes of this standard, the following definitions apply :

3.1 product (for chemical disinfection and/or antisepsis)

Chemical agent or formulation used as a chemical disinfectant and/or antiseptic [EN 1040].

3.2 hygienic handrub

Postcontamination treatment procedure that involves rubbing hands without the addition of water, using a bactericidal preparation directed against transient microorganisms to prevent their transmission regardless of the resident skin flora.

3.3 prevalue

Number of colony forming units (cfu) sampled from hands before treatment.

3.4 postvalue

Number of colony forming units (cfu) sampled from hands after treatment.

3.5 reduction factor (RF)

Ratio of prevalues and postvalues, generally expressed by decimal logarithms :

$$\log_{10} RF = \log_{10} \text{prevalue} - \log_{10} \text{postvalue}$$

4 Requirements

When tested in accordance with clause 5, the mean reduction of the release of test organisms achieved by the hygienic handrub product shall not be significantly smaller than that achieved by a reference handrub (R) (see 5.6.4.2) with propan-2-ol 60 % (V/V).

Products under test shall at least have a bactericidal activity as specified in prEN 12054.

5 Test method

5.1 Principle

The number of test organisms released from the fingertips of artificially contaminated hands is assessed before and after the hygienic handrub. The ratio of the two resulting values is called the reduction factor. It represents a measure of the antimicrobial activity of the hygienic handrub product tested. The necessary precision is achieved by repeating the test on 12 to 15 subjects. To compensate for extraneous influences it is compared with the reduction factor obtained with a parallel reference handrub procedure (R) which is performed with the same subjects, on the same day and under comparable environmental conditions.

5.2 Experimental design

For testing one product at a time a cross-over design is used. The subjects are randomly divided into two groups of approximately the same size. The test is first performed with group 1 using the reference handrub procedure (see 5.6.4.2) and group 2 using the handrub procedure with the test product (see 5.6.4.3).

The test is then repeated on the same day with group 1 using the handrub procedure with the test product and group 2 using the reference handrub procedure. Before every reference handrub procedure and every handrub procedure with the test product, the procedure described in 5.6.2 and 5.6.3 shall be carried out.

For testing more than one product at a time, a Latin-square design is used with as many groups of subjects and as many experimental runs as there are handrub products (including the reference propan-2-ol). In each run all handrub procedures are employed in parallel. At the end of the whole series of runs every subject shall have used each handrub product once.

5.3 Subjects

The test shall be performed on 12 to 15 healthy persons who have hands with healthy skin, without cuts or abrasions, and with short and clean fingernails. Although, in general, age is not a limiting factor, subjects should be at least 18 years of age.

5.4 Materials

5.4.1 Test organism

Escherichia coli K12 NCTC[1)] 10538.

NOTE : This test organism has been specifically chosen to meet health and safety guidance and ethical committee considerations. It is a K12 strain of E. coli of normal flora origin internationally recognized as being non-pathogenic. According to the UK catalogue of the National Collections of Industrial & Marine Bacteria (see [1] in Annex D), NCIMB strain 10083 is identical to NCTC 10538 and classified as a risk group 1 organism. The German Safety Ordinance on Gene Technology [2] also assigns the K12 strain to group 1. Directive 93/88/EEC [3] (Annex III to Directive 90/679/EEC [4]) explicitly states that non-pathogenic strains of Escherichia coli are *excluded* from the group 2 assignment.

5.4.2 Media and reagents

5.4.2.1 General

The reagents shall be of analytical grade and/or appropriate for microbiological purposes.

NOTE : To improve reproducibility, it is recommended that commercially available dehydrated material is used for the preparation of culture media. The manufacturer's instructions relating to the preparation of these products should be rigorously followed.

5.4.2.2 Water

The water shall be free from substances that are toxic or inhibiting to the bacteria. It shall be freshly glass distilled and not demineralised water.

Sterilize in the autoclave (see 5.5.2.1).

NOTE 1 : If the water is sterilized during the sterilization of the reagents, this is not necessary.

NOTE 2 : If distilled water of adequate quality is not available, water for injectable preparations (see European Pharmacopoeia) can be used.

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1) NCTC 10538 is the collection number of a strain supplied by the National Collection of Type Cultures. This information is given for the convenience of users of this standard and does not constitute an endorsement by CEN of the product named. Corresponding strains supplied by another culture collection may be used if they can be shown to lead to the same results.

5.4.2.3 Tryptone soya agar (TSA)

For maintenance of bacterial strains and performance of viable counts.

Tryptone, pancreatic digest of casein	15,0 g
Soya peptone, papaic digest of Soybean meal	5,0 g
NaCl	5,0 g
Agar	15,0 g
Water (see 5.4.2.2)	to 1000,0 ml

Sterilize in the autoclave (see 5.5.2.1). After sterilization the pH of the medium shall be equivalent to 7,2 ± 0,2 when measured at 20 °C.

For quantitative cultures, TSA with added sodium-desoxycholate (0,5 g/l) shall be used to inhibit the growth of skin staphylococci.

5.4.2.4 Tryptone soya broth (TSB)

For preparation of the contamination fluid.

Tryptone, pancreatic digest of casein	15,0 g
Soya peptone, papaic digest of Soybean meal	5,0 g
NaCl	5,0 g
Water (see 5.4.2.2)	to 1000,0 ml

Sterilize in the autoclave (see 5.5.2.1). After sterilization the pH of the medium shall be equivalent to 7,2 ± 0,2 when measured at 20 °C.

5.4.2.5 Neutralizer

A neutralizer validated according to prEN 12054 shall be incorporated in the sampling fluids and diluents (TSB, see 5.4.2.4) for the assessment of postvalues in both test and reference procedure, but neither in those for the prevalues nor in the counting plates.

NOTE : A list of neutralizers which can be used is given in annex B.

5.4.2.6 **Soft soap**, 200 g/L

Linseed oil	50 parts[2)]
Potassium hydroxide	9,5 parts
Ethanol	7 parts
Distilled water	as needed

[2)] By weight.

Add linseed oil to a solution of potassium hydroxyde in 15 parts distilled water and heat up to approximately 70 °C while constantly stirring. Add the ethanol and continue heating while stirring until the saponification process is completed and a sample dissolves clearly in water and almost clearly in alcohol. The weight of the soft soap is then brought up to 100 parts by addition of hot distilled water. Take 200 g of the soft soap in 1 l of distilled water and sterilize in the autoclave (see 5.5.2.1).

5.4.2.7 Propan-2-ol 60 % (V/V) (see European Pharmacopoeia)

5.5 Apparatus and glassware

5.5.1 General

Sterilize all glassware and parts of the apparatus that will come into contact with the culture media and reagents or the sample, except those that are supplied sterile, by one of the following methods :

a) in the autoclave (see 5.5.2.1) by maintaining it at 121 $^{+3}_{0}$ °C for a minimum holding time of 15 min ;

b) in the dry heat sterilizer (see 5.5.2.1) by maintaining it at 180 °C for a minimum holding time of 30 min, at 170 °C for a minimum holding time of 1 h or at 160 °C for a minimum holding time of 2 h.

5.5.2 Usual microbiological laboratory equipment[3)] and, in particular, the following.

5.5.2.1 Apparatus for sterilization

a) For moist heat sterilization an autoclave capable of being maintained at 121 $^{+3}_{0}$ °C for a minimum holding time of 15 min ;

b) For dry heat sterilization a hot air oven capable of being maintained at 180 °C for a minimum holding time of 30 min, at 170 °C for a minimum holding time of 1 h or at 160 °C for a minimum holding time of 2 h.

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3) Disposable equipment is an acceptable alternative to reusible equipment

5.5.2.2 Incubator, capable of being controlled at (36 ± 1) °C.

5.3.2.3 pH-meter, having an accuracy of calibration of ± 0,1 pH units at 25 °C.

5.5.2.4 Stopwatch

5.5.2.5 Graduated pipettes of nominal capacities 10 ml and 1,0 ml and 0,1 ml. Calibrated automatic pipettes may be used.

5.5.2.6 Petri dishes, of diameter 90 mm

5.5.2.7 Container of sufficient capacity to take both hands immersed vertically up to the mid-metacarpals

5.5.2.8 Bottles of at least 1 l capacity

5.6 Procedure

5.6.1 Preparation of the contamination fluid

Grow the E. coli (see 5.4.1) in two tubes each containing 5 ml of TSB (see 5.4.2.4) for 18 h to 24 h at (36 ± 1) °C. Inoculate these cultures into two bottles (see 5.5.2.8) with 1 l TSB (see 5.4.2.4) each and incubate for 18 h to 24 h at (36 ± 1) °C. Pool the resulting bacterial suspension.

This contamination fluid shall contain between 2 x 10^8 cfu/ml and 2 x 10^9 cfu/ml which shall be confirmed by a standard quantitative culture technique in accordance with prEN 12054.

5.6.2 Application of the contamination fluid

Prepare the hands by washing for 1 min with soft soap (see 5.4.2.6) to remove natural transients. Dry them thoroughly on paper towels. Pour the contamination fluid into the container (see 5.5.2.7) and immerse the hands up to the mid-metacarpals for 5 s with fingers spread apart. Carefully allow surplus liquid to drain back into the container.

NOTE : During this procedure care should be taken to avoid contamination of the immediate work area.

Allow the hands to dry in the air for 3 min, holding them in a horizontal position with the fingers spread out and rotating them to and fro to avoid the formation of droplets.

One batch of contamination fluid shall be used not longer than 3 h after the first subject's hands have been contaminated. Additionally, it shall be ensured that, in a test, all subjects' hands shall be treated with the same batch of contamination fluid, even if various products are tested against the reference product.