SLOVENSKI STANDARD
SIST EN 12791:2005

01-september-2005

Kemiļ na razkuģila in antiseptiki ï Razkuģila za roke v kirurgiji ï Preskusna metoda in zahteve (faza 2, stopnja 2)

Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirement (phase 2/step 2)

Chemische Desinfektionsmittel und Antiseptika - Chirurgische Händedesinfektionsmittel - Prüfverfahren und Anforderungen (Phase 2/Stufe 2)

Antiseptiques et désinfectants chimiques - Désinfectants chirurgicaux pour les mains - Méthodes d'essai et prescriptions (phase 2/étape 2)

Ta slovenski standard je istoveten z: **EN 12791:2005**

ICS:

11.080.20	Dezinfektanti in antiseptiki	Disinfectants and antiseptics

SIST EN 12791:2005 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 12791

July 2005

ICS 11.080.20

English Version

Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirement (phase 2/step 2)

Antiseptiques et désinfectants chimiques - Désinfectants chirurgicaux pour les mains - Méthodes d'essai et prescriptions (phase 2/étape 2)

Chemische Desinfektionsmittel und Antiseptika - Chirurgische Händedesinfektionsmittel - Prüfverfahren und Anforderungen (Phase 2/Stufe 2)

This European Standard was approved by CEN on 21 March 2005.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN 12791:2005: E

Contents

page

Foreword

This document (EN 12791:2005) 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 January 2006, and conflicting national standards shall be withdrawn at the latest by January 2006.

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

1 Scope

This European Standard specifies a test method simulating practical conditions for establishing whether a product for surgical hand disinfection reduces the release of hand flora according to requirements described in clause 4 when used for the disinfection of the clean hands of volunteers.

2 Normative references

The following referenced documents are indispensable for the application 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.

prEN 12054, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of bactericidal activity of products for hygienic and surgical handrub and handwash used in human medicine — Test method and requirements (phase 2/step 1).*

3 Terms and definitions

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

3.1
product
chemical agent or formulation used as a chemical disinfectant or antiseptic

3.2
surgical hand disinfection
preoperative treatment procedure that involves applying a bactericidal product directed against the bacterial flora of hands to prevent the risk of transmission of bacteria into the surgical wound

NOTE This procedure may consist of a handrub alone or a handwash alone or a combination of both.

This treatment can be performed with products claiming or not claiming to have a sustained effect (see 3.5)

3.3
immediate effect
reduction of the release of skin flora from the hands as assessed immediately after surgical hand disinfection

3.4
3-hour effect
reduction of the release of skin flora from the hands as assessed after wearing surgical gloves for 3 h following disinfection

3.5
sustained effect
3-hour effect of the product significantly larger than that of a reference disinfection procedure with propan-1-ol 60 % (volume concentration) (see 5.6.3.2)

3.6
prevalue (immediate)
number of colony-forming units (cfu) sampled immediately before treatment from the hand from which the immediate effect has to be assessed

3.7
prevalue (3-hour)
number of colony-forming units (cfu) sampled immediately before treatment from the hand from which the sustained effect has to be assessed

3.8
postvalue (immediate)
number of colony-forming units (cfu) sampled immediately after treatment from the hand sampled for the prevalue (immediate)

3.9
postvalue (3-hour)
number of colony-forming units (cfu) sampled 3 h after treatment from the hand sampled for the prevalue (sustained)

3.10
reduction factor (RF) (immediate)
ratio of prevalue (immediate) and postvalue (immediate), generally expressed by decimal logarithms:

$$\lg RF(\text{immediate}) = \lg \text{prevalue (immediate)} - \lg \text{postvalue (immediate)}$$

3.11
reduction factor (3-hour)
ratio of prevalue (3-hour) and postvalue (3-hour), generally expressed by decimal logarithms:

$$\lg RF\ (3\text{-hour}) = \lg \text{prevalue (3-hour)} - \lg \text{postvalue (3-hour)}$$

3.12
surgical glove
sterile, un-powdered medical latex glove free of antimicrobial activity, as demonstrated by agar diffusion test on Mueller-Hinton agar (see Annex B) intended for use in invasive surgery

4 Requirements

When tested and evaluated in accordance with clause 5, the mean reduction factors for immediate (see 3.10) and 3 hours (3.11) effects shall not be significantly smaller than the respective ones obtained with propan-1-ol 60 % (volume concentration).

If the explicit claim for a sustained effect exists, the mean reduction factor for the 3-hour effect shall, additionally, be significantly larger than that obtained with propan-1-ol 60 % (volume concentration).

5 Test methods

5.1 Principle

A preparatory handwash (see 5.6.1) is carried-out in order to remove transient flora and foreign material, that would otherwise influence the presample counts. Hand samples, for bacterial counts, are then taken:

— immediately after the prewash (before treatment);

— immediately after the disinfection procedure;

— 3 h after the disinfection procedure.

The ratio of the resulting values before and after treatment is called the reduction factor. It represents a measure for the antimicrobial activity of the disinfection product tested. The immediate effect is characterized by the reduction factor (immediate), which is the ratio of the two values (prevalue and postvalue) assessed on the hand from which the postvalue (immediate) is derived. The 3-hour effect is characterized by the reduction factor (3-hour), which is the ratio of prevalue and postvalue (3-hour) of the other hand. To compensate for extraneous influences, these reduction factors are compared individually with the corresponding reduction factors of a reference surgical hand disinfection procedure (R) performed in parallel with the same subjects.

5.2 Experimental design

For testing a single product, a crossover design is used. The volunteers are randomly divided into two groups of the same size. In a first run, volunteers of group 1 use the reference procedure, those of group 2 the procedure with the test product. After at least one week, allowing reconstitution of the normal skin flora, the test is repeated with changed roles in a second run.

For testing more than one product at a time, a Latin-square design is used with as many groups of volunteers and as many experimental runs as there are disinfection products (including the reference propan-1-ol). In each run all disinfection procedures are employed in parallel. At least one week is required between the individual experimental runs, allowing reconstitution of the normal skin flora. At the end of the whole series every subject shall have used each disinfection product, including propan-1-ol, once.

NOTE In a Latin-square design, only products can be simultaneously tested for which either no neutralisation is necessary or for which the same neutraliser can be used for the assessment of postvalues.

5.3 Volunteers

The test shall be performed on 20 healthy persons who have hands with healthy skin, without cuts or abrasions, and with short and clean fingernails. Starting from one week prior to the test, they should not use substances with antimicrobial action (e.g. medicated soaps, medicated hand creams). Although, in general, age is not a limiting factor, volunteers should be at least 18 years of age.

5.4 Media and reagents

5.4.1 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 be 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 Water

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

Sterilize in the autoclave (5.5.2.1).

NOTE 1 Sterilization is not necessary if the water is used – e.g. for the preparation of culture media – and subsequently sterilized.

NOTE 2 If distilled water of adequate quality is not available, water for injectable preparations (see [1]) can be used.

5.4.3 Tryptone soya agar (TSA)

For quantitative surface cultures.

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 (5.4.2)	to 1000,0 ml

Sterilize in the autoclave (5.5.2.1). After sterilization the pH of the medium shall be equivalent to 7,2 ± 0,2 when measured at 20 °C ± 1 °C.

5.4.4 Tryptone soya broth (TSB)

Serves as a sampling fluid and diluent.

Tryptone, pancreatic digest of casein	15,0 g
Soya peptone, papaic digest of Soybean meal	5,0 g
NaCl	5,0 g
Water (5.4.2)	to 1000,0 ml

Sterilize in the autoclave (5.5.2.1). After sterilization the pH of the medium shall be equivalent to 7,2 ± 0,2 when measured at 20 °C ± 1 °C.

5.4.5 Neutralizer

A neutralizer validated according to prEN 12054 shall be incorporated in the sampling fluids and diluents (TSB, 5.4.4) 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 may be used is given in Annex C.

5.4.6 Dilute soft soap, 200 g/1000 g

Linseed oil [2]	50 parts[1)]
Potassium hydroxide [3]	9,5 parts
Ethanol 96 % (volume concentration) [3]	7parts
Distilled water (see 5.4.2)	as needed

Add linseed oil to a solution of potassium hydroxide 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 ethanol 96 %. 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, fill up to 1 000 g with distilled water and sterilize in the autoclave (see 5.5.2.1). The pH of the final dilute soft soap shall range between 10,0 and 11,0.

For quality control see Annex E.

A.1.1 ———————————

1) By weight.

5.4.7 Propan-1-ol 60 % (volume concentration)

See [1] and for preparation see Annex D.

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 (5.5.2.1);

b) in the dry heat sterilizer (5.5.2.1).

5.5.2 Usual microbiological laboratory equipment[2)]

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 $^{+5}_{0}$) °C for a minimum holding time of 30 min, at (170 $^{+5}_{0}$) °C for a minimum holding time of 1 h or at (160 $^{+5}_{0}$) °C for a minimum holding time of 2 h.

5.5.2.2 **Incubator**, capable of being controlled at 37 °C ± 1 °C.

5.5.2.3 **pH-meter**, having a precision of 0,1 pH units at 25 °C.

5.5.2.4 **Stopwatch**

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

5.5.2.6 **Petri dishes**, having a diameter of 90 mm.

5.5.2.7 **Glass spreaders**

5.5.2.8 **Water bath**, adjustable to 20 °C ± 1 °C.

5.6 Procedure

5.6.1 Preparatory handwash

Hands are prepared by washing without use of a brush for 1 min with 10 ml soft soap (5.4.6). After being rinsed with running tap water, they are thoroughly dried with paper towels.

A.1.1 ———————————

2) Disposable equipment is an acceptable alternative to reusable equipment.

5.6.2 Prevalues

Immediately after drying, rub the fingertips (including that of the thumb) for 1 min on the base of a Petri dish (5.5.2.6) containing 10 ml of TSB (5.4.4) without neutralizer in order to assess the release of skin bacteria before treatment of hands (prevalues). A separate dish is used for each hand.

Dilutions of 10^{-1} and 10^{-2} of these sampling fluids are prepared in TSB (5.4.4). For each dilution, 0,1 ml is spread over the surface of a TSA plate (see 5.4.3) using glass spreaders. The interval between sampling and plating shall not exceed 30 min.

5.6.3 Surgical hand disinfection procedure

5.6.3.1 General

Immediately after sampling for the prevalues, the fingertips are rubbed against each other until dry. Subsequently, either the reference disinfection procedure, R, or (one of) the procedure(s) under test, P (1 to n), is (are) performed.

5.6.3.2 Reference surgical hand disinfection procedure (R)

Pour 3 ml of propan-1-ol 60 % (5.4.7) into the cupped dry hands and rub vigorously onto the skin up to the wrists in accordance with the standard handrub procedure shown in Annex A (Figure A.1) to ensure total coverage of the hands. This comprises five strokes backwards and forwards, palm to palm, right over left dorsum, left palm over right dorsum, palm to palm with fingers interlaced, back of fingers to opposing palms with fingers interlocked, rotational rubbing of right thumb clasped in left palm and left thumb clasped in right palm, rotational rubbing with clasped fingers of right hand in palm of left hand and clasped fingers of left hand in palm of right hand. When nearly dry, additional aliquots of 3 ml of propan-1-ol are applied as it evaporates.

As many applications of the alcohol are necessary as are needed to keep the hands wet for 3 min, the total application time of R.

The volume of the alcohol used per person shall be recorded.

5.6.3.3 Surgical hand disinfection procedure with product under test (P)

This procedure shall be performed according to information provided by the manufacturer. For products involving **rubbing hands** this shall include: volume of product, total time of application and frequency of application. The latter requirement may also include the instructions to keep hands wet with the product for a given time. For details of the rubbing procedure see 5.6.3.2 and Annex A.

For products involving **washing hands** this information shall include: the need for pre-wetting of hands, volume of product, total time and frequency of its application and any special instructions on the use of water. In addition to this information hands are washed according to a standard handwash procedure (see Annex A). This comprises five strokes backwards and forwards, palm to palm, right over left dorsum, left palm over right dorsum, palm to palm with fingers interlaced, back of fingers to opposing palms with fingers interlocked, rotational rubbing of right thumb clasped in left palm and left thumb clasped in right palm, rotational rubbing with clasped fingers of right hand in palm of left hand and clasped fingers of left hand in palm of right hand. The hands and wrists are washed in this way until the end of the appropriate time period.

The maximum allowable application time for any procedure for surgical hand disinfection is 5 min.

If P includes the use of a disinfectant-detergent this shall be rinsed off under running tap water for 15 s after the end of the required application time.

If the manufacturer's instructions require the wearing of gloves on hands still covered with the remainder of the disinfectant (-detergent), only the hand allotted for assessment of the postvalue (immediate) is rinsed.