SLOVENSKI STANDARD
SIST EN 12791:2016/oprA1:2017

01-marec-2017

Kemična razkužila in antiseptiki - Razkužila za roke v kirurgiji - Preskusna metoda in zahteve (faza 2, stopnja 2)

Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirements (phase 2, step 2)

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

Antiseptiques et désinfectants chimiques - Désinfection chirugicale des mains - Méthodes d'essai et prescriptions (phase 2/étape 2)

Ta slovenski standard je istoveten z: **EN 12791:2016/prA1:2017**

ICS:

11.080.20	Dezinfektanti in antiseptiki	Disinfectants and antiseptics

SIST EN 12791:2016/oprA1:2017 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirements (phase 2, step 2)

Antiseptiques et désinfectants chimiques - Désinfection chirugicale des mains - Méthodes d'essai et prescriptions (phase 2/étape 2)

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

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

This draft amendment A1, if approved, will modify the European Standard EN 12791:2016. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

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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
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN 12791:2016/prA1:2017) 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.

1 Modification to Annex C, Examples of reporting of results and significance testing

Replace Annex C (informative) "Examples of reporting of results and significance testing" by the following:

"

Table C.1 — Reference surgical hand disinfection procedure – Experimental results

Preparation:"RP" (propan-1-ol 60 % v/v)

Dates of experiment: 15 July 2011 / 22 July 2011

Application: rubbing hands during 3 min

Volunteer		Number of cfu per plate from dilution 10^x									
		Hand	Prevalues			Immediate postvalues			3 h postvalues		
No	Sequence	left or right	−1	−2	−3	0	−1	−2	0	−1	−2
1	RP- > PP	l	> 330	> 330	188	> 330	39	1			
		r	> 330	> 330	226				> 330	184	11
2	RP- > PP	l	> 330	> 330	71				> 330	184	11
		r	> 330	> 330	43	47	4	1			
3	PP- > RP	l	> 330	> 330	121				> 330	215*	25*
		r	> 330	> 330	147	105*	17*	3			
4	RP- > PP	l	> 330	> 330	48				> 330	> 330	232
		r	> 330	> 330	45	> 330	124	9			
5	PP- > RP	l	> 330	> 330	56	> 330	36	8			
		r	> 330	> 330	38				> 330	> 330	43
6	PP- > RP	l	> 330	67	4				> 330	> 330	58
		r	> 330	46	2	~~20**~~	~~2**~~	~~0**~~			
7	RP- > PP	l	> 330	175	12				214*	19*	3
		r	> 330	310*	31*	143*	14*	0			
8	PP- > RP	l	> 330	> 330	73	> 330	134*	17*			
		r	> 330	131*	16*				> 330	84	5
9	RP- > PP	l	> 330	> 330	81				> 330	188*	18*
		r	> 330	> 330	54	> 330	151*	16*			
10	RP- > PP	l	> 330	181*	18*	193*	22*	2			
		r	> 330	243*	26*				96	8	1
11	RP- > PP	l	> 330	272*	34*				> 330	42	3
		r	> 330	231*	33*	42	4	0			
12	PP- > RP	l	> 330	> 330	86	102	12	0			

Volunteer		Number of cfu per plate from dilution 10^x									
		Hand	Prevalues			Immediate postvalues			3 h postvalues		
No	Sequence	left or right	−1	−2	−3	0	−1	−2	0	−1	−2
		r	> 330	> 330	181				> 330	> 330	53
13	PP- > RP	l	> 330	> 330	106				> 330	> 330	37
		r	> 330	201*	17*	68	9	0			
14	PP- > RP	l	> 330	161*	28*	122	12	1			
		r	> 330	208*	23*				> 330	> 330	76
15	RP- > PP	l	> 330	141*	16*	> 330	> 330	102			
		r	> 330	122	12				> 330	> 330	87
16	PP- > RP	l	320*	32*	5				44	4	0
		r	> 330	35	1	0	0	0			
17	PP- > RP	l	> 330	> 330	148	6	0	0			
		r	> 330	> 330	71				> 330	69	9
18	RP- > PP	l	> 330	> 330	145				> 330	243*	32*
		r	> 330	> 330	126	> 330	80	12			
19	PP- > RP	l	> 330	195*	25*	> 330	52	7			
		r	> 330	116	12				242*	26*	1
20	PP- > RP	l	> 330	> 330	71				> 330	92	6
		r	> 330	> 330	37	28	3	0			
21	RP- > PP	l	> 330	> 330	61	> 330	62	8			
		r	> 330	> 330	153				32	3	0
22	RP- > PP	l	> 330	> 330	131	32	7	0			
		r	> 330	> 330	320				> 330	93	5
23	PP- > RP	l	> 330	> 330	97				192*	26*	1
		r	> 330	> 330	31	119	13	2			
24	RP- > PP	l	> 330	> 330	278	> 330	> 330	156			
		r	> 330	> 330	136				> 330	61	3

Underlined = count used for further computation

* indicates adjacent dilutions used for computation

**values cannot be used for further computation (infringement of control of weighted mean counts 5.7.2 for PP, s. table C2)

Table C.2 — Surgical hand rub procedure with test product – Experimental results

Preparation:"PP"

Dates of experiment: 15 July 2011 / 22 July 2011

Application: rubbing hands with 3 × 3 ml during 2 min

Volunteer		Number of cfu per plate from dilution 10^x									
		Hand	Prevalues			Immediate postvalues			3 h postvalues		
No	Sequence	left or right	−1	−2	−3	0	−1	−2	0	−1	−2
1	RP - > PP	l	> 330	> 330	186	> 330	133*	16*			
		r	> 330	> 330	68				> 330	> 330	153
2	RP - > PP	l	80	8	0				> 330	251*	40*
		r	156*	23*	4	201*	27*	0			
3	PP - > RP	l	> 330	> 330	95				> 330	> 330	329
		r	> 330	> 330	73	> 330	69	9			
4	RP - > PP	l	> 330	> 330	121				> 330	> 330	320
		r	> 330	> 330	171	> 330	> 330	81			
5	PP - > RP	l	> 330	> 330	66	> 330	106	12			
		r	> 330	> 330	71				> 330	> 330	143
6	PP - > RP	l	> 330	36	1				> 330	> 330	47
		r	171	12	1	~~109**~~	~~34**~~	1			
7	RP - > PP	l	> 330	176*	27*				> 330	> 330	124
		r	> 330	> 330	85	> 330	54	5			
8	PP - > RP	l	> 330	> 330	131	> 330	143*	20*			
		r	> 330	> 330	176				> 330	249*	21*
9	RP - > PP	l	> 330	> 330	54				> 330	> 330	74
		r	> 330	> 330	53	> 330	103	8			
10	RP - > PP	l	> 330	> 330	57	> 330	104	7			
		r	> 330	146	12				> 330	128*	15*
11	RP - > PP	l	> 330	191	12				> 330	143*	15*
		r	> 330	118*	14*	> 330	77	13			
12	PP - > RP	l	> 330	> 330	115	> 330	96*	14*			
		r	> 330	> 330	110				> 330	> 330	245
13	PP - > RP	l	> 330	> 330	146				> 330	> 330	101
		r	> 330	> 330	93	> 330	> 330	34			
14	PP - > RP	l	> 330	242*	23*	> 330	103	12			

Volunteer		Number of cfu per plate from dilution 10^x									
		Hand	Prevalues			Immediate postvalues			3 h postvalues		
No	Sequence	left or right	−1	−2	−3	0	−1	−2	0	−1	−2
		r	> 330	310*	31*				> 330	> 330	144
15	RP - > PP	l	> 330	59	7	> 330	> 330	155			
		r	> 330	59	5				> 330	> 330	320
16	PP - > RP	l	> 330	> 330	54				> 330	206*	29*
		r	> 330	41	4	78	12	1			
17	RP - > PP	l	> 330	> 330	43	125	13	1			
		r	> 330	> 330	81				> 330	114*	14*
18	RP - > PP	l	> 330	> 330	126				> 330	> 330	268
		r	> 330	> 330	114	> 330	191*	18*			
19	PP - > RP	l	> 330	> 330	42	> 330	> 330	35			
		r	> 330	> 330	56				> 330	> 330	61
20	PP - > RP	l	> 330	149*	18*				> 330	> 330	216
		r	> 330	174*	21*	> 330	> 330	81			
21	RP - > PP	l	> 330	121*	14*	237*	21*	3			
		r	> 330	> 330	69				> 330	133*	17*
22	RP - > PP	l	> 330	> 330	143	193*	29*	2			
		r	> 330	> 330	298				> 330	> 330	39
23	PP - > RP	l	> 330	> 330	179				> 330	> 330	329
		r	> 330	> 330	128	> 330	237*	24*			
24	RP - > PP	l	> 330	> 330	262	> 330	107	7			
		r	> 330	> 330	321				> 330	> 330	103

Underlined = count used for further computation
* indicates adjacent dilutions used for computation
**values cannot be used for further computation (infringement of control of weighted mean counts 5.7.2)