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Letter to the Editor

Practical considerations for infection prevention of near-patient surfaces: validation of an alternative polyvinyl chloride carrier in the 4-field test EN 16615:2015

Sir,

Many studies emphasize the need for effective surface disinfection of the patient environment [1–4]. Thus, standardized tests for disinfectant evaluation under simulated practical conditions are of utmost importance to evaluate effective measures to prevent transmission of infectious agents from contaminated surfaces. Within the framework of CEN/TC 216, the 4-field test EN 16615 provides a phase 2/step 2 test simulating practical conditions to test microbicidal efficacy of surface disinfectants applied by wiping, i.e. with mechanical action [5]. Employing EN 16615, practical conditions of application are simulated. This includes contact time, temperature, organic soiling, and application of the disinfectant/wipe as well as pre-drying of specified test organisms on a test surface as carrier.

Using the 4-field test EN 16615 we recently demonstrated the impact of applied volume on microbicidal efficacy of 70% (v/v) propan-2-ol, thus underlining the importance of

standardized test models to demonstrate efficacy of decontamination strategies under simulated practical conditions [6].

EN 16615 was published in 2015, and it has gained in importance ever since. The conditions described are intended to cover general purposes [5]. The carrier specified in EN 16615:2015 is polyvinyl chloride (PVC) with polyurethane (PUR) surface coating, thickness 2.5 mm and measuring 20 cm × 50 cm, which was chosen to reflect a surface frequently used as flooring. In recent years it has been shown that application of EN 16615 is of relevance on not only floorings but also especially when it comes to prevention of transmission of infectious agents in more near patient areas. Consequently, other PVC materials reflecting surfaces frequently found in near patient areas are of interest when applying EN 16615 (5).

Therefore, the expert group of CEN/TC 216 Working Group 1 sought an alternative PVC carrier. As an alternative carrier reflecting near-patient areas, PVC plate free foam (Forex classic) was chosen, as this is frequently used for decorative and/or hygienic cladding or furniture (e.g. patient bed tables). Additionally, this alternative PVC carrier must also be suitable to provide representative data covering all applications for surface disinfection with mechanical action in the medical area. Thus, in order to test for comparability, a ring trial according to EN 16615 was conducted using either PVC with PUR surface coating (PVC solid PUR, Lotter + Liebherr GmbH, Germany) or PVC plate free foam; 20 × 50 cm, thickness 2 mm (Forex classic; thyssenkrupp Plastics GmbH, Germany) to serve as standard test carriers. A total of 12 laboratories participated in the ring trial. The test included three different biocidal

Table 1

Comparison of antimicrobial efficacy related to test field 1 using two different carriers in the 4-field test EN 16615:2015

Variable	Formulation					
	A (0.025%/15 min)		B (2%/15 min)		C (ready-to-use/5 min)	
	Forex classic	PVC solid PUR	Forex classic	PVC solid PUR	Forex classic	PVC solid PUR
No. of participants	12	12	12	12	12	12
Mean ± 95% CI (log ₁₀ R)	4.10 ± 0.29	4.32 ± 0.29	6.91 ± 0.32	6.81 ± 0.50	5.28 ± 0.44	5.22 ± 0.67
Reproducibility (SD)	0.54	0.50	0.80	0.93	0.87	1.16
Repeatability (SD)	0.19	0.07	0.67	0.51	0.49	0.09
<i>t</i> -value (<i>t</i> -test)	1.03		0.28		0.15	
Critical value	2.07		2.07		2.09	
Empirical deviation (test on equivalence)	5.45%		−1.45%		−1.19%	
Max. tolerated empirical deviation (test on equivalence)	± 6.20%		± 6.22%		± 2.75%	

PVC, polyvinyl chloride; PUR, polyurethane; CI, confidence interval; SD, standard deviation.

formulations, based on two different active substances, quaternary ammonium compounds (QAC) and alcohol, respectively (formulation A: didecyltrimethylammonium chloride 6 g/100 g; N-(3-aminopropyl)-N-dodecylpropan-1,3-diamine 5.5 g/100 g; formulation B: didecyltrimethylammonium chloride 6 g/100 g; N-(3-aminopropyl)-N-dodecylpropan-1,3-diamine 5.5 g/100 g; formulation C: ethanol 45 g/100 g). As a test organism *Staphylococcus aureus* ATCC 6538 was used under conditions of low organic soiling (clean conditions).

Counts of >330 and >660 which result in a reduction of \log_{10} values (especially at product A) were taken as real value for the calculation, because they present the detection limit according to the given standards. The results were calculated according to the Q/Hampel method described in ISO 13528 using PROLab Standard version 2018.6.19.0 (QuoData GmbH, Dresden, Germany) [7]. The robust mean for test field 1 (T1) is given as logarithmic reduction ($\lg_{10} R$) \pm the 95% confidence interval. In addition, the reproducibility SD (inter-laboratory standard deviation) and repeatability SD (intra-laboratory standard deviation) are specified (Table 1). To verify the equivalence of PVC and Forex, a test on significant differences using *t*-test (level of significance: 5%) and a test on equivalence (maximum tolerated theoretical difference: $\pm 15\%$) were performed additionally with Pro-Lab (QuoData GmbH, Dresden, Germany).

The results of the efficacy experiments using either carrier were comparable with all three test formulations (Table 1). Furthermore, the test on equivalence confirms the equivalence of PVC and Forex under the given test conditions. Thus, based on these data, PVC plate free foam, 20 cm \times 50 cm, thickness 2 mm, white matt finished (Forex classic) may be used as an alternative validated and representative carrier when conducting EN 16615 as of now. These data will be considered for the current revision of EN 16615.

Conflict of interest statement

None declared.

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