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Results report	UDCX0002_1-2-EN	2
Document Title: Quantitative carrier test for automated airborne room disinfection according to EN 17272	Release date: 2021-02-04	Page (total pages): 1 (9)
Issued by: Lisa Rabe	Approved by: Andreas Bengtsson	
Customer: Decon-X lnternational AS	Contact person: Frode Lorentzen florentzen@deconx.com	
Customer address: Vollsveien 13C 1366 Lysaker Norway		

Results report

Evaluation of the customer's product in a quantitative carrier test for automated airborne room disinfection according to EN 17272: 2020.

1 Test data

Sample information

Name of the product	Decon-X 521
Batch number	M0104B0
Producer	Decon-X
Disinfection device	Decon- X, DX1
Producer	Decon-X
Serial number	DECONX273
Type of airborne disinfection	Mist
Disinfection process	DECONX180

Analysis

Start date of analysis	2021-01-20
End date of analysis	2021-01-30
Test organisms	*Staphylococcus aureus* ATCC 6538
	Enterococcus hirae ATCC 10541
	Escherichia coli ATCC 10536
	Acinetobacter baumanii ATCC 19606
	Candida albicans ATCC 10231

Experimental conditions

Contact time	3 hours
Temperature	20±2°C
Incubation temperature	36 ±1°C
Type of membrane filter	Cellulose nitrate-filter, 47 mm, 0.45 µm
Method for removal of bacteria from carrier	Mechanical using pipette tip

Experimental conditions continued

Interfering substance	Clean conditions: 0.3 g/L bovine albumin solution Sensitive organisms: 0.3 g/L bovine albumin+ skimmed milk 1/20
Neutralisation solution	Sodium thiosulphate solution content: 3 g/L Sodium thiosulphate, 1g/L Tryptone, 8.5 g/L NaCl, pH 7.2±0.2

Summary of results

Decon-X product "Decon-X 521" does meet the requirements of EN 17272 for the **distribution** of airborne room disinfection against *Staphylococcus aureus* and for **effectiveness** of airborne room disinfection against *Staphylococcus aureus, Enterococcus hirae, Escherichia coli, Acinetobacter baumanii* and *Candida albicans.*

The tests were performed in clean conditions at a temperature of 20±2°C and with a contact time of 3 hours. Requirements for approved product at clean condition is a log reduction ≥ 5 for bacteria and ≥ 4 for yeast.

Solutions were prepared with sterile deionized water unless otherwise stated. Validation and control have been carried out and approved for the strain according to calculations and requirements, specified under the heading "Analysis results".

2 Analysis results *S.aureus*

Method: EN 17272:2020
Product: Decon-X 521
Test organism: *Staphylococcus aureus* ATCC 6538
Date for the experiment: 2021-01-19
Analysis date: 2021-01-20/21
Conditions: Clean (0.3 g/L bovine albumin)
Test temperature: 20±2°C
Contact time: 3 hours

Results

Label of carrier	N (CFU/mL)	T (CFU/carrier)	n'1 + n'2 (Σ CFU/carrier)	Log reduction
DISTRIBUTION TEST				
S.a 1:V	$1.3x10^8$	$3.1x10^6$	0.0	**6.5**
S.a 1:H	$1.3x10^8$	$3.1x10^6$	0.0	**6.5**
S.a 2:V	$1.3x10^8$	$3.1x10^6$	0.0	**6.5**
S.a 2:H	$1.3x10^8$	$3.1x10^6$	0.0	**6.5**
S.a 3:V	$1.3x10^8$	$3.1x10^6$	0.0	**6.5**
S.a 3:H	$1.3x10^8$	$3.1x10^6$	0.0	**6.5**
S.a 4:V	$1.3x10^8$	$3.1x10^6$	3.5	**6.0**
S.a 4:H	$1.3x10^8$	$3.1x10^6$	2.3	**6.1**
EFFICACY TEST				
I	$1.3x10^8$	$3.1x10^6$	0.0	6.5
II	$1.3x10^8$	$3.1x10^6$	0.0	6.5
III	$1.3x10^8$	$3.1x10^6$	5.8	5.7
		Average Log reduction		**6.2**

Requirements:
N = $5x10^7$ – $2x10^9$ CFU/mL
T ≥ 6 lg

Validation

Test validation		
n1/N1	**n2/N2**	**n3/N1**
n1: $2.8x10^8$ CFU/mL	n2: $3.3x10^8$ CFU/mL	n3: $2.7x10^8$ CFU/mL
Requirements n1 > 0.5 N1 0.5N1 = $7.0x10^7$ CFU/mL Approved	Requirements n2 > 0.5 N2 0.5N2 = $1.0x10^8$ CFU/mL Approved	Requirements n3 > 0.5 N1 0.5N3 = $7.0x10^7$ CFU/mL Approved

Explanations:
N: Number of colony-forming units per mL in test solution
T: Number of colony-forming units per non-disinfected test area
n1: Validation that neutralisation solution is non-toxic: Pour plate agar
n2: Validation that neutralisation solution is non-toxic: Filtration
n3: Validation that neutralisation solution is non-toxic: Pour plate agar with carrier
n'1: Number of colony-forming units on filter and pour plate per 100 mL after disinfection
n'2: Number of colony-forming units on carrier after disinfection
N1: Validation of N on disk: Pour plate agar
N2: Validation of N on disk: Filtration
R: Reduction (log (T) -log (processed carrier)
I-III: Efficacy test carrier 1-3
Sa 1, 3:V/H: Carrier placed at the ceiling in front of (1) and behind (3) the device. V/H, vertical and horizontal placement respectively
Sa 2, 4:V/H: H Carrier placed at floor in front of (2) and behind (4) the device. V/H, vertical and horizontal placement respectively

3 Analysis results *E.hirae*

Method: EN 17272:2020
Product: Decon-X 521
Test organism: *Enterococcus hirae* ATCC 10541
Date for the experiment: 2021-01-20
Analysis date: 2021-01-21/22
Conditions: Clean (0.3 g/L bovine albumin)
Test temperature: 20±2°C
Contact time: 3 hours

Results

Label of carrier	N (CFU/mL)	T (CFU/carrier)	n'1 + n'2 (Σ CFU/carrier)	Log reduction
EFFICACY TEST				
I	$1.1x10^8$	$1.5x10^6$	1.2	6.1
II	$1.1x10^8$	$1.5x10^6$	0.0	6.2
III	$1.1x10^8$	$1.5x10^6$	1.2	6.1
		Average Log reduction		**6.1**

Requirements:
N = $5x10^7$ – $2x10^9$ CFU/mL
T ≥ 6 lg

Validation

Test validation		
n1/N1	**n2/N2**	**n3/N1**
n1: $1.1x10^8$ CFU/mL	n2: $1.7x10^8$ CFU/mL	n3: $1.4x10^8$ CFU/mL
Requirements n1 > 0.5 N1 0.5N1 = $2.5x10^7$ CFU/mL Approved	Requirements n2 > 0.5 N2 0.5N2 = $5.3x10^7$ CFU/mL Approved	Requirements n3 > 0.5 N1 0.5N3 = $2.5x10^7$ CFU/mL Approved

Explanations:
N: Number of colony-forming units per mL in test solution
T: Number of colony-forming units per non-disinfected test area
n1: Validation that neutralisation solution is non-toxic: Pour plate agar
n2: Validation that neutralisation solution is non-toxic: Filtration
n3: Validation that neutralisation solution is non-toxic: Pour plate agar with carrier
n'1: Number of colony-forming units on filter and pour plate per 100 mL after disinfection
n'2: Number of colony-forming units on carrier after disinfection
N1: Validation of N on disk: Pour plate agar
N2: Validation of N on disk: Filtration
R: Reduction (log (T) -log (processed carrier)
I-III: Efficacy test carrier 1-3

4 Analysis results *E.coli*

Method: EN 17272:2020
Product: Decon-X 521 **Test organism:** *Escherichia coli* ATCC 10536
Date for the experiment: 2021-01-28 **Analysis date**: 2021-01-29/30
Conditions: Clean (0.3 g/L bovine albumin+ skimmed milk 1/20)
Test temperature: 20±2°C **Contact time**: 3 hours

Results

Label of carrier	N (CFU/mL)	T (CFU/carrier)	n'1 + n'2 (Σ CFU/carrier)	Log reduction
EFFICACY TEST				
I	$5.0x10^9$	$3.4x10^6$	27.6	5.1
II	$5.0x10^9$	$3.4x10^6$	14.9	5.4
III	$5.0x10^9$	$3.4x10^6$	21.8	5.2
		Average Log reduction		**5.2**

Requirements:
N = $5x10^7$ – $5x10^9$ CFU/mL
T ≥ 6 lg

Validation

Test validation		
n1/N1	**n2/N2**	**n3/N1**
n1: >$3.3x10^9$ CFU/mL	n2: >$1.7x10^9$ CFU/mL	n3: >$3.3x10^9$ CFU/mL
Requirements n1 > 0.5 N1 0.5N1 = $2.5x10^9$ CFU/mL Approved	Requirements n2 > 0.5 N2 0.5N2 = >$8.3x10^8$ CFU/mL Approved	Requirements n3 > 0.5 N1 0.5N3 = $2.5x10^9$ CFU/mL Approved

Explanations:
N: Number of colony-forming units per mL in test solution
T: Number of colony-forming units per non-disinfected test area
n1: Validation that neutralisation solution is non-toxic: Pour plate agar
n2: Validation that neutralisation solution is non-toxic: Filtration
n3: Validation that neutralisation solution is non-toxic: Pour plate agar with carrier
n'1: Number of colony-forming units on filter and pour plate per 100 mL after disinfection
n'2: Number of colony-forming units on carrier after disinfection
N1: Validation of N on disk: Pour plate agar
N2: Validation of N on disk: Filtration
R: Reduction (log (T) -log (processed carrier)
I-III: Efficacy test carrier 1-3

5 Analysis results *A. baumanii*

Method: EN 17272:2020
Product: Decon-X 521
Test organism: *Acinetobacter baumanii* ATCC 19606
Date for the experiment: 2021-01-20
Analysis date: 2021-01-21/22
Conditions: Clean (0.3 g/L bovine albumin+ skimmed milk 1/20)
Test temperature: 20±2°C
Contact time: 3 hours

Results

Label of carrier	N (CFU/mL)	T (CFU/carrier)	n'1 + n'2 (Σ CFU/carrier)	Log reduction
EFFICACY TEST				
I	$2.7x10^8$	$3.9x10^6$	2.3	6.2
II	$2.7x10^8$	$3.9x10^6$	6.9	5.8
III	$2.7x10^8$	$3.9x10^6$	2.2	6.3
		Average Log reduction		**6.1**

Requirements:
N = $5x10^7$ – $2x10^9$ CFU/mL
T ≥ 6 lg

Validation

Test validation		
n1/N1	**n2/N2**	**n3/N1**
n1: $3.4x10^8$ CFU/mL	n2: $4.4x10^8$ CFU/mL	n3: $2.6x10^8$ CFU/mL
Requirements n1 > 0.5 N1 0.5N1 = $1.5x10^8$ CFU/mL Approved	Requirements n2 > 0.5 N2 0.5N2 = $1.8x10^8$ CFU/mL Approved	Requirements n3 > 0.5 N1 0.5N3 = $1.5x10^8$ CFU/mL Approved

Explanations:
N: Number of colony-forming units per mL in test solution
T: Number of colony-forming units per non-disinfected test area
n1: Validation that neutralisation solution is non-toxic: Pour plate agar
n2: Validation that neutralisation solution is non-toxic: Filtration
n3: Validation that neutralisation solution is non-toxic: Pour plate agar with carrier
n'1: Number of colony-forming units on filter and pour plate per 100 mL after disinfection
n'2: Number of colony-forming units on carrier after disinfection
N1: Validation of N on disk: Pour plate agar
N2: Validation of N on disk: Filtration
R: Reduction (log (T) -log (processed carrier)
I-III: Efficacy test carrier 1-3

6 Analysis results *C.albicans*

Method: EN 17272:2020
Product: Decon-X 521
Test organism: *Candida albicans* ATCC 10231
Date for the experiment: 2021-01-20
Analysis date: 2021-01-21/22
Conditions: Clean (0.3 g/L bovine albumin+ skimmed milk 1/20)
Test temperature: 20±2°C
Contact time: 3 hours

Results

Label of carrier	N (CFU/mL)	T (CFU/carrier)	n'1 + n'2 (Σ CFU/carrier)	Log reduction
EFFICACY TEST				
I	$2.1x10^7$	$2.3x10^5$	0.0	5.4
II	$2.1x10^7$	$2.3x10^5$	1.2	5.3
III	$2.1x10^7$	$2.3x10^5$	0.0	5.4
		Average Log reduction		**5.3**

Requirements:
N = $2x10^7$ – $1x10^8$ CFU/mL
T ≥ 5 lg

Validation

Test validation		
n1/N1	**n2/N2**	**n3/N1**
n1: $1.5x10^8$ CFU/mL	n2: $1.3x10^8$ CFU/mL	n3: $9.0x10^7$ CFU/mL
Requirements n1 > 0.5 N1 0.5N1 = $1.2x10^7$ CFU/mL Approved	Requirements n2 > 0.5 N2 0.5N2 = $5.3x10^6$ CFU/mL Approved	Requirements n3 > 0.5 N1 0.5N3 = $1.2x10^7$ CFU/mL Approved

Explanations:
N: Number of colony-forming units per mL in test solution
T: Number of colony-forming units per non-disinfected test area
n1: Validation that neutralisation solution is non-toxic: Pour plate agar
n2: Validation that neutralisation solution is non-toxic: Filtration
n3: Validation that neutralisation solution is non-toxic: Pour plate agar with carrier
n'1: Number of colony-forming units on filter and pour plate per 100 mL after disinfection
n'2: Number of colony-forming units on carrier after disinfection
N1: Validation of N on disk: Pour plate agar
N2: Validation of N on disk: Filtration
R: Reduction (log (T) -log (processed carrier)
I-III: Efficacy test carrier 1-3

7 Quality and environmental management system

Microbial Analytics Sweden AB is certified according to ISO 9001: 2015 and ISO 14001: 2015, certificate 1565 from AAA Certification AB and accredited according to ISO 17025: 2018 by Swedac, the Board of Accreditation and Technical Control, accreditation number: 10351.

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Date 2021-02-04

Karsten Pedersen
(VD)

8 Appendix

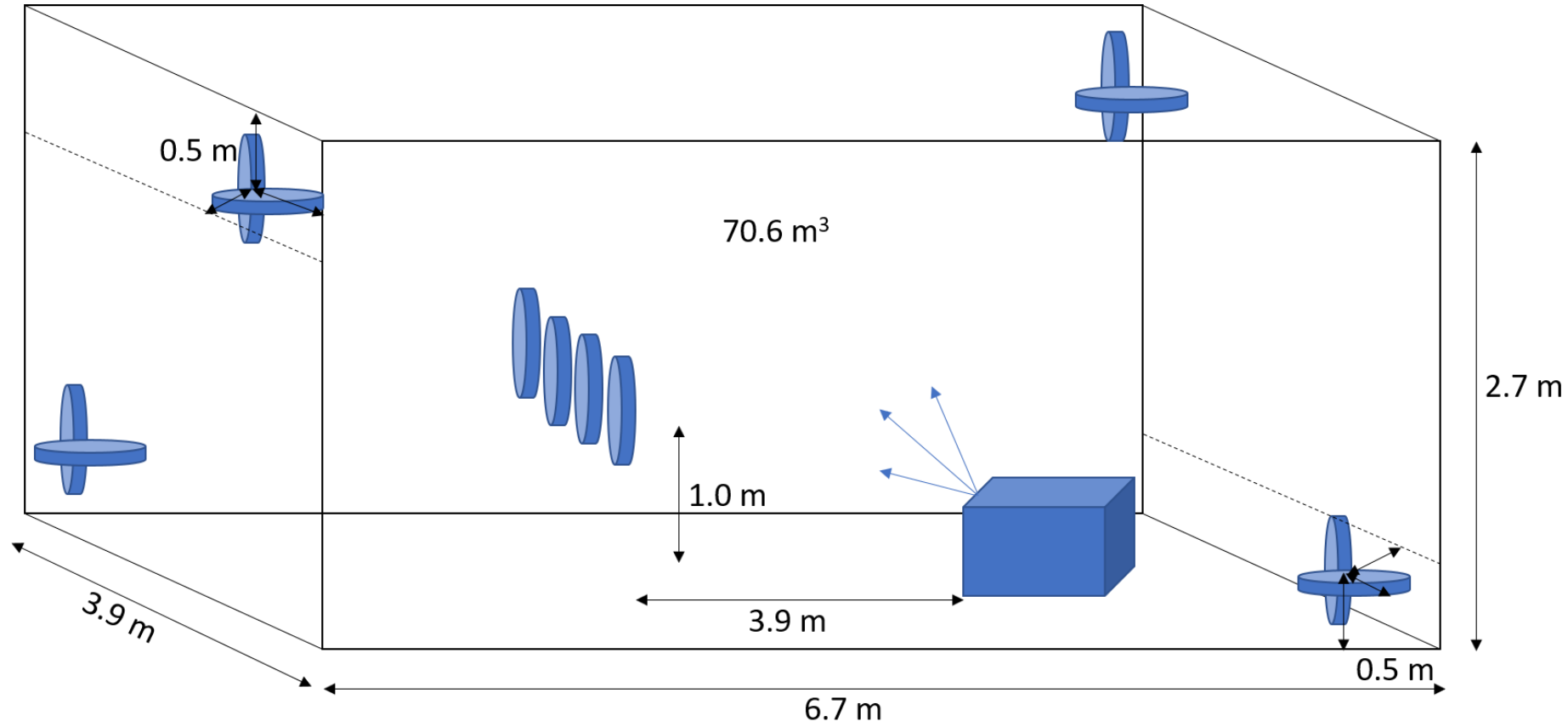

Figure 1. Schematic drawing of the test room. Not to scale.