

Test Report No. L17/0602.5

Quantitative Non-Porous Surface Test for Evaluation of Bactericidal and/or Fungicidal Activity of Chemical Disinfectants and Antiseptics Used in Food, Industrial, Domestic, and Institutional Areas (NF T 72-281: 2014; Phase 2/Step 2)

In accordance with your order, we tested the preparation **Decon-X 521** for its activity according to NF T 72-281: 2014 under organic load of 0.03 % bovine albumin.

1 General Information and Material

1.1 Client

Client: Decon-X International AS, Mr Lars Corlin Christensen, Vollsveien 13c,
NO-1366 Lysaker
Date of order: 18/04/2017
Confirmation no.: 203119

1.2 Identification of Test Laboratory

Site: Dr. Brill + Partner GmbH · Institute for Hygiene and Microbiology,
Stiegstück 34, DE - 22339 Hamburg, Germany
Study manager: Dipl.-Biol. Henrik Gabriel
Scientific assistant: Dipl.-Biol. Dr. rer. nat. Jan-Hendrik Klock
Execution: Dr. Britta Becker (test), Martina Müller (analysis)

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1.4 Identification of Device

Name of product: **Decon-X 521**
Serial no.: -



Manufacturer:	Decon-X International AS, NO-1366 Lysaker
Date of delivery:	10/10/2017
Storage conditions:	room temperature and darkness
Appearance of product:	clear liquid
Odour:	characteristic
Product type:	room disinfectant
Recommended diluent:	Product is ready for use
Diluent used:	not applicable
pH value, concentrate:	not applicable
Active agents (Manufacturer's data):	5.00000 % Hydrogen peroxide 0.00415 % Silver

1.5 Test Conditions

Test period:	10/10/ - 16/10/2017; 15/02/ - 28/02/2018
Lab task no.:	L17/0602.1 and .2
Test temperature:	20.0°C ± 2.0°C
Test room ground area:	4.95 m x 4.95 m (24.50 m ²)
Test room height (volume):	2.55 m (62.48 m ³)
Humidity:	51 – 84 %rH
Machine (Fumigator):	Decon DX1
Output / Diffusion rate:	Not specified
Concentration:	80.6 ppm H ₂ O ₂ average, not specified for L17/0602.2 run
Total exposure times:	120 minutes
Organic load:	0.03 % bovine albumin
Neutraliser:	1 g/L Tween 80, 1 g/L cystein, 1 g/L sodium thiosulphate (TC-Nt) 1 g/L Tween 80, 1 g/L cystein, 1 g/L calcium chloride (TC-CC)
Identification of test organisms:	<i>Staphylococcus aureus</i> ATCC 6538 <i>Enterococcus hirae</i> ATCC 10541 <i>Escherichia coli</i> ATCC 10536 <i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Bacillus subtilis</i> (spores) ATCC 6633 <i>Candida albicans</i> ATCC 10231 <i>Aspergillus brasiliensis</i> (spores) ATCC 16404



2 Methods

The tests were carried out according to NF T 72-281: 2014 "Methods of airborne disinfection of surfaces – Determination of bactericidal, fungicidal, yeasticidal and sporicidal activity (Phase 2/Step 2)".

The germ carriers were placed vertically in 3.6 m distance to the device.

Modified inactivation was used with 10 ml neutraliser vessels instead of 100 ml. Membrane filtration was discarded for this reason.

3 Results

The test results according to NF T 72-281: 2011 are summarised in table 1.

The outcome of the test is presented in condensed form in Table a.

Table a: Summary of results for Decon-X 521

Strain	N Titer of initial suspension	Preliminary test			T Controls	Tests: reductions, d in log base-10 after [min]	
		n1/N1	n2/N2	n3/N1			120
	Bacteria						
Standard	10 ⁸ to 5x10 ⁹ per ml	n1>0.5N1	n2>0.5N2	n3>0.5N1	T ≥ 10 ⁶	d ≥ 5	
S. aureus	Yes	Yes	n.t.	Yes	Yes	d1=	Yes
E. hirae	Yes	Yes	n.t.	Yes	Yes	d2=	Yes
E. coli	Yes	Yes	n.t.	Yes	Yes	d3=	Yes
P. aeruginosa	Yes	Yes	n.t.	Yes	Yes	d4=	Yes
Bacterial spores							
Standard	2 - 5 x10 ⁵ per ml	n1>0.5N1	n2>0.5N2	n3>0.5N1	T ≥ 10 ⁵	d ≥ 3	
B. subtilis	Yes	Yes	n.t.	Yes	Yes	d5=	Yes
Yeast and moulds							
Standard	< 10 ⁸ per ml (C. albicans)	n1>0.5N1	n2>0.5N2	n3>0.5N1	T ≥ 10 ⁶	d ≥ 4	
C. albicans	Yes	Yes	n.t.	Yes	Yes	d6=	Yes
A. brasiliensis	Yes	Yes	n.t.	Yes	Yes	d7=	Yes



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Author HG Version 02 Date 08/05/2018
Replaces Version 01 Date 04/05/2018

Name of Product: **Decon-X 521**
Method NF T 72-281, 2014

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The test organisms were sufficiently inactivated by **Decon-X 521** using Decon DX1 as fumigator for 64 m³ room volume in the quantitative surface test at the test temperature of 20 °C under organic load of 0.03 % bovine albumin in 120 minutes contact time.

Hamburg, 08/05/2018

Dipl.-Biol. Henrik Gabriel
Head of Laboratory

Dipl.-Ing. Dr. rer. nat. Andreas Kampe
Quality control





Table 1.1: Validation, Controls and Evaluation

Test preparation: **Decon-X 521** Batch: -
Test organism: *Staphylococcus aureus* Test temperature: 20.0°C ± 2.0°C
Organic load: 0.03 % bovine albumin Inactivation: TC-CC
Contact time: **120 minutes** Lab task no.: L17/0602.2

Test and validation suspension (N)			Control count suspension (N1)			Control count membrane filter (N2)		
	x	x'		a	a'		a	a'
1,00E-07	200	174	1,00E-07	160	145	1,00E-06		
1,00E-08	18	20	1,00E-08	17	18	1,00E-07		
$\bar{x} = 1,87E+09 = 9,27 \lg$			$\bar{x} = 1,55E+09 = 9,19 \lg$			$\bar{x} = 0,00E+00 = n.t.$		
8,00 ≤ lg N ≤ 9,71 ?			Yes					

Inhibitory effect on Agar (n1)			Inhibitory effect on membranes (n2)			carrier-vetored in agar (n3)		
	x	x'		a	a'		a	a'
1,00E-06	>300	>300	1,00E-06			1,00E-07	>300	>300
1,00E-07	180	185	1,00E-07			1,00E-08	21	21
$\bar{x} = 1,83E+09 = 9,26 \lg$			$\bar{x} = 0,00E+00 = n.t.$			$\bar{x} = 2,10E+09 = 9,32 \lg$		
n1 > 0,5 x N1 ?			n2 > 0,5 x N2 ?			n3 > 0,5 x N1 ?		
Yes			n.t.			Yes		

Water control

Water control (T):	T	a	a'	$\bar{x} = 8,23E+07$	
	1,00E-04	>300	>300	lgT =	7,92
	1,00E-05	79	85	lgT > 6 lg ?	Yes

Test

Concentration of product in test solution [%]	Dilution step	n'1	n'1	N _d ($\bar{x} \pm \sqrt{\bar{x} \cdot \bar{x}}$) cfu/ml	lg N _d = lg ($\bar{x} \pm \sqrt{\bar{x} \cdot \bar{x}}$)	d (lgT =7,92)	Exposure time (min)	
100	1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 7,82	120	
	1,00E-01	0	0					
	1,00E-02	0	0					
	n'2 =	-						
	1,00E+00	>300	>300	3,20E+03	3,51	4,41	120	
	1,00E-01	34	30					
	1,00E-02	6	6					
	n'2 =	-						
	1,00E+00	160	104	1,32E+03	3,12	4,79	120	
	1,00E-01	14	17					
	1,00E-02	2	0					
	n'2 =	-						
	Mean reduction at 120 min:				d1= 5,67	Standard deviation:		1,87



Table 1.2: Validation, Controls and Evaluation

Test preparation:	Decon-X 521	Batch:	-
Test organism:	<i>Enterococcus hirae</i>	Test temperature:	20.0°C ± 2.0°C
Organic load:	0.03 % bovine albumin	Inactivation:	TC-Nt
Contact time:	120 minutes	Lab task no.:	L17/0602.1

Test and validation suspension (N)			Control count suspension (N1)			Control count membrane filter (N2)		
	x	x'		a	a'		a	a'
1,00E-06	>300	>300	1,00E-06	228	230	1,00E-06		
1,00E-07	34	40	1,00E-07	14	21	1,00E-07		
$\bar{x} =$	3,70E+08 =	8,57 lg	$\bar{x} =$	2,24E+08 =	8,35 lg	$\bar{x} =$	0,00E+00 =	n.t.
8,00 ≤ lg N ≤ 9,71 ?			Yes					

Inhibitory effect on Agar (n1)			Inhibitory effect on membranes (n2)			carrier-vetored in agar (n3)		
	x	x'		a	a'		a	a'
1,00E-06	>300	>300	1,00E-06			1,00E-06	>300	>300
1,00E-07	44	49	1,00E-07			1,00E-07	25	38
$\bar{x} =$	4,65E+08 =	8,67 lg	$\bar{x} =$	0,00E+00 =	n.t.	$\bar{x} =$	3,15E+08 =	8,50 lg
n1 > 0,5 x N1 ?			Yes			n2 > 0,5 x N2 ?		
						n.t.		
						n3 > 0,5 x N1 ?		
						Yes		

Water control	Water control (T):	T	a	a'	$\bar{x} =$	1,20E+08
		1,00E-04	>300 >300	>300 >300	lgT =	8,08
		1,00E-05	88 97	142 152	lgT > 6 lg ?	Yes

Test	Concentration of product in test solution [%]	Dilution step	n'1	n'1	N _d ($\bar{x} \pm \bar{x} \text{ wm}$) cfu/ml	lg N _d = lg ($\bar{x} \pm \bar{x} \text{ wm}$)	d (lgT =8,08)	Exposure time (min)	
100		1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 7,98	120	
		1,00E-01	0	0					
		1,00E-02	0	0					
		n'2 =	-						
		1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 7,98	120	
		1,00E-01	0	0					
		1,00E-02	0	0					
		n'2 =	-						
		1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 7,98	120	
		1,00E-01	0	0					
		1,00E-02	0	0					
		n'2 =	-						
	Mean reduction at 120 min:					d2= 7,98	Standard deviation: 0,00		



Table 1.3: Validation, Controls and Evaluation

Test preparation:	Decon-X 521	Batch:	-
Test organism:	<i>Escherichia coli</i>	Test temperature:	20.0°C ± 2.0°C
Organic load:	0.03 % bovine albumin	Inactivation:	TC-Nt
Contact time:	120 minutes	Lab task no.:	L17/0602.1

Test and validation suspension (N)			Control count suspension (N1)			Control count membrane filter (N2)		
	x	x'		a	a'		a	a'
1,00E-06	180	174	1,00E-06	174	171	1,00E-06		
1,00E-07	16	19	1,00E-07	14	16	1,00E-07		
$\bar{x} =$	1,77E+08 =	8,25 lg	$\bar{x} =$	1,70E+08 =	8,23 lg	$\bar{x} =$	0,00E+00 =	n.t.
8,00 ≤ lg N ≤ 9,71 ?			Yes					

Inhibitory effect on Agar (n1)			Inhibitory effect on membranes (n2)			carrier-vetored in agar (n3)		
	x	x'		a	a'		a	a'
1,00E-06	>300	>300	1,00E-06			1,00E-06	>300	>300
1,00E-07	13	22	1,00E-07			1,00E-07	10	12
$\bar{x} =$	1,75E+08 =	8,24 lg	$\bar{x} =$	0,00E+00 =	n.t.	$\bar{x} =$	1,10E+08 =	8,04 lg
n1 > 0,5 x N1 ?			Yes			n2 > 0,5 x N2 ?		
			n.t.			n3 > 0,5 x N1 ?		
			Yes					

Water control	Water control (T):	T	a	a'	$\bar{x} =$	6,43E+07
		1,00E-04	>300	>300	lgT =	7,81
		1,00E-05	115	126	lgT > 6 lg ?	Yes

Test	Concentration of product in test solution [%]	Dilution step	n'1	n'1	N _d ($\bar{x} \pm \bar{x} \text{wm}$) cfu/ml	lg N _d = lg ($\bar{x} \pm \bar{x} \text{wm}$)	d (lgT =7,81)	Exposure time (min)	
100		1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 7,71	120	
		1,00E-01	0	0					
		1,00E-02	0	0					
		n'2 =	-						
		1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 7,71	120	
		1,00E-01	0	0					
		1,00E-02	0	0					
		n'2 =	-						
		1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 7,71	120	
		1,00E-01	0	0					
		1,00E-02	0	0					
		n'2 =	-						
		Mean reduction at 120 min:				d3= 7,59	Standard deviation: 0,00		



Table 1.4: Validation, Controls and Evaluation

Test preparation:	Decon-X 521	Batch:	-
Test organism:	<i>Pseudomonas aeruginosa</i>	Test temperature:	20.0°C ± 2.0°C
Organic load:	0.03 % bovine albumin	Inactivation:	TC-CC
Contact time:	120 minutes	Lab task no.:	L17/0602.2

Test and validation suspension (N)			Control count suspension (N1)			Control count membrane filter (N2)		
	x	x'		a	a'		a	a'
1,00E-07	>300	>300	1,00E-07	129	177	1,00E-06		
1,00E-08	35	35	1,00E-08	16	20	1,00E-07		
$\bar{x} = 3,50E+09 = 9,54 \lg$			$\bar{x} = 1,55E+09 = 9,19 \lg$			$\bar{x} = 0,00E+00 = n.t.$		
8,00 ≤ lg N ≤ 9,71 ?								
Yes								

Inhibitory effect on Agar (n1)			Inhibitory effect on membranes (n2)			carrier-vetored in agar (n3)		
	x	x'		a	a'		a	a'
1,00E-06	>300	>300	1,00E-06			1,00E-07	>300	>300
1,00E-07	245	250	1,00E-07			1,00E-08	30	30
$\bar{x} = 2,48E+09 = 9,39 \lg$			$\bar{x} = 0,00E+00 = n.t.$			$\bar{x} = 3,00E+09 = 9,48 \lg$		
n1 > 0,5 x N1 ?			n2 > 0,5 x N2 ?			n3 > 0,5 x N1 ?		
Yes			n.t.			Yes		

Water control	Water	T	a	a'	$\bar{x} = 6,05E+07$			
	control	1,00E-04	>300	>300	>300	>300	$\lg T = 7,78$	
	(T):	1,00E-05	62	73	48	59	$\lg T > 6 \lg ?$ Yes	

Test	Concentration of product in test solution [%]	Dilution step	n'1	n'1	N _d ($\bar{x} \vee \bar{x} \text{ wm}$) cfu/ml	lg N _d = lg ($\bar{x} \vee \bar{x} \text{ wm}$)	d (lgT =7,78)	Exposure time (min)	
100		1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 7,68	120	
		1,00E-01	0	0					
		1,00E-02	0	0					
		n'2 =	-						
		1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 7,68	120	
		1,00E-01	0	0					
		1,00E-02	0	0					
		n'2 =	-						
		1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 7,68	120	
		1,00E-01	0	0					
		1,00E-02	0	0					
		n'2 =	-						
	Mean reduction at 120 min:					d4= 7,68	Standard deviation: -		



Table 2.1: Validation, Controls and Evaluation

Test preparation:	Decon-X 521	Batch:	-
Test organism:	<i>Bacillus subtilis</i>	Test temperature:	20.0°C ± 2.0°C
Organic load:	0.03 % bovine albumin	Inactivation:	TC-CC
Contact time:	120 minutes	Lab task no.:	L17/0602.2

Test and validation suspension (N)			Control count suspension (N1)			Control count membrane filter (N2)		
	x	x'		a	a'		a	a'
1,00E-03	>300	>300	1,00E-03	>300	>300	1,00E-05		
1,00E-04	35	37	1,00E-04	70	55	1,00E-06		
$\bar{x} =$	3,60E+05 =	5,56 lg	$\bar{x} =$	6,25E+05 =	5,80 lg	$\bar{x} =$	0,00E+00 =	n.t.
5,30 > lg N < 5,70			Yes					

Inhibitory effect on Agar (n1)			Inhibitory effect on membranes (n2)			carrier-vectored in agar (n3)		
	x	x'		a	a'		a	a'
1,00E-03	>300	>300	1,00E-05			1,00E-03	>300	>300
1,00E-04	71	78	1,00E-06			1,00E-04	69	73
$\bar{x} =$	7,45E+05 =	5,87 lg	$\bar{x} =$	0,00E+00 =	n.t.	$\bar{x} =$	7,10E+05 =	5,85 lg
n1 > 0,5 x N1 ?			n2 > 0,5 x N2 ?			n3 > 0,5 x N1 ?		
Yes			n.t.			Yes		

Water control

Water control (T):	T	a	a'	$\bar{x} =$	2,68E+05
	1,00E-02	>300	>300	lgT =	5,43
	1,00E-03	30	25	lgT > 5 lg ?	Yes

Test

Concentration of product in test solution [%]	Dilution step	n'1	n'1	N _d ($\bar{x} \pm \sqrt{s^2 \cdot n}$) cfu/ml	lg N _d = lg ($\bar{x} \pm \sqrt{s^2 \cdot n}$)	d (lgT =5,43)	Exposure time (min)
100	1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 5,33	120
	1,00E-01	0	0				
	1,00E-02	0	0				
	n'2 =	-					
	1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 5,33	120
	1,00E-01	0	0				
	1,00E-02	0	0				
	n'2 =	-					
	1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 5,33	120
	1,00E-01	0	0				
	1,00E-02	0	0				
	n'2 =	-					
	Mean reduction at 120min:				d5= 5,33	Standard deviation:	



Table 3.1: Validation, Controls and Evaluation

Test preparation: **Decon-X 521** Batch: -
Test organism: *Candida albicans* Test temperature: 20.0°C ± 2.0°C
Organic load: 0.03 % bovine albumin Inactivation: TC-Nt
Contact time: **120 minutes** Lab task no.: L17/0602.1

Test and validation suspension (N)			Control count suspension (N1)			Control count membrane filter (N2)		
	x	x'		a	a'		a	a'
1,00E-06	>300	>300	1,00E-06	>300	>300	1,00E-05		
1,00E-07	30	30	1,00E-07	36	48	1,00E-06		
$\bar{x} = 3,00E+08 = 8,48 \lg$			$\bar{x} = 4,20E+08 = 8,62 \lg$			$\bar{x} = 0,00E+00 = n.t.$		
$\lg N > 8,00$								
Yes								

Inhibitory effect on Agar (n1)			Inhibitory effect on membranes (n2)			carrier-vectored in agar (n3)		
	x	x'		a	a'		a	a'
1,00E-06	>300	>300	1,00E-05			1,00E-06	>300	>300
1,00E-07	61	72	1,00E-06			1,00E-07	22	21
$\bar{x} = 6,65E+08 = 8,82 \lg$			$\bar{x} = 0,00E+00 = n.t.$			$\bar{x} = 2,15E+08 = 8,33 \lg$		
$n1 > 0,5 \times N1 ?$			$n2 > 0,5 \times N2 ?$			$n3 > 0,5 \times N1 ?$		
Yes			n.t.			Yes		

Water control	Water control	T	a	a'	$\bar{x} = 2,85E+06$			
		1,00E-03	>300	>300	66	44	$\lg T = 6,45$	
	(T):	1,00E-04	53	46	8	7	$\lg T > 6 \lg ?$ Yes	

Test	Concentration of product in test solution [%]	Dilution step	n'1	n'1	N _d ($\bar{x} \pm \bar{x} \text{ wm}$) cfu/ml	lg N _d = lg ($\bar{x} \pm \bar{x} \text{ wm}$)	d (lgT =6,45)	Exposure time (min)		
100		1,00E+00	0	13	6,50E+01	1,81	4,64	120		
		1,00E-01	4	1						
		1,00E-02	0	0						
		n'2 =	-							
		1,00E+00	87	89	8,80E+02	2,94	3,51	120		
		1,00E-01	14	17						
		1,00E-02	2	2						
		n'2 =	-							
		1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 6,35	120		
		1,00E-01	0	0						
		1,00E-02	0	0						
		n'2 =	-							
		Mean reduction at 120 min:					d6= 4,83	Standard deviation: 1,43		



Table 3.2: Validation, Controls and Evaluation

Test preparation: **Decon-X 521** Batch: -
Test organism: *Aspergillus brasiliensis* Test temperature: 20.0°C ± 2.0°C
Organic load: 0.03 % bovine albumin Inactivation: TC-CC
Contact time: **120 minutes** Lab task no.: L17/0602.2

Test and validation suspension (N)			Control count suspension (N1)			Control count membrane filter (N2)		
	x	x'		a	a'		a	a'
1,00E-06	>165	>165	1,00E-05	66	52	1,00E-05		
1,00E-07	17	19	1,00E-06	8	16	1,00E-06		
$\bar{x} = 1,80E+08 = 8,26 \lg$			$\bar{x} = 6,45E+06 = 6,81 \lg$			$\bar{x} = 0,00E+00 = \text{n.t.}$		
$\lg N > 7,70$								
Yes								

Inhibitory effect on Agar (n1)			Inhibitory effect on membranes (n2)			carrier-vectored in agar (n3)		
	x	x'		a	a'		a	a'
1,00E-05	>165	>165	1,00E-05			1,00E-05	>165	>165
1,00E-06	21	21	1,00E-06			1,00E-06	22	22
$\bar{x} = 2,10E+07 = 7,32 \lg$			$\bar{x} = 0,00E+00 = \text{n.t.}$			$\bar{x} = 2,20E+07 = 7,34 \lg$		
$n1 > 0,5 \times N1$?			$n2 > 0,5 \times N2$?			$n3 > 0,5 \times N1$?		
Yes			n.t.			Yes		

Water control		T		a		a'		$\bar{x} = 2,85E+06$	
Water control		1,00E-03	>165	>165	>165	>165	$\lg T = 6,45$		
(T):		1,00E-04	21	28	33	32	$\lg T > 6 \lg$?	Yes	

Test	Concentration of product in test solution [%]	Dilution step	n'1	n'1	N _d ($\bar{x} \vee \bar{x}' \text{wm}$) cfu/ml	lg N _d = lg ($\bar{x} \vee \bar{x}' \text{wm}$)	d (lgT =6,45)	Exposure time (min)
100		1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 6,35	120
		1,00E-01	0	0				
		1,00E-02	0	0				
		n'2 =	-					
		1,00E+00	120	131	1,26E+03	3,10	3,36	120
		1,00E-01	7	16				
		1,00E-02	1	2				
		n'2 =	-					
		1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 6,35	120
		1,00E-01	0	0				
		1,00E-02	0	0				
		n'2 =	-					
	Mean reduction at 120 min:		d7= 5,35		Standard deviation:		1,73	



4 List of Abbreviations

cfu	=	colony forming units (viable microbial count)
N1	=	control count suspension (pour plate)
N2	=	control count suspension (membrane filtration)
n1	=	inhibitory effect on agar
n2	=	inhibitory effect on membranes
n3	=	carrier-vectored in agar (inhibitory effect of carrier)
N	=	test suspension
N _d	=	log ₁₀ cfu per test surface of disinfection test
n.t.	=	not tested
d	=	germicidal activity (N _c – N _d)
x, x'	=	viable microbial count per ml of the test suspension
a, a'	=	viable microbial count per ml of the suspension after examination and validation
$\bar{x}$	=	mean of a and a' and x and x'