LAB – TEST LABORATORIUM S.C.
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AB 815

TEST REPORT NR DZ/33/05/20 CONTAINS 6 NUMBERED PAGES

Evaluation of activity according to PN-EN 1500:2013-07 'Hygienic handrub'

A. Laboratory:

LAB – TEST LABORATORIUM S.C. 40-868 KATOWICE, Poland

B. Identification of the sample:

1. Product tested.....**LogicSept**
2. Batch.....na
3. Test sponsor.....MP Logistics
4. Date of delivery.....08.05.2020; sample delivered by the test sponsor
5. Storage conditions.....ambient
6. Active substances:.....0,25% BKC, 25% propyl alcohol

C.1. Test method.....handrub according to PN-EN 1500:2013-07

D. Test conditions:

1. Test period.....08.05.2020 – 13.05.2020
2. Number of persons / hands in the test.....20 / 20x2
3. Test strain.....*Escherichia coli* K12 NCTC 10538
4. Neutralizer.....Tween 80, 100 g/l; lecithin 30 g/l; sodium thiosulphate 5 g/l, in TSB
5. Soft soap.....prepared according to PN-EN 1500:2013-07
6. Volume of product for single rub.....3,0 ml
7. Single handrub time.....30 s
8. Number of handrubs.....2
9. Handrub procedure.....according to annex A to PN-EN 1500:2013-07
10. Incubation.....37ºC ± 1ºC; 48 h

E. Test results..... tables 1 – 4

F. Conclusion:

Product: **LogicSept** tested according to **PN-EN 1500:2013-07,** applied: 3 ml on dry hands, 30 s handrub, repeated, is not significantly worse than the reference procedure, and so meets the requirements of **PN-EN 1500:2013-07 'Hygienic handrub'.**

TABLE 1

dilution – neutralization validation

Product: **LogicSept**

test strain	validation test		
	bacterial suspensions	neutralizer control	dilution-neutralization control
Escherichia coli K12 NCTC 10538	Vc: 10^{-3}: 108;127 Nv_0: $1,2 \cdot 10^2$ Nv_B: $1,2 \cdot 10^5$	Vc: 102;129 B: $1,2 \cdot 10^2$	Vc: 69;73 C: $7,1 \cdot 10^1$

Nv - cfu/ml in the bacterial suspension in the dilution-neutralization control test, Nv_0= Nv/10
Nv_B - cfu/ml in the bacterial suspension in the neutralizer toxicity control test,

B - cfu/ml in neutralizer control test
C - cfu/ml in the dilution - neutralization control test

Validation criteria verification:

$3,0 \cdot 10^2 \leq N_v \leq 1,6 \cdot 10^3$	**-**	**met**	**$C \geq 0,5\ Nv_0$**	**-**	**met**
$3,0 \cdot 10^4 \leq Nv_B \leq 1,6 \cdot 10^5$	**-**	**met**	**$B \geq 0,0005\ Nv_B$**	**-**	**met**

TABLE 2 Reference handrub procedure – experimental results

Reference product: 2-propanol 60% v/v
Application: 3 ml on dry hands; 30 s rub; performed 2 times
Test date: 11.05.2020
Test strain: *Escherichia coli* K12 NCTC 10538
Microbial suspension: $4{,}1 \cdot 10^8$ cfu/ml

subject		Number of cfu / 1,0 ml TSB on plate from dilutions					
Nr	hand	pre-count			post-count		
	L left/ R right	10^{-3}	10^{-4}	10^{-5}	10^{-1}	10^{-2}	10^{-3}
1	L	157	17	10	9	1	0
	R	241	27	3	2	0	0
2	L	>330	88	10	12	1	0
	R	>330	105	12	42	3	0
3	L	>330	53	6	66	5	0
	R	>330	74	6	21	2	0
4	L	>330	61	7	73	9	1
	R	>330	85	11	48	5	0
5	L	>330	64	8	62	9	1
	R	>330	97	11	22	2	0
6	L	>330	41	5	26	3	0
	R	>330	81	13	35	4	0
7	L	321	36	4	9	1	0
	R	149	16	1	5	1	0
8	L	209	26	2	12	3	0
	R	192	23	4	2	0	0
9	L	>330	93	9	78	10	0
	R	>330	107	13	54	5	0
10	L	157	18	1	4	0	0
	R	124	9	1	8	1	0
11	L	>330	121	15	72	8	1
	R	>330	36	4	23	2	0
12	L	>330	55	7	37	4	0
	R	>330	75	8	44	5	0
13	L	>330	43	3	11	1	0
	R	>330	62	7	30	2	0
14	L	>330	95	11	5	1	0
	R	>330	80	7	25	3	0
15	L	>330	72	5	69	6	1
	R	>330	46	4	28	2	0
16	L	>330	60	8	40	3	0
	R	>330	39	4	7	1	0
17	L	>330	56	5	4	0	0
	R	>330	89	11	8	1	0
18	L	>330	113	14	6	0	0
	R	>330	41	6	19	2	0
19	L	>330	53	7	12	1	0
	R	309	35	3	41	5	0
20	L	>330	52	5	34	4	0
	R	233	28	4	15	1	0

TABLE 3 Handrub test procedure – experimental results

Test product: **LogicSept**
Application: 3 ml on dry hands; 30 s rub, performed 2 times
Test date: 11.05.2020
Test strain: *Escherichia coli* K12 NCTC 10538
Microbial suspension: $4{,}1 \cdot 10^8$ cfu/ml

subject		Number of cfu / 1,0 ml TSB on plate from dilutions					
Nr	hand	pre-count			post-count		
	L left/ R right	10^{-3}	10^{-4}	10^{-5}	10^{-1}	10^{-2}	10^{-3}
1	L	208	23	2	15	1	0
	R	310	36	3	32	4	0
2	L	>330	67	6	70	7	1
	R	>330	138	12	197	17	2
3	L	>330	94	13	91	9	1
	R	>330	109	10	42	4	0
4	L	306	34	3	26	3	0
	R	>330	45	6	18	2	0
5	L	>330	147	13	85	7	0
	R	>330	166	21	115	13	0
6	L	>330	56	7	57	6	0
	R	>330	63	8	69	10	1
7	L	211	19	3	11	1	0
	R	89	6	0	5	1	0
8	L	288	34	3	37	5	0
	R	163	14	1	2	0	0
9	L	>330	127	14	230	26	2
	R	>330	151	15	186	18	3
10	L	52	5	0	4	0	0
	R	81	9	1	7	1	0
11	L	>330	173	15	44	5	0
	R	>330	204	19	207	19	2
12	L	>330	78	11	10	1	0
	R	>330	114	12	82	7	1
13	L	>330	39	5	24	3	0
	R	>330	92	11	38	4	0
14	L	>330	79	9	117	13	0
	R	>330	63	5	87	9	1
15	L	>330	130	14	125	11	1
	R	>330	46	3	32	3	0
16	L	>330	60	7	26	2	0
	R	>330	77	9	73	5	1
17	L	>330	96	11	66	8	1
	R	>330	83	12	154	13	1
18	L	>330	54	7	91	8	1
	R	>330	65	7	52	4	0
19	L	>330	80	8	17	2	0
	R	>330	73	10	58	6	1
20	L	>330	45	3	71	9	1
	R	>330	118	15	104	12	1

TABLE 4

Calculated logs (means for two hands) and reduction factors according to tables 2,3

Test person/testing order		Reference procedure (R) 2 – propanol 60%			**Test procedure (P) LogicSept**		
		Log x	Log y	Log z	Log x	Log y	Log z
1	PP/RP	6,29	1,63	4,66	6,41	2,34	4,07
2		6,98	2,35	4,63	6,98	3,07	3,91
3		6,80	2,57	4,23	7,01	2,79	4,22
4		6,86	2,77	4,09	6,57	2,34	4,23
5		6,90	2,57	4,33	7,20	3,00	4,20
6		6,76	2,48	4,28	6,77	2,80	3,97
7		6,34	1,83	4,51	6,13	1,87	4,26
8		6,31	1,69	4,62	6,34	1,93	4,41
9		7,00	2,81	4,19	7,14	3,32	3,82
10		6,15	1,75	4,40	5,81	1,72	4,09
11	RP/PP	6,82	2,61	4,21	7,27	2,98	4,29
12		6,81	2,61	4,20	6,97	2,46	4,51
13		6,71	2,26	4,45	6,78	2,48	4,30
14		6,94	2,05	4,89	6,85	3,00	3,85
15		6,76	2,64	4,12	6,89	2,80	4,09
16		6,68	2,22	4,46	6,83	2,66	4,17
17		6,85	1,75	5,10	6,95	3,00	3,95
18		6,84	2,03	4,81	6,77	2,84	3,93
19		6,61	2,31	4,30	6,88	2,50	4,38
20		6,55	2,35	4,20	6,87	2,93	3,94
Total							
X(m)		6,70	2,26	4,43	6,77	2,64	4,13
S		0,25	0,38	0,28	0,36	0,43	0,20
N		20	20	20	20	20	20
Testing order: PP / RP							
X(m)		6,64	2,25	4,39	6,64	2,52	4,12
S		0,33	0,47	0,2	0,46	0,56	0,18
N		10	10	10	10	10	10
Testing order: RP / PP							
X(m)		6,76	2,28	4,47	6,91	2,77	4,14
S		0,12	0,29	0,34	0,14	0,22	0,22
N		10	10	10	10	10	10

Log x = log of pre-count value
Log y = log of post-count value
Log z = log of reduction factor

S = standard deviation
X(m) = mean
N = number of subjects in the test

Mean reduction for the product (4,13) is lower than for the reference procedure (4,43).

TABLE 5

Computation of individual differences of lgR for:
RP (reference procedure) and PP (test procedure for: LogicSept)

person	Log RF for:		Difference
	RP	PP	RP-PP
1	4,66	4,07	0,59
2	4,63	3,91	0,72
3	4,23	4,22	0,01
4	4,09	4,23	-0,14
5	4,33	4,20	0,13
6	4,28	3,97	0,31
7	4,51	4,26	0,25
8	4,62	4,41	0,21
9	4,19	3,82	0,37
10	4,40	4,09	0,31
11	4,21	4,29	-0,08
12	4,20	4,51	-0,31
13	4,45	4,30	0,15
14	4,89	3,85	1,04
15	4,12	4,09	0,03
16	4,46	4,17	0,29
17	5,10	3,95	1,15
18	4,81	3,93	0,88
19	4,30	4,38	-0,08
20	4,20	3,94	0,26

Statistical comparison – sorting of individual differences and computation for Hodges-Lehmann 97,5% upper confidence limit test.

The agreed inferiority margin is 0,6.

Because only 31 mean-pair differences are larger than 0,6, for the critical value of 52 such differences for 20 paired data different than 0, the hypothesis of inferiority of **PP (test procedure for: LogicSept)** to **RP (reference procedure)** is rejected with level of significance at least 0,25.

Signed off: Lab-test deputy manager.....Date .....