

ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 510917/20/CGDA

A) IDENTIFICATION OF THE SAMPLE:	
Name of the product	ALCO CREME
The active substance	70 % (v/v) CAS nr. 64-17-5 Ethanol
B) TEST METHOD :	
Method	EN 1500:2013 Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2, step 2)
Neutralizer	Polysorbate 80 30 g/l, saponine 30g/l, histidine 1g/l, cysteine 1g/l
C) EXPERIMENTAL CONDITIONS:	
Product test concentrations (%V/V)	100%
Test temperature	20°C
Contact time	3ml of the preparation for 30s
Incubation temperature	36±1 °C
Test-organism	<i>E. coli</i> K12 NCTC 10538

Date: 08.10.2020

Authorized by: Agnieszka Erber, Expert Analyst, Microbiology Laboratory

Approved by: Hanna Wachowska, Laboratory Director (*Approved with qualified electronic signature*)

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Table 1. PROCEDURE FOR REFERENCE HYGIENIC HANDRUB

PRODUCT: Standard 2-propanol 60% (V/V)

 TEST ORGANISM: *E. coli* K12 NCTC 10538

 NUMBER IN CONTAMINATION FLUID: $2,8 \times 10^8$ cfu/g

volunteer		number of cfu per plate from dilution 10x							Reduction	
Nr	Hand left/right	prevalues			postvalues				log z	
		$\times 10^{-4}$	$\times 10^{-5}$	log x	$\times 10^0$	$\times 10^{-1}$	$\times 10^{-2}$	log y		
1	l	176	19	6,23	56	7	0	1,77	4,46	
	r	165	15		61	5	0			
2	l	248	25	6,29	47	5	0	1,72	4,57	
	r	156	16		59	6	0			
3	l	168	17	6,11	55	6	0	1,71	4,40	
	r	100	11		48	5	0			
4	l	192	21	6,29	39	4	0	1,50	4,79	
	r	198	20		25	3	0			
5	l	143	15	6,14	48	5	0	1,76	4,38	
	r	132	14		69	7	0			
6	l	188	21	6,25	71	8	0	1,80	4,45	
	r	172	15		55	6	0			
7	l	176	18	6,27	54	4	0	1,76	4,51	
	r	192	22		62	7	0			
8	l	180	16	6,14	73	8	0	1,85	4,29	
	r	108	11		69	7	0			
9	l	156	16	6,19	54	4	0	1,66	4,53	
	r	152	14		39	4	0			
10	l	130	12	6,12	41	3	0	1,52	4,60	
	r	138	11		28	2	0			
11	l	196	21	6,26	17	2	0	1,32	4,94	
	r	172	16		25	3	0			
12	l	104	11	6,26	31	4	0	1,62	4,64	
	r	314	33		55	6	0			
13	l	152	16	6,09	48	5	0	1,72	4,38	
	r	100	11		56	6	0			
14	l	184	19	6,21	23	3	0	1,32	4,89	
	r	144	12		18	2	0			
15	l	264	27	6,37	32	2	0	1,56	4,81	
	r	208	21		45	2	0			
16	l	215	22	6,38	71	8	0	1,84	4,54	
	r	265	28		66	6	0			
17	l	234	24	6,40	32	3	0	1,45	4,96	
	r	271	28		25	2	0			
18	l	298	31	6,49	41	4	0	1,66	4,83	
	r	312	32		52	3	0			
19	l	301	28	6,49	36	4	0	1,61	4,88	
	r	314	30		45	5	0			
20	l	178	18	6,29	75	8	0	1,78	4,51	
	r	216	22		48	5	0			
Xavg				6,26				1,65	4,62	
s				0,12				0,16	0,21	

log x-logarithm of the average value of the initial left and right hand

log y-logarithm of the average value of the final left and right hand

log z-logarithm reduction

x avg - overall average of log x, log y, log z

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Table 2. HYGIENIC HANDRUB PROCEDURE WITH THE PRODUCT

PRODUCT P

 TEST ORGANISM: *E. coli* K12 NCTC 10538

 NUMBER IN CONTAMINATION FLUID: $2,8 \times 10^8$ cfu/g

volunteer		number of cfu per plate from dilution 10x						Reduction	
Nr	Hand left/right	prevalues			postvalues			log y	log z
		$\times 10^{-4}$	$\times 10^{-5}$	log x	$\times 10^0$	$\times 10^{-1}$	$\times 10^{-2}$		
1	l	162	18	6,19	45	6	0	1,72	4,47
	r	148	12		61	5	0		
2	l	184	20	6,23	38	4	0	1,54	4,69
	r	160	15		32	3	0		
3	l	176	18	6,13	45	5	0	1,71	4,42
	r	104	11		58	6	0		
4	l	172	18	6,13	25	2	0	1,44	4,69
	r	104	10		32	2	0		
5	l	164	15	6,14	47	5	0	1,71	4,43
	r	120	11		56	5	0		
6	l	166	17	6,24	62	7	0	1,66	4,58
	r	184	19		35	2	0		
7	l	196	20	6,22	48	5	0	1,74	4,47
	r	140	12		63	7	0		
8	l	192	21	6,17	18	2	0	1,29	4,88
	r	112	12		21	2	0		
9	l	165	17	6,24	23	3	0	1,46	4,78
	r	181	19		34	4	0		
10	l	111	12	6,04	47	5	0	1,62	4,43
	r	110	10		36	4	0		
11	l	124	13	6,18	58	6	0	1,71	4,48
	r	188	19		46	3	0		
12	l	132	14	6,19	30	2	0	1,36	4,83
	r	182	19		18	2	0		
13	l	192	20	6,29	29	3	0	1,54	4,75
	r	198	21		42	4	0		
14	l	208	22	6,20	65	8	0	1,74	4,47
	r	124	11		45	4	0		
15	l	296	32	6,45	28	2	0	1,47	4,98
	r	272	25		31	4	0		
16	l	191	20	6,31	72	8	0	1,83	4,48
	r	214	22		64	4	0		
17	l	185	19	6,25	15	2	0	1,31	4,95
	r	172	16		26	3	0		
18	l	196	21	6,31	31	4	0	1,55	4,76
	r	214	22		39	5	0		
19	l	254	28	6,43	42	4	0	1,66	4,77
	r	284	31		50	6	0		
20	l	236	24	6,38	63	6	0	1,83	4,55
	r	245	22		72	8	0		
X_{avg}				6,24				1,59	4,64
s				0,10				0,16	0,19

log x-logarithm of the average value of the initial left and right hand

log y-logarithm of the average value of the final left and right hand

log z-logarithm reduction

x avg - overall average of log x, log y, log z

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Table 3. LIST OF COMPUTED IG VALUES AND IG REDUCTIONS

volunteer		R 2-propanol 60% (V/V)			P		
Nr		log x	log y	log z	log x	log y	log z
1	R-P	6,23	1,77	4,46	6,19	1,72	4,47
2	R-P	6,29	1,72	4,57	6,23	1,54	4,69
3	R-P	6,11	1,71	4,40	6,13	1,71	4,42
4	R-P	6,29	1,50	4,79	6,13	1,44	4,69
5	R-P	6,14	1,76	4,38	6,14	1,71	4,43
6	P-R	6,25	1,80	4,45	6,24	1,66	4,58
7	P-R	6,27	1,76	4,51	6,22	1,74	4,47
8	P-R	6,14	1,85	4,29	6,17	1,29	4,88
9	P-R	6,19	1,66	4,53	6,24	1,46	4,78
10	P-R	6,12	1,52	4,60	6,04	1,62	4,43
11	R-P	6,26	1,32	4,94	6,18	1,71	4,48
12	R-P	6,26	1,62	4,64	6,19	1,36	4,83
13	R-P	6,09	1,72	4,38	6,29	1,54	4,75
14	R-P	6,21	1,32	4,89	6,20	1,74	4,47
15	R-P	6,37	1,56	4,81	6,45	1,47	4,98
16	P-R	6,38	1,84	4,54	6,31	1,83	4,48
17	P-R	6,40	1,45	4,96	6,25	1,31	4,95
18	P-R	6,49	1,66	4,83	6,31	1,55	4,76
19	P-R	6,49	1,61	4,88	6,43	1,66	4,77
20	P-R	6,29	1,78	4,51	6,38	1,83	4,55
X ₂₀		6,26	1,65	4,62	6,24	1,59	4,64
X10(R-P)		6,23	1,60	4,63	6,22	1,59	4,62
X10 (P-R)		6,30	1,69	4,61	6,26	1,59	4,66

Criteria:

$$R_s (R-P) = 4,63 - 4,62 = 0,01$$

$$R_s (P-R) = 4,61 - 4,66 = -0,05$$

$$Abs = 0,01 - (-0,05) = 0,06$$

$$\log x(R) = 6,26 > 5$$

$$\log x(P) = 6,24 > 5$$

$$\log z (P), \log z (R) > 3$$

Validation conditions of neutralizer and methods have been satisfied

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Table 4. COMPUTATION OF INDIVIDUAL DIFFERENCES OF lg R-P

volunteer	log RF		difference R-P	difference high to low	Range +/-
	R	P			
1	4,46	4,47	0,00	0,46	1
2	4,57	4,69	-0,12	0,42	2
3	4,40	4,42	-0,02	0,18	3
4	4,79	4,69	0,11	0,11	4
5	4,38	4,43	-0,06	0,11	5
6	4,45	4,58	-0,13	0,07	6
7	4,51	4,47	0,03	0,06	7
8	4,29	4,88	-0,59	0,03	8
9	4,53	4,78	-0,25	0,01	9
10	4,60	4,43	0,18	0,00	10
11	4,94	4,48	0,46	-0,02	-11
12	4,64	4,83	-0,19	-0,04	-12
13	4,38	4,75	-0,37	-0,06	-13
14	4,89	4,47	0,42	-0,12	-14
15	4,81	4,98	-0,17	-0,13	-15
16	4,54	4,48	0,06	-0,17	-16
17	4,96	4,95	0,01	-0,19	-17
18	4,83	4,76	0,07	-0,25	-18
19	4,88	4,77	0,11	-0,37	-19
20	4,51	4,55	-0,04	-0,59	-20
sum range (+): 55					
sum range (-): 155					

Table 5. SORTING OF INDIVIDUAL DIFFERENCES AND COMPUTATION FOR HODGES-LEHMANN 97,5% UPPER CONFIDENCE LIMITS FOR THE DIFFERENCE IN lg BETWEEN R-P

	0,46	0,42	0,18	0,11	0,11	0,07	0,06	0,03	0,01
1	0,46	0,46							
2	0,42	0,44	0,42						
3	0,18	0,32	0,30	0,18					
4	0,11	0,29	0,27	0,15	0,11				
5	0,11	0,29	0,27	0,15	0,11	0,11			
6	0,07	0,27	0,25	0,13	0,09	0,09	0,07		
7	0,06	0,26	0,24	0,12	0,09	0,09	0,07	-0,06	
8	0,03	0,25	0,23	0,11	0,07	0,07	0,05	-0,05	-0,03
9	0,01	0,24	0,22	0,10	0,06	0,06	0,04	-0,04	-0,02
10	0,00	0,23	0,21	0,09	0,06	0,06	0,04	-0,03	-0,02
11	-0,02	0,22	0,20	0,08	0,05	0,05	0,03	-0,02	-0,01
12	-0,04	0,21	0,19	0,07	0,04	0,04	0,02	-0,01	0,01
13	-0,06	0,20	0,18	0,06	0,03	0,03	0,01	0,00	
14	-0,12	0,17	0,15	0,03	-0,01	-0,01	-0,03		
15	-0,13	0,17	0,15	0,03	-0,01	-0,01			
16	-0,17	0,15	0,13	0,00	-0,03				
17	-0,19	0,14	0,12	-0,01					
18	-0,25	0,11	0,09						
19	-0,37	0,05							
20	-0,59								

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Table 6. WILCOXON'S TMATCHED PAIRS SIGNED-RANKS TEST:
CRITICAL VALUES LESS WITH RANG SUM (+) OR (-) AT DIFFERENT LEVELS OF SIGNIFICANCE

n	one-sided level of significance		
	0,05	0,025	0,01
18	47	40	32
19	53	46	27
20	60	52	43
21	68	59	49
22	75	66	56

For the designated level of significance 0,025 for n=20 the value read from the table 6 is 52.

Hence $c = 52+1 = 53$.

For the distribution of 53 Table 5 assigns a value of 0,09 which is less than the agreed inferiority margin of 0,6.

Therefore, the hypothesis of inferiority of PP compared to the reference RP is rejected.

The test preparation (PP) is non-inferior to RP.

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