

LAB – TEST LABORATORIUM S.C.
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AB 815

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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..... 37°C ± 1°C; 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 : 1,2·10 ² Nv _B : 1,2·10 ⁵	Vc: 102;129 B: 1,2·10 ²	Vc: 69;73 C: 7,1·10 ¹

N_v - cfu/ml in the bacterial suspension in the dilution-neutralization control test, Nv₀ = N_v/10N_{vB} - 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

$C \geq 0,5 N_{v_0}$

-

met

$3,0 \cdot 10^4 \leq N_{vB} \leq 1,6 \cdot 10^5$

-

met

$B \geq 0,0005 N_{vB}$

-

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

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

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