

## Test Report for BS EN 1500:2013

**Results:**
**Inoculum (N)** – 4.90x 10<sup>8</sup> cfu/ml

**Reference Handrub:** Reference (60% Propan-2-ol)

Subject	Hand	Mean Pre Value	Mean L+R	Mean Log Pre Value	Mean Post Value	Mean L+R	Mean Log Post Value	Log Reduction Factor
1	L	6.66E+06	6.04E+06	6.78	3.30E+03	4.40E+03	3.64	3.14
	R	5.41E+06			5.50E+03			
2	L	8.50E+05	9.25E+05	5.97	1.95E+03	2.88E+03	3.46	2.51
	R	1.00E+06			3.80E+03			
3	L	1.03E+06	8.45E+05	5.93	5.80E+02	5.85E+02	2.77	3.16
	R	6.60E+05			5.90E+02			
4	L	3.60E+06	2.50E+06	6.40	1.39E+03	2.30E+03	3.36	3.04
	R	1.40E+06			3.20E+03			
5	L	1.80E+06	2.05E+06	6.31	2.50E+03	2.75E+03	3.44	2.87
	R	2.30E+06			3.00E+03			
6	L	5.80E+06	4.05E+06	6.61	2.10E+02	1.63E+03	3.21	3.40
	R	2.30E+06			3.05E+03			
7	L	5.10E+06	5.65E+06	6.75	2.60E+03	2.05E+03	3.31	3.44
	R	6.20E+06			1.50E+03			
8	L	2.70E+06	2.80E+06	6.45	2.70E+02	7.19E+03	3.86	2.59
	R	2.90E+06			1.41E+04			
9	L	4.80E+06	4.50E+06	6.65	3.40E+03	4.40E+03	3.64	3.01
	R	4.20E+06			5.40E+03			
10	L	2.17E+06	1.46E+06	6.16	9.40E+02	1.44E+03	3.16	3.00
	R	7.40E+05			1.94E+03			
11	L	5.60E+06	4.80E+06	6.68	4.40E+02	9.70E+02	2.99	3.69
	R	4.00E+06			1.50E+03			
12	L	6.10E+06	5.75E+06	6.76	5.30E+02	1.02E+03	3.01	3.75
	R	5.40E+06			1.50E+03			
13	L	7.10E+05	7.00E+05	5.85	2.80E+02	5.10E+02	2.71	3.14
	R	6.90E+05			7.40E+02			
14	L	9.20E+05	8.75E+05	5.94	4.50E+02	7.15E+02	2.85	3.09
	R	8.30E+05			9.80E+02			
15	L	6.50E+06	7.50E+06	6.88	6.30E+02	1.87E+03	3.27	3.60
	R	8.50E+06			3.10E+03			
16	L	3.60E+06	3.80E+06	6.58	4.00E+02	3.50E+02	2.54	4.04
	R	4.00E+06			3.00E+02			
17	L	3.30E+06	3.40E+06	6.53	1.74E+03	1.32E+03	3.12	3.41
	R	3.50E+06			8.90E+02			
18	L	8.50E+06	9.25E+06	6.97	3.60E+03	3.85E+03	3.59	3.38
	R	1.00E+07			4.10E+03			

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**Test Product: Hand Sanitiser (063/20A)**

Subject	Hand	Mean Pre Value	Mean L+R	Mean Log Pre Value	Mean Post Value	Mean L+R	Mean Log Post Value	Log Reduction Factor
1	L	1.00E+07	8.25E+06	6.92	3.10E+02	2.56E+02	2.41	4.51
	R	6.50E+06			2.01E+02			
2	L	1.80E+06	1.35E+06	6.13	1.04E+03	9.75E+02	2.99	3.14
	R	9.00E+05			9.10E+02			
3	L	2.70E+06	3.10E+06	6.49	1.90E+03	1.40E+03	3.15	3.35
	R	3.50E+06			9.00E+02			
4	L	1.91E+06	1.81E+06	6.26	3.80E+02	3.60E+02	2.56	3.70
	R	1.70E+06			3.40E+02			
5	L	5.00E+05	1.10E+06	6.04	3.00E+02	2.75E+02	2.44	3.60
	R	1.70E+06			2.50E+02			
6	L	2.20E+06	1.70E+06	6.23	2.70E+02	3.45E+02	2.54	3.69
	R	1.20E+06			4.20E+02			
7	L	3.70E+06	4.50E+06	6.65	3.00E+02	6.65E+02	2.82	3.83
	R	5.30E+06			1.03E+03			
8	L	3.50E+05	2.08E+06	6.32	2.12E+02	4.06E+03	3.61	2.71
	R	3.80E+06			7.90E+03			
9	L	3.50E+06	4.65E+06	6.67	1.20E+03	1.65E+03	3.22	3.45
	R	5.80E+06			2.10E+03			
10	L	2.30E+06	1.75E+06	6.24	6.20E+02	9.10E+02	2.96	3.28
	R	1.20E+06			1.20E+03			
11	L	2.50E+06	2.85E+06	6.45	1.31E+03	9.40E+02	2.97	3.48
	R	3.20E+06			5.70E+02			
12	L	2.50E+06	2.25E+06	6.35	6.40E+02	4.20E+02	2.62	3.73
	R	2.00E+06			2.00E+02			
13	L	7.80E+05	7.25E+05	5.86	2.90E+02	8.45E+02	2.93	2.93
	R	6.70E+05			1.40E+03			
14	L	5.90E+06	5.00E+06	6.70	4.30E+02	6.65E+02	2.82	3.88
	R	4.10E+06			9.00E+02			
15	L	5.20E+06	4.80E+06	6.68	3.40E+03	1.95E+03	3.29	3.39
	R	4.40E+06			5.00E+02			
16	L	3.30E+06	2.85E+06	6.45	3.50E+02	2.50E+02	2.40	4.06
	R	2.40E+06			1.50E+02			
17	L	1.70E+06	1.90E+06	6.28	3.00E+02	3.40E+02	2.53	3.75
	R	2.10E+06			3.80E+02			
18	L	3.40E+06	4.15E+06	6.62	5.20E+02	4.80E+02	2.68	3.94
	R	4.90E+06			4.40E+02			

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**Summary:**

	<b>Mean of Pre-Values (Log)</b>	<b>Mean of Post-Values (Log)</b>
Reference Product	6.45	3.22
Test Product	6.41	2.83

	<b>Mean Log Reduction</b>
Reference Product	3.23
Test Product	3.58

	RP-PP	PP-RP
Mean lg R RP	3.02	3.46
Mean lg R PP	3.55	3.60
Difference of Means	-0.53	-0.14

Absolute Difference of Differences  $(-0.53 - (-0.14)) = -0.39$   
 (<2.0 hence acceptable).

**Validations:**

Neutraliser Control B (NV<sub>B</sub>  $3.0 \times 10^4 - 1.6 \times 10^5$  cfu/ml) – Inoculum  $7.85 \times 10^4$ cfu/ml

<b>Organism</b>	<b>Cfu/ml</b>
<i>E. coli</i> K12	$4.20 \times 10^1$

Method Validation C (NV  $3.0 \times 10^2 - 1.6 \times 10^3$  cfu/ml) – Inoculum  $4.60 \times 10^2$ cfu/ml

<b>Product</b>	<b><i>E. coli</i> (cfu/ml)</b>
Test Product 16285	$3.45 \times 10^1$

**Verification:**

A complete set of results from at least 18 volunteers is available.

The overall means of the Ig prevalues for RP and PP is at least 5.00.

There are no more than three individual Ig reductions less than 3.00 occurring in RP.

The absolute difference of mean differences between Ig reductions of RP and PP of group

RP → PP and group PP → RP is less than 2.00.

Control of weighted mean counts: quotient  $>5 < 15$ .

N is between  $1.5 \times 10^8$  and  $5.0 \times 10^8$

NV is between  $3.0 \times 10^2$  and  $1.6 \times 10^3$

NV<sub>B</sub> is between  $3.0 \times 10^4$  and  $1.6 \times 10^5$

B is  $\geq 0.0005 \times NV_B$

C is  $\geq 0.5 \times NV_0$

**Reduction Factor Difference:**

Subject	Reduction Factor Difference
1	-1.37
2	-0.63
3	-0.19
4	-0.66
5	-0.73
6	-0.30
7	-0.39
8	-0.12
9	-0.44
10	-0.28
11	0.21
12	0.02
13	0.20
14	-0.79
15	0.21
16	-0.02
17	-0.33
18	-0.56

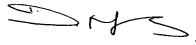
**Hodges-Lehmann 97.5% Upper Confidence Limits:**

Sorted Differences	Mean Pairwise Differences						
	0.21	0.21	0.20	0.02	-0.02	-0.12	-0.19
0.21	0.21						
0.21	0.21	0.21					
0.20	0.21	0.21	0.20				
0.02	0.12	0.12	0.11	0.02			
-0.02	0.10	0.10	0.09	0.00			
-0.12	0.05	0.05	0.04				
-0.19	0.01	0.01	0.01				
-0.28							
-0.30							
-0.33							
-0.39							

The median is between the 9th and 10th value:  $(-0.30 + (-0.33)) / 2 = -0.32$

The mean pairwise differences that do not exceed the median (here -0.32) are computed. The critical values for Wilcoxon's matched pairs signed ranks test the entry for  $n=18$  and a one-sided 0.025 level of significance, the critical value of 40 is found. Hence,  $c = 40 + 1 = 41$ . The 41st entry is  $<0.0$ . Hence, the Hodges-Lehmann upper one sided 97.5% confidence limit for the difference in lg reductions between RP and PP is  $<0.0$  which is less than the agreed inferiority margin of 0.6 lg units. Therefore, the hypothesis of inferiority of PP (test product) is rejected and it can be concluded that the test preparation PP is not inferior to RP (reference product).

Report Authorised By:



Dawn Mellors

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Technical Director

This is the end of the test report