

Customer Details: Ingenia Life Solutions Ltd.

Customer Contact Name: Dan Gay

Purchase Order Number: N/A

Date of Report: 21.06.20

Date on Test: 11.06.20

Date Received: 20.05.20

MelBec Reference Number: 17505

No. of samples: 1

Sample Details:

Manufacturer/Supplier: Ingenia Life Solutions Ltd

Name of Product: Ingen Hand Gel

Storage: Room Temperature

Experimental Conditions as outlined in the standard:

Neutraliser: BU Broth

Bacterial Strains: *E. coli* K12 NCTC 10538

Product Dilution: Neat (as supplied)

Test Product Application: 5ml applied to dry hands. Hands rubbed for 60s.

Incubation Temperature: 36°C ± 1°C

Conclusion:

The test product was not inferior to the reference product and hence has met the requirements of EN 1500.

Test Report for BS EN 1500:2013

Results:
Inoculum (N) – 3.00 x 10⁸ 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	9.40E+05	1.12E+06	6.05	1.18E+03	1.09E+03	3.04	3.01
	R	1.29E+06			9.90E+02			
2	L	1.23E+06	1.57E+06	6.20	7.50E+02	9.15E+02	2.96	3.23
	R	1.91E+06			1.08E+03			
3	L	3.60E+06	2.73E+06	6.44	1.90E+02	2.28E+02	2.36	4.08
	R	1.86E+06			2.65E+02			
4	L	5.10E+05	8.30E+05	5.92	1.34E+03	1.34E+03	3.13	2.79
	R	1.15E+06			1.34E+03			
5	L	4.10E+06	4.00E+06	6.60	5.60E+02	2.58E+03	3.41	3.19
	R	3.90E+06			4.60E+03			
6	L	1.60E+06	1.44E+06	6.16	5.50E+02	1.38E+03	3.14	3.02
	R	1.27E+06			2.20E+03			
7	L	1.02E+06	1.16E+06	6.06	5.50E+02	6.50E+02	2.81	3.25
	R	1.30E+06			7.50E+02			
8	L	6.80E+05	2.24E+06	6.35	3.00E+02	1.65E+03	3.22	3.13
	R	3.80E+06			3.00E+03			
9	L	9.20E+06	4.79E+06	6.68	2.60E+02	9.30E+02	2.97	3.71
	R	3.70E+05			1.60E+03			
10	L	4.20E+05	1.81E+06	6.26	3.00E+02	3.45E+02	2.54	3.72
	R	3.20E+06			3.90E+02			
11	L	8.30E+05	8.75E+05	5.94	2.30E+02	6.50E+02	2.81	3.13
	R	9.20E+05			1.07E+03			
12	L	1.30E+05	1.19E+05	5.07	2.00E+02	1.80E+02	2.26	2.82
	R	1.07E+05			1.60E+02			
13	L	8.30E+05	2.57E+06	6.41	6.60E+02	2.38E+03	3.38	3.03
	R	4.30E+06			4.10E+03			
14	L	1.40E+05	2.35E+05	5.37	3.60E+02	3.35E+02	2.53	2.85
	R	3.30E+05			3.10E+02			
15	L	4.20E+06	3.85E+06	6.59	3.00E+02	3.10E+02	2.49	4.09
	R	3.50E+06			3.20E+02			
16	L	3.50E+05	4.95E+05	5.69	3.00E+02	4.50E+02	2.65	3.04
	R	6.40E+05			6.00E+02			
17	L	8.50E+06	7.10E+06	6.85	2.70E+03	4.15E+03	3.62	3.23
	R	5.70E+06			5.60E+03			
18	L	7.30E+05	1.04E+06	6.02	3.00E+02	4.50E+02	2.65	3.36
	R	1.35E+06			6.00E+02			

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Test Product: Solo Hand Gel

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	1.16E+06	1.13E+06	6.05	1.80E+03	4.80E+03	3.68	2.37
	R	1.10E+06			7.80E+03			
2	L	1.40E+06	1.08E+06	6.03	1.60E+02	2.30E+02	2.36	3.67
	R	7.60E+05			3.00E+02			
3	L	4.30E+06	4.00E+06	6.60	1.10E+03	1.40E+03	3.15	3.46
	R	3.70E+06			1.70E+03			
4	L	3.20E+06	2.85E+06	6.45	4.30E+03	9.65E+03	3.98	2.47
	R	2.50E+06			1.50E+04			
5	L	3.00E+06	4.50E+06	6.65	1.46E+03	4.03E+03	3.61	3.05
	R	6.00E+06			6.60E+03			
6	L	8.80E+05	9.55E+05	5.98	6.80E+02	8.65E+02	2.94	3.04
	R	1.03E+06			1.05E+03			
7	L	4.50E+06	4.40E+06	6.64	3.10E+03	3.55E+03	3.55	3.09
	R	4.30E+06			4.00E+03			
8	L	2.40E+06	2.55E+06	6.41	5.20E+02	4.65E+02	2.67	3.74
	R	2.70E+06			4.10E+02			
9	L	2.70E+06	2.25E+06	6.35	6.90E+02	4.90E+02	2.69	3.66
	R	1.80E+06			2.90E+02			
10	L	5.70E+06	7.15E+06	6.85	8.50E+02	8.60E+02	2.93	3.92
	R	8.60E+06			8.70E+02			
11	L	9.90E+05	5.50E+05	5.74	2.30E+02	4.40E+02	2.64	3.10
	R	1.10E+05			6.50E+02			
12	L	1.69E+06	1.34E+06	6.13	1.40E+02	2.00E+02	2.30	3.82
	R	9.80E+05			2.60E+02			
13	L	7.60E+05	5.90E+05	5.77	1.38E+03	1.03E+03	3.01	2.76
	R	4.20E+05			6.80E+02			
14	L	1.15E+06	6.53E+05	5.81	1.40E+03	1.50E+03	3.18	2.64
	R	1.55E+05			1.60E+03			
15	L	4.00E+06	2.90E+06	6.46	1.51E+03	1.41E+03	3.15	3.31
	R	1.80E+06			1.30E+03			
16	L	4.70E+05	6.25E+05	5.80	4.60E+02	1.73E+03	3.24	2.56
	R	7.80E+05			3.00E+03			
17	L	3.10E+06	2.95E+06	6.47	1.40E+03	2.30E+03	3.36	3.11
	R	2.80E+06			3.20E+03			
18	L	1.90E+05	1.81E+05	5.26	8.80E+02	5.89E+03	3.77	1.49
	R	1.72E+05			1.09E+04			

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Summary:

	Mean of Pre-Values (Log)	Mean of Post-Values (Log)
Reference Product	6.15	2.89
Test Product	6.19	3.12

	Mean Log Reduction
Reference Product	3.26
Test Product	3.07

	RP-PP	PP-RP
Mean lg R RP	3.27	3.25
Mean lg R PP	3.17	2.97
Difference of Means	0.10	0.28

Absolute Difference of Differences (0.10 – 0.28) = -0.18
 (<2.0 hence acceptable).

Validations:

Neutraliser Control B (NV_B 3.0 x 10⁴ – 1.6 x 10⁵ cfu/ml) – Inoculum 9.75 x 10⁴cfu/ml

Organism	Cfu/ml
<i>E. coli</i> K12	8.25 x 10 ¹

Method Validation C (NV 3.0 x 10² – 1.6 x 10³ cfu/ml) – Inoculum 6.65 x 10²cfu/ml

Product	<i>E. coli</i> (cfu/ml)
Test Product 17505	6.15 x 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 1.5×10^8 and 5.0×10^8

NV is between 3.0×10^2 and 1.6×10^3

NV_B is between 3.0×10^4 and 1.6×10^5

B is $\geq 0.0005 \times NV_B$

C is $\geq 0.5 \times NV_0$

Reduction Factor Difference:

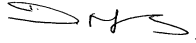
Subject	Reduction Factor Difference
1	0.64
2	-0.44
3	0.62
4	0.32
5	0.14
6	-0.02
7	0.16
8	-0.61
9	0.05
10	-0.20
11	0.03
12	-1.01
13	0.27
14	0.21
15	0.78
16	0.48
17	0.13
18	1.88

Sorted Differences	Mean Pairwise Differences									
	1.88	0.78	0.64	0.62	0.48	0.32	0.27	0.21	0.16	0.14
1.88	1.88									
0.78	1.33	0.78								
0.64	1.26	0.71	0.64							
0.62	1.25	0.70	0.63	0.62						
0.48	1.18	0.63	0.56	0.55	0.48					
0.32	1.10	0.55	0.48	0.47	0.40	0.32				
0.27	1.08	0.53	0.46	0.45	0.38	0.30	0.27			
0.21	1.04	0.49	0.42	0.42	0.35	0.26	0.24	0.21		
0.16	1.02	0.47	0.40	0.39	0.32	0.24	0.22	0.18	0.16	
0.14	1.01	0.46	0.39	0.38	0.31	0.23	0.21	0.18	0.15	
0.13	1.00	0.45	0.38	0.37	0.30	0.22	0.20	0.17		
0.05	0.96	0.41	0.34	0.34	0.27	0.19	0.16			
0.03	0.95	0.41	0.34	0.33	0.26	0.18				
-0.02	0.93	0.38	0.31	0.30	0.23					
-0.20	0.84	0.29	0.22	0.21						
-0.44	0.72	0.17	0.10							
-0.61	0.63	0.09								
-1.01	0.44									

The median is between the 9th and 10th value: $(0.16 + 0.14) / 2 = 0.15$

The mean pairwise differences that do not exceed the median (here 0.15) 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 0.41. Hence, the Hodges-Lehmann upper one sided 97.5% confidence limit for the difference in lg reductions between RP and PP is 0.41 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

Technical Director

This is the end of the test report