

**Comparison of Clinell Biocidal Wipes with
Purell Alcohol Hand Gel Using the Protocol
Outline in BSEN1500**

~

**Project Report Prepared for GAMA
Healthcare Ltd**

~

**Prepared by
Dr Paul Humphreys
July '06**



Commercial in Confidence

Comparison of Clinell Biocidal Wipes with Alcohol Hand Gel Using the Protocol Outline in BSEN1500:1997

July 2006

Author: P. Humphreys

Executive Summary

The aim of this work was to compare the biocidal efficiency of Clinell biocidal wipes with a commercially available alcohol hand gels to demonstrate that the Clinell wipes were as effective as the alcohol gels. This comparison was carried out using a modification of the protocol outlined in BSEN1500:1997[1]. The most significant departure from BSEN1500:1997 was to use of 5 volunteers rather than the 15 specified in the test. The volunteers used were all graduate students with microbiological training, however none were familiar with the standard hand washing protocol employed in the NHS. Volunteers were trained in the standard hand washing procedure prior to carrying out the test.

The test was carried out using a 1.1×10^9 cfu/ml culture of E.coli K12 NCTC 10538. Using 1 Clinell wipe the average \log_{10} reduction in bacterial load was 2.8. The corresponding test with 0.8g of the hand gel generated a \log_{10} reduction of 2.0. Comparison of the two data sets using the Wilcoxon Matched Pairs Signed Rank test as specified in BSEN1500:1997[1] indicated that the Clinell wipes were significantly more effective than the alcohol gel under these test conditions.

A number of the volunteers commented that the alcohol gel had dried before they had finished the washing procedure (duration 30 seconds). The standard hand washing procedure (Appendix 1) begins by focussing on the palms and backs of the hands and focuses on the fingers towards the end of the procedure. Since BSEN1500:1997 compares bacterial counts from the finger tips, drying of the alcohol gel before the end of the process may explain the low reduction factors seen with the alcohol gel. The Clinell wipes remained moist through out the test.

To conclude these results indicate that the Clinell wipes are as effective and potentially more effective than commonly available alcohol gels at sanitising the hands.

Table of Contents

1	Introduction.....	1
1.1	Selection of Volunteers.....	1
1.2	Ethics.....	1
2	Experimental Procedure.....	1
2.1	Media, Equipment and Reagents.....	1
2.2	Preparation of the contamination fluid.....	1
2.3	Application of the contamination fluid.....	2
2.4	Prevalues.....	2
2.5	Hygienic handrub procedure.....	2
2.6	Postvalues.....	3
3	Results.....	3
3.1	Contamination Fluid.....	3
3.2	Test Results.....	3
4	References.....	5
5	Appendix 1.....	7
6	Appendix 2.....	8

Comparison of Clinell Biocidal Wipes with Purell Alcohol Hand Gel Using the Protocol Outline in BSEN1500

1 Introduction

The aim of this work was to compare the effectiveness of Clinell biocidal wipes with commercially available alcohol gels when used to sanitise the hands. This comparison employs a modified version of the standard protocol outlined in BSEN1500:1997[1]. The main departure from BSEN1500:1997 being the use of 5 volunteers rather than the 15 specified in the test.

1.1 Selection of Volunteers

All volunteers used were drawn from the School of Applied Sciences University of Huddersfield. The volunteers used were all graduate students with microbiological training, however none were familiar with the standard hand washing protocol employed in the NHS and consequently the volunteers were trained in the standard hand washing procedure prior to carrying out the test.

1.2 Ethics

The test was carried out inline with guidance provided by the Chair of the University Ethics Committee and the Chair of the School of Applied Sciences Research Committee.

2 Experimental Procedure

2.1 Media, Equipment and Reagents

All media, equipment and reagents used were as specified in BSEN1500:1997.

2.2 Preparation of the contamination fluid

The bacteria used was *E.coli* K12 NCTC 10538 provided by the NCIMB. A new freeze dried culture was sourced specifically for the test. The

contamination fluid was prepared by grow the *E. coli* in two tubes containing 10 ml of Tryptone Soya Broth (TSB) for 24 h at 37 °C. These two cultures were then used to inoculate four 1 litre flasks containing 500ml of TSB. These flasks were incubated for 24 h at 37 °C in an orbital shaker. Immediately prior to the test the contents of these flasks were mixed to generate a stock *E. coli* broth. The total bacterial content of this broth was estimated by reference to a standard curve of transmission (@ 600nm) against cell numbers. If necessary the broth was diluted with sterile diluent to produce a contamination fluid containing between 2×10^8 cfu/ml and 2×10^9 cfu/ml. Once the contamination fluid was prepared the fial bacterial count was determined via serial dilution and plating out on Tryptone Soya Agar (TSA).

2.3 Application of the contamination fluid

Prior to the application of contamination fluid the volunteers washed their hands for 1 min with soft soap to remove natural transients. Following washing the hands were dried on paper towels. Following drying the volunteers immersed their hands in the contamination fluid up to the mid-metacarpals for 5 s with fingers spread apart. The hands were then allowed to dry in air for 3 min, by holding them horizontally with fingers spread out and rotating them occasionally.

The same batch of contamination fluid was used throughout the test.

2.4 Prevalues

Immediately after drying each volunteer rubbed their fingertips (including that of the thumb) for 1 min on the base of a Petri dish containing 10 ml of TSB. A separate Petri dish was used for each hand. These sampling fluids were diluted to 10^{-3} and 10^{-4} in diluent and 0,1 ml of each dilution was plated out via the spread plate technique.

2.5 Hygienic handrub procedure

Immediately after sampling for the prevalues and without recontaminating the hands, the volunteers performed the handrub procedure with either the

alcohol gel or the Clinell wipe. In the case of the alcohol gel two applications (approximately 0.8g) were placed in the palm of one hand and the hands were rubbed vigorously for 30 s following the standard handrub procedure outlined in Appendix 1. In the case of the Clinell wipes each volunteer was provided with 1 wipe. The standard hand rub procedure was performed with the wipe between the hands or fingers.

2.6 Postvalues

Immediately after performing the hand rub procedure each volunteer rubbed their fingertips and thumbtips on the base of a Petri dish containing 10 ml TSB for 1 min. A separate Petri dish was used for each hand. Following sampling for the post values 10^{-1} and 10^{-2} dilutions of the sampling fluid were prepared. Bacterial counts in 1.0ml, 0.1ml of the sampling fluid and 0.1ml of each dilution were determined using the filtration approach outlined in BSEN1276 [2]. Following filtration the filters were placed on the surface of TSA and incubated at 37°C for 24 hours. The filtration technique was employed to overcome the difficulties of neutralising alcohol based products.

3 Results

Microbial counts and \log_{10} reductions in counts were calculated as outlined in BSEN1500:1997. Statistical analysis was carried out using the Wilcoxon Matched Pairs Signed Rank test. T-values for a samples size of 5 were obtained from University of Oxford (2005).

3.1 Contamination Fluid

Plate counts from the contamination fluid indicated a total viable count of 1.1×10^9 cfu/ml E.coli K12 NCTC 10538. This falls within the range specified by BSEN1500:1997 of 2.0×10^8 cfu/ml to 2.0×10^9 cfu/ml.

3.2 Test Results

Calculated \log_{10} values derived from the mean counts (right and left hand) are outlined in Table 1 along with the corresponding reduction factors. Data in Table 1 was used to prepare the statistical comparison using the

Commercial in Confidence

Wilcoxon's matched pairs signed rank test [1] (Table 2). When compared against the relevant statistical tables (Appendix 2 [3]) at the 0.1 level of significance (90%) the minimum sum of ranks (0 See Table 2) is lower than the tabulated value of 2 (See Appendix 2). Indicating that under these test conditions the Clinell wipes are significantly more effective than the alcohol gel.

Subject	Clinell			Alcohol Gel		
	Log Prevalues	Log Postvalues	Log Reduction Factor (RF)	Log Prevalues	Log Postvalues	Log Reduction Factor (RF)
1	7.1	4.1	3.0	6.3	4.8	1.4
2	6.4	4.6	1.9	6.1	4.8	1.4
3	6.7	3.2	3.5	6.8	3.4	3.3
4	7.1	4.6	2.5	6.4	5.0	1.4
5	7.0	4.0	3.0	6.3	3.9	2.4
Mean	6.9	4.1	2.8	6.4	4.4	2.0

Table 1. Mean Count Log₁₀ Values and Corresponding Log₁₀ Reduction values

Subject	Log RF Derived From		Difference	Rank of Difference	
	Clinell	Alcohol Gel		Without Sign	With Sign
1	3.0	1.4	1.5	5	5
2	1.9	1.4	0.5	2	2
3	3.5	3.3	0.1	1	1
4	2.5	1.4	1.1	4	4
5	3.0	2.4	0.6	3	3
Sum of Rank (+) = 15					
Sum of Rank (-) = 0					

Table 2. Statistical Comparison of Experimental Data using Wilcoxon's Matched-Pair Signed-Rank Test.

4 Discussion and Conclusions

The aim of this test was to compare the effectiveness of Clinell biocidal wipes with alcohol hand gels using a simplified version of the approach outlined in BSEN 1500:1997[1]. The main simplification being the use of 5 volunteers rather than the 15 specified by BSEN 1500:1997[1].

The test results indicate that the Clinell wipes are as good, if not better, than the alcohol hand gel. The results indicate that the Clinell wipes were significantly better than the hand gel under these test conditions. However, since a panel size of only 5 was used this significant improvement should be treated with some caution.

Feedback from the panel suggested that one advantage of the wipes were the fact that they stayed moist for the duration of the hand washing process. On the other hand the panel felt that the alcohol gel dried out before the standard hand washing protocol was complete. This may explain the low reduction factors (Table 1) seen with the alcohol gels. The standard hand washing protocol may also be contributing to these low reduction factors. Since it starts focussing on the palms and backs of the hand and then moves onto the fingers. Since the BSEN1500:1997[1] protocol samples the finger tips, it is possible that the alcohol gel had dried before the panel had reached the section of the hand washing protocol which focuses on the fingers. This suggests that wipes are more appropriate for hand sanitisation than gels due to the active ingredients being present through out the hand washing. This may be particularly the case with non-health professionals who are not as aware of the need to focus on the finger and thumb tips when sanitising the hands.

5 References

[1] BSI (1997) BS EN1500:1997 Chemical Disinfectants and Antiseptics-Hygienic Handrub-test Method and Requirements (Phase 2/Step2).

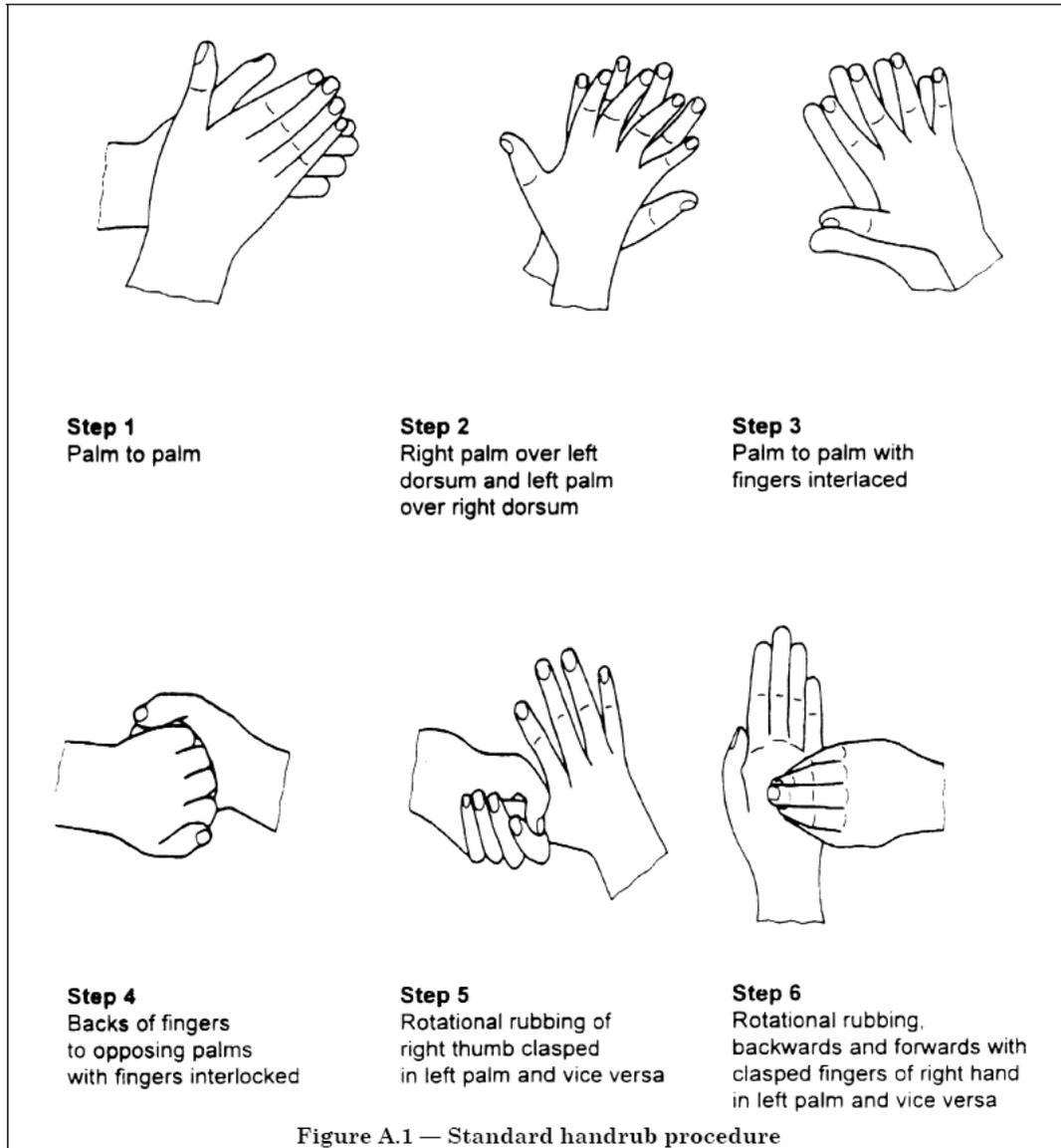
Commercial in Confidence

[2] BSI (1997) BS EN1276:1997 Chemical Disinfectants and Antiseptics- Quantitative Suspension Test for the Evaluation of Bactericidal Activity of Chemical Disinfectants and Antiseptics used in Food, Industrial, Domestic and Institutional Areas – Test Method and Requirements (Phase 2/Step1).

[3] University of Oxford (2005) Definitions and Formulae with Statistical Tables for Elementary Statistics and Quantitative Methods Courses. Department of Statistics, University of Oxford.

6 Appendix 1

Standard hand rub procedure [1].



7 Appendix 2

Critical Values for T in the Wilcoxon Matched-Pairs Signed-Rank Test [2]. For a significant result calculated values of T must be equal to or less than the tabulated value.

n	P = 0.10	P = 0.05
5	2	-
6	2	0
7	3	2
8	5	3
9	8	5
10	10	8
11	14	10
12	17	13
13	21	17
14	26	21
15	30	25
16	36	29
17	41	34
18	47	40
19	53	46
20	60	52
21	67	58
22	75	65
23	83	73
24	91	81
25	100	89