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March 12, 2009

FINAL REPORT #081211-150

DETERMINATION OF THE ANTIMICROBIAL EFFICACY OF THREE (3) TEST ARTICLES USED IN FOUR (4) APPLICATION CONFIGURATIONS USING A VARIATION OF THE HEALTH CARE PERSONNEL HANDWASH PROCEDURE

Prepared for:

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EXECUTIVE SUMMARY

Twelve subjects used each of the four test article configurations over the course of two consecutive hand contaminations with *Escherichia coli* (ATCC #11229) in a beef broth medium as the indicator microorganism for each configuration. The four test configurations were assigned randomly according to an incomplete crossover design; that is, the order of use of each configuration was randomly determined. The first was followed by a sample for baseline, and the second by a product application. The subject then decontaminated their hands with a 70% ethanol rinse and a nonmedicated soap wash, and used a second test article configuration. This procedure was repeated twice more with the remaining test article configurations. The baseline and all post-application samples were evaluated for the presence of *Escherichia coli* (ATCC #11229). Testing was performed per a modification of the methodology in the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450).

The critical index for this study was a 2.0 $\log_{10}$ reduction in baseline populations after product application.

For Test Article #1, GOJO Luxury Foam Handwash (5400-520; Lot Number 322503), applied per Test Article Configuration #1 Application Procedure (two pumps [approximately 1.4 mL] of Test Article #1 into wet hands, 15-second lather, 10-second rinse, pat-dry hands with paper towels), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean $\log_{10}$ reduction of 2.92 after product application and met the critical index of the study.

For Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), applied per Test Article Configuration #2 Application Procedure (one pump [approximately 1.5 mL] of Test Article #2 rubbed until dry), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2, applied per Test Article Configuration #2 Application Procedure, produced a mean $\log_{10}$ reduction of 4.44 after product application and met the critical index of the study.

For Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), applied per Test Article Configuration #3 Application Procedure (two pumps [approximately 3.0 mL] of Test Article #2, pat-dry hands with paper towels, then an additional one pump [approximately 1.5 mL] rubbed until dry), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2, applied per Test Article Configuration #3 Application Procedure, produced a mean $\log_{10}$ reduction of 4.61 after product application and met the critical index of the study.

For Test Article #3, PURELL® Instant Hand Sanitizer Foam (9800-502; Lot Number 320887), applied per Test Article Configuration #4 Application Procedure (four pumps [approximately 2.8 mL] of Test Article #3, pat-dry hands with paper towels, then an additional two pumps [approximately 1.4 mL] rubbed until dry), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 produced a mean $\log_{10}$ reduction of 3.64 after product application and met the critical index of the study.

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1.0 TITLE: **DETERMINATION OF THE ANTIMICROBIAL EFFICACY OF THREE (3) TEST ARTICLES USED IN FOUR (4) APPLICATION CONFIGURATIONS USING A VARIATION OF THE HEALTH CARE PERSONNEL HANDWASH PROCEDURE**

2.0 SPONSOR: **GOJO INDUSTRIES, INC.**
One GOJO Plaza, Suite 500
Akron, Ohio 44311

3.0 TESTING FACILITY: **BIOSCIENCE LABORATORIES, INC.**
300 N. Willson Avenue
Bozeman, Montana 59715

4.0 STUDY DIRECTORS:

Robert R. McCormack - Principal Study Director
Kendra Drake - Associate Study Director

5.0 PURPOSE OF STUDY:

The purpose of this study was to evaluate the antimicrobial efficacy of three test articles used in four application configurations using a modification of the Health Care Personnel Handwash evaluation for use in the food service industry.

6.0 SCOPE:

A total of twelve subjects used each of the four test article configurations over the course of two consecutive hand contaminations with *Escherichia coli* (ATCC #11229) in a beef broth medium as the indicator microorganism for each configuration. The first was followed by a sample for baseline, and the second by a product application. The subject then decontaminated their hands with a 70% ethanol rinse and a nonmedicated soap wash, and used a second test article configuration. This procedure was repeated twice more with the remaining test article configurations. The baseline and all post-application samples were evaluated for the presence of *Escherichia coli* (ATCC #11229). The four test configurations were assigned randomly according to an incomplete crossover design; that is, the order of use of each configuration was randomly determined. Testing was performed per a modification of the methodology in the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450). The Study Protocol was approved by the Gallatin Institutional Review Board (GIRB) on 02/10/09. No deviations from the methodology described in the Study Protocol or from BioScience Laboratories, Inc., Standard Operating Procedures occurred during the course of this evaluation.

7.0 STUDY DATES:

STUDY INITIATION DATE: 02/06/09

EXPERIMENTAL START DATE: 02/13/09

EXPERIMENTAL END DATE: 02/23/09

STUDY COMPLETION DATE: 03/12/09

8.0 TEST MATERIALS:

The test articles were provided to the Testing Facility by the Sponsor. Responsibility for determination of the identity, strength, purity, composition, stability, and solubility of the test articles, as well as responsibility for retention of the test articles, remained with the Sponsor.

Test Article #1:	GOJO Luxury Foam Handwash (5400-520)
Active Ingredient:	N/A
Lot Number:	322503
Expiration Date:	11/2011

Test Article #2:	PURELL® Hand Sanitizing Gel VF481 (9900-501)
Active Ingredient:	70% ethanol
Lot Number:	306273
Expiration Date:	04/2010

Test Article #3:	PURELL® Instant Hand Sanitizer Foam (9800-502)
Active Ingredient:	62% ethanol
Lot Number:	320887
Expiration Date:	11/2010

9.0 EQUIPMENT AND SUPPLIES:

The equipment and supplies used for this study are summarized in the Study Protocol, included as Addendum I of this Final Report, and are also detailed on the Clinical Trials Equipment Tracking Forms (Form No. 01-L-009) and the Clinical Trials Supplies Tracking Forms (Form 01-L-008) in Addendum VII of this Final Report.

10.0 MEDIA:

The growth media and diluting fluids used in this study are as described in the Study Protocol in Addendum I of this Final Report. Additional details are recorded on the Media/Diluent Tracking Forms (Form No. 97-L-007) in Addendum VII of this Final Report.

11.0 SUBJECT DEMOGRAPHICS:

Twenty overtly healthy subjects at least 18 years of age were admitted into the study. Twelve subjects received product during testing. Insofar as possible, the group of subjects selected was of mixed sex, age, and race. Hands and forearms were free from clinically evident dermatoses, injuries, and/or any other disorders that may have compromised the subject and the study. All subjects who participated in the Study signed the Study Description and Informed Consent Form, Subject Confidential Information and Acceptance Criteria, and Authorization to Use and Disclose Protected Health Information Form (Appendix I of Addendum I of this Final Report) and List of Restricted Products (Appendix II of Addendum I of this Final Report) prior to participating in the study. The demographics of the study are presented in the table below.

DEMOGRAPHIC SUMMARY	ALL SUBJECTS	
	Recruited	Received Product
AGE		
Minimum Age	18	19
Median Age	42	49
Maximum Age	71	71
SEX		
Males (M)	8	3
Females (F)	12	9
Total	*20*	*12*
RACE		
White/Caucasian (C)	20	12
Total	*20*	*12*
DID NOT PARTICIPATE IN TESTING		
QC = Qualification (Inclusion/Exclusion) Criteria Failure	6	
NS = No Show	2	

12.0 ADVERSE EVENTS:

No subject experienced an adverse event during or following completion of this study.

13.0 NEUTRALIZATION:

A neutralization assay was performed to assure that the neutralizer(s) used in the recovery medium quenched the antibacterial properties of the test articles. Study procedures were based on guidelines set forth in ASTM E 1054-08, *Standard Test Methods for Evaluation of Inactivators of Antimicrobial Agents. Escherichia coli* (ATCC #11229) was used as the challenge species in the neutralizer validation study.

14.0 TEST METHODS:

14.1 Each subject was in testing for approximately five hours on a single day and used each of the four test article configurations. Prior to being admitted into testing, subjects were questioned regarding their adherence to protocol requirements. Subjects clipped their fingernails to a free edge of ≤ 1 mm, if they had not already done so. All jewelry was removed from the hands and arms prior to washing.

14.2 A handwash was performed using a nonmedicated soap to remove dirt and oil from the hands. A technician instructed subjects in the appropriate technique and verified its proper execution. The temperature of the water used for this and any subsequent wash or rinse procedures was controlled at 40° ± 2°C.

Inoculum Application Procedure

14.3 A total of 4.5 mL of the beef broth suspension containing at least 1×10^9 CFU/mL of *Escherichia coli* (ATCC #11229) was transferred into each subject's cupped hands in three aliquant amounts.

14.3.1 A 1.5 mL aliquot of the challenge suspension was dispensed into the subject's cupped hands. The suspension was distributed over the entire surface of the hands (front and back), not reaching above the wrists, for 20 ± 5 seconds. Following distribution of the inoculum, the hands were held motionless, away from the body, and allowed to air-dry for 30 ± 5 seconds.

14.3.2 The procedure in Section 14.3.1 was repeated.

14.3.3 A final 1.5 mL of the challenge suspension was dispensed into the subject's cupped hands and distributed over the entire surface of the hands (front and back), not reaching above the wrists, for 20 ± 5 seconds. The hands were allowed to air-dry for 90 seconds.

14.4 After the timed 90-second air-dry, the Glove Juice Sampling Procedure (Section 12.45 of the Study Protocol) was performed. This first contamination cycle provided the baseline population level. It was followed with a 30-second handwash using nonmedicated soap.

14.5 The challenge suspension was again dispensed into each subject's cupped hands and distributed. After a timed 90-second air-dry, the subjects applied their randomly assigned test article configuration according to the directions below.

14.6 Test Article Configuration #1 Application Procedure

14.6.1 Subject wet their hands within 10 seconds of completing the drying step (Section 14.5).

14.6.2 Two pumps (approximately 1.4 mL) of Test Article #1 were placed in the subject's cupped hands.

14.6.3 Subject lathered Test Article #1 for 15 seconds, followed by a 10-second rinse with water.

14.6.4 Following the water rinse, the subject used two paper towels to pat-dry hands for 10 seconds.

14.7 Test Article Configuration #2 Application Procedure

14.7.1 Within 10 seconds of completing the drying step (Section 14.5), one pump (approximately 1.5 mL) of Test Article #2 was placed in the subject's cupped hands, and the hands were rubbed together until dry.

14.8 Test Article Configuration #3 Application Procedure

14.8.1 Two pumps (approximately 3.0 mL) of Test Article #2 were placed in the subject's cupped hands within 10 seconds of completing the drying step (Section 14.5).

14.8.2 Subject rubbed Test Article #2 into the hands in a vigorous manner for 15 seconds.

14.8.3 Subject then used two paper towels to pat-dry hands for 10 seconds.

14.8.4 An additional one pump (approximately 1.5 mL) of Test Article #2 was placed in the subject's cupped hands, and the hands were rubbed together until dry.

14.9 Test Article Configuration #4 Application Procedure

14.9.1 Four pumps (approximately 2.8 mL) of Test Article #3 were placed in the subject's cupped hands within 10 seconds of completing the drying step (Section 14.5).

14.9.2 Subject rubbed Test Article #3 into the hands in a vigorous manner for 15 seconds.

14.9.3 Subject then used two paper towels to pat-dry hands for 10 seconds.

14.9.4 An additional two pumps (approximately 1.4 mL) of Test Article #3 were placed in the subject's cupped hands, and the hands were rubbed together until dry.

14.10 Each subject used each of the four test article configurations, one at a time, per specified application procedures. After the Glove Juice Sampling Procedure was performed following test article application, and prior to use of another test article configuration, subjects were required to perform a 1-minute rinse with 70% ethanol and an air-dry, followed by a 30-second handwash using a nonmedicated soap. Subjects waited a minimum of 20 minutes following the use of the nonmedicated soap before using another test article.

15.0 STATISTICAL ANALYSIS:

15.1 Minitab® Statistical Software package was used for all statistical calculations. All statistical tests were calculated using the 0.05 level of significance for Type I (α) error.

15.2 Descriptive statistics and confidence intervals were calculated using the 0.05 level of significance for Type I (α) error. Statistical calculations of means and standard deviations were generated on the $\log_{10}$ recovery data from baseline samples, post-product application samples, and the $\log_{10}$ differences between baseline and post-application samples.

15.3 The critical index for this study was a 2.0 $\log_{10}$ reduction after product application.

16.0 RESULTS - TABLES I THROUGH VIII AND FIGURE 1:

16.1 Table I presents a statistical summary of the $\log_{10}$ recovery values following application of Test Article #1, GOJO Luxury Foam Handwash (5400-520; Lot Number 322503), per Test Article Configuration #1 Application Procedure (two pumps [approximately 1.4 mL] into wet hands, 15-second lather, 10-second rinse, pat-dry hands with paper towels).

16.2 Table II presents the $\log_{10}$ values and $\log_{10}$ reduction from baseline values, by subject and hand, following application of Test Article #1, GOJO Luxury Foam Handwash (5400-520; Lot Number 322503), per Test Article Configuration #1 Application Procedure (two pumps [approximately 1.4 mL] into wet hands, 15-second lather, 10-second rinse, pat-dry hands with paper towels).

16.3 Table III presents a statistical summary of the $\log_{10}$ recovery values following application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #2 Application Procedure (one pump [approximately 1.5 mL] rubbed until dry).

16.4 Table IV presents the $\log_{10}$ values and $\log_{10}$ reduction from baseline values, by subject and hand, following application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #2 Application Procedure (one pump [approximately 1.5 mL] rubbed until dry).

16.5 Table V presents a statistical summary of the $\log_{10}$ recovery values following application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #3 Application Procedure (two pumps [approximately 3.0 mL], pat-dry hands with paper towels, then an additional one pump [approximately 1.5 mL] rubbed until dry).

16.6 Table VI presents the $\log_{10}$ values and $\log_{10}$ reduction from baseline values, by subject and hand, following application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #3 Application Procedure (two pumps [approximately 3.0 mL], pat-dry hands with paper towels, then an additional one pump [approximately 1.5 mL] rubbed until dry).

16.7 Table VII presents a statistical summary of the $\log_{10}$ recovery values following application of Test Article #3, PURELL® Instant Hand Sanitizer Foam (9800-502; Lot Number 320887), per Test Article Configuration #4 Application Procedure (four pumps [approximately 2.8 mL], pat-dry hands with paper towels, then an additional two pumps [approximately 1.4 mL] rubbed until dry).

16.8 Table VIII presents the $\log_{10}$ values and $\log_{10}$ reduction from baseline values, by subject and hand, following application of Test Article #3, PURELL® Instant Hand Sanitizer Foam (9800-502; Lot Number 320887), per Test Article Configuration #4 Application Procedure (four pumps [approximately 2.8 mL], pat-dry hands with paper towels, then an additional two pumps [approximately 1.4 mL] rubbed until dry).

16.9 Figure 1 presents a graphical presentation of the mean $\log_{10}$ reductions from baseline following application of each test article per the four test article application procedures.

Table I: Statistical Summary of the log_{10} Recovery Values Following Application of Test Article #1, GOJO Luxury Foam Handwash (5400-520; Lot Number 322503), per Test Article Configuration #1 Application Procedure (two pumps [approximately 1.4 mL] into wet hands, 15-second lather, 10-second rinse, pat-dry hands with paper towels)

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	24	7.77	0.31	7.64 to 7.90
Application 1	24	4.85	0.53	4.63 to 5.07
Application 1 Log_{10} Reduction	24	2.92	0.61	2.66 to 3.18

Table II: Log_{10} Values and Log_{10} Reduction from Baseline Values by Subject and Hand Following Application of Test Article #1, GOJO Luxury Foam Handwash (5400-520; Lot Number 322503), per Test Article Configuration #1 Application Procedure (two pumps [approximately 1.4 mL] into wet hands, 15-second lather, 10-second rinse, pat-dry hands with paper towels)

Subject	Side	Baseline log_{10} Values	Application 1 log_{10} Values	Application 1 log_{10} Reduction from Baseline
1	Left	7.91	4.82	3.09
	Right	7.87	4.96	2.91
2	Left	7.55	5.11	2.43
	Right	7.72	5.17	2.56
3	Left	7.82	4.69	3.13
	Right	7.77	4.96	2.81
6	Left	8.01	3.49	4.52
	Right	7.99	3.18	4.82
7	Left	8.07	5.08	2.99
	Right	8.11	5.38	2.73
8	Left	7.99	4.90	3.09
	Right	7.96	5.25	2.72
10	Left	6.92	4.51	2.41
	Right	6.93	4.76	2.16
11	Left	7.64	5.28	2.36
	Right	7.71	5.44	2.28
13	Left	7.78	4.70	3.08
	Right	7.98	5.04	2.94
14	Left	7.47	4.75	2.72
	Right	7.56	4.96	2.60
15	Left	7.84	4.81	3.04
	Right	7.86	4.80	3.06
16	Left	8.00	5.02	2.98
	Right	7.99	5.29	2.70

Table III: Statistical Summary of the log_{10} Recovery Values Following Application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #2 Application Procedure (one pump [approximately 1.5 mL] rubbed until dry)

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	24	7.88	0.29	7.76 to 8.00
Application 1	24	3.44	0.47	3.24 to 3.64
Application 1 Log_{10} Reduction	24	4.44	0.47	4.24 to 4.64

Table IV: Log_{10} Values and Log_{10} Reduction from Baseline Values by Subject and Hand Following Application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #2 Application Procedure (one pump [approximately 1.5 mL] rubbed until dry)

Subject	Side	Baseline log_{10} Values	Application 1 log_{10} Values	Application 1 log_{10} Reduction from Baseline
1	Left	7.99	3.18	4.81
	Right	7.99	3.18	4.81
2	Left	7.89	3.18	4.71
	Right	7.95	3.18	4.76
3	Left	7.86	3.18	4.69
	Right	7.95	3.18	4.78
6	Left	7.99	3.18	4.81
	Right	8.02	3.18	4.84
7	Left	8.13	4.36	3.77
	Right	8.19	4.72	3.48
8	Left	7.98	3.18	4.80
	Right	7.98	3.18	4.80
10	Left	6.99	3.18	3.82
	Right	7.05	3.18	3.88
11	Left	8.03	4.14	3.89
	Right	8.02	4.39	3.63
13	Left	7.87	3.49	4.39
	Right	8.05	3.49	4.57
14	Left	7.63	3.49	4.14
	Right	7.63	3.66	3.97
15	Left	7.87	3.18	4.69
	Right	8.05	3.18	4.87
16	Left	8.03	3.18	4.86
	Right	7.98	3.18	4.80

Table V: Statistical Summary of the log_{10} Recovery Values Following Application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #3 Application Procedure (two pumps [approximately 3.0 mL], pat-dry hands with paper towels, then an additional one pump [approximately 1.5 mL] rubbed until dry)

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	24	7.79	0.33	7.65 to 7.93
Wash 1	24	3.18	0.00	3.18 to 3.18
Wash 1 Log_{10} Reduction	24	4.61	0.33	4.47 to 4.75

Table VI: Log_{10} Values and Log_{10} Reduction from Baseline Values by Subject and Hand Following Application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #3 Application Procedure (two pumps [approximately 3.0 mL], pat-dry hands with paper towels, then an additional one pump [approximately 1.5 mL] rubbed until dry)

Subject	Side	Baseline log_{10} Values	Application 1 log_{10} Values	Application 1 log_{10} Reduction from Baseline
1	Left	7.90	3.18	4.73
	Right	7.96	3.18	4.78
2	Left	7.58	3.18	4.40
	Right	7.71	3.18	4.53
3	Left	7.95	3.18	4.78
	Right	7.98	3.18	4.79
6	Left	7.99	3.18	4.82
	Right	7.95	3.18	4.77
7	Left	8.19	3.18	5.02
	Right	8.23	3.18	5.06
8	Left	7.89	3.18	4.71
	Right	7.90	3.18	4.73
10	Left	7.34	3.18	4.16
	Right	7.21	3.18	4.03
11	Left	7.95	3.18	4.77
	Right	7.89	3.18	4.71
13	Left	7.75	3.18	4.58
	Right	7.85	3.18	4.68
14	Left	7.07	3.18	3.89
	Right	6.98	3.18	3.81
15	Left	7.80	3.18	4.62
	Right	7.73	3.18	4.55
16	Left	8.01	3.18	4.83
	Right	8.16	3.18	4.98

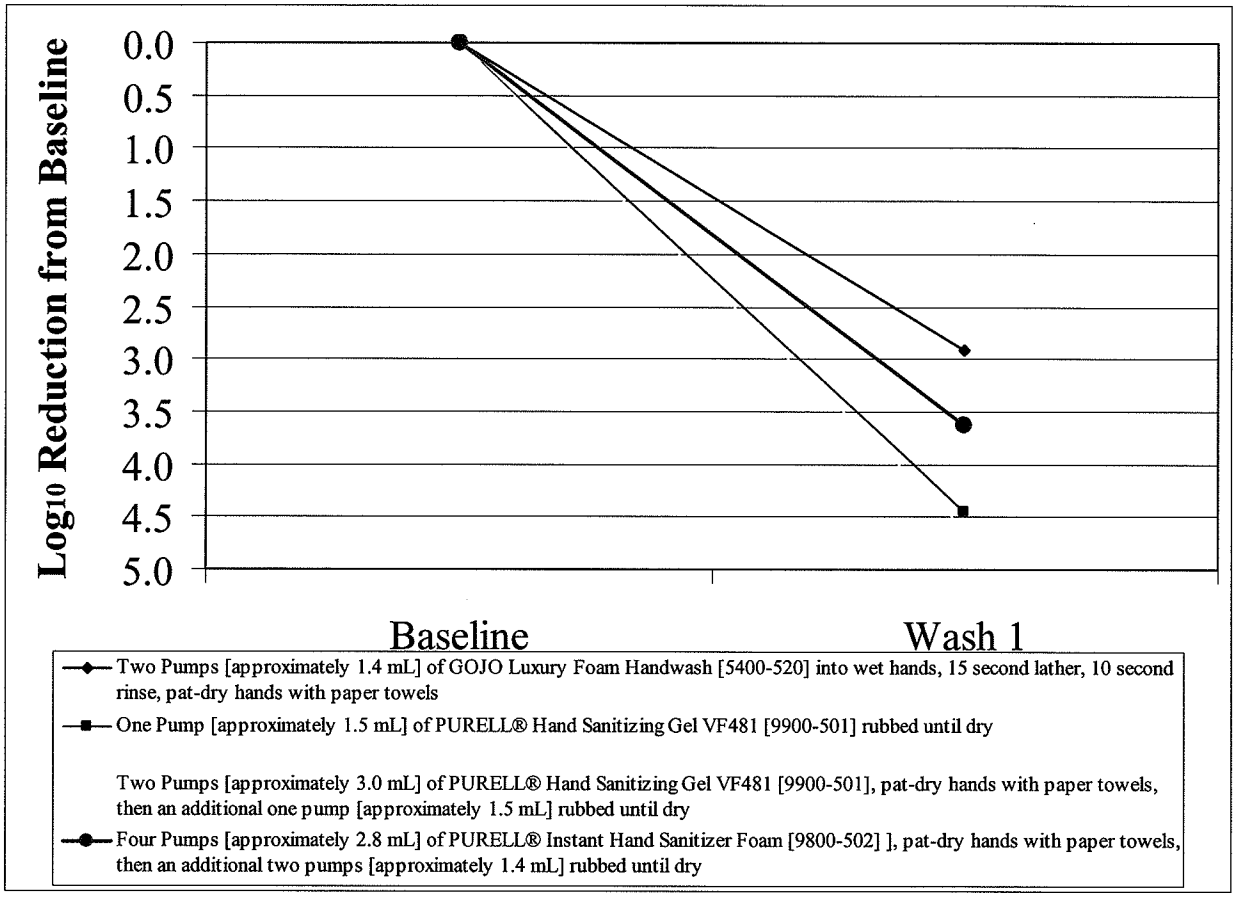
Table VII: Statistical Summary of the log_{10} Recovery Values Following Application of Test Article #3, PURELL® Instant Hand Sanitizer Foam (9800-502; Lot Number 320887), per Test Article Configuration #4 Application Procedure (four pumps [approximately 2.8 mL], pat-dry hands with paper towels, then an additional two pumps [approximately 1.4 mL] rubbed until dry)

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	24	7.80	0.34	7.66 to 7.94
Wash 1	24	4.16	0.56	3.93 to 4.40
Wash 1 Log_{10} Reduction	24	3.64	0.57	3.40 to 3.88

Table VIII: Log_{10} Values and Log_{10} Reduction from Baseline Values by Subject and Hand Following Application of Test Article #3, PURELL® Instant Hand Sanitizer Foam (9800-502; Lot Number 320887), per Test Article Configuration #4 Application Procedure (four pumps [approximately 2.8 mL], pat-dry hands with paper towels, then an additional two pumps [approximately 1.4 mL] rubbed until dry)

Subject	Side	Baseline log_{10} Values	Application 1 log_{10} Values	Application 1 log_{10} Reduction from Baseline
1	Left	7.98	4.19	3.79
	Right	8.03	4.55	3.48
2	Left	7.89	4.53	3.37
	Right	7.79	4.51	3.28
3	Left	7.64	3.79	3.85
	Right	7.73	4.23	3.51
6	Left	7.79	4.72	3.08
	Right	7.80	4.81	2.99
7	Left	8.08	3.18	4.90
	Right	8.10	4.03	4.07
8	Left	8.18	4.23	3.95
	Right	8.19	5.03	3.16
10	Left	7.32	3.18	4.14
	Right	7.02	3.18	3.84
11	Left	7.96	4.57	3.39
	Right	7.88	4.58	3.29
13	Left	7.91	4.27	3.64
	Right	7.80	4.58	3.22
14	Left	7.21	4.85	2.36
	Right	7.03	3.79	3.24
15	Left	7.84	3.96	3.87
	Right	7.94	3.18	4.75
16	Left	8.06	4.23	3.83
	Right	8.11	3.79	4.32

Figure 1: Graphical Presentation of the Mean log_{10} Reductions from Baseline Following Application of Each Test Article per the Four Test Article Application Procedures



17.0 CONCLUSION:

The critical index for this study was a 2.0 log_{10} reduction in baseline populations after product application.

For Test Article #1, GOJO Luxury Foam Handwash (5400-520; Lot Number 322503), applied per Test Article Configuration #1 Application Procedure (two pumps [approximately 1.4 mL] of Test Article #1 into wet hands, 15-second lather, 10-second rinse, pat-dry hands with paper towels), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean log_{10} reduction of 2.92 after product application and met the critical index of the study.

For Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), applied per Test Article Configuration #2 Application Procedure (one pump [approximately 1.5 mL] of Test Article #2 rubbed until dry), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2, applied per Test Article Configuration #2 Application Procedure, produced a mean log_{10} reduction of 4.44 after product application and met the critical index of the study.

For Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), applied per Test Article Configuration #3 Application Procedure (two pumps [approximately 3.0 mL] of Test Article #2, pat-dry hands with paper towels, then an additional one pump [approximately 1.5 mL] rubbed until dry), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2, applied per Test Article Configuration #3 Application Procedure, produced a mean $\log_{10}$ reduction of 4.61 after product application and met the critical index of the study.

For Test Article #3, PURELL® Instant Hand Sanitizer Foam (9800-502; Lot Number 320887), applied per Test Article Configuration #4 Application Procedure (four pumps [approximately 2.8 mL] of Test Article #3, pat-dry hands with paper towels, then an additional two pumps [approximately 1.4 mL] rubbed until dry), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 produced a mean $\log_{10}$ reduction of 3.64 after product application and met the critical index of the study.

18.0 LABORATORY PERSONNEL:

The following employees of BioScience Laboratories, Inc., were involved in the testing or ancillary support of this Study. The laboratory personnel have been appropriately trained, and their training records are on file in the Quality Assurance Unit at the Testing Facility.

STUDY DIRECTOR:	Robert R. McCormack Microbiologist
ASSOCIATE STUDY DIRECTOR:	Kendra Drake Microbiologist
Tammy Anderson IRB Coordinator	Nathan Nash Microbiologist
Jessica Baumgartner Microbiologist	Ron Neibauer Manager of Clinical Laboratories
Amanda Berry Supervisor of Subject Recruitment	Jeana Paulson Microbiologist
Stephanie Cebulla Laboratory Support Technician	Stephanie Scarff Laboratory Support Technician
Collette Duley Microbiologist	Amanda Shaffer Microbiologist
B. Cole Irvin Microbiologist	Jessica Sheehy Microbiologist
Patricia A. Mays Suko Supervisor of Laboratory Support	Clare Wilson Microbiologist

19.0 QUALITY ASSURANCE PERSONNEL:

Alicia Bogert
Quality Assurance Associate/Product Handling

Scott D. Ferraro
Manager of Quality Control

Amy L. Juhnke
Manager of Quality Assurance/Document Control

John A. Mitchell, Ph.D.
Director of Quality Assurance

Janis Smoke
Quality Assurance Associate

20.0 DOCUMENTATION AND RECORD-KEEPING:

All documentation and records were compiled, analyzed, and will be retained by BioScience Laboratories, Inc., at its facility in Bozeman, Montana. All raw data for this study, as well as the Final Report, will be retained in safe storage by the Testing Facility for a period of at least three years. BioScience Laboratories, Inc. will notify the Sponsor before any documents or records are destroyed.

21.0 ACCEPTANCE:

BIOSCIENCE LABORATORIES, INC. (TESTING FACILITY)
300 N. Willson Avenue
Bozeman, Montana 59715

President & CEO: Daryl S Paulson — 03-12-09
Daryl S. Paulson, Ph.D. — Date

Principal Study Director: Robert R. McCormack — 03/12/09
Robert McCormack — Study Completion Date

Associate Study Director: Kendra Drake — 03/12/09
Kendra Drake — Date

Senior Clinical Director: Christopher M. Beausoleil — 03/12/09
Christopher M. Beausoleil, CCRP — Date

QUALITY ASSURANCE STATEMENT:

This study was inspected by the Quality Assurance Unit, and reports were submitted to the Study Director and Management in accordance with Standard Operating Procedures, as follows:

Phase	Date
Neutralization Assay	02/13/09
Product Testing	02/18/09
Data Audit	03/03/09 and 03/04/09
Final Report Review	03/11/09
Reports to Study Director and Management	02/13/09, 02/18/09, and 03/12/09

This study was conducted in compliance with Good Laboratory Practices standards, as described by the FDA (reference CFR 21 Parts 50, 56, 312, and 314), with the following exception: test article preparations were not analyzed at BioScience Laboratories, Inc., to confirm concentration, stability, or homogeneity.

Quality Assurance/ Associate: Janis E. Smoke — 03/12/09
Janis Smoke — Date

INDEX OF ADDENDA

I GIRB-Approved Protocol #081211-150

II Qualification Criteria Questionnaire for Study 081211-150
Qualification Criteria of the Subject for Study 081211-150

III Sampling Data Sheets for Healthcare Personnel Handwash Study 081211-150
Irritation Evaluations for Study 081211-150

IV Neutralization Evaluation
- Neutralization Evaluation Results for Study 081211-150
- Project Notes (Form No. 95-G-001)
- Neutralization Evaluation Data Sheets for Protocol 081211-150
- Neutralization Statistics

V Q-Count™ Plate Counter Data Sheets (Form No. 00-L-009)
Q-Count™ Plate Count Data

VI Statistical Analysis

VII Study Notes and General Records
- Project Notes (Form No. 95-G-001)
- Age Calculation and Demographics Worksheet
- Study 081211-150 Randomization Scheme
- Clinical Trials Equipment Tracking Forms (Form No. 01-L-009)
- Clinical Trials Supplies Tracking Forms (Form No. 01-L-008)
- Water Temperature Monitoring Sheet (Form No. 96-CT-017)
- Incubator Log Forms (Form No. 96-L-008)
- Refrigerator Log Form (Form No. 96-L-015)
- Inoculum Preparation Tracking Form - Solid Media Preparation (Form No. 07-CT-002)
- Inoculum Preparation Tracking Form - Flask Preparation (Form No. 07-CT-001)
- Autoplate® 4000 Data Sheet for Healthcare Personnel Handwash Study 081211-150
- Media/Diluent Tracking Forms (Form No. 97-L-007)

VIII Product Information
- Product Receipt Log (Form No. 92-L-023)
- Sample Submission Form and Document Compliance Statement (Form No. 94-G-007)
- Material Safety Data Sheet (MSDS)
- Product-Tracking Forms (Form No. 93-L-029)