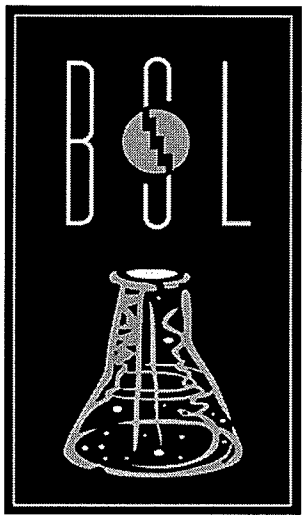

January 17, 2008

FINAL REPORT #070723-150

DETERMINATION OF THE ANTIMICROBIAL EFFICACY OF THREE (3) TEST ARTICLES USING A VARIATION OF THE HEALTH CARE PERSONNEL HANDWASH PROCEDURE

Prepared for:

(SPONSOR)

Prepared by:

BIOSCIENCE LABORATORIES, INC. (TESTING FACILITY)
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This Study has been approved by the GIRB on _____

EXECUTIVE SUMMARY

The purpose of this study was to evaluate the antimicrobial efficacy of three (3) test articles using a modification of the Health Care Personnel Handwash evaluation. The indicator microorganism used for hand contaminations was *Escherichia coli* (ATCC #11229). Eleven (11) subjects used each of the three (3) test articles (reference Section 14.0 of this Final Report and a Protocol and/or SOP Deviation Recording Form [Form No. 99-QA-004] in Addendum I of this Final Report), one (1) at a time. Subjects performed two (2) consecutive hand contaminations with the challenge suspension in a beef broth medium, the first followed by a sample for baseline, and the second by a product application. Subjects then decontaminated their hands with a 70% Ethanol rinse and a nonmedicated soap wash, and then used a second Test Article. This procedure was repeated again with the remaining Test Article. The baseline and post-application samples were evaluated for the presence of *Escherichia coli* (ATCC #11229). The testing methods were based on 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) and ASTM E1174-06, *Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations.*

The critical index for this study was a two (2) $\log_{10}$ reduction in baseline populations after product application.

STATISTICAL ANALYSIS #1

For Test Article #1, Bland Foaming Handwash (Lot Number 275543), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean $\log_{10}$ reduction of 2.80 after product application and met the critical index of the study.

For Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2 produced a mean $\log_{10}$ reduction of 2.64 after product application and met the critical index of the study.

For Test Article #3, Sanitizing Hand Wipes (68.15% Ethanol; Lot Number 973-12), followed by Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), applied per Test Article #3 Application Procedure, the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 followed by Test Article #2, applied per Test Article #3 Application Procedure, produced a mean $\log_{10}$ reduction of 2.47 after product application and met the critical index of the study.

STATISTICAL ANALYSIS #2

Upon completion of the statistical analysis, Subject #12's data were determined to be outliers. Further investigation revealed that the subject appeared to have a learning disability and needed repeated instruction by the monitoring laboratory technician to be able to perform each of the steps required by the study protocol. The conclusions below results from a statistical analysis excluding data from testing of Subject #12.

For Test Article #1, Bland Foaming Handwash (Lot Number 275543), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean $\log_{10}$ reduction of 2.93 after product application and met the critical index of the study.

Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2 produced a mean $\log_{10}$ reduction of 2.83 after product application and met the critical index of the study.

Test Article #3, Sanitizing Hand Wipes (68.15% Ethanol; Lot Number 973-12), followed by Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), applied per Test Article #3 Application Procedure, the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 followed by Test Article #2, applied per Test Article #3 Application Procedure, produced a mean $\log_{10}$ reduction of 2.63 after product application and met the critical index of the study.

This Study has been approved by the GIRB on _____

January 17, 2008

FINAL REPORT # 070723-150

1.0 TITLE: **DETERMINATION OF THE ANTIMICROBIAL EFFICACY OF THREE (3) TEST ARTICLES USING A VARIATION OF THE HEALTH CARE PERSONNEL HANDWASH PROCEDURE**

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

3.0 STUDY DIRECTORS:

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

4.0 PURPOSE OF STUDY:

The purpose of this study was to evaluate the antimicrobial efficacy of three (3) test articles for use in the food service industry. Testing was performed per methodology based on 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) and ASTM E1174-06, *Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations.*

5.0 SCOPE:

The purpose of this study was to evaluate the antimicrobial efficacy of three (3) test articles using a modification of the Health Care Personnel Handwash evaluation. The indicator microorganism used for hand contaminations was *Escherichia coli* (ATCC #11229). Eleven (11) subjects used each of the three (3) test articles, one (1) at a time. Subjects performed two (2) consecutive hand contaminations with the challenge suspension in a beef broth medium, the first followed by a sample for baseline, and the second by a product application. Subjects then decontaminated their hands with a 70% Ethanol rinse and a nonmedicated soap wash, and then used a second Test Article. This procedure was repeated again with the remaining Test Article. The baseline and post-application samples were evaluated for the presence of *Escherichia coli* (ATCC #11229). The testing methods were based on 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) and ASTM E1174-06, *Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations.* The Study Protocol was approved by the Gallatin Institutional Review Board (GIRB) on 12/04/07 (See Addendum I of this Final Report). One (1) deviation from the methodology described in the Study Protocol occurred (reference Section 14.0 of this Final Report), and as is detailed on a Protocol and/or SOP Deviation Recording Form (Form No. 99-QA-004) in Addendum I of this Final Report, it had no adverse effect upon the study outcome. No deviations from BioScience Laboratories, Inc., Standard Operating Procedures occurred during the course of this evaluation.

This Study has been approved by the GIRB on _____

6.0 STUDY DATES:

STUDY INITIATION DATE: 11/30/07

EXPERIMENTAL START DATE: 12/19/07

EXPERIMENTAL END DATE: 01/07/08

STUDY COMPLETION DATE: 01/17/08

7.0 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. All documentation provided with the test articles is included in Addendum IX of this Final Report.

Test Article #1:	Bland Foaming Handwash
Lot Number:	275543
Expiration Date:	01/2010
Test Article #2:	Instant Hand Sanitizer Gel
Active Ingredient:	62% Ethanol
Lot Number:	240041 5179
Expiration Date:	06/2008
Test Article #3:	Sanitizing Hand Wipes
Active Ingredient:	68.15% Ethanol
Lot Number:	973-12
Expiration Date:	04/19/08

8.0 TEST ARTICLE APPLICATION PROCEDURES:

Test Period

8.1 Each subject was in testing for approximately four (4) hours on a single day and used each of the three (3) test articles. Prior to being admitted into testing, subjects were questioned regarding their adherence to the 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.

NOTE: Each subject used each of the three (3) test articles, one (1) 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, the subjects were required to decontaminate their hands by performing a one (1) minute rinse with 70% Ethanol and an air-dry, followed by a thirty (30) second handwash using a nonmedicated soap. The subjects waited a minimum of twenty (20) minutes following the use of the nonmedicated soap and prior to use of another test article.

8.2 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 by subjects. The temperature of the water used for all wash or rinse procedures was controlled at 40° ± 2°C (see Water Temperature Monitoring Sheets [Form No. 96-CT-017] in Addendum VII of this Final Report]).

This Study has been approved by the GIRB on _____

Inoculum Application Procedure

8.3 Four and one-half (4.5) mLs of the beef broth suspension containing at least 1 x 10^9 CFU/mL of *Escherichia coli* (ATCC #11229) were transferred into each subject's cupped hands in three (3) aliquant amounts of one and one-half (1.5) mLs.

8.4 The suspension was distributed over the entire surface of the hands (front and back), not reaching above the wrists, for twenty (20) ± five (5) seconds. Following distribution of the inoculum, the hands were held motionless, away from the body, and allowed to air-dry for thirty (30) ± five (5) seconds.

8.5 The procedure in Section 8.4 was repeated.

8.6 A final one and one-half (1.5) mL aliquant amount 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 twenty (20) ± five (5) seconds. The hands were allowed to air-dry for ninety (90) seconds.

8.7 After the timed ninety (90) second air-dry, the Glove Juice Sampling Procedure was performed. This first contamination cycle provided the baseline population level. It was followed with a thirty (30) second handwash using nonmedicated soap.

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

Test Article #1 Application Procedure

8.9 The subject wet hands within ten (10) seconds of completing the drying step.

8.10 Two (2) pumps (1.4 mL) of Test Article #1 were placed in the subject's cupped hands.

8.11 The subject lathered Test Article #1 for fifteen (15) seconds, followed by a ten (10) second rinse with water.

8.12 Following the water rinse, the subject used two (2) paper towels to pat-dry hands for ten (10) seconds.

Test Article #2 Application Procedure

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

8.14 The subject rubbed Test Article #2 into the hands in a vigorous manner for fifteen (15) seconds.

8.15 Following Test Article #2 application, the subject used two (2) paper towels to pat-dry hands for ten (10) seconds.

8.16 An additional one (1) pump of Test Article #2 was placed in the subject's cupped hands (1.5 mL), and the hands were rubbed together until dry.

Test Article #3 Application Procedure

8.17 Within ten (10) seconds of completing the drying step, the subject wiped both hands with Test Article #3 in a standardized fashion for twenty-five (25) seconds.

8.18 Following the wiping procedure, one (1) pump of Test Article #2 was placed in the subject's cupped hands, and hands were rubbed together until dry.

9.0 EQUIPMENT AND SUPPLIES:

The equipment and supplies used for this study are summarized in the Study Protocol, included in Addendum I of this Final Report, and are also detailed on Clinical Trials Equipment Tracking Forms (Form No. 01-L-009) and 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 Media/Diluent Tracking Forms (Form No. 97-L-007) in Addendum VIII of this Final Report.

11.0 SUBJECT DEMOGRAPHICS:

Twenty-seven (27) overtly healthy subjects, at least eighteen (18) years of age were admitted into the study. Eleven (11) subjects completed the study (reference Protocol and/or SOP Deviation Recording Form [Form No. 99-QA-004] in Addendum I of this Final Report). Insofar as possible, the group of subjects selected was of mixed sex, age, and race. Hands and forearms were free from clinically evident dermatoses, other injuries to the area, 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	19	19
Median Age	*35*	*45*
Maximum Age	69	69
SEX		
Males (M)	14	5
Females (F)	13	6
Total	*27*	*11*
RACE		
White/Caucasian (C)	26	10
Latino (L)	1	1
Total	*27*	*11*

This Study has been approved by the GIRB on _____

DID NOT PARTICIPATE IN TESTING	
SC = Schedule Conflict	1
QC = Qualification (Inclusion/Exclusion) Criteria Failure	10
NS = No Show	5

12.0 ADVERSE EVENTS:

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

13.0 NEUTRALIZATION EVALUATION:

The results of a neutralization evaluation (BSLI SOP CT-1006) indicated that the neutralizer(s) used in the recovery medium successfully quenched the antimicrobial activity of the test articles. Study procedures followed guidelines set forth in ASTM E 1054-02, *Standard Test Methods for Evaluation of Inactivators of Antimicrobial Agents*, except that the microorganism was added to the neutralizer prior to the addition of the test articles. *Escherichia coli* (ATCC #11229) was used as the challenge species in the neutralizer validation study. All data resulting from the Neutralization Assay are included in Addendum VI of this Final Report.

14.0 DEVIATION FROM PROTOCOL:

Section 12.40 in Protocol 070723-150 states, "Within ten (10) seconds of completing the drying step (Section 12.31), the subject will wipe both hands with Test Article #3 in a standardized fashion for twenty-five (25) seconds." Subject 21 did not use Test Article #3 on both hands in a standardized fashion nor for the full twenty-five (25) seconds. Subject 21 dropped wipe with three (3) seconds left on the rub, continued without wipe, and one (1) pump of Test Article #2 was then placed in the subject's cupped hands. Subject 21 failed to follow applications instructions as directed by the monitoring laboratory technician. Subject 21's data for Test Article #3 were disregarded from the analysis, so there is no effect on the outcome of the study.

15.0 RESULTS - TABLES I THROUGH XII:

15.1 Table I presents the statistical summary of the $\log_{10}$ values following performance of Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]).

Table I: Statistical Summary of the $\log_{10}$ Recovery Values following Performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543])

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	22	8.18	0.24	8.08 to 8.29
Application 1	22	5.38	0.58	5.13 to 5.64
Application 1 Log_{10} Reduction	22	2.80	0.68	2.50 to 3.10

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15.2 Table II presents the log_{10} values and log_{10} reduction from baseline values, by subject, following performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]).

Table II: Log_{10} Values and Log_{10} Reduction from Baseline Values, by subject, following Performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543])

Subject	Side	Baseline log_{10} Values	Application 1 log_{10} Values	Application 1 log_{10} Reduction from Baseline
1	Left	8.31	5.66	2.65
	Right	8.12	5.81	2.31
16	Left	8.34	4.33	4.01
	Right	8.34	5.27	3.07
3	Left	8.23	5.12	3.11
	Right	8.11	5.60	2.51
9	Left	8.43	4.97	3.46
	Right	8.19	5.11	3.07
20	Left	8.04	4.82	3.22
	Right	8.11	4.69	3.42
7	Left	8.19	4.14	4.05
	Right	8.14	4.69	3.45
18	Left	8.01	6.00	2.01
	Right	8.04	6.09	1.95
12	Left	7.66	5.87	1.79
	Right	7.58	6.22	1.36
21	Left	8.58	5.64	2.94
	Right	8.48	5.96	2.52
27	Left	8.21	5.55	2.67
	Right	8.21	5.76	2.44
26	Left	8.32	5.47	2.85
	Right	8.38	5.60	2.78

This Study has been approved by the GIRB on _____

15.3 Table III presents the statistical summary of the log_{10} values following performance of Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]).

Table III: Statistical Summary of the log_{10} Recovery Values following Performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179])

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	22	8.14	0.31	8.00 to 8.28
Application 1	22	5.50	0.79	5.15 to 5.85
Application 1 Log_{10} Reduction	22	2.64	0.89	2.24 to 3.03

15.4 Table IV presents the log_{10} values and log_{10} reduction from baseline values, by subject, following performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]).

Table IV: Log_{10} Values and Log_{10} Reduction from Baseline Values by subject following Performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179])

Subject	Side	Baseline log_{10} Values	Application 1 log_{10} Values	Application 1 log_{10} Reduction from Baseline
1	Left	8.14	5.96	2.18
	Right	8.23	5.80	2.43
16	Left	8.28	5.99	2.29
	Right	8.25	6.45	1.80
3	Left	8.02	5.36	2.67
	Right	8.21	5.34	2.87
9	Left	8.43	4.96	3.47
	Right	8.39	5.56	2.84
20	Left	8.11	4.74	3.37
	Right	8.03	5.82	2.21
7	Left	8.29	4.19	4.10
	Right	8.20	4.85	3.35
18	Left	7.74	4.33	3.40
	Right	7.88	3.66	4.22
12	Left	7.25	6.47	0.78
	Right	7.45	6.90	0.55
21	Left	8.44	5.85	2.59
	Right	8.27	5.90	2.37
27	Left	8.27	6.21	2.06
	Right	8.31	5.61	2.69
26	Left	8.42	5.77	2.66
	Right	8.42	5.34	3.08

This Study has been approved by the GIRB on _____

15.5 Table V presents the statistical summary of the log_{10} values following performance of Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]).

Table V: Statistical Summary of the log_{10} Recovery Values following Performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Log Number 240041 5179])

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	20	8.07	0.34	7.92 to 8.23
Wash 1	20	5.60	0.64	5.30 to 5.90
Wash 1 Log_{10} Reduction	20	2.47	0.76	2.12 to 2.83

15.6 Table VI presents the log_{10} values and log_{10} reduction from baseline values, by subject, following performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]).

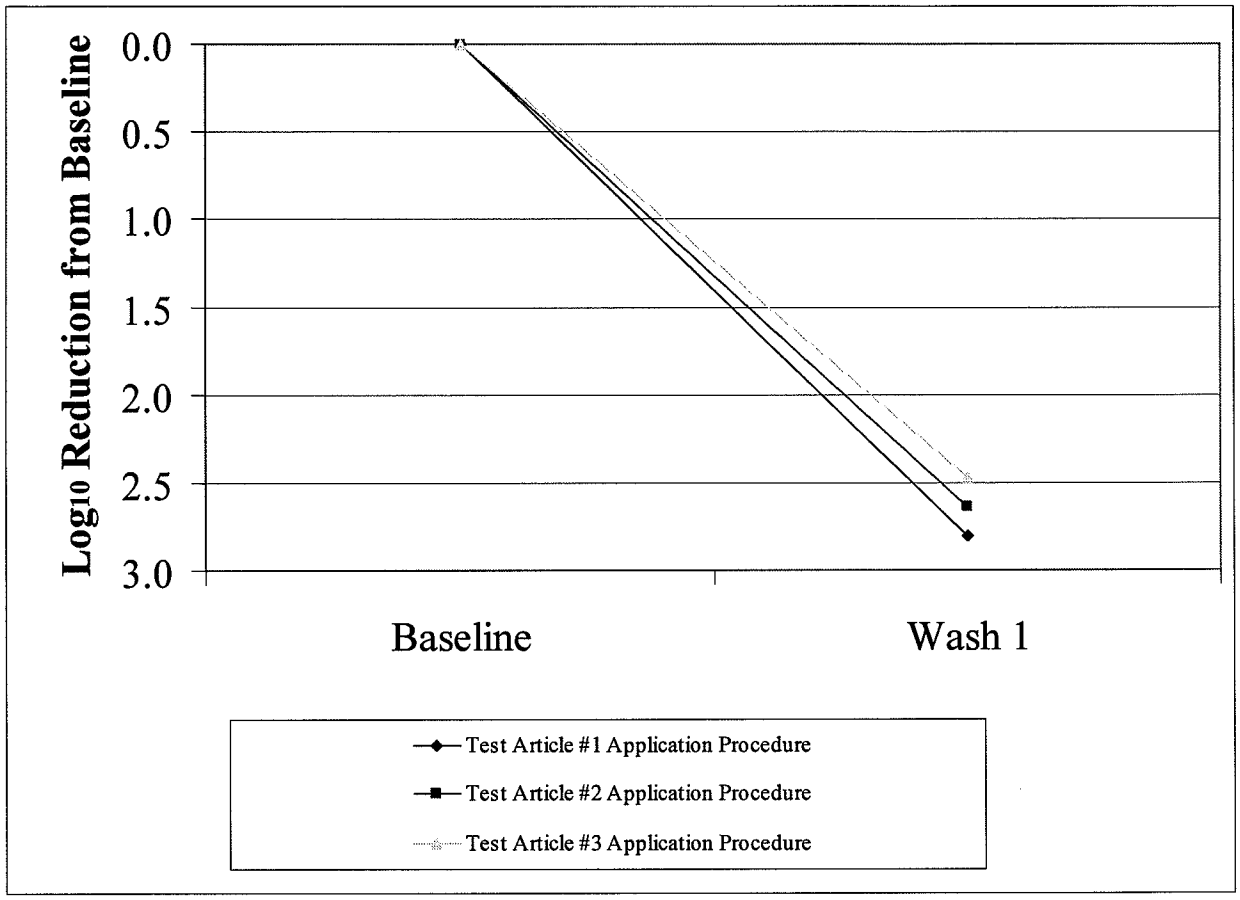
Table VI: Log_{10} Values and Log_{10} Reduction from Baseline Values by subject following Performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Log Number 240041 5179])

Subject	Side	Baseline log_{10} Values	Application 1 log_{10} Values	Application 1 log_{10} Reduction from Baseline
1	Left	8.37	6.20	2.17
	Right	8.33	6.37	1.97
16	Left	8.13	5.31	2.82
	Right	8.29	5.81	2.48
3	Left	8.09	4.88	3.21
	Right	8.22	4.14	4.08
9	Left	8.41	5.18	3.23
	Right	8.35	5.33	3.02
20	Left	7.69	4.75	2.94
	Right	7.70	5.48	2.22
7	Left	8.16	5.07	3.09
	Right	8.23	6.32	1.91
18	Left	7.79	5.65	2.14
	Right	8.25	5.18	3.07
12	Left	7.23	6.21	1.03
	Right	7.35	6.30	1.05
21	Left	*	*	*
	Right	*	*	*
27	Left	8.16	5.33	2.83
	Right	8.23	5.86	2.38
26	Left	8.24	6.28	1.96
	Right	8.27	6.39	1.88

This Study has been approved by the GIRB on _____

15.7 Figure 1 presents the graphical presentation of the mean log10 reductions from baseline from each of the three (3) test article application procedures.

Figure 1: Graphical Presentation of the Mean log_{10} Reductions from Baseline From the Three (3) Test Article Application Procedures



15.8 Table VII presents the statistical summary of the log_{10} values following performance of Test Article #1 Application Procedure (Bland Foaming Handwash (Lot Number 275543)) excluding data from Subject 12.

Table VII: Statistical Summary of the log_{10} Recovery Values following Performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]) excluding Data from Subject #12

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	20	8.24	0.16	8.17 to 8.31
Application 1	20	5.32	0.56	5.05 to 5.58
Application 1 Log_{10} Reduction	20	2.93	0.58	2.66 to 3.19

This Study has been approved by the GIRB on _____

15.9 Table VIII presents the log_{10} values and log_{10} reduction from baseline values, by subject, following performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]) excluding data from Subject #12.

Table VIII: Log_{10} Values and Log_{10} Reduction from Baseline Values, by subject, following Performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]) excluding Data from Subject #12

Subject	Side	Baseline log_{10} Values	Application 1 log_{10} Values	Application 1 log_{10} Reduction from Baseline
1	Left	8.31	5.66	2.65
	Right	8.12	5.81	2.31
16	Left	8.34	4.33	4.01
	Right	8.34	5.27	3.07
3	Left	8.23	5.12	3.11
	Right	8.11	5.60	2.51
9	Left	8.43	4.97	3.46
	Right	8.19	5.11	3.07
20	Left	8.04	4.82	3.22
	Right	8.11	4.69	3.42
7	Left	8.19	4.14	4.05
	Right	8.14	4.69	3.45
18	Left	8.01	6.00	2.01
	Right	8.04	6.09	1.95
12	Left	*	*	*
	Right	*	*	*
21	Left	8.58	5.64	2.94
	Right	8.48	5.96	2.52
27	Left	8.21	5.55	2.67
	Right	8.21	5.76	2.44
26	Left	8.32	5.47	2.85
	Right	8.38	5.60	2.78

This Study has been approved by the GIRB on _____

15.10 Table IX presents the statistical summary of the log_{10} values following performance of Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding data from Subject #12.

Table IX: Statistical Summary of the log_{10} Recovery Values following Performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding Data from Subject #12

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	20	8.22	0.19	8.13 to 8.30
Application 1	20	5.38	0.73	5.05 to 5.72
Application 1 Log_{10} Reduction	20	2.83	0.66	2.53 to 3.14

15.11 Table X presents the log_{10} values and log_{10} reduction from baseline values, by subject, following performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding data from Subject #12.

Table X: Log_{10} Values and Log_{10} Reduction from Baseline Values by subject following Performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding Data from Subject #12

Subject	Side	Baseline log_{10} Values	Application 1 log_{10} Values	Application 1 log_{10} Reduction from Baseline
1	Left	8.14	5.96	2.18
	Right	8.23	5.80	2.43
16	Left	8.28	5.99	2.29
	Right	8.25	6.45	1.80
3	Left	8.02	5.36	2.67
	Right	8.21	5.34	2.87
9	Left	8.43	4.96	3.47
	Right	8.39	5.56	2.84
20	Left	8.11	4.74	3.37
	Right	8.03	5.82	2.21
7	Left	8.29	4.19	4.10
	Right	8.20	4.85	3.35
18	Left	7.74	4.33	3.40
	Right	7.88	3.66	4.22
12	Left	*	*	*
	Right	*	*	*
21	Left	8.44	5.85	2.59
	Right	8.27	5.90	2.37
27	Left	8.27	6.21	2.06
	Right	8.31	5.61	2.69
26	Left	8.42	5.77	2.66
	Right	8.42	5.34	3.08

This Study has been approved by the GIRB on _____

15.12 Table V presents the statistical summary of the log_{10} values following performance of Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding data from Subject #12.

Table XI: Statistical Summary of the log_{10} Recovery Values following Performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Log Number 240041 5179]) excluding Data from Subject #12

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	18	8.16	0.22	8.05 to 8.27
Wash 1	18	5.53	0.63	5.21 to 5.85
Wash 1 Log_{10} Reduction	18	2.63	0.61	2.33 to 2.93

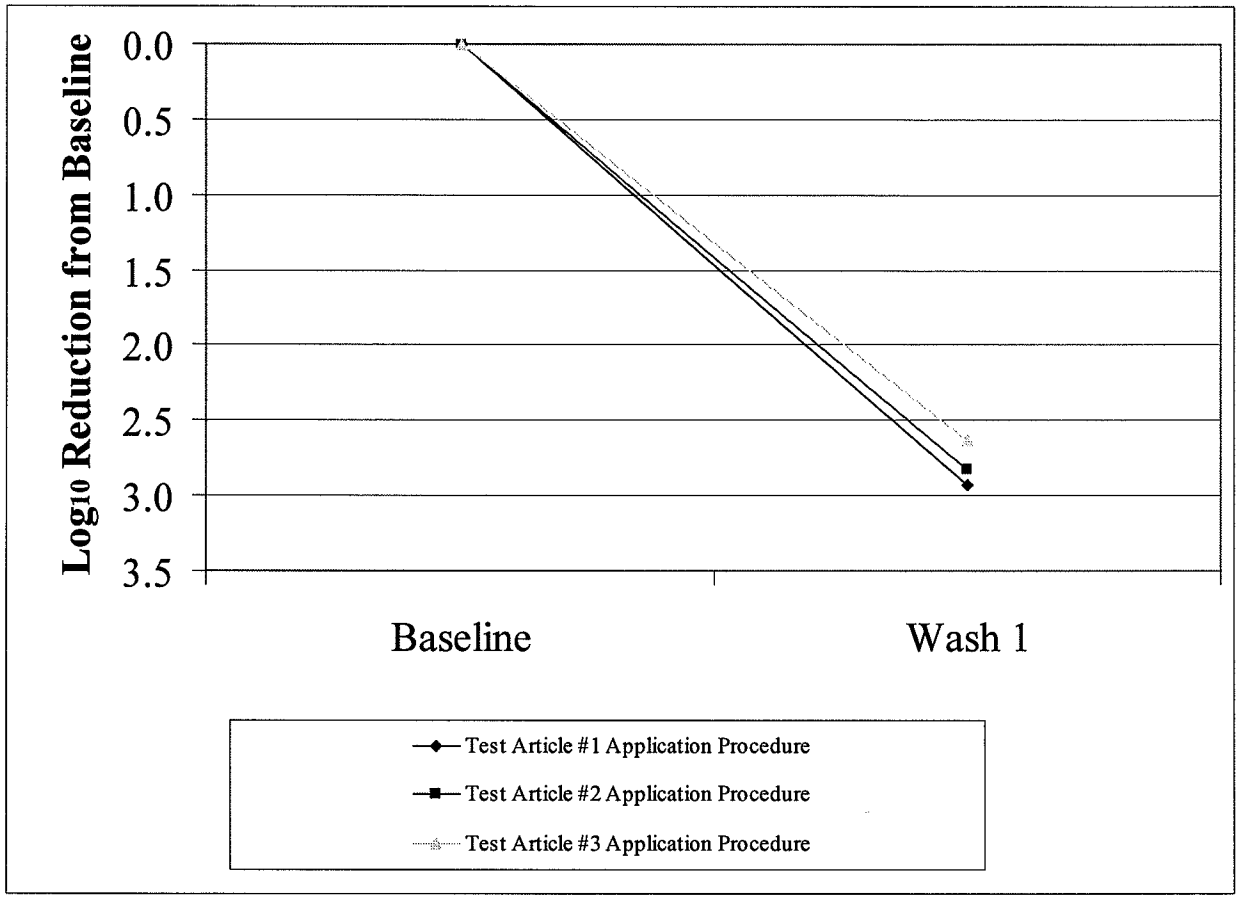
15.13 Table XII presents the log_{10} values and log_{10} reduction from baseline values, by subject, following performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding data from Subject #12.

Table XII: Log_{10} Values and Log_{10} Reduction from Baseline Values by subject following Performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Log Number 240041 5179]) excluding Data from Subject #12

Subject	Side	Baseline log_{10} Values	Application 1 log_{10} Values	Application 1 log_{10} Reduction from Baseline
1	Left	8.37	6.20	2.17
	Right	8.33	6.37	1.97
16	Left	8.13	5.31	2.82
	Right	8.29	5.81	2.48
3	Left	8.09	4.88	3.21
	Right	8.22	4.14	4.08
9	Left	8.41	5.18	3.23
	Right	8.35	5.33	3.02
20	Left	7.69	4.75	2.94
	Right	7.70	5.48	2.22
7	Left	8.16	5.07	3.09
	Right	8.23	6.32	1.91
18	Left	7.79	5.65	2.14
	Right	8.25	5.18	3.07
12	Left	*	*	*
	Right	*	*	*
21	Left	*	*	*
	Right	*	*	*
27	Left	8.16	5.33	2.83
	Right	8.23	5.86	2.38
26	Left	8.24	6.28	1.96
	Right	8.27	6.39	1.88

15.14 Figure 2 presents the graphical presentation of the mean log10 reductions from baseline from each of the three (3) test article application procedures excluding data from Subject #12.

Figure 2: Graphical Presentation of the Mean log_{10} Reductions from Baseline From the Three Test Article Application Procedures excluding Data from Subject #12



16.0 CONCLUSION:

The critical index for this study was a two (2) log_{10} reduction in baseline populations after product application.

STATISTICAL ANALYSIS #1

For Test Article #1, Bland Foaming Handwash (Lot Number 275543), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean log_{10} reduction of 2.80 after product application and met the critical index of the study.

For Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2 produced a mean log_{10} reduction of 2.64 after product application and met the critical index of the study.

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For Test Article #3, Sanitizing Hand Wipes (68.15% Ethanol; Lot Number 973-12), followed by Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), applied per Test Article #3 Application Procedure, the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 followed by Test Article #2, applied per Test Article #3 Application Procedure, produced a mean $\log_{10}$ reduction of 2.47 after product application and met the critical index of the study.

STATISTICAL ANALYSIS #2

Upon completion of the statistical analysis, Subject #12's data were determined to be outliers. Further investigation revealed that the subject appeared to have a learning disability and needed repeated instruction by the monitoring laboratory technician to be able to perform each of the steps required by the study protocol. The conclusions below results from a statistical analysis excluding data from testing of Subject #12.

For Test Article #1, Bland Foaming Handwash (Lot Number 275543), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean $\log_{10}$ reduction of 2.93 after product application and met the critical index of the study.

Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2 produced a mean $\log_{10}$ reduction of 2.83 after product application and met the critical index of the study.

Test Article #3, Sanitizing Hand Wipes (68.15% Ethanol; Lot Number 973-12), followed by Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), applied per Test Article #3 Application Procedure, the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 followed by Test Article #2, applied per Test Article #3 Application Procedure, produced a mean $\log_{10}$ reduction of 2.63 after product application and met the critical index of the study.

17.0 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
Sabrina Bakich Marketing Manager/Product Handling	Paul O' Brien Clinical Laboratory Technician
Amanda Berry Subject Recruitment	Alicia Pfile Microbiologist
Stephanie Cebulla Laboratory Support Technician	Christine Roath Microbiologist
Kendra F. Drake Associate Study Director, Microbiologist	Lori Schlotfeldt Supervisor of Laboratory Support

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LABORATORY PERSONNEL (Continued)

Collette Duley
Microbiologist

Erika Ecton
Subject Recruitment

Amanda Henry
Microbiologist

August Grace Johnson
Microbiologist

Jacqueline Joyner
Subject Recruitment

Lisa Lehman
Microbiologist

Ron Neibauer
Manager of Clinical Laboratories

Jessica Sheehy
Laboratory Support Technician

Carl Schmidt
Microbiologist

Brian Stancil
Clinical Laboratory Technician

Robert H. Stancil
Microbiologist

Clare Wilson
Microbiologist

Annette C. Woods
Microbiologist

Kristy Wuebber
Microbiologist

18.0 QUALITY ASSURANCE PERSONNEL:

Liv Graving
Quality Assurance Associate

Amy Juhnke
Manager of Quality Assurance/Document Control

Scott McCommon
Manager of Quality Control

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

Janis Smoke
Quality Assurance Associate

19.0 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 (3) years.

This Study has been approved by the GIRB on _____

20.0 ACCEPTANCE:

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	01/04/08
Product Testing	12/19/07 and 12/26/07
Data Audit	01/14/08
Final Report Review	01/17/08
Reports to Study Director and Management	12/19/07, 12/26/07, 01/04/08, and 01/17/08

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.

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INDEX OF ADDENDA

I GIRB-Approved Protocol #070723-150
Protocol and/or SOP Deviation Recording Form (Form No. 99-QA-004)

II Qualification Criteria for Study 070723-150

III Sampling Data Sheets for Healthcare Personnel Handwash Study 070723-150
Irritation Evaluations for Study 070723-150

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

V Statistical Analysis

VI Neutralization Evaluation
- Project Notes (Form No. 95-G-001) for Neutralization Assay
- Neutralization Evaluation Data Sheets for Study 070723-150
- Neutralization Statistics

VII Study Notes and General Records
- Age Calculation and Demographics Worksheet
- Project Notes (Form No. 95-G-001)
- Protocol 070723-150 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 Sheets (Form No. 96-CT-017)
- Incubator Log Forms (Form No. 96-L-008)
- Refrigerator Log Form (Form No. 96-L-015)
- Inoculum Preparation Tracking Forms - Flask Preparation (Form No. 07-CT-001)
- Inoculum Preparation Tracking Forms - Solid Media Preparation (Form No. 07-CT-002)
- Autoplate® 4000 Data Sheets for Healthcare Personnel Handwash Study 070723-150

VIII Media/Diluent Tracking Forms (Form No. 97-L-007)

IX 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 Sheets (MSDS)
- Product-Tracking Forms (Form No. 93-L-029)

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