May 8, 2018

FINAL REPORT #1803148-150

EVALUATION OF THE RESIDUAL ANTIMICROBIAL ACTIVITY OF ONE TEST PRODUCT VERSUS A COMPARATOR PRODUCT FOR BACTERICIDAL PROPERTIES BASED ON THE ASTM E2752 TEST METHOD

Prepared for:

BEST SANITIZERS / TREY KING (SPONSOR)
PO Box 1423
Corinth, Mississippi 38835

Prepared by:

BIOSCIENCE LABORATORIES, INC. (TESTING FACILITY)
1755 South 19th Avenue
Bozeman, Montana 59718
(406) 587-5735

EXECUTIVE SUMMARY

STUDY NUMBER:	**1803148-150**
TITLE:	**EVALUATION OF THE RESIDUAL ANTIMICROBIAL ACTIVITY OF ONE TEST PRODUCT VERSUS A COMPARATOR PRODUCT FOR BACTERICIDAL PROPERTIES BASED ON THE ASTM E2752 TEST METHOD**
SPONSOR:	**BEST SANITIZERS / TREY KING** PO Box 1423 Corinth, Mississippi 38835
TESTING FACILITY:	**BIOSCIENCE LABORATORIES, INC.** 1755 South 19th Avenue Bozeman, Montana 59718
STUDY INITIATION DATE:	04/06/2018
STUDY COMPLETION DATE:	05/08/2018

The purpose of this study was to evaluate the residual antimicrobial efficacy of one test product versus a comparator ethanol product as defined by the difference between the number of a challenge bacterial species recovered following exposure to the test materials and the number recovered from untreated (negative control) test sites. The challenge bacterial species used was *Staphylococcus aureus* (ATCC #6538). Testing was performed using a modification of the standardized test method described in ASTM E2752-10 (2015) *Standard Guide for Evaluation of Residual Effectiveness of Antibacterial Personal Cleansing Products*. Bacterial recoveries were assayed after application of the test materials, using the forearms as a substrate.

Twenty-four subjects between the ages of 18-65 years, with healthy skin were tested in this study. The test product was applied to three test sites on one randomized forearm, followed by an approximate 5-minute dry-time. Treated test sites were challenged with bacteria, at approximately 1 hour, 2 hours, and 4 hours after product application. The opposite arm was used for the comparator product (two test sites) and untreated control recoveries (three test sites). Comparator product test sites were challenged with bacteria, at approximately 1 hour and 4 hours after product application. Untreated control test sites were challenged with bacteria, at approximately 1 hour, 2 hours, and 4 hours after product application. The challenge bacterial species used was *Staphylococcus aureus* (ATCC #6538).

The test sites were sampled using the cup scrub procedure 20 - 25 minutes following each inoculation. Mean $\log_{10}$ reductions of microbial populations of treated versus untreated sites was the basis for assessing the residual antimicrobial effectiveness of the test product and the comparator product.

For the Test Product, 220-007-00 MOD UV, 0.12% Benzalkonium, Lot #18046RD1, at 1 hour, 2 hours, and 4 hours post-product application, the mean $\log_{10}$ reduction from untreated controls were 4.12, 4.16, and 3.75 respectively.

For the Comparator Product, germ-X® moisturizing original hand sanitizer, Ethyl Alcohol 63%, Lot #0367025, at 1 hour and 4 hours post-product application, the mean $\log_{10}$ reduction from untreated controls were 0.70, and 0.32 respectively.

TABLE OF CONTENTS

May 8, 2018

FINAL REPORT #1803148-150

1.0 TITLE **EVALUATION OF THE RESIDUAL ANTIMICROBIAL ACTIVITY OF ONE TEST PRODUCT VERSUS A COMPARATOR PRODUCT FOR BACTERICIDAL PROPERTIES BASED ON THE ASTM E2752 TEST METHOD**

2.0 SPONSOR **BEST SANITIZERS / TREY KING**
PO Box 1423
Corinth, Mississippi 38835

3.0 TESTING FACILITY **BIOSCIENCE LABORATORIES, INC.**
1755 South 19th Avenue
Bozeman, Montana 59718

4.0 KEY PERSONNEL

Collette Duley – Principal Investigator
Becky Quigley – Subinvestigator
Amanda Ruegsegger - Subinvestigator
Gabor Benda, M.D. – Consulting Physician
David McLaughlin, M.D. – Consulting Physician
Daryl S. Paulson, Ph.D. – Statistician

5.0 PURPOSE OF STUDY

The purpose of this study was to evaluate the residual antimicrobial efficacy of one test product versus a comparator ethanol product as defined by the difference between the number of a challenge bacterial species recovered following exposure to the test materials and the number recovered from untreated (negative control) test sites. The challenge bacterial species used was *Staphylococcus aureus* (ATCC #6538). Testing was performed using a modification of the standardized test method described in ASTM E2752-10 (2015) *Standard Guide for Evaluation of Residual Effectiveness of Antibacterial Personal Cleansing Products*. Bacterial recoveries were assayed after application of the test materials, using the forearms as a substrate.

6.0 SCOPE

Twenty-four subjects between the ages of 18-65 years, with healthy skin were tested in this study. The test product was applied to three test sites on one randomized forearm, followed by an approximate 5-minute dry-time. Treated test sites were challenged with bacteria, at approximately 1 hour, 2 hours, and 4 hours after product application. The opposite arm was used for the comparator product (two test sites) and untreated control recoveries (three test sites). Comparator product test sites were challenged with bacteria, at approximately 1 hour and 4 hours after product application. Untreated control test sites were challenged with bacteria, at approximately 1 hour, 2 hours, and 4 hours after product application. The challenge bacterial species used was *Staphylococcus aureus* (ATCC #6538).

The test sites were sampled using the cup scrub procedure 20 - 25 minutes following each inoculation. Mean $\log_{10}$ reductions of microbial populations of treated versus untreated sites was the basis for assessing the residual antimicrobial effectiveness of the test product and the comparator product.

Protocol #1803148-150 and Version 01 of the Informed Consent Form (ICF) were approved by the Gallatin Institutional Review Board (GIRB) on April 6, 2018. The Protocol was amended once to correct a typographical error. One deviation from Protocol occurred that did not have an adverse effect on the outcome of the study (reference Section 15.0). No deviations from BioScience Laboratories, Inc., Standard Operating Procedures occurred during the course of this study.

7.0 STUDY DATES

STUDY INITIATION DATE	04/06/2018
EXPERIMENTAL START DATE	04/16/2018
EXPERIMENTAL END DATE	04/26/2018
STUDY COMPLETION DATE	05/08/2018

8.0 TEST MATERIALS

The test products were provided to the Testing Facility by the Study Sponsor, complete with appropriate documentation. The test materials were received and stored in accordance with instructions from the Sponsor and retained in secure quarantine when not being used in testing. The Testing Facility maintained an inventory of the test materials and a log of use. Responsibility for determination of the identity, strength, purity, composition, stability, and solubility of the test materials, as well as responsibility for retention of the test materials, remained with the Sponsor.

Test Product:	220-007-00 MOD UV
Active Ingredient:	0.12% Benzalkonium Chloride
Lot Number:	18046RD1
Expiration Date:	N/A
Manufacture Date:	02/15/2018

Comparator Product:	germ-X® moisturizing original hand sanitizer
Active Ingredient:	Ethyl Alcohol 63%
Lot Number:	0367025
Expiration Date:	08/2020
Manufacture Date:	Not Provided

9.0 EQUIPMENT AND SUPPLIES

The equipment and supplies used during this study were detailed on Clinical Trials Equipment Tracking Forms, and Clinical Trials Supplies Tracking Forms. All equipment and instrumentation were calibrated in accordance with applicable BioScience Laboratories, Inc., Standard Operating Procedures.

10.0 TEST SOLUTIONS AND MEDIA

The growth media and diluting fluids used in this study were as described in the Study Protocol. Additional details were recorded on a Clinical Media/Diluent Tracking Form.

11.0 NEUTRALIZATION:

A neutralization study assured that the neutralizers used in the recovery medium quenched the antimicrobial activity of each test material and were not toxic to the challenge species. Study procedures were based on ASTM E1054-08(2013), *Standard Test Methods for Evaluation of Inactivators of Antimicrobial Agents. Staphylococcus aureus* (ATCC #6538) was used as the challenge species in the neutralization study. Results of the Neutralization Assay are presented in Table 1 below.

Table 1: Validation of Neutralizer Effectiveness Results

Test Description	Sample Size	Mean	Standard Deviation	Significantly Different[1]
Test C Test Organism Viability / Initial Population, 1 Minute Exposure	4	1.97	0.04	N/A
X Test C Test Organism Viability / Initial Population, 30 Minute Exposure	4	1.94	0.07	Not Significantly Different
Test A-1 Neutralization Effectiveness Evaluation Test Product 1 Minute Exposure	4	1.82	0.05	Not Significantly Different
X Test A-1 Neutralization Effectiveness Evaluation Test Product 30 Minute Exposure	4	1.86	0.04	Not Significantly Different
Test A-2 Neutralization Effectiveness Evaluation Comparator Product 1 Minute Exposure	4	1.81	0.02	Not Significantly Different
X Test A-2 Neutralization Effectiveness Evaluation Comparator Product 30 Minute Exposure	4	1.85	0.02	Not Significantly Different
Test B-1 Diluting Fluid Toxicity Evaluation (BBP++) 1 Minute Exposure	4	1.93	0.09	Not Significantly Different
X Test B-1 Diluting Fluid Toxicity Evaluation (BBP++) 30 Minute Exposure	4	1.80	0.05	Not Significantly Different
Test B-2 Sampling/Neutralizing Fluid Toxicity Evaluation (SSF++) 1 Minute Exposure Test Material	4	1.90	0.03	Not Significantly Different
X Test B-2 Sampling/Neutralizing Fluid Toxicity Evaluation (SSF++) 30 Minute Exposure	4	1.81	0.04	Not Significantly Different
Test D-1 Test Material Control / Product Efficacy, Test Product	4	0.00	0.00	Significantly Different
Test D-2 Test Material Control / Product Efficacy, Comparator Product	4	0.00	0.00	Significantly Different

[1] Significantly Different from Inoculum Population ($p \leq 0.05$ and difference of means greater than 0.20 $\log_{10}$ difference)

12.0 TEST METHODS

Indicator Microorganism Preparation

12.1 The indicator microorganism was *Staphylococcus aureus* (ATCC #6538).

12.2 For each test day, a stock culture of *S. aureus* was prepared by aseptically transferring a stock culture or contents of a lyophilized vial to approximately 5.0 mL of sterile TSB, which was incubated at 35 °C ± 2 °C for 24 hours ± 4 hours.

12.3 The broth cultures were transferred onto the surface of Tryptic Soy Agar (TSA) and incubated at 35 °C ± 2 °C for 24 hours ± 4 hours.

12.4 Immediately prior to initiating the test procedure, the suspensions of indicator microorganism were prepared by transferring growth from the solid media into test tubes containing Phosphate Buffered Saline (PBS), to result in suspension titers of approximately 1.0×10^9 CFU/mL, determined on the basis of turbidity.

12.5 The challenge suspensions were diluted in PBS to achieve challenge inoculums containing approximately 1.0×10^8 CFU/mL.

12.6 The final challenge inoculum suspensions were assayed for number of organisms at the beginning and end of the use-periods. The suspensions were not used for more than 8 hours.

Subject Assignment (Reference Table 4 for the randomization scheme/assigned subjects)

12.7 Each subject had one forearm assigned to be treated with the Test Product and the other forearm assigned to have two sites treated with the Comparator Product and three sites left untreated for the Untreated Control.

12.8 The sites on the forearms were randomized to be inoculated and sampled 1 hour, 2 hours, and 4 hours post product application, as applicable.

12.8.1 For the comparator product sites, the two sample sites were always side by side due to them fitting in the 2" x 4" product application area.

Test Period

12.9 Each subject was in testing for approximately 5-6 hours on a single day. Prior to being admitted into testing, subjects were questioned regarding their adherence to the Protocol requirements. All jewelry was removed from the hands and arms prior to testing, and subjects donned protective garments (for example, plastic apron).

12.10 Subjects performed a 30-second wash of the forearms with 5.0 mL of nonmedicated soap and a 30-second rinse of the forearms to remove any dirt or oil from the forearms. Subjects dried their hands and forearms with disposable paper towels. The temperature of the water was controlled at 40 °C ± 2 °C. The forearms were decontaminated with 10 mL of 70% isopropyl alcohol (IPA) dispensed over the surface of both forearms (20 mL total) and air-dried.

12.11 Using a surgical skin marker a 2" x 6" product application area was demarcated on the volar surface of the forearm randomized to the test product, with three test sites approximately 2 cm in diameter marked within that area using a steel cylinder. On the forearm randomized to the comparator/untreated sites, a 2" x 4" product application area was demarcated on the volar surface of the forearm with two test sites approximately 2 cm in diameter marked within that area using a steel cylinder. Additionally the three untreated test sites were marked using the steel cylinder.

12.12 The application test sites were re-marked as needed throughout testing.

12.13 A technician applied the Test Product and the Comparator Product according to application instructions provided below.

Test Product Application

12.14 3-mL (4 pumps from the foaming dispenser) of the Test Product were applied to the demarcated 2" x 6" product application area by a technician wearing sterile gloves, as follows:

12.14.1 Following each individual pump, the product was spread on the demarcated product application area, followed by an approximately 1 to 2 minute wait before the next pump was added.

12.14.2 Following the last pump/spread, the product was allowed do dry for approximately 5 minutes.

Comparator Product Application

12.15 2-mL of the Comparator Product were applied to the demarcated 2" x 4" product application area by a technician wearing sterile gloves, as follows:

12.15.1 A 1-mL aliquot of product was dispensed via syringe and the product was spread on the demarcated product application area, followed by an approximately 1 to 2 minute wait.

12.15.2 A second 1-mL aliquot of product was dispensed via syringe and the product was spread on the demarcated product application area. The product was allowed do dry for approximately 5 minutes.

Inoculum Application

12.16 Inoculations began 1 hour ± 15 minutes, 2 hours ± 15 minutes, and 4 hours ± 15 minutes after the completion of the Test Material application, as appropriate.

12.17 At the appropriate post-product application time points (Comparator: 1 and 4 hours, Test: 1, 2, and 4 hours), a 10 µL (0.01 mL) aliquot of the challenge inoculum was applied to the randomly assigned test sites on each forearm, and sterile glass rods were used to distribute the inoculum over the demarcated ~ 2 cm diameter test area (but not reaching the edges of the demarcated area) and air-dried for at least 20 minutes but no more than 25 minutes.

12.18 The corresponding untreated control sites were inoculated after treated-site(s) were inoculated. A 10 µL (0.01 mL) aliquot of the challenge inoculum was applied to the randomly assigned test sites on the forearm, and sterile glass rods were used to distribute the inoculum over the demarcated ~ 2 cm diameter test area (but not reaching the edges of the demarcated area) and air-dried for at least 20 minutes but no more than 25 minutes.

12.19 The contaminated sites were covered with weigh-boats held to the skin using surgical tape.

12.20 The contaminated sites were sampled using the Cup Scrub Technique following the 20-25 minute inoculum air-dry.

Cup Scrub Technique

12.21 A sterile stainless-steel cylinder with an inside area of 3.46 cm^2 was held firmly onto the site to be sampled. A 2.5 mL aliquot of Sterile Stripping Suspending Fluid with product neutralizers (SSF++) was dispensed into the cylinder, and the skin area inside the cylinder was massaged in a circumferential manner for 1 minute ±10 seconds with a sterile glass rod.

12.22 The 2.5 mL of SSF++ were removed with a pipette and transferred to a sterile test tube. A second 2.5 mL aliquot of SSF++ was dispensed into the cylinder, and the skin area massaged for 1 minute ± 10 seconds with the sterile glass rod.

12.23 The second 2.5 mL aliquot was pooled in the test tube with the first aliquot.

12.24 Gauze soaked in 70% isopropyl alcohol (IPA) was used to decontaminate each site following sampling completion.

Subject Safety

12.25 Subjects were not allowed to leave the laboratory for any reason once inoculation began except in the case of an emergency. Additionally, subjects were required to wear protective garments, face shields (during inoculation/cup scrub sampling procedures), and were instructed to not touch their clothing, faces, or any other body parts with their hands or forearms during the test period.

12.26 At the completion of each time-point the site was wiped with gauze soaked in 70% isopropyl alcohol (IPA) and then allowed to air-dry. On completion of testing, subjects performed a 1-minute rinse of the hands and forearms with 70% isopropyl alcohol (IPA) and air-dry, followed by a supervised 4-minute wash with a 4% chlorhexidine gluconate solution. Following the final decontamination procedure, a topical antibiotic ointment was applied to the hands and forearms. Subjects were instructed to allow the ointment to absorb into the skin for at least 2 hours.

12.27 Due to the use of the chlorhexidine gluconate (CHG) solution, subjects were instructed to seek immediate emergency medical help if they experienced any of the following symptoms: hives, severe skin rash, wheezing, difficulty breathing, cold sweats, feeling light-headed, or swelling of the face/lips/tongue/throat. No subjects experienced these reactions.

12.28 To ensure that any delayed adverse events, such as primary skin infections, were reported to the Principal Investigator, all test subjects were given instructions before leaving the testing facility to examine their hands, wrists, and forearms daily for one week for the presence of pimples, blisters, or raised, red itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection. Subjects who noticed any such reaction were instructed to call the testing facility. No subject experienced an adverse reaction.

12.29 An antibiotic sensitivity profile for *Staphylococcus aureus* (ATCC #6538) used in this study was retained on file at BSLI.

Plating and Data Collection

12.30 Aliquots of the microorganism suspension (10^0 dilution) were serially diluted in Butterfield's Phosphate Buffer Solution with product neutralizers (BBP++), as appropriate.

12.31 Duplicate spread plates were prepared from appropriate dilutions using Mannitol Salt Agar (MSA), and incubated at 35 °C ± 2 °C for approximately 48 hours or until sufficient growth was observed.

12.32 *Staphylococcus aureus* (ATCC #6538) produces golden-yellow colonies on MSA, and only those colonies were counted.

12.33 Average colony counts of 0 at the -1 dilution were recorded as <5.00 CFU/mL.

13.0 SUBJECT DEMOGRAPHICS

Forty overtly healthy subjects between 18 and 65 years of age were admitted into the study. Twenty-four subjects received product and completed testing. Data from all 24 subjects were used in the final analysis. Insofar as possible, the group of subjects selected was of mixed sex, age, and race, and the hands and forearms were free from clinically evident dermatoses, cuts, lesions, and/or any other skin disorders that may have compromised the subject and the study. All subjects signed the Informed Consent Form, Subject Confidential Information and Acceptance Criteria, and Authorization to Use and Disclose Protected Health Information Form prior to participating in the study. The demographics of the study are presented in Table 2 below.

Table 2: Demographics Summary

DEMOGRAPHIC SUMMARY	Recruited	Received Test Material	Completed Testing
AGE			
Minimum Age	19	19	19
Median Age	38	36	36
Maximum Age	65	63	63
SEX			
Males	32	16	16
Females	8	8	8
Total	40	24	24
RACE			
White/Caucasian	36	23	23
African American/Black	1	0	0
American Indian/Alaskan Native	1	0	0
Asian	1	1	1
Subject Chose Not to Disclose	1	0	0
Total	40	24	24
ETHNICITY			
Non-Hispanic/Non-Latino	34	20	20
Latino	3	1	1
Subject Chose Not to Disclose	3	3	3
Total	40	24	24
DID NOT PARTICIPATE IN TESTING			
Qualification (Inclusion/Exclusion) Criteria Failure		2	
Subject Failed to Appear for Testing		2	
Schedule Conflict		1	
Study Requirements Fulfilled		11	
Total		16	

14.0 ADVERSE EVENTS

No subjects experienced adverse events during or following completion of this study.

15.0 DEVIATION FROM STUDY PROTOCOL:

On 04/19/18, a single 2.5 mL 1-minute scrub was performed for the 2-hour untreated site sampling procedure for Subject #8. The deviation occurred because the assisting technician placed the post-sampling site-decontamination supplies by the sampler prematurely. The data for this sample were not used in analysis, resulting in a sample size of 23 instead of 24 for the 2-hour test product samples. While the sample size for the test product was reduced, the test product achieved high reductions from untreated control and therefore, one additional sample would not likely change this result. There was no adverse effect on the outcome of the study.

16.0 STATISTICAL ANALYSIS AND RESULTS – TABLES 3 THROUGH 10

Microbial Recoveries and Statistical Calculations

16.1 The MiniTab® Version 18 statistical computer package was used for all statistical calculations.

16.2 The estimated $\log_{10}$ number of viable microorganisms per cm^2 recovered from each sample site were designated the "R-value."

To convert the volumetric measure of the sample into the number of colony-forming units per square centimeter (cm^2), the following formula was employed:

$$R = Log_{10}\left[\frac{F\left(\frac{\sum c_i}{n}\right)10^{-D}}{A}\right]$$

where:

R = the average colony-forming unit count in $\log_{10}$ scale per cm^2 of sampling surface
F = total number of mL of stripping fluid added to the sampling cylinder; in this study, $F = 5$ mL
$\frac{\sum c_i}{n}$ = average of the duplicate colony counts used for each sample collected
D = dilution factor of the plate counts
A = inside area of the scrub cup in cm^2; in this study, $A = 3.46$ cm^2.

NOTE: The $\log_{10}$ transformation is performed on these data to convert them to a linear scale. A linear scale, more appropriately a $\log_{10}$ linear scale, was a requirement of the statistical models to be used.

16.3 Tables 3 through 7 present statistical summaries of treated and untreated mean $\log_{10}$ microbial recoveries of *Staphylococcus aureus* (ATCC #6538) for the 1-hour, 2-hour and 4-hour time-points, and mean $\log_{10}$ microbial differences from untreated controls, as appropriate.

Table 3: Mean Log_{10} Microbial Recoveries and Reductions from Untreated Control of *Staphylococcus aureus* (ATCC #6538), 1 hour following Application of the Test Product: 220-007-00 MOD UV, 0.12% Benzalkonium, Lot #18046RD1

Sample	Sample Size	Mean	Standard Deviation
1-hour Untreated Log_{10} Microbial Recovery	24	5.20	0.19
1-hour Treated Log_{10} Microbial Recovery	24	1.08	0.40
1-hour Log_{10} Difference	24	4.12	0.36

Table 4: Mean Log_{10} Microbial Recoveries and Reductions from Untreated Control of *Staphylococcus aureus* (ATCC #6538), 2 hours following Application of the Test Product: 220-007-00 MOD UV, 0.12% Benzalkonium, Lot #18046RD1

Sample	Sample Size	Mean	Standard Deviation
2-hour Untreated Log_{10} Microbial Recovery	23	5.17	0.20
2-hour Treated Log_{10} Microbial Recovery	24	1.01	0.37
2-hour Log_{10} Difference	23	4.16	0.35

Table 5: Mean Log_{10} Microbial Recoveries and Reductions from Untreated Control of *Staphylococcus aureus* (ATCC #6538), 4 hours following Application of the Test Product: 220-007-00 MOD UV, 0.12% Benzalkonium, Lot #18046RD1

Sample	Sample Size	Mean	Standard Deviation
4-hour Untreated Log_{10} Microbial Recovery	24	4.92	0.42
4-hour Treated Log_{10} Microbial Recovery	24	1.16	0.50
4-hour Log_{10} Difference	24	3.75	0.60

Table 6: Mean Log_{10} Microbial Recoveries and Reductions from Untreated Control of *Staphylococcus aureus* (ATCC #6538), 1 hour following Application of the Comparator Product: germ-X® moisturizing original hand sanitizer, Ethyl Alcohol 63%, Lot #0367025

Sample	Sample Size	Mean	Standard Deviation
1-hour Untreated Log_{10} Microbial Recovery	24	5.20	0.19
1-hour Treated Log_{10} Microbial Recovery	24	4.50	0.73
1-hour Log_{10} Difference	24	0.70	0.70

Table 7: Mean Log_{10} Microbial Recoveries and Reductions from Untreated Control of *Staphylococcus aureus* (ATCC #6538), 4-hours following Application of the Comparator Product: germ-X® moisturizing original hand sanitizer, Ethyl Alcohol 63%, Lot #0367025

Sample	Sample Size	Mean	Standard Deviation
4-hour Untreated Log_{10} Microbial Recovery	24	4.92	0.42
4-hour Treated Log_{10} Microbial Recovery	24	4.59	0.65
4-hour Log_{10} Difference	24	0.32	0.60

16.4 Tables 8 and 9 present the log_{10} microbial recoveries of *Staphylococcus aureus* (ATCC #6538) for treated and untreated sites and log_{10} microbial differences, by subject; 1 hour, 2 hours, and 4 hours following application of the Test Materials.

Table 8: Log_{10} Microbial Recoveries and Reductions from Untreated Control of *Staphylococcus aureus* (ATCC #6538), by Subject; 1 hour, 2 hours, and 4 hours following Application of the Test Product: 220-007-00 MOD UV, 0.12% Benzalkonium, Lot #18046RD1

	1 hour Post-Product Application			2 hours Post-Product Application			4 hours Post-Product Application		
Subject	**Untreated Log_{10} Microbial Recovery**	**Treated Log_{10} Microbial Recovery**	**Log_{10} Difference**	**Untreated Log_{10} Microbial Recovery**	**Treated Log_{10} Microbial Recovery**	**Log_{10} Difference**	**Untreated Log_{10} Microbial Recovery**	**Treated Log_{10} Microbial Recovery**	**Log_{10} Difference**
3	4.90	0.86	4.04	5.08	0.86	4.23	3.69	0.86	2.83
11	5.39	1.56	3.83	5.34	1.34	4.00	4.81	1.46	3.35
4	5.38	1.81	3.57	5.26	0.86	4.40	5.36	1.16	4.20
6	5.39	0.86	4.53	5.34	0.86	4.49	5.09	0.86	4.24
1	5.32	0.86	4.46	5.12	0.86	4.26	5.05	0.86	4.19
15	5.34	2.03	3.31	5.25	0.86	4.39	5.11	2.09	3.02
7	5.23	0.86	4.37	5.10	0.86	4.24	5.12	0.86	4.26
9	5.05	1.16	3.89	5.16	0.86	4.31	5.07	1.34	3.74
8	5.17	0.86	4.31	*	0.86	*	4.01	0.86	3.15
10	5.22	1.16	4.06	5.09	1.16	3.93	4.77	0.86	3.91
17	5.12	0.86	4.26	5.09	0.86	4.24	5.03	0.86	4.17
2	4.91	0.86	4.05	5.15	0.86	4.29	5.13	0.86	4.27
22	5.30	0.86	4.44	5.17	0.86	4.31	5.13	1.16	3.97
24	5.17	0.86	4.31	5.19	0.86	4.33	5.14	0.86	4.28
27	5.14	0.86	4.28	5.14	0.86	4.28	5.00	0.86	4.14
12	5.29	0.86	4.43	4.80	0.86	3.94	4.77	0.86	3.91
23	4.86	0.86	4.00	5.06	0.86	4.20	4.34	0.86	3.48
20	4.75	0.86	3.89	4.53	0.86	3.67	4.33	2.11	2.22
34	5.40	2.14	3.27	5.40	2.47	2.93	5.29	2.42	2.87
32	5.44	0.86	4.58	5.35	0.86	4.49	5.32	0.86	4.46
37	5.34	1.16	4.18	5.36	1.56	3.80	5.24	2.16	3.08
36	5.14	1.16	3.98	5.17	0.86	4.31	4.96	0.86	4.10
33	5.31	0.86	4.45	5.42	0.86	4.56	5.11	0.86	4.25
35	5.21	0.86	4.35	5.35	1.34	4.01	5.11	1.16	3.95

Note: The lowest detectable limit of the study was 0.86 log_{10} CFU/cm^2 * Data unavailable due to deviation during testing.

Table 9: Log_{10} Microbial Recoveries and Reductions from Untreated Control of *Staphylococcus aureus* (ATCC #6538), by Subject; 1-hour and 4-hours following Application of the Comparator Product: germ-X® moisturizing original hand sanitizer, Ethyl Alcohol 63%, Lot #0367025

	1 hour Post-Product Application			4 hours Post-Product Application		
Subject	**Untreated Log_{10} Microbial Recovery**	**Treated Log_{10} Microbial Recovery**	**Log_{10} Difference**	**Untreated Log_{10} Microbial Recovery**	**Treated Log_{10} Microbial Recovery**	**Log_{10} Difference**
3	4.90	3.76	1.14	3.69	4.23	-0.54
11	5.39	4.01	1.37	4.81	4.09	0.72
4	5.38	3.20	2.18	5.36	3.68	1.68
6	5.39	5.26	0.13	5.09	5.46	-0.36
1	5.32	4.25	1.08	5.05	5.24	-0.19
15	5.34	4.24	1.11	5.11	4.51	0.61
7	5.23	5.15	0.08	5.12	4.76	0.35
9	5.05	3.84	1.22	5.07	4.28	0.80
8	5.17	5.31	-0.14	4.01	4.10	-0.09
10	5.22	4.75	0.47	4.77	4.46	0.31
17	5.12	5.30	-0.18	5.03	5.12	-0.08
2	4.91	4.84	0.07	5.13	5.02	0.11
22	5.30	3.58	1.72	5.13	3.70	1.43
24	5.17	5.00	0.17	5.14	4.59	0.55
27	5.14	5.21	-0.07	5.00	5.09	-0.10
12	5.29	3.38	1.90	4.77	4.57	0.21
23	4.86	3.46	1.40	4.34	4.38	-0.04
20	4.75	3.50	1.25	4.33	2.66	1.67
34	5.40	5.41	0.00	5.29	5.32	-0.03
32	5.44	4.85	0.59	5.32	5.09	0.23
37	5.34	5.00	0.34	5.24	5.12	0.12
36	5.14	5.05	0.09	4.96	5.18	-0.22
33	5.31	4.77	0.54	5.11	5.07	0.04
35	5.21	4.86	0.35	5.11	4.53	0.58

16.5 Table 10 presents the initial and final populations of the *Staphylococcus aureus* (ATCC #6538) inoculum suspension used in testing.

Table 10: Initial and Final Populations of the *Staphylococcus aureus* (ATCC #6538) Inoculum Suspensions

Test Date	Initial Population (CFU/mL)	Final Population (CFU/mL)
04/19/18	9.55×10^7	7.35×10^7
04/20/18	9.75×10^7	6.50×10^7
04/24/18	1.01×10^8	1.01×10^8

17.0 CONCLUSIONS:

For the Test Product, 220-007-00 MOD UV, 0.12% Benzalkonium, Lot #18046RD1, at 1 hour, 2 hours, and 4 hours post-product application, the mean $\log_{10}$ reduction from untreated controls were 4.12, 4.16, and 3.75 respectively.

For the Comparator Product, germ-X® moisturizing original hand sanitizer, Ethyl Alcohol 63%, Lot #0367025, at 1 hour and 4 hours post-product application, the mean $\log_{10}$ reduction from untreated controls were 0.70, and 0.32 respectively.

18.0 DOCUMENTATION AND RECORD-KEEPING:

All documentation and records will be compiled, analyzed, and retained by BioScience Laboratories, Incorporated, 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 5 years. BioScience Laboratories, Inc. will notify the Study Sponsor before any documents or records are destroyed.

19.0 ACCEPTANCE:

Report Prepared by:

Collette Duley
Principal Investigator, BioScience Laboratories, Inc.

05/08/18
Date of Study Completion

Reviewed by Quality Assurance:

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

Phase Inspected	Audit Date	Date reported to Principal Investigator	Date reported to Management
Neutralization	04/16/2018	04/17/2018	04/19/2018
Product Testing	04/19/2018	04/23/2018	04/27/2018
Data Audit	05/07/2018	05/08/2018	05/08/2018
Final Report Review	05/07/2018	05/08/2018	05/08/2018

This study was conducted in compliance with Good Clinical Practice Regulations including 21 CFR Parts 50 (*Protection of Human Subjects*), 56 (*Institutional Review Boards*), and Part 58 (*Good Laboratory Practice for Non-Clinical Laboratory Studies)*, with the following exception: the characterization of the identity, strength, purity, composition, stability, and solubility of the test products was not performed by BioScience Laboratories, Inc. One deviation from the Study Protocol was documented appropriately. No deviations from the BioScience Laboratories, Inc., Standard Operating Procedures occurred during the course of this study. This statement also serves to confirm that the Final Report reflects the raw data.

Danielle Goveia
Quality Assurance Specialist, BioScience Laboratories, Inc.

05/08/18
Date

Reviewed and Approved by:

Daryl S. Paulson, Ph.D.
President & CEO, BioScience Laboratories, Inc.

05-08-18
Date