April 21, 2020

FINAL REPORT #2001505-201

AN IN-VITRO TIME-KILL EVALUATION OF ONE TEST MATERIAL WHEN CHALLENGED WITH VARIOUS BACTERIAL SPECIES

Prepared for:

APHEX BIOCLEANSE SYSTEMS, INC. (SPONSOR)
15 Fishers Road, Suite 111
Pittsford, New York 14534

Prepared by:

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

TABLE OF CONTENTS

EXECUTIVE SUMMARY

STUDY NUMBER: **2001505-201**

TITLE: **AN IN-VITRO TIME-KILL EVALUATION OF ONE TEST MATERIAL WHEN CHALLENGED WITH VARIOUS BACTERIAL SPECIES**

SPONSOR: **APHEX BIOCLEANSE SYSTEMS, INC.**
15 Fishers Road, Suite 111
Pittsford, New York 14534

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

STUDY INITIATION DATE: 03/18/2020

STUDY COMPLETION DATE: 04/21/2020

An In-Vitro Time-Kill evaluation of one test material was performed versus suspensions of four bacterial species - American Type Culture Collection (ATCC), *Escherichia coli* (ATCC #35150), *Listeria monocytogenes* (ATCC #19117), *Salmonella enteric* Paratyphi B (ATCC #8759), and *Shigella sonnei* (ATCC #29031). The percent and $\log_{10}$ reductions in the microbial population of each challenge species was determined following exposure of the Test Material at room temperature (22 to 26 °C) for 1 minute, 3 minutes and 10 minutes. Three replicates of testing of each challenge species was evaluated versus the Test Material. All agar-plating was performed in duplicate. The results listed below are the Mean Log_{10} Reductions listed per time of exposure (1 minute, 3 minutes and 10 minutes) for each microorganism tested.

Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701 reduced the microbial populations of *Escherichia coli* (ATCC #35150), by an average of 2.17 $\log_{10}$ following a 1 minute, an average of 3.96 $\log_{10}$ following a 3 minute, and an average of 4.16 $\log_{10}$ following a 10-minute exposure time.

Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701 reduced the microbial populations of *Listeria monocytogenes* (ATCC #19117), by an average of 1.50 $\log_{10}$ following a 1 minute, an average of 3.11 $\log_{10}$ following a 3 minute, and an average of 4.68 $\log_{10}$ following a 10-minute exposure time.

Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701 reduced the microbial populations of *Salmonella enteric* Paratyphi B (ATCC #8759), by an average of 4.05 $\log_{10}$ following a 1 minute, 3 minute, and 10-minute exposure times.

Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701 reduced the microbial populations of *Shigella sonnei* (ATCC #29031), by an average of 3.40 $\log_{10}$ following a 1 minute and an average of 4.70 $\log_{10}$ following 3 minute and 10-minute exposure times.

April 21, 2020

FINAL REPORT #2001505-201

1.0 TITLE: **AN IN-VITRO TIME-KILL EVALUATION OF ONE TEST MATERIAL WHEN CHALLENGED WITH VARIOUS BACTERIAL SPECIES**

2.0 SPONSOR: **APHEX BIOCLEANSE SYSTEMS, INC.**
15 Fishers Road, Suite 111
Pittsford, New York 14534

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

4.0 STUDY DIRECTOR: Dan Dragotoiu

5.0 PURPOSE:

This study used an In-Vitro Time-Kill Method to evaluate the antimicrobial properties of one test material when challenged with suspensions of four bacterial species. This procedure is based upon the methodology described in ASTM E2783-11 (2016), *Standard Test Method for Assessment of Antimicrobial Activity for Water Miscible Compounds Using a Time-Kill Procedure*[1]. All testing was performed in accordance with Good Laboratory Practices, as specified in 21 CFR Part 58, with the following exception: The characterization of the identity, strength, purity, composition, stability, and solubility of the test material remained the responsibility of the Study Sponsor and was not performed by the Testing Facility (GLP 58.105 and GLP 58.113).

6.0 SCOPE:

An In-Vitro Time-Kill evaluation of one test material was performed versus suspensions of four bacterial species. American Type Culture Collection (ATCC) *Escherichia coli* (ATCC #35150), *Listeria monocytogenes* (ATCC #19117), *Salmonella enterica* Paratyphi B (ATCC #8759), and *Shigella sonnei* (ATCC #29031). The percent and $\log_{10}$ reductions in the microbial population of each challenge species were determined following exposure to the test material at room temperature (22 to 26 °C) for 1 minute, 3 minutes and 10 minutes. Three replicates of testing of each challenge species were evaluated versus the Test Material. All agar-plating was performed in duplicate.

The Study Protocol, included as Addendum 1 of this Final Report, presents the study methodology, in detail, as do the Data Gathering Forms in Addenda 4 and 5 of this Final Report. Two deviations from the methodology described in the Study Protocol occurred during the course of this evaluation. No deviations from applicable BioScience Laboratories, Inc., Standard Operating Procedures occurred during the course of this evaluation.

7.0 STUDY DATES:

STUDY INITIATION DATE:	03/18/2020
EXPERIMENTAL START DATE:	03/30/2020
EXPERIMENTAL END DATE:	04/01/2020
STUDY COMPLETION DATE:	04/21/2020

8.0 TEST MATERIAL:

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

Test Material:	Gen 1 Hy-IQ (Electrolytic Water)
Active Ingredient:	Electrolytic Ionized Water
Lot Number:	2000701
Manufacture Date:	1.07.2020
Expiration Date:	01.10.2025

9.0 CHALLENGE MICROORGANISM STRAINS:

The challenge microorganism species (American Type Culture Collection [ATCC]) that were evaluated are designated below.

9.1 *Escherichia coli* (ATCC #35150)
9.2 *Listeria monocytogenes* (ATCC #19117)
9.3 *Salmonella enterica* Paratyphi B (ATCC #8759)
9.4 *Shigella sonnei* (ATCC #29031)

10.0 EQUIPMENT AND SUPPLIES:

The equipment and supplies used in this study are as described in the Study Protocol in Addendum 1 of this Final Report. Additional details are recorded on the Equipment Tracking Forms in Addendum 6 of this Final Report. All applicable equipment and instrumentation were calibrated in accordance with BioScience Laboratories, Inc., Standard Operating Procedures.

11.0 MEDIA:

11.1 The Neutralizing Formulation employed for this evaluation was Neutralizing solution – Phosphate Buffered Saline with 0.1% (w/v) Sodium Thiosulfate and 0.1% (v/v) Tween 80, pH 7.2 (PBS-T/ST)

11.2 The growth media and other diluting fluids used in this study are as described in the Study Protocol in Addendum 1 of this Final Report. Additional details are recorded on the Media/Diluent Tracking Forms in Addendum 6 of this Final Report.

12.0 DEVIATION FROM THE STUDY PROTOCOL:

12.1 Section 12.16 of the Study Protocol states that 1.0 mL and 0.1 mL aliquots will be pour-plated in duplicate using the appropriate agar media (with no added neutralizers; reference Table 1 of the Study Protocol). Table 1 of the Study Protocol lists the appropriate agar as TSA. On test date 03/30/2020, 1.0 mL and 0.1 mL aliquots were spread-plated on Tryptic Soy Agar (TSA) for *Shigella sonnei* (ATCC #29031) Replicates 2 and 3 of the Neutralization Assay (Test Material Control - Test D). Since the data obtained from replicate #2 and #3 were comparable to replicate #1, which was pour-plated, spread-plating replicate #2 and #3 had no adverse effect on the outcome of the study.

12.2 Section 5.0 of the Study Protocol states, "The percent and $\log_{10}$ reduction in the microbial population of each challenge species will be determined following exposure to the test material at room temperature (20 to 25 °C) for 1, 3, and 10 minutes." On 03/30/2020, the temperature of the In-Vitro lab, where testing was conducted, reached 26° C during testing. This was a result of a typographical error in the study protocol which should of stated, "… (nominally 20 to 25 °C)." There was no observable detrimental effect on the survivability of any of the challenge species as demonstrated by the concentration of the Initial and Final Populations of all four challenge species. As such, there is no adverse impact on the study outcome.

13.0 NEUTRALIZATION STUDIES – RESULTS (TABLES 1 THROUGH 4):

13.1 A Neutralization study of the test material was performed versus *Escherichia coli* (ATCC #35150), *Listeria monocytogenes* (ATCC #19117), *Salmonella enterica* Paratyphi B (ATCC #8759), and *Shigella sonnei* (ATCC #29031) to ensure that the neutralizing solution employed (Phosphate Buffered Saline with 0.1% (w/v) Sodium Thiosulfate and 0.1% (v/v) Tween 80, pH 7.2 [PBS-T/ST]) was effective in neutralizing the antimicrobial properties of the test material and was non-toxic to these representative challenge species.

13.2 When challenged with *Escherichia coli* (ATCC #35150), *Listeria monocytogenes* (ATCC #19117), *Salmonella enterica* Paratyphi B (ATCC #8759), and *Shigella sonnei* (ATCC #29031), PBS-T/ST effectively neutralized the antimicrobial properties of the Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701. Neutralization of the test material was accomplished, in part, by dilution. Therefore, the 10^{-2} dilution plated in the time-kill exposures was the lowest reliable dilution used for calculation of post-exposure populations of all species tested in the Time-kill. PBS-T/ST was demonstrated to be non-toxic to *Escherichia coli* (ATCC #35150), *Listeria monocytogenes* (ATCC #19117), *Salmonella enterica* Paratyphi B (ATCC #8759), and *Shigella sonnei* (ATCC #29031).

13.3 All results from the Neutralization Validation Studies are presented in Tables 1 through 4 and are included in Addendum 4 of this Final Report.

TABLE 1
Neutralization Evaluation – Results
Test Date 03/30/2020

Organism	Replicate	Neutralization Phase	Post-Exposure Population (Log_{10})	Log_{10} Average Post-Exposure Population	Results of Neutralization
Escherichia coli (ATCC #35150)	1	Initial Population **Immediate** (Test C)	2.10	2.10	N/A
	2		2.09		
	3		2.12		
	1	Initial Population **≥ 15 minutes** (Test C)	2.07	2.05	N/A
	2		2.06		
	3		2.03		
	1	Neutralizer Toxicity (Test B) **Immediate** Neutralizing Formulation PBS-T/ST	2.09	2.10	Neutralizer Non-Toxic❶
	2		2.09		
	3		2.13		
	1	Neutralizer Toxicity (Test B) **≥ 15 minutes** Neutralizing Formulation PBS-T/ST	2.12	2.11	Neutralizer Non-Toxic❶
	2		2.11		
	3		2.10		
	1	Neutralizer Efficacy (Test A) **Immediate** Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701	2.08	2.09	Neutralizer Efficacious❶
	2		2.09		
	3		2.10		
	1	Neutralizer Efficacy (Test A) **≥ 15 minutes** Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701	2.18	2.14	Neutralizer Efficacious❶
	2		2.12		
	3		2.12		
	1	Test Material Control (Test D) **≤ 15 minutes** Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701	0.00	0.00	Test Material demonstrates antimicrobial activity ❷
	2		0.00		
	3		0.00		

❶ = The 95% Confidence Interval for this population overlapped that of the Initial Population and/or the mean log_{10} population was not more than 0.2 log_{10} lower than the initial population.
❷ = The mean log_{10} population is significantly lower than the Initial Population. Test Material Control (Test D).

TABLE 2
Neutralization Evaluation – Results
Test Date 03/30/2020

Organism	Replicate	Neutralization Phase	Post-Exposure Population (Log_{10})	Log_{10} Average Post-Exposure Population	Results of Neutralization
Listeria monocytogenes (ATCC #19117)	1	Initial Population **Immediate** (Test C)	2.71	2.66	N/A
	2		2.61		
	3		2.67		
	1	Initial Population **≥ 15 minutes** (Test C)	2.61	2.58	N/A
	2		2.54		
	3		2.59		
	1	Neutralizer Toxicity (Test B) **Immediate** Neutralizing Formulation PBS-T/ST	2.71	2.69	Neutralizer Non-Toxic❶
	2		2.72		
	3		2.64		
	1	Neutralizer Toxicity (Test B) **≥ 15 minutes** Neutralizing Formulation PBS-T/ST	2.72	2.66	Neutralizer Non-Toxic❶
	2		2.66		
	3		2.59		
	1	Neutralizer Efficacy (Test A) **Immediate** Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701	2.68	2.65	Neutralizer Efficacious❶
	2		2.71		
	3		2.56		
	1	Neutralizer Efficacy (Test A) **≥ 15 minutes** Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701	2.64	2.65	Neutralizer Efficacious❶
	2		2.63		
	3		2.67		
	1	Test Material Control (Test D) **≤ 15 minutes** Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701	0.00	0.00	Test Material demonstrates antimicrobial activity ❷
	2		0.00		
	3		0.00		

❶ = The 95% Confidence Interval for this population overlapped that of the Initial Population and/or the mean log_{10} population was not more than 0.2 log_{10} lower than the initial population.
❷ = The mean log_{10} population is significantly lower than the Initial Population. Test Material Control (Test D).

TABLE 3
Neutralization Evaluation – Results
Test Date 03/30/2020

Organism	Replicate	Neutralization Phase	Post-Exposure Population (Log_{10})	Log_{10} Average Post-Exposure Population	Results of Neutralization
Salmonella enterica Paratyphi B (ATCC #8759)	1	Initial Population **Immediate** (Test C)	2.05	2.08	N/A
	2		2.13		
	3		2.06		
	1	Initial Population **≥ 15 minutes** (Test C)	2.06	2.07	N/A
	2		2.11		
	3		2.03		
	1	Neutralizer Toxicity (Test B) **Immediate** Neutralizing Formulation PBS-T/ST	2.09	2.08	Neutralizer Non-Toxic❶
	2		2.10		
	3		2.04		
	1	Neutralizer Toxicity (Test B) **≥ 15 minutes** Neutralizing Formulation PBS-T/ST	2.09	2.07	Neutralizer Non-Toxic❶
	2		2.11		
	3		2.02		
	1	Neutralizer Efficacy (Test A) **Immediate** Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701	2.05	2.05	Neutralizer Efficacious❶
	2		2.03		
	3		2.08		
	1	Neutralizer Efficacy (Test A) **≥ 15 minutes** Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701	2.03	2.07	Neutralizer Efficacious❶
	2		2.08		
	3		2.09		
	1	Test Material Control (Test D) **≤ 15 minutes** Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701	0.00	0.00	Test Material demonstrates antimicrobial activity ❷
	2		0.00		
	3		0.00		

❶ = The 95% Confidence Interval for this population overlapped that of the Initial Population and/or the mean log_{10} population was not more than 0.2 log_{10} lower than the initial population.
❷ = The mean log_{10} population is significantly lower than the Initial Population. Test Material Control (Test D).

TABLE 4
Neutralization Evaluation – Results
Test Date 03/30/2020

Organism	Replicate	Neutralization Phase	Post-Exposure Population (Log_{10})	Log_{10} Average Post-Exposure Population	Results of Neutralization
Shigella sonnei (ATCC #29031)	1	Initial Population **Immediate** (Test C)	2.68	2.67	N/A
	2		2.62		
	3		2.71		
	1	Initial Population **≥ 15 minutes** (Test C)	2.76	2.71	N/A
	2		2.67		
	3		2.71		
	1	Neutralizer Toxicity (Test B) **Immediate** Neutralizing Formulation PBS-T/ST	2.69	2.66	Neutralizer Non-Toxic❶
	2		2.64		
	3		2.65		
	1	Neutralizer Toxicity (Test B) **≥ 15 minutes** Neutralizing Formulation PBS-T/ST	2.70	2.71	Neutralizer Non-Toxic❶
	2		2.74		
	3		2.70		
	1	Neutralizer Efficacy (Test A) **Immediate** Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701	2.58	2.63	Neutralizer Efficacious❶
	2		2.69		
	3		2.63		
	1	Neutralizer Efficacy (Test A) **≥ 15 minutes** Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701	2.69	2.65	Neutralizer Efficacious❶
	2		2.62		
	3		2.63		
	1	Test Material Control (Test D) **≤ 15 minutes** Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701	0.00	0.00	Test Material demonstrates antimicrobial activity ❷
	2		0.00		
	3		0.00		

❶ = The 95% Confidence Interval for this population overlapped that of the Initial Population and/or the mean log_{10} population was not more than 0.2 log_{10} lower than the initial population.
❷ = The mean log_{10} population is significantly lower than the Initial Population. Test Material Control (Test D).

14.0 IN-VITRO TIME-KILL EVALUATION – RESULTS (TABLES 5 THROUGH 8):

14.1 Table 5 presents the Initial Population, the Final Population, the Numbers Control Population, and the Post-Exposure Populations (CFU/mL) of *Escherichia coli* (ATCC #35150), as well as the $\log_{10}$, the mean $\log_{10}$ and percent reductions produced by Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701 following 1 minute, 3 minute and 10 minute exposures.

14.2 Table 6 presents the Initial Population, the Final Population, the Numbers Control Population, and the Post-Exposure Populations (CFU/mL) of *Listeria monocytogenes* (ATCC #19117), as well as the $\log_{10}$, the mean $\log_{10}$ and percent reductions produced by Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701 following 1 minute, 3 minute and 10 minute exposures.

14.3 Table 7 presents the Initial Population, the Final Population, the Numbers Control Population, and the Post-Exposure Populations (CFU/mL) of *Salmonella enterica* Paratyphi B (ATCC #8759), as well as the $\log_{10}$, the mean $\log_{10}$ and percent reductions produced by Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701 following 1 minute, 3 minute and 10 minute exposures.

14.4 Table 8 presents the Initial Population, the Final Population, the Numbers Control Population, and the Post-Exposure Populations (CFU/mL) of *Shigella sonnei* (ATCC #29031), as well as the $\log_{10}$, the mean $\log_{10}$ and percent reductions produced by Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701 following 1 minute, 3 minute and 10 minute exposures.

14.5 All results from the Time-Kill Evaluation are presented in Tables 5 through 8 and are included in Addendum 5 of this Final Report.

TABLE 5

Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701

Test Date 03/30/2020

Microorganism Species (ATCC #)	Initial Population (Log_{10})	Final Population (Log_{10})	Numbers Control (Log_{10}) (10-minute Exposure)	Replicate	Product Exposure Time	Post-Exposure Log_{10} Recovery	Percent Reduction	Log_{10} Reduction	Mean Log_{10} Reduction
Escherichia coli (ATCC #35150)	8.01	7.99	6.16	1	1 minute	5.45×10^3	99.62%	2.42	2.17
				2		1.01×10^4	99.30%	2.16	
				3		1.68×10^4	98.84%	1.93	
				1	3 minutes	$< 1.00 \times 10^2$	99.99%	4.16	3.96
				2		2.00×10^2	99.99%	3.86	
				3		2.00×10^2	99.99%	3.86	
				1	10 minutes	$< 1.00 \times 10^2$	99.99%	4.16	4.16
				2		$< 1.00 \times 10^2$	99.99%	4.16	
				3		$< 1.00 \times 10^2$	99.99%	4.16	

TABLE 6

Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701

Test Date 03/30/2020

Microorganism Species (ATCC #)	Initial Population (Log_{10})	Final Population (Log_{10})	Numbers Control (Log_{10}) (10-minute Exposure)	Replicate	Product Exposure Time	Post-Exposure Log_{10} Recovery	Percent Reduction	Log_{10} Reduction	Mean Log_{10} Reduction
Listeria monocytogenes (ATCC #19117)	8.62	8.60	6.68	1	1 minute	1.76×10^5	96.29%	1.43	1.50
				2		1.28×10^5	97.31%	1.57	
				3		1.48×10^5	96.88%	1.51	
				1	3 minutes	4.55×10^3	99.90%	3.02	3.11
				2		4.15×10^3	99.91%	3.06	
				3		2.70×10^3	99.94%	3.25	
				1	10 minutes	$< 1.00 \times 10^2$	99.99%	4.68	4.68
				2		$< 1.00 \times 10^2$	99.99%	4.68	
				3		$< 1.00 \times 10^2$	99.99%	4.68	

TABLE 7

Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701

Test Date 03/30/2020

Microorganism Species (ATCC #)	Initial Population (Log_{10})	Final Population (Log_{10})	Numbers Control (Log_{10}) (10-minute Exposure)	Replicate	Product Exposure Time	Post-Exposure Log_{10} Recovery	Percent Reduction	Log_{10} Reduction	Mean Log_{10} Reduction
Salmonella enterica Paratyph B (ATCC #8759)	8.00	8.06	6.05	1	1 minute	$< 1.00 \times 10^2$	99.99%	4.05	4.05
				2		$< 1.00 \times 10^2$	99.99%	4.05	
				3		$< 1.00 \times 10^2$	99.99%	4.05	
				1	3 minutes	$< 1.00 \times 10^2$	99.99%	4.05	4.05
				2		$< 1.00 \times 10^2$	99.99%	4.05	
				3		$< 1.00 \times 10^2$	99.99%	4.05	
				1	10 minutes	$< 1.00 \times 10^2$	99.99%	4.05	4.05
				2		$< 1.00 \times 10^2$	99.99%	4.05	
				3		$< 1.00 \times 10^2$	99.99%	4.05	

TABLE 8

Test Product, Gen 1 Hy-IQ (Electrolytic Water), Lot #2000701

Test Date 03/30/2020

Microorganism Species (ATCC #)	Initial Population (Log_{10})	Final Population (Log_{10})	Numbers Control (Log_{10}) (10-minute Exposure)	Replicate	Product Exposure Time	Post-Exposure Log_{10} Recovery	Percent Reduction	Log_{10} Reduction	Mean Log_{10} Reduction
Shigella sonnei (ATCC #29031)	8.61	8.68	6.70	1	1 minute	1.65×10^3	99.97%	3.48	3.40
				2		1.90×10^3	99.96%	3.42	
				3		2.55×10^3	99.95%	3.29	
				1	3 minutes	$< 1.00 \times 10^2$	99.99%	4.70	4.70
				2		$< 1.00 \times 10^2$	99.99%	4.70	
				3		$< 1.00 \times 10^2$	99.99%	4.70	
				1	10 minutes	$< 1.00 \times 10^2$	99.99%	4.70	4.70
				2		$< 1.00 \times 10^2$	99.99%	4.70	
				3		$< 1.00 \times 10^2$	99.99%	4.70	

15.0 STATISTICAL ANALYSIS:

A statistical analysis of the data derived from the Neutralization Studies was performed as described in the Study Protocol, included as Addendum 1 of this Final Report. The results of the Neutralization Studies are summarized in Tables 1 through 4 of this Final Report. A statistical analysis was not performed on the data derived from the Time-Kill Evaluation.

16.0 QUALITY ASSURANCE AUDITS:

Quality Assurance (QA) conducted in-phase audits of the test procedures and advised the Study Director and Management of the outcome. On completion of testing, QA performed an audit of the raw data and of the Final Report, in its entirety. Two deviations from the methodology described in the Study Protocol occurred during the course of this evaluation. No deviations from applicable BioScience Laboratories, Inc., Standard Operating Procedures occurred during the course of this evaluation.

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 at the Testing Facility.

STUDY DIRECTOR:

Dan Dragotoiu
In-Vitro Study Director

LABORATORY PERSONNEL:

Rachel Cohen
Microbiologist

Brett Griggs
Microbiologist

Mackenzie Kautzman, M.S.
Microbiologist

Lisa Lehman
Senior Scientist

Stephanie Cebulla
Laboratory Support Technician

Marc Charnholm
Manager of Laboratory Support

Jared R. Montana, M.S.
Microbiologist

Eric Olsen
Microbiologist

Angelo Porcella
Microbiologist

Alexander Stanley
Laboratory Technician

Brooke Kapalka
Laboratory Support Technician

Dakotah Olson
Product Handler

18.0 QUALITY ASSURANCE AND QUALITY CONTROL PERSONNEL:

Jeremy Duley
Systems Administrator/QC Specialist

Danielle Goveia
Quality Assurance Specialist

Amy L. Juhnke, RQAP-GLP
Director of Quality Assurance

Renee LaFond, M.S.
Quality Assurance Specialist

Carl Schmidt
ISO Technical Manager (QC, Safety)

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 5 years. BioScience Laboratories, Inc., will notify the Study Sponsor before any documents or records are destroyed.

20.0 APPROVAL:

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

Study Director: _____ 04/21/2020
Dan Dragotoiu — Study Completion Date

QUALITY ASSURANCE STATEMENT:

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

Phase Inspected	Audit Date	Date reported to Study Director	Date reported to Management
Neutralization and Product Testing	03/30/2020	03/30/2020	03/31/2020
Data Audit	04/17/2020 04/20/2020	04/21/2020	04/21/2020
Final Report Review	04/20/2020	04/21/2020	04/21/2020

This study was conducted in compliance with Good Laboratory Practices standards, as described by the FDA (21 CFR Part 58), with the exception that the characterization of the identity, strength, purity, composition, stability, and solubility of the test products was not performed by BioScience Laboratories, Inc. Deviations to the Study Protocol were documented appropriately. This statement also serves to confirm that the Final Report reflects the raw data.

Quality Assurance Specialist: _____ 04/21/2020
Danielle Goveia — Date

INDEX OF ADDENDA

1 Protocol #2001505-201
Deviation Recording Forms

2 Product Information
- Product Receipt Logs
- Sample Submission Forms
- Product-Tracking Forms

3 Inoculum Preparation Tracking Form

4 Neutralization Validation Studies
- General Data Gathering Forms – *Neutralization Assay*
- Neutralization Evaluation – Raw Data Collection Forms
- Statistical Analyses of Neutralization Assay Results

5 Time-Kill Evaluation
- General Data Gathering Forms – *Time-Kill Evaluation*
- Initial Population-Inoculum Level Data Sheets
- Numbers Control Data Sheets
- Time-Kill Data Forms: ASTM E2783

6 General Records
- Media/Diluent Tracking Forms
- Equipment Tracking Forms
- Water Bath Temperature Recording Forms
- Incubator Log Forms
- Environmental Monitoring System BSLI #181201