STUDY REPORT

Study Title
(Custom) Virucidal Efficacy of a Test Device For Use on Inanimate, Nonporous Surfaces

Product Identity
PhoneSoap3

Test Microorganism
Human coronavirus, Strain 229E, ATCC VR-740

Study Identification Number
NG15155

Author
Tamisha J. Smith, B.S.

Study Completion Date
16JUL2020

Testing Facility
Microchem Laboratory
1304 W. Industrial Blvd.
Round Rock, Texas 78681

Study Sponsor
PhoneSoap
Evan Price
1837 S. East Bay Blvd., Ste 201
Provo, UT 84606

STUDY REPORT SUMMARY

General Study Information

Study Title:	(Custom) Virucidal Efficacy of a Test Device For Use on Inanimate, Nonporous Surfaces
Study Identification Number:	NG15155

Test System

Test Microorganism:	Human coronavirus, Strain 229E, ATCC VR-740
Host Cell:	MRC-5 (CCL-171)
Test Substance:	PhoneSoap3 Device
Test Substance Receipt Date:	07APR2020

Test Parameters

Test Substance Preparation:	Ready to use device (10-minute warm-up cycle)
Test Substance Application:	Ready to use device
Organic Soil Load:	5% fetal bovine serum (FBS)
Number of Replicates Per Contact Time:	Three test carriers assessed
Inoculum Volume:	0.100 ml
Contact Time:	10 minutes
Exposure Temperature:	Ambient room temperature
Neutralization Method(s):	2% FBS EMEM

Study Dates

Experimental Start Date	23JUN2020
Experimental Termination Date	30JUN2020
Study Completion Date:	16JUL2020

TEST PROCEDURE

Summary

- Stock virus was thawed and was supplemented with an organic soil load.
- Sterile glass slides (1 x 3mm) were inoculated with a volume of virus suspension. A sufficient number of test and control carriers were prepared.
- Inoculated carriers were dried at room temperature under laminar flow conditions.
- The test device was prepared according to the Study Sponsor's instructions as requested
- The treated carriers were held in the device for the predetermined contact time(s), and then neutralized in a manner appropriate for the test device (e.g. dilution and/or gel filtration).
- The control carrier was held covered for the contact time then harvested and neutralized in the same manner as the test.
- Following neutralization of test and control carriers, the viral suspensions were quantified to determine the levels of infectious virus using standard cell culture (e.g. $TCID_{50}$ or plaque assay techniques.)
- Assay trays/plates were incubated for the period most suitable for the virus-host cell system (e.g. 7 days).
- After the incubation period, the assay was scored for the presence/absence of test virus and cytotoxic effects. The appropriate calculations were performed (e.g. Spearman-Karber) to determine viral titers and levels of test device cytotoxicity, where applicable.
- Log_{10} and percent reductions were calculated for viral films exposed to the test product relative to the titer obtained for the study control carrier(s), and reported to the Study Sponsor.

SUCCESS CRITERIA

The following measures are met to ensure the acceptability of virucidal efficacy data:

- A minimum of 4.80 $\log_{10}$ infective units/control carrier is recovered from each plate recovery control film(s).
- The virus titer control demonstrate obvious and or typical cytopathic effects on the monolayers unless a detection method other than cytopathic effect is used.
- Neutralization of the test substance with a low titer (e.g. 1000-5000 infective units) of the test virus is demonstrated.
- Quantification of the test and control parameters are conducted at a minimum of four determinations per dilution.

The product performance criteria follows:

- In the presence or absence of cytotoxicity, the product should demonstrate a $\geq$3.00 $\log_{10}$ reduction in viral titer on each surface.
- If cytotoxicity is present, the virus control titer should be increased if necessary to demonstrate a $\geq$3.00 $\log_{10}$ reduction in viral titer on each surface beyond the cytotoxicity level.

CALCULATIONS AND STATISTICAL ANALYSIS

The $TCID_{50}$ (Tissue Culture Infectivity Dose) represents the endpoint dilution where 50% of the cell cultures exhibit cytopathic effects due to infection by the test virus. The endpoint dilution at which 50% of the host cell monolayers exhibit cytotoxicity is termed the Tissue Culture Dose (TCD_{50}). The $TCID_{50}$, and TCD_{50} was determined using the Spearman-Kärber method and calculated as follows:

Negative logarithm of endpoint titer =

[– Log of first dilution inoculated] – [((sum of % mortality at each dilution/100) – 0.5) x Logarithm of dilution]

The result of this calculation is expressed as $TCID_{50}$/0.1 ml (or volume of dilution inoculated) for the test, virus control, and neutralization control and TCD_{50}/0.1 ml (or volume of dilution inoculated) for the cytotoxicity control.

Calculation of the Log Reduction

The log reduction in viral titer was calculated as follows:

Plate Recovery Control Log_{10} $TCID_{50}$ – Virus-Test Substance Log_{10} $TCID_{50}$

Calculation of the Percent Reduction

The percent reduction in viral titer was calculated as follows:

Percent Reduction = 1- (C/B) x 100, where:
B = Average $TCID_{50}$ of virus in control suspensions.
C = Average $TCID_{50}$ of virus in virus-test suspensions.

The presence of any test substance cytotoxicity were taken into account when calculating the log and percent reductions in viral titer.

If multiple virus control and test replicates were performed, the average $TCID_{50}$ of each parameter was calculated and the average result used to calculate the log reductions in viral titer.

RESULTS

Table 1: Virus Plate Recovery Control Results

		Virus Titer	Virus Plate Recovery Control 10 minutes
Cell Control		0 0 0 0	0 0 0 0
Dilution	10^{-1}	+ + + +	+ + + +
	10^{-2}	+ + + +	+ + + +
	10^{-3}	+ + + +	+ + + +
	10^{-4}	+ + + +	+ + + +
	10^{-5}	0 + + 0	+ 0 0 +
	10^{-6}	0 0 0 0	0 0 0 0
$TCID_{50}$ per 0.1 ml		5.00 Log_{10}	5.00 Log_{10}
$TCID_{50}$ per Carrier		N/A	5.30 Log_{10}

Key: + = Virus recovered; 0 = Virus not recovered and/or no cytotoxicity observed; T = Cytotoxicity observed

Table 2: Test Results

		PhoneSoap3 Replicate #1 10 minutes	PhoneSoap3 Replicate #2 10 minutes	PhoneSoap3 Replicate #3 10 minutes
Cell Control		0 0 0 0	0 0 0 0	0 0 0 0
Dilution	10^{-1}	0 0 0 0	0 0 0 0	0 0 0 0
	10^{-2}	0 0 0 0	0 0 0 0	0 0 0 0
	10^{-3}	0 0 0 0	0 0 0 0	0 0 0 0
$TCID_{50}$ per 0.1 ml		≤0.50 Log_{10}	≤0.50 Log_{10}	≤0.50 Log_{10}
$TCID_{50}$ per Carrier		≤0.80 Log_{10}	≤0.80 Log_{10}	≤0.80 Log_{10}
Log_{10} Reduction Per Carrier		≥4.50 Log_{10}	≥4.50 Log_{10}	≥4.50 Log_{10}
Percent Reduction		99.996%	99.996%	99.996%
Average Reduction (all replicates)		≥4.50 Log_{10} (99.996%)		

Key: + = Virus recovered; 0 = Virus not recovered and/or no cytotoxicity observed; T = Cytotoxicity observed; [†]*Taking cytotoxicity and neutralization controls into account.*

STUDY CONCLUSION

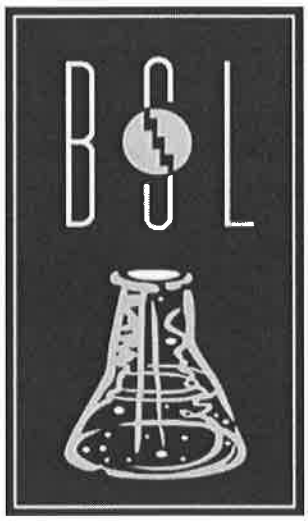
The purpose of the study was to determine the virucidal efficacy of PhoneSoap3 device against Human coronavirus Strain 229E, with a 5% FBS organic soil load, at a contact time of 10 minutes, and at an exposure temperature of room temperature.

The Plate Recovery Control demonstrated a viral titer of 5.00 Log_{10} $TCID_{50}$ per 0.1 ml and 5.30 Log_{10} $TCID_{50}$ per carrier.

PhoneSoap3, demonstrated an average ≥4.50 Log_{10} reduction in viral titer (99.996%) at a contact time of 10 minutes.

The test substance will be disposed of 30 days after the completion of this study, unless otherwise requested by the Study Sponsor.

The results of this study apply to the tested substances(s) only. Extrapolation of findings to related materials is the responsibility of the Sponsor.



September 6, 2018

FINAL REPORT #1807335-404

EVALUATION OF VIRUCIDAL EFFICACY OF ONE UV DEVICE VERSUS THREE VIRAL STRAINS

Prepared for:

PHONESOAP (SPONSOR)
1396 W. 200 S., Building 1 Unit C
Lindon, Utah 84042

Prepared by:

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

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EXECUTIVE SUMMARY

STUDY NUMBER: **1807335-404**

TITLE: **EVALUATION OF VIRUCIDAL EFFICACY OF ONE UV DEVICE VERSUS THREE VIRAL STRAINS**

SPONSOR: **PHONESOAP**
1396 W. 200 S., Building 1 Unit C
Lindon, Utah 84042

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

STUDY INITIATION DATE: 07/30/2018

STUDY COMPLETION DATE: 09/06/2018

The purpose of this study was to evaluate virucidal efficacy of one type of UV device when challenged with **"flu virus"** (Influenza A), **"cold virus"** (Rhinovirus), and **Rotavirus**. Testing was based upon the procedures outlined in the American Society for Test Materials (ASTM) test method designated E1053-11, *Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces*. All testing was performed in accordance with Good Laboratory Practices, as specified in 21 CFR Part 58. The percent and $\log_{10}$ reductions of virus populations were determined following pre-set UVC exposure (approximately 10 minutes). Testing was performed in triplicate, plating was performed in four replicates.

STUDY CONCLUSIONS:

The UVC Device, PhoneSoap 3, reduced infectivity of **flu virus**, **cold virus** and **Rotavirus** by **>99.99%** following exposure of these viruses to UVC for ~10 minutes.

September 6, 2018

FINAL REPORT #1807335-404

1.0 TITLE: **EVALUATION OF VIRUCIDAL EFFICACY OF ONE UV DEVICE VERSUS THREE VIRAL STRAINS**

2.0 SPONSOR: **PHONESOAP**
1396 W. 200 S., Building 1 Unit C
Lindon, Utah 84042

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

4.0 STUDY DIRECTOR: Volha Teagle, Ph.D.

5.0 PURPOSE:

The purpose of this study was to evaluate virucidal efficacy of one type of UV device when challenged with Influenza A, Rhinovirus, and Rotavirus.

Testing was based upon the procedures outlined in the American Society for Test Materials (ASTM) test method designated E1053-11, *Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces*. All testing was performed in accordance with Good Laboratory Practices, as specified in 21 CFR Part 58, with the exception that the Study Sponsor retained responsibility for the determination of the identity, strength, purity, composition, and stability of the test device.

6.0 SCOPE:

This study evaluated the virucidal efficacy of one UV device, when used on dry, non-porous, inanimate surfaces. One lot of the device was tested. The test device was evaluated versus Influenza A, Rhinovirus, and Rotavirus without an Organic Soil Load. A challenge suspension was used to inoculate the glass microscope slide (76mm x 26mm) carriers (two carriers per test device) to yield a minimum of 10^4 viruses per carrier following drying. After drying, carriers were placed inside of the device and exposed to the UV light at room temperature for the exposure time determined by the device, approximately 10 minutes. Following the timed exposure, slides were removed from the device and placed in a sterile container. The remaining viruses were rinsed with medium and scraped with the cell scrapers from the surface of the glass slide. An aliquot of the obtained suspension was serially diluted in medium and assayed for the presence of viable viruses using the susceptible to the virus cell culture. The viral titers were determined using a 50% tissue culture infectious dose (TCID50) calculation -- the Quantal test (Spearman-Kärber Method). Three test replicates were performed.

The Study Protocol, included in Addendum 1 of this Final Report, presents the study methodology, in detail. One deviation from the methodology described in the Study Protocol and one deviation from an applicable BioScience Laboratories Standard Operating Procedure occurred during the course of this evaluation (reference Section 15.0 of this Final Report), and as is detailed on the Deviation Recording Forms (Template Form QA-DEVIATION) in Addendum 1 of this Final Report, they had no adverse effect upon the study outcome.

7.0 STUDY DATES:

STUDY INITIATION DATE:	07/30/2018
EXPERIMENTAL START DATE:	08/07/2018
EXPERIMENTAL END DATE:	08/17/2018
STUDY COMPLETION DATE:	09/06/2018

8.0 TEST PRODUCT:

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

Test Device:	PhoneSoap 3
Active Ingredients:	UV-C
Lot Number:	Not Provided
Manufacture Date:	Not Provided
Model Cell Phone:	Apple iPhone
Dimensions:	13.5 cm x 6.5 cm x 0.6 cm

9.0 CHALLENGE VIRAL STRAINS:

9.1 Influenza A H1N1 strain A/WS/33 (ATCC #VR-1520)
9.2 Rhinovirus type 14 strain 1059 (ATCC #VR-284)
9.3 Rotavirus strain Wa (ATCC #VR-2018)
ATCC = American Type Culture Collection

10.0 HOST CELLS:

10.1 MDCK (Madin-Darby Canine Kidney cells; ATCC #CCL-34)
10.2 MRC-5 cells (human lung fibroblasts; ATCC #CCL-171)
10.3 MA-104 (green monkey kidney cells; ATCC #CRL-2378.1)

11.0 SUPPLIES AND EQUIPMENT:

The equipment and supplies used in this study are as described in the study Protocol in Addendum 1 of this Final Report. All applicable equipment and instrumentation were calibrated in accordance with BioScience Laboratories, Inc., Standard Operating Procedures.

12.0 MEDIA:

The growth media and diluting fluids used in this study are as described in the study Protocol in Addendum 1 of this Final Report.

13.0 HOST CELL PREPARATION:

Cells were maintained as monolayers in disposable cell culture labware and were used for the Virucidal Suspension Test of Murine Norovirus. Prior to testing, host cell cultures were seeded onto 24-well cell culture plates. Cell monolayers were 80% to 90% confluent and less than 48 hours old before inoculation with the virus. The growth medium (GM) and maintenance medium (MM) was 1X Advanced Minimal Essential Medium (MEM) with appropriate supplements.

14.0 TEST VIRUS PREPARATION:

The test virus used for this study was from BSLI high titer virus stock. On the day of use, aliquots of the stock virus were removed from a -70°C freezer and thawed prior to use in testing.

15.0 DEVIATIONS:

15.1 Section 7.0 of the Protocol states: All testing will be performed in accordance with Good Laboratory Practices, as specified in 40 CFR 160. All testing was performed in accordance with Good Laboratory Practices, as specified in 21 CFR Part 58. The deviation was due to typographical error and did not affect the study outcome.

15.2 Section 3.3 of the SOP L-0005, *PRODUCT HANDLING AND DISPOSITION*, states "Product will be logged into appropriate quarantine prior to the start of the study (Product Receipt Log [TEMPLATE Form L-PR-RECEIPT] and Product-Tracking Form [TEMPLATE Form L-PR-TRACK]). Product-Tracking Form (TEMPLATE Form L-PR-TRACK) was not filled out prior to testing." The product log was recorded on the General Data Gathering Form (Form No.91-L-002) and later transcribed into the appropriate Product-Tracking Form. The deviation did not affect the outcome of the study.

16.0 RESULTS – TABLES 1 THROUGH 3:

16.1 Table 1 presents the data from the Virus Control infectivity ($TCID_{50}$) and the post-exposure infectivity ($TCID_{50}$); the log_{10} and percent reductions observed following exposure of Influenza A H1N1 strain A/WS/33 (**flu virus**) to the Test Device, PhoneSoap 3.

TABLE 1

Test Device: PhoneSoap 3, UVC Device
Virus: Influenza A H1N1 strain A/WS/33 (ATCC #VR-1520)
Host Cell Line: MDCK Host Cell Line ATCC #CCL-34
Volume Plated per Well: 1.0 mL
Exposure Time: 10 minutes

Dilution (- Log_{10})	**VC**		**Test**						**IP**	**Sterility**	**CC**
	R1	R2	R1 Top	R1 Bottom	R2 Top	R2 Bottom	R3 Top	R3 Bottom			
											0000
-2	NT	NT	0000	+00+	0000	++00	+000	++++	NT	0000	
-3	++++	++++	0000	00+0	0000	0000	0000	00++	NT		
-4	++++	++++	0000	0000	0000	0000	0000	0000	++++		
-5	++++	++++	0000	0000	0000	0000	0000	0000	++++		
-6	++++	++++	0000	0000	0000	0000	0000	0000	++++	N/A	
-7	0+++	0+++	0000	0000	0000	0000	0000	0000	++++		
-8	NT	NT	NT	NT	NT	NT	NT	NT	+0++		
$TCID_{50}$ (log_{10})	7.25	7.25	≤1.50	2.25	≤1.50	2.00	1.75	3.00	8.25		
Average $TCID_{50}$ (log_{10})	7.25		2.00						N/A		N/A
Log_{10} Reduction	N/A		**≥5.75**	**5.00**	**≥5.75**	**5.25**	**5.50**	**4.25**			
Average Log_{10} Reduction			**5.25**						N/A		
Percent Reduction			**>99.99**	**>99.99**	**>99.99**	**>99.99**	**>99.99**	**>99.99**			
Average Percent Reduction			**>99.99**								

\+ CPE (cytopathic/cytotoxic effect) present
0 CPE (cytopathic/cytotoxic effect) not detected
N/A Not applicable
NT Not Tested
VC Virus Control
R Replicate
IP Initial Population
CC Cell Control

16.2 Table 2 presents the data from the Virus Control infectivity ($TCID_{50}$) and the post-exposure infectivity ($TCID_{50}$); the log_{10} and percent reductions observed following exposure of Rhinovirus type 14 strain 1059 **(cold virus)** to the Test Device, PhoneSoap 3.

TABLE 2

Test Device: PhoneSoap 3, UVC Device
Virus: Rhinovirus type 14 strain 1059 (ATCC #VR-284)
Host Cell Line: MRC-5 Host Cell Line ATCC #CCL-171
Volume Plated per Well: 1.0 mL
Exposure Time: 10 minutes

Dilution (- Log_{10})	**VC**		**Test**						**IP**	**Sterility**	**CC**
	R1	R2	R1 Top	R1 Bottom	R2 Top	R2 Bottom	R3 Top	R3 Bottom			
											0000
-2	NT	NT	+000	0000	0000	0000	0000	0000	NT	0000	
-3	++++	++++	0000	0000	0000	0000	0000	0000	++++		
-4	++++	++++	0000	0000	0000	0000	0000	0000	++++		
-5	++++	++++	0000	0000	0000	0000	0000	0000	++++		
-6	+000	+00+	0000	0000	0000	0000	0000	0000	++++	N/A	
-7	0000	0000	0000	0000	0000	0000	0000	0000	000+		
$TCID_{50}$ (log_{10})	5.75	6.00	1.75	≤1.50	≤1.50	≤1.50	≤1.50	≤1.50	6.75		
Average $TCID_{50}$ (log_{10})	5.88		1.54								N/A
Log_{10} Reduction	N/A		**4.13**	**≥4.38**	**≥4.38**	**≥4.38**	**≥4.38**	**≥4.38**	N/A		
Average Log_{10} Reduction			**4.34**								
Percent Reduction			**>99.99**	**>99.99**	**>99.99**	**>99.99**	**>99.99**	**>99.99**			
Average Percent Reduction			**>99.99**								

\+ CPE (cytopathic/cytotoxic effect) present
0 CPE (cytopathic/cytotoxic effect) not detected
N/A Not applicable
NT Not Tested
VC Virus Control
R Replicate
IP Initial Population
CC Cell Control

16.3 Table 3 presents the data from the Virus Control infectivity (TCID50) and the post-exposure infectivity (TCID50); the log10 and percent reductions observed following exposure of Rotavirus strain Wa to the Test Device, PhoneSoap 3.

TABLE 3

Test Device: PhoneSoap 3, UVC Device
Virus: Rotavirus strain Wa (ATCC #VR-2018)
Host Cell Line: MA-104 Host Cell Line ATCC #CRL-2378.1
Volume Plated per Well: 1.0 mL
Exposure Time: 10 minutes

Dilution (- Log_{10})	VC		Test						IP	Sterility	CC
	R1	R2	R1 Top	R1 Bottom	R2 Top	R2 Bottom	R3 Top	R3 Bottom			
											0000
-2	NT	NT	0000	0000	0000	0000	0000	0000	NT	0000	
-3	++++	++++	0000	0000	0000	0000	0000	0000	++++		
-4	++++	++++	0000	0000	0000	0000	0000	0000	++++		
-5	++++	++++	0000	0000	0000	0000	0000	0000	++++		
-6	+000	0000	0000	0000	0000	0000	0000	0000	++00	N/A	
-7	0000	0000	0000	0000	0000	0000	0000	0000	0000		
$TCID_{50}$ (log_{10})	5.75	5.50	≤1.50	≤1.50	≤1.50	≤1.50	≤1.50	≤1.50	6.00		
Average $TCID_{50}$ (log_{10})	5.63		≤1.50								N/A
Log_{10} Reduction	N/A		**≥4.13**	**≥4.13**	**≥4.13**	**≥4.13**	**≥4.13**	**≥4.13**	N/A		
Average Log_{10} Reduction			**≥4.13**								
Percent Reduction			**>99.99**	**>99.99**	**>99.99**	**>99.99**	**>99.99**	**>99.99**			
Average Percent Reduction			**>99.99**								

\+ CPE (cytopathic/cytotoxic effect) present
0 CPE (cytopathic/cytotoxic effect) not detected
N/A Not applicable
NT Not Tested
VC Virus Control
R Replicate
IP Initial Population
CC Cell Control

17.0 STUDY CONCLUSION :

The UVC Device, PhoneSoap 3, reduced infectivity of "flu virus" (Influenza A), "cold virus" (Rhinovirus), and Rotavirus by >99.99% following exposure of these viruses to UVC for ~10 minutes.

18.0 STATISTICAL ANALYSIS:

A statistical analysis was not performed on the data derived from this study.

19.0 QUALITY ASSURANCE AUDITS:

Quality Assurance (QA) conducted an in-phase audit of the critical test procedures over the course of testing and advised the Study Director and Management of the outcomes of these. On completion of testing, QA performed an audit of the raw data and of the Final Report, in its entirety. One deviation from the Study Protocol and one deviation from an applicable BioScience Laboratories, Inc., Standard Operating Procedure occurred during the course of this evaluation and were documented appropriately.

20.0 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: Volha Teagle, Ph.D.
Virologist

Kelly Burningham
Virologist

Stephanie Cebulla
Laboratory Support Technician

Marc Charnholm
Manager of Laboratory Support

Megan Landes
Laboratory Support Technician/Product Handler

Jessica Wells
Purchasing Agent/Inventory Controller

21.0 QUALITY ASSURANCE AND QUALITY CONTROL PERSONNEL:

Kevin Crawford
QC/Maintenance Specialist

Jeremy Duley
QC/Maintenance 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; Training, Safety)

22.0 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.

23.0 ACCEPTANCE:

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

Study Director: _____ 09-06-2018
Volha Teagle, Ph.D. Date of Study Completion

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 Inspected	Audit Date	Date reported to Study Director	Date reported to Management
Product Testing	08/07/2018	08/14/2018	08/15/2018
Data Audit	08/29/2018 08/30/2018	08/31/2018	09/05/2018
Final Report Review	08/30/2018	08/31/2018	09/05/2018

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 materials was not performed by BioScience Laboratories, Inc. One deviation from the Study Protocol and one deviation from an applicable BioScience Laboratories, Inc., Standard Operating Procedure were observed. A statistical analysis was not performed on the data derived from the Time-Kill Evaluation. This statement also serves to confirm that the Final Report reflects the raw data.

Director of Quality Assurance: _____ 09/06/18
Amy L. Juhnke, RQAP-GLP Date

ADDENDUM 1

Protocol #1807335-404
Deviation Recording Forms (Template Form: QA-DEVIATION)

July 27, 2018

PROTOCOL # 1807335-404

EVALUATION OF VIRUCIDAL EFFICACY OF ONE UV DEVICE VERSUS THREE VIRAL STRAINS

Prepared for:

PHONESOAP (SPONSOR)
1396 W. 200 S., Building 1 Unit C
Lindon, Utah 84042

Prepared by:

BIOSCIENCE LABORATORIES, INC. (TESTING FACILITY)
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July 27, 2018

PROTOCOL #1807335-404

1.0 TITLE: **EVALUATION OF VIRUCIDAL EFFICACY OF ONE UV DEVICE VERSUS THREE VIRAL STRAINS**

2.0 SPONSOR: **PHONESOAP**
1396 W. 200 S., Building 1 Unit C
Lindon, Utah 84042

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

4.0 STUDY DIRECTOR: Volha Teagle, Ph.D.

5.0 PROPOSED EXPERIMENTAL START DATE: August, 2018

6.0 PROPOSED EXPERIMENTAL COMPLETION DATE: August, 2018

7.0 PURPOSE:

The purpose of this study is to evaluate virucidal efficacy of one type of UV device when challenged with Influenza A, Rhinovirus, and Rotavirus.
Testing will be based upon the procedures outlined in the American Society for Test Materials (ASTM) test method designated E1053-11, *Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surface*. All testing will be performed in accordance with Good Laboratory Practices, as specified in 40 CFR 160, with the exception that the Study Sponsor retains responsibility for the determination of the identity, strength, purity, composition, and stability of the test device.

8.0 SCOPE:

This study will evaluate the virucidal efficacy of one UV device, when used on dry, non-porous, inanimate surfaces. One lot of the device will be tested. The test device will be evaluated versus Influenza A, Rhinovirus, and Rotavirus without an Organic Soil Load. A challenge suspension will be used to inoculate the glass microscope slides (76mm x 26mm) carriers (two carriers per test device) to yield a minimum of 10^4 viruses per carrier following drying. After drying, carriers will be placed inside of the device and exposed to the UV light at room temperature for the exposure time determined by the device, approximately 10 minutes. Following the timed exposure, slides will be removed from the device and placed in a sterile container. The remaining viruses will be rinsed with medium and scraped with the cell scrapers from the surface of the glass slide. An aliquot of the obtained suspension will be serially diluted in medium and assayed for the presence of viable viruses using the susceptible to the virus cell culture. The viral titers will be determined using a 50% tissue culture infectious dose ($TCID_{50}$) calculation -- the Quantal test (Spearman-Kärber Method). Three test replicates will be performed.

9.0 TEST MATERIAL:

The test devices to be evaluated will be provided to the Testing Facility by the Study Sponsor, complete with appropriate documentation. If the product name and/or lot number are not documented below, the information will be presented in the Final Report. Responsibility for the determination of the identity, strength, purity, composition, stability, and solubility of the test product, as well as the retention of the test product, rests with the Sponsor.

Test Device:	PhoneSoap 3
Active Ingredients:	UV-C
Lot Number:	Not Provided
Manufacture Date:	Not Provided
Model Cell Phone:	Apple
Dimensions:	13.5 cm x 6.5 cm x 0.6 cm

10.0 TEST CONDITIONS:

10.1	Exposure Time:	approximately 10 minutes
10.2	Exposure Temperature:	18 °C to 25 °C

11.0 EQUIPMENT:

11.1 CO_2 Incubator, Temperature Range 37 °C ± 2 °C
11.2 CO_2 Incubator, Temperature Range 33 °C ± 2 °C
11.3 Incubator Thermometers
11.4 Portable Pipetters
11.5 Continuously Adjustable Pipettes, 100 µL – 1000 µL Capacity
11.6 Continuously Adjustable Pipettes, 20 µL – 200 µL Capacity
11.7 Inverted Compound Microscope
11.8 Laminar Flow Biological Safety Cabinets
11.9 Waste Pan
11.10 Calibrated Minute/Second Timers

12.0 SUPPLIES:

12.1 Sterile Disposable Pipettes
12.2 Sterile, Powder-Free Gloves
12.3 Sterile Tissue Culture Treated Multi-Well Plates
12.4 Sterile Filtered 100 µL and 1000 µL Tips
12.5 Sterile Flasks
12.6 Sterile 15-50 mL Centrifuge Tubes
12.7 Sterile Pipette Reservoir
12.8 Non-Sterile Waste Beaker for discarded tips, etc.
12.9 Sterile Cell Scrapers
12.10 Sterile Glass Slides

13.0 MEDIA:

13.1 1X Minimum Essential Medium (1X MEM) or, other appropriate medium
13.2 Maintenance Medium (MM) – with 2% Fetal Bovine Serum and supplements (L-Glutamine, antibiotics) and/or MM – without serum with 1 µg/mL or 2 µg/mL TPCK Trypsin and supplements (L-Glutamine, antibiotics)
13.3 Growth Medium (GM) – with 10% Fetal Bovine Serum and supplements (L-Glutamine, antibiotics)
13.4 TPCK treated Trypsin
13.5 Trypsin/EDTA

13.6 Antibiotics (e.g., Penicillin-Streptomycin-Amphotericin B)

14.0 ORGANIC SOIL LOAD:

None

15.0 CHALLENGE VIRAL STRAINS:

15.1 Influenza A H1N1 strain A/WS/33 (ATCC #VR-1520)
15.2 Rhinovirus type 14 strain 1059 (ATCC #VR-284)
15.3 Rotavirus strain Wa (ATCC #VR-2018)
ATCC = American Type Culture Collection

16.0 HOST CELLS:

16.1 MDCK (Madin-Darby Canine Kidney cells; ATCC #CCL-34)
16.2 MRC-5 cells (human lung fibroblasts; ATCC #CCL-171)
16.3 MA-104 (green monkey kidney cells; ATCC #CRL-2378.1)

17.0 HOST CELL PREPARATION:

Cell cultures will be maintained as monolayers in disposable cell culture labware. Cell monolayers will be approximately 80% to 90% confluent and less than 48 hours old before inoculation with the virus. Cells will be grown using GM and viruses – using MM.

18.0 TEST VIRUS PREPARATION:

Viruses from BSLI high-titer virus stock will be used for this study. On the day of use, aliquots of the stock virus will be removed from a -70°C freezer and thawed. .

19.0 TEST PROCEDURE:

19.1 Preparation of Carriers

Sterilized glass microscope slides (~ 76 mm x 26 mm) with frosted area will be used as the carriers for this evaluation.

19.2 Contamination of Carriers

19.2.1 A 0.2 mL aliquot of the prepared virus suspension will be transferred to the smooth unfrosted area of the glass slide (~57 mm x 26 mm). A sterile cell scraper will be used to spread the inoculum uniformly and avoiding frosted area.

19.2.2 The virus suspension will be air-dried at room temperature until visibly dry.

19.2.3 Two carriers will be used per test replicate.

19.2.4 Carriers will be handled using a frosted uncontaminated area.

19.3 Placement of Carriers

19.3.1 Prior to testing the UV bulb and Quarts Plate of the Test Device will be wiped using a KimWipe briefly sprayed with 70% Isopropanol (IPA). Following cleaning the Device will be turned on to ensure it functions correctly.

19.3.2 Slides will be positioned on both sides of a model cell phone to face UVC light from the top and the bottom of the Test Device. One contaminated slide will be placed on a surface of Quarts Plate in such way that contaminated area faces the UVC bulb located under the Quarts Plate. The model cell phone will be placed on the top of the contaminated slide #1. The second contaminated slide will be placed on a top of the model cell phone. Contaminated side of slide #2 will face the UVC bulb located on the lid of the Test Device.

19.4 Test

19.4.1 After the inoculated carriers have been appropriately placed, the test devices will be turned on by closing the lid of the Test Device. The test carriers will be exposed for the exposure time pre-set by the device (approximately 10 minutes). A calibrated minute/second timer will be used to determine the precise exposure time. The exposure will be terminated by the Test device automatically. Timing will commence after UVC bulb has turned on. The carriers will be kept undisturbed for the duration of the contact time. Three replicates of test will be performed.

19.4.2 After the exposure time has elapsed, the slides will be removed from holders and placed into sterile containers. Slides will be washed with 20.0 mL of MM and will be scraped using a sterile cell scraper to recover the surviving virus from the surface of the glass slides. Subsequent 10-fold dilutions will be made in MM and plated in four replicates.

19.4.3 *Virus control.* Two carriers will be used for Virus Control. The test virus will be treated as described in Section 19.2. Following drying, slides will be washed with 20.0 mL of MM and will be scraped using a sterile cell scraper to recover the surviving virus from the surface of the glass slides. Subsequent 10-fold dilutions will be made in MM and plated in four replicates.

19.4.4 *Initial Population.* The test virus will be diluted 10-fold dilutions will be performed in MM. Each dilution will be plated in four replicates.

19.4.5 *Sterility/Cytotoxicity Control.* Two sterile uncontaminated slides will be placed onto the Test Device as described in Section 19.3.2. After the sterile carriers have been appropriately placed, the test device will be turned on. The test carrier will be exposed for the exposure time pre-set by the device (approximately 10 minutes). The slides will be removed from the device and placed into containers. Slides will be washed with 20.0 mL of MM and will be scraped using a sterile cell scraper. The obtained liquid will be plated.

19.4.6 *Cell Culture Control.* Intact cell culture monolayers will serve as the control of cell culture viability. The Growth Medium will be replaced by MM in all cell culture control wells (minimum four wells).

19.4.7 The plates will be incubated for 5 to 14 days at the appropriate for each virus temperature in a CO_2 incubator. Cytopathic/ cytotoxic effect will be monitored using an inverted compound microscope.

20.0 CALCULATIONS:

20.1 Viral titers will be expressed as -Log_{10} of the 50% titration end point for infectivity. To calculate the viral titer, a 50% tissue culture infectious dose ($TCID_{50}$) calculation - the Quantal test (Spearman-Kärber Method) - will be applied.

$$\text{Log } TCID_{50} = L - d\,(s - 0.5)$$

Where:
L = – Log_{10} of the lowest dilution;
d = difference between dilution steps;
s = sum of proportions of positive wells.

20.2 The Log_{10} and percent (%) of infectivity reductions will be calculated as follows:

$$\%\ \text{Reduction} = \left[1 - \frac{TCID_{50}\ test}{TCID_{50}\ virus\ control}\right] \times 100$$

Log_{10} Reduction = (Log_{10} $TCID_{50}$ of the Virus Control) - (Log_{10} $TCID_{50}$ of the Virucidal Test)

21.0 TEST ACCEPTANCE CRITERIA:

A valid test requires: 1) at least 4 log_{10} of $TCID_{50}$ be recovered from the Virus control; 2) cells in the Cell Control wells be viable and attached to the bottom of the well; 3) the medium be free of contamination in all wells of the plate; 4) when cytotoxicity is evident, at least a 3 Log_{10} reduction in titer be demonstrated beyond the cytotoxic level.

22.0 STATISTICAL ANALYSIS:

A statistical analysis will not be performed on the data derived from this evaluation.

23.0 FINAL REPORT:

A Final Report will be issued that presents the results in a clear and concise manner.

24.0 EXCEPTIONAL CONDITIONS:

The Sponsor will be notified by telephone, email, and/or letter of any exceptions encountered in this study. The exceptional conditions or occurrences will be detailed in full and formally recorded. Exceptional conditions that occur and are not addressed in this Protocol will be subject to Out-of-Scope charges (See Proposal/Contract).

25.0 LIABILITY AND INDEMNIFICATION:

The Testing Facility's liability to the Study Sponsor under this Protocol shall be limited to the price of this evaluation. The Study Sponsor shall be responsible to Study Participants (when applicable) and to other third parties for the fitness of the product for use as defined in the Study Protocol.

26.0 DOCUMENTATION AND RECORD-KEEPING:

All documentation and records will be compiled, analyzed, and retained by BioScience Laboratories, Inc., at its facility in Bozeman, Montana. All raw data for this study will be retained in safe storage for the life of the product registration with the EPA, or as specified by the Sponsor.

27.0 PRODUCT DISPOSITION:

It is the responsibility of the Sponsor to retain a sample of the test substance(s) for future audit or evaluation. All unused test material will be disposed of following study completion, unless otherwise indicated by the Sponsor prior to initiation of the study.

28.0 QUALITY ASSURANCE AUDITS:

The Quality Assurance Unit (QAU) will conduct in-phase audits of critical processes in testing at least once and advise the Study Director and Management of the outcomes of these. On completion of testing, the QAU will perform an audit of the data and of the Final Report in its entirety.

29.0 ACCEPTANCE:

EVALUATION OF VIRUCIDAL EFFICACY OF ONE UV DEVICE VERSUS THREE VIRAL STRAINS

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

Study Director: Volha Teagle, Ph.D. — 07-30-18 Date of Study Initiation

ACCEPTED BY: PHONESOAP (SPONSOR)
1396 W. 200 S., Building 1 Unit C
Lindon, Utah 84042

Representative — 7/30/18 Date

CEO
Title

DEVIATION RECORDING FORM

STUDY NUMBER: 1807335-404 **DEVIATION NUMBER:** 01

STUDY TITLE: EVALUATION OF VIRUCIDAL EFFICACY OF ONE UV DEVICE VERSUS THREE VIRAL STRAINS

SOP / DOCUMENT NUMBER AND TITLE: N/A

DEVIATION WAS TO (Document Type -Check all that apply): ☒ **Protocol** ☐ **SOP** ☐ **Other**

PROCEDURE AS OUTLINED: Section 7.0 of the Protocol states: All testing will be performed in accordance with Good Laboratory Practices, as specified in 40 CFR 160.

DEVIATION FROM PROCEDURE [Include Date(s) of Deviation]: All testing was performed in accordance with Good Laboratory Practices, as specified in 21 CFR Part 58.

REASON FOR DEVIATION: Typographical error

EFFECT ON OUTCOME: The deviation did not affect the outcome of the study.

REPORTED BY:

Deanna Lee — 09-05-2018
TITLE: Study Director — DATE

APPROVAL SIGNATURES:

NA — NA
①TITLE: — DATE

Marsha Paulson — 9/5/18
MANAGER/SUPERVISOR — DATE

Marsha Paulson — 9-5-18
CORPORATE MANAGEMENT — DATE

① Must be Principal Investigator or Study Director for study related deviations.

QUALITY ASSURANCE REVIEW

[signature] — 09/05/18
QUALITY ASSURANCE — DATE

DEVIATION RECORDING FORM

STUDY NUMBER: 1807335-404 **DEVIATION NUMBER:** 02

STUDY TITLE: EVALUATION OF VIRUCIDAL EFFICACY OF ONE UV DEVICE VERSUS THREE VIRAL STRAINS

SOP / DOCUMENT NUMBER AND TITLE: L-0005 PRODUCT HANDLING AND DISPOSITION

DEVIATION WAS TO (Document Type -Check all that apply): ☐ **Protocol** ☒ **SOP** ☐ **Other**

PROCEDURE AS OUTLINED: Section 3.3 of the SOP states: Product will be logged into appropriate quarantine prior to the start of the study (Product Receipt Log [TEMPLATE Form L-PR-RECEIPT] and Product-Tracking Form [TEMPLATE Form L-PR-TRACK]).

DEVIATION FROM PROCEDURE [Include Date(s) of Deviation]: Product-Tracking Form (TEMPLATE Form L-PR-TRACK) was not filled out prior to testing.

REASON FOR DEVIATION: Technician error.

EFFECT ON OUTCOME: The deviation did not affect the outcome of the study as the product log was recorded on the General Data Gathering Form (Form No.91-L-002) and later transcribed into the appropriate Product-Tracking Form.

REPORTED BY:

TH Caudle — TITLE: Study Director — 09-05-2018 DATE

APPROVAL SIGNATURES:

NH — ①TITLE: — NA DATE

Marsha Paulson — MANAGER/SUPERVISOR — 9-5-18 DATE

Marsha Paulson — CORPORATE MANAGEMENT — 9-5-18 DATE

① Must be Principal Investigator or Study Director for study related deviations.

QUALITY ASSURANCE REVIEW

Amy Entrekin — QUALITY ASSURANCE — 09/05/18 DATE