March 9, 2020

FINAL REPORT #2001017-402

EVALUATION OF ONE TEST PRODUCT FOR ITS VIRUCIDAL PROPERTIES

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: **2001017-402**

TITLE: **EVALUATION OF ONE TEST PRODUCT FOR ITS VIRUCIDAL PROPERTIES**

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: 01/28/2020

STUDY COMPLETION DATE: 03/09/2020

This study evaluated the virucidal properties of one test product when challenged with Coronavirus. A Virucidal Suspension Test (In-Vitro Time-Kill method) based upon the ASTM E1052-11, "*Standard Test Method to Assess the Activity of Microbicides against Viruses in Suspension*" was used. The percent and $\log_{10}$ reductions from the initial population of the viral strain was determined following exposure to the test product for 1 minute, 3 minutes, 5 minutes 7 minutes, and 10 minutes. All testing was performed in accordance with Good Laboratory Practices, as specified in 21 CFR Part 58, with the exception that the characterization of the identity, strength, purity, composition, stability, and solubility of the test product remained the responsibility of the Study Sponsor and was not performed by the Testing Facility (GLP 58.105).

Under the conditions of this evaluation Test Product #1, Gen 1 Special (Lot #X-106-18) reduced the infectivity of Coronavirus by 2.75 $\log_{10}$ (99.82%) following a 1-minute exposure, by $\geq$ 3.25 $\log_{10}$ ($\geq$ 99.94%) following a 3-minute, 5-minute, 7-minute and 10 minute exposure.

March 9, 2020

FINAL REPORT #2001017-402

1.0 TITLE: **EVALUATION OF ONE TEST PRODUCT FOR ITS VIRUCIDAL PROPERTIES**

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: Kelly Burningham

5.0 PURPOSE:

This study evaluated the virucidal properties of one test product when challenged with Coronavirus, using a Virucidal Suspension Test (In-Vitro Time-Kill Method) following ASTM E1052-11, *Standard Test Method to Assess the Activity of Microbicides against Viruses in Suspension.* All testing was performed in accordance with Good Laboratory Practices, as specified in 21 CFR Part 58, with the exception that the characterization of the identity, strength, purity, composition, stability, and solubility of the test product remained the responsibility of the Study Sponsor and was not performed by the Testing Facility (GLP 58.105).

6.0 SCOPE:

A Virucidal Suspension Test (In-Vitro Time-Kill method) based upon the ASTM E1052-11 Method, "*Standard Test Method to Assess the Activity of Microbicides against Viruses in Suspension*" was used to evaluate the virucidal properties of one test product versus Coronavirus. The percent and $\log_{10}$ reductions from the initial population of the viral strain was determined following exposure to the test product for 1 minute, 3 minutes, 5 minutes, 7 minutes, and 10 minutes. Plating was performed in four replicates. The viral titers were determined using a 50% tissue culture infectious dose ($TCID_{50}$) calculation -- the Quantal test (Spearman-Kärber Method).

The Study Protocol, included as Addendum 1 of this Final Report, presents the study methodology, in detail. The protocol was amended once to add an exposure time. One deviation from the Study Protocol and no deviations from applicable Standard Operating Procedures occurred during the course of this evaluation.

7.0 STUDY DATES:

STUDY INITIATION DATE:	01/28/2020
EXPERIMENTAL START DATE:	02/05/2020
EXPERIMENTAL END DATE:	03/04/2020
STUDY COMPLETION DATE:	03/09/2020

8.0 TEST PRODUCT:

The test product evaluated 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 product, as well as responsibility for retention of the test product, remained with the Study Sponsor.

Test Product #1:	Gen 1 Special
Active Ingredients:	>0.10% Peracetic Acid
Lot Number:	X-106-18
Manufacture Date:	11/16/2019
Expiration Date:	01/10/2025

9.0 CHALLENGE VIRAL STRAIN:

Human Coronavirus, strain 229E (ATCC #VR-740)

10.0 HOST CELLS:

MRC-5 (ATCC #CCL-171; human lung fibroblasts)

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:

MRC-5 cells were maintained as monolayers in disposable cell culture labware and were used for the Virucidal Suspension Test for testing Coronavirus. Prior to testing, host cell cultures were seeded onto 24-well cell culture plates. Cell monolayers were sufficiently confluent (80-90%) and less than 48 hours old before inoculation with the virus. The growth medium (GM) was replaced by maintenance medium (MM) to support virus propagation.

14.0 TEST VIRUS PREPARATION:

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

15.0 TEST PRODUCT PREPARATION:

The test product was used as received. Test concentrations were 90%.

16.0 VIRUCIDAL SUSPENSION TEST:

The Virucidal Suspension Test included the following parameters (Table 1):

TABLE 1

Parameters of Virucidal Suspension Test

Parameter	Summary	Test Replicates
Virucidal Suspension Test	Virus + Product → Exposure → Neutralization → Dilution → Plating	1 per virus strain
Virus Control	Virus + Diluent → Exposure → Dilution → Plating	1 per virus strain
Cytotoxicity Control	Product + Diluent → Neutralization → Dilution → Plating	1 per cell culture type
Neutralization Control	Product + Diluent → Neutralization → Virus inoculation →Dilution → Plating	1 per virus strain
Neutralizer Toxicity Control	Virus + Diluent → Neutralizer → Dilution → Plating	1 per virus strain
Cell Culture Control	Maintenance medium	At least 4 cell monolayers

17.0 DEVIATION FROM STUDY PROTOCOL:

Section 7.0 of the Study Protocol lists the lot of the Test Product as X0106-18. The correct lot number listed as X-106-18 was tested on 02/05/2020 and 02/19/2020. This was a typographical error in the Study Protocol and the correct lot number was recorded on study documentation and is reported throughout this final report, and as such, there is no adverse effect on the study outcome.

18.0 RESULTS – TABLE 2:

18.1 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 a 1-minute, 3-minute, 5-minute, 7-minute and 10-minute exposure of Coronavirus strain 229E to Test Product #1, Gen 1 Special (Lot #X-106-18).

TABLE 2

Test Formulation #1: Gen 1 Special (Lot #X-106-18)
Virus: Coronavirus strain 229E (ATCC #VR-740)
Host Cell Line: MRC-5 (ATCC #CCL-171)
Volume Plated per Well: 1.0 mL

Dilution (- Log_{10})	**Virus Control**	**Test**					**NTC**	**NC**	**CTC**	**CC**
		1 minute	**3 minutes**	**5 minutes**	**7 minutes**	**10 minutes**				
										0000
-2	NT	CT	CT	CT	CT	CT	CT	NT	++++	N/A
-3	++++	00+0	0000	0000	0000	0000	++++	++++	0000	
-4	++++	0+00	0000	0000	0000	0000	+++0	++++	0000	
-5	++++	0000	0000	0000	0000	0000	00++	+0+0	NT	
-6	000+	0000	0000	0000	0000	0000	0000	+000	NT	
-7	0000	0000	0000	0000	0000	0000	0000	0000	NT	
$TCID_{50}$ (log_{10})	5.75	3.00	≤2.50	≤2.50	≤2.50	≤2.50	4.75	5.25	2.50	
Log_{10} Reduction	N/A	**2.75**	**≥3.25**	**≥3.25**	**≥3.25**	**≥3.25**	N/A			
Percent Reduction		**99.82**	**≥99.94**	**≥99.94**	**≥99.94**	**≥99.94**				

\+ CPE (cytopathic/cytotoxic effect) present
0 CPE (cytopathic/cytotoxic effect) not detected
CC Cell Control
CTC Cytotoxicity Control
NC Neutralization Control
NTC Neutralizer Toxicity Control
NT Not tested
N/A Not applicable
CT Cytotoxicity

19.0 STUDY CONCLUSIONS:

Under the conditions of this evaluation Test Product #1, Gen 1 Special (Lot #X-106-18) reduced the infectivity of Coronavirus by 2.75 log_{10} (99.82%) following a 1-minute exposure, by ≥ 3.25 log_{10} (≥ 99.94%) following a 3-minute, 5-minute, 7-minute and 10 minute exposure.

20.0 STATISTICAL ANALYSIS:

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

21.0 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, the QA performed an audit of the raw data and of the Final Report, in its entirety. One deviation from the Study Protocol and no deviations from applicable BioScience Laboratories, Inc., Standard Operating Procedures were observed.

22.0 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:

Kelly Burningham
Virologist

Rachel Byrd, M.S.
Microbiologist

Brooke Kapalka
Laboratory Support Technician

Stephanie Cebulla
Laboratory Support Technician

Dakotah Olson
Product Handler

Marc Charnholm
Manager of Laboratory Support

Volha Teagle, Ph.D.
Principal Scientist

Jared Montana, M.S.
Microbiologist

23.0 QUALITY ASSURANCE AND QUALITY CONTROL PERSONNEL:

Kevin Crawford
QC/Maintenance Specialist

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

Jeremy Duley
Systems Administrator/QC Specialist

Renee LaFond, M.S.
Quality Assurance Specialist

Danielle Goveia
Quality Assurance Specialist

Carl Schmidt
ISO Technical Manager (QC, Safety)

24.0 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.

25.0 ACCEPTANCE:

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

Study Director: Kelly Burningham — Kelly Burningham

03-09-2020 — Date of Study Completion

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
Product Testing	02/05/2020	02/05/2020	02/10/2020
Data Audit	03/06/2020	03/09/2020	03/092020
Final Report Review	03/06/2020	03/09/2020	03/09/2020

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 materials were not performed by BioScience Laboratories, Inc. This statement also serves to confirm that the Final Report reflects the raw data.

Quality Assurance Specialist: Danielle Gomez for Renee LaFond M.S. — Renee LaFond, M.S.

03/09/2020 — Date

ADDENDA

Protocol #2001017-402
Protocol #2001017-402 Amendment 01 (Template Form: G-AMEND-PR)
Deviation Recording Form (Template Form: QA-DEVIATION)

January 27, 2020

PROTOCOL #2001017-402

EVALUATION OF ONE TEST PRODUCT FOR ITS VIRUCIDAL PROPERTIES

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

CONFIDENTIAL

TABLE OF CONTENTS

January 27, 2020

PROTOCOL #2001017-402

1.0 TITLE: **EVALUATION OF ONE TEST PRODUCT FOR ITS VIRUCIDAL PROPERTIES**

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:

Kelly Burningham

5.0 PURPOSE OF STUDY:

This study will evaluate the virucidal properties of one test product when challenged with Coronavirus. The testing will be based upon ASTM E1052-11, *Standard Test Method to Assess the Activity of Microbicides against Viruses in Suspension.* All testing will be performed in accordance with Good Laboratory Practices, as specified in 21 CFR Part 58, with the exception that the characterization of the identity, strength, purity, composition, stability, and solubility of the test product(s) remains the responsibility of the Study Sponsor and will not be performed by the Testing Facility (GLP 58.105).

6.0 SCOPE:

This study is designed to evaluate the virucidal properties of one test product versus Coronavirus using a Virucidal Suspension Test (In-Vitro Time-Kill method). The percent and $\log_{10}$ reductions from the initial population of the viral strain(s) will be determined following exposure to the test product(s) for 1 minute, 3 minutes, 5 minutes and 10 minutes. Plating will be performed in four replicates.

7.0 TEST PRODUCT:

The test product to be evaluated will be provided to the Testing Facility by the Study Sponsor, complete with appropriate documentation. Responsibility for the determination of the identity, strength, purity, composition, and stability of the test product(s), as well as the retention of the test product(s), rests with the Sponsor.

Test Product #1:	Gen 1 Special
Lot Number:	X0106-18
Manufacture Date:	11/16/2019
Expiration Date:	01/10/2025

8.0 CHALLENGE VIRAL STRAIN:

Human Coronavirus, strain 229E (ATCC #VR-740)

9.0 HOST CELLS :

MRC-5 (ATCC #CCL-171; human lung fibroblasts)

10.0 EQUIPMENT:

10.1 Ultralow Temperature Freezer, Temperature Range ≤ -70°C
10.2 CO_2 Incubator, Temperature Range 37 °C ± 2 °C
10.3 CO_2 Incubator, Temperature Range 35 °C ± 2 °C
10.4 Refrigerators, 2 °C - 8 °C
10.5 Water Bath, 37 °C ± 2 °C
10.6 Incubator, Refrigerator, Freezer, and Water Bath Thermometers
10.7 Continuously Adjustable Pipettes, 100 µL – 1000 µL Capacity
10.8 Continuously Adjustable Pipettes, 20 µL – 200 µL Capacity
10.9 Portable Pipetter
10.10 Inverted Compound Microscope
10.11 Laminar Flow Biological Safety Cabinet
10.12 Calibrated Minute/Second Timers

11.0 SUPPLIES:

11.1 Sterile Disposable Pipettes
11.2 Sterile Polystyrene Test Tubes
11.3 Sterile Universal 1.0 and 0.2 mL Pipette Tips
11.4 Powder-free Gloves
11.5 Sterile Tissue Culture Treated Multi-well Plates
11.6 Viral suspension
11.7 Sterile 100 µL and 1000 µL Positive Displacement Tips
11.8 Sterile Flasks
11.9 Sterile 50 mL Centrifuge Tubes
11.10 Sterile Reservoirs
11.11 Waste Pan
11.12 Non-Sterile Waste Beaker for discarded tips, etc.

12.0 MEDIA:

12.1 1X Minimum Essential Medium (MEM)
12.2 Growth Medium (GM): MEM with 10% FBS and 1% Antibiotic and L-glutamine
12.3 Maintenance Medium (MM): MEM with 2% FBS and 1% Antibiotic and L-glutamine
12.4 Trypsin
12.5 Antibiotics (e.g., Penicillin-Streptomycin-Amphotericin B)
12.6 Fetal Bovine Serum (FBS)
12.7 D/E Neutralizing Broth

13.0 HOST CELL PREPARATION:

MRC-5 cells, obtained from American Type Culture Collection (ATCC), will be maintained as monolayers in disposable cell culture labware in accordance with BSLI SOP L-2084, "*Procedure for Subculturing of Cells.*" Prior to testing, host cell cultures will be seeded onto multi-well cell culture treated plates. Cell monolayers will be 80% to 90% confluent and less than 48 hours old before inoculation with the virus. The growth medium (GM) and maintenance medium (MM) will be MEM or as appropriate for each cell culture.

14.0 TEST VIRUS PREPARATION:

Virus propagated and stored per BSLI SOP L-2102, *Procedure for Production of High-Titered Virus Stock*, will be used for this study. On the day of use, aliquots of a stock virus suspensions will be removed from a -70°C freezer and thawed.

15.0 VIRUCIDAL SUSPENSION TEST:

15.1 The Virucidal Suspension Test will include the following parameters:

Parameter	Summary	Replicates
Virucidal suspension test	Virus + Test Product → Exposure → Neutralization → Dilution → Plating	4 per group
Virus Control	Virus + Diluent → Neutralization → Dilution → Plating	4 per group
Cytotoxicity Control	Test Product + Diluent → Neutralization → Dilution → Plating	4 per group
Neutralization Control	Test Product + Diluent → Neutralization → Virus inoculation → Dilution → Plating	4 per group
Cell Culture Control	Maintenance medium	4 per group

15.2 *Test.* A 0.5 mL aliquot of test virus(s) will be added to a vial containing 4.5 mL of the undiluted test product to achieve a 90% (v/v) concentration of the test product. The test virus(s) will be exposed to the test product for 1 minute, 3 minutes, 5 minutes and 10 minutes, timed using a calibrated minute/second timer. The calibrated minute/second timer will be started within ± 1 second of adding the challenge suspension. Immediately after each exposure, the test virus(s)/product suspensions will be neutralized in D/E Neutralizing Broth, mixed thoroughly, and serially diluted in MM. Each dilution will be plated in four replicates.

15.3 *Virus Control.* A 0.5 mL aliquot of test virus(s) will be added to 4.5 mL of MM and exposed for 10 minutes at ambient temperature. The subsequent test virus dilution will be made in MM and serially diluted in MM. Each dilution will be plated in four replicates.

15.4 *Cytotoxicity Control.* A 0.5 mL aliquot of MM will be added to a vial containing 4.5 mL of the undiluted test product. The MM/product mixture will be neutralized in D/E Neutralizing Broth, mixed thoroughly and serially diluted in MM. Each dilution will be plated in four replicates.

15.5 *Neutralization Control.* A 0.5 mL aliquot of MM will be added to a vial containing 4.5 mL of the undiluted test product. The MM/product mixture will be diluted 1:10 in D/E Neutralizing Broth. An aliquot of the virus(s) will be added to the neutralized product and thoroughly mixed and exposed to the neutralized product for 10 to 20 minutes. Additionally, the effect of the neutralizer on virus infectivity will be assessed by adding virus to the neutralizer (D/E Neutralizing Broth) alone followed by exposure for 10 to 20 minutes. Subsequent 10-fold dilutions of neutralized test product/virus suspension will be made in MM. Each dilution will be plated in four replicates.

15.6 *Cell Culture Control.* Intact cell culture will serve as the control of cell culture viability. The GM will be replaced by MM in all cell control wells.

15.7 The plates will be incubated in a CO_2 incubator for 5 to 14 days at 35 °C ± 2 °C in a CO_2 incubator. Cytopathic/cytotoxic effect will be monitored using an Inverted Compound Microscope.

Note: In cases when viral CPE is undetectable using Inverted Compound Microscope, additional immunostaining with virus specific antibodies can be performed.

16.0 CALCULATIONS:

16.1 Viral and toxicity 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.

16.2 The $\log_{10}$ of infectivity reduction will be calculated as follows:

Log_{10} Reduction Formula:

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

16.3 The percent reduction will be calculated as follows:

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

17.0 STATISTICAL ANALYSIS:

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

18.0 TEST ACCEPTANCE CRITERIA:

A valid test requires that: 1) at least 4 $\log_{10}$ of $TCID_{50}$ be recovered from the Virus Control; 2) cells in the cell culture 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, and 5) the test product be fully neutralized after the timed exposure such that the difference in virus titer for the Neutralization Control and Virus Control does not exceed 1.0 $\log_{10}$.

19.0 FINAL REPORT:

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

20.0 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).

21.0 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.

22.0 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, 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 Sponsor before any records or documents are destroyed.

23.0 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 returned to the Sponsor at the conclusion of the study.

24.0 QUALITY ASSURANCE AUDITS:

Quality Assurance (QA) 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 QA will perform an audit of the data and of the Final Report in its entirety.

25.0 ACCEPTANCE:

EVALUATION OF ONE TEST PRODUCT FOR ITS VIRUCIDAL PROPERTIES

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

Study Director: Kelly Burningham — 01-28-2020
Kelly Burningham — Date of Study Initiation

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

David J. Weaver — 1/28/2020
Representative — Date

Pres/CEO
Title

PROTOCOL AMENDMENT FORM

DATE: 02/14/2020 **AMENDMENT NUMBER:** 01

PROTOCOL NUMBER: 2001017-402

SPONSOR: APHEX BIOCLEANSE SYSTEMS, INC.

PROTOCOL TITLE: EVALUATION OF ONE TEST PRODUCT FOR ITS VIRUCIDAL PROPERTIES

REASON FOR CHANGE(S): Per request by the sponsor, an additional time point will be added to testing.

CHANGE(S): One exposure time, 7 minutes, will be added to testing. The exposure times will include 1 minute, 3 minutes, 5 minutes, 7 minutes and 10 minutes.

Initial testing did not meet the acceptance criteria due to low titer of the virus. This data will not be presented in the final report but will be maintained for file only.

APPROVALS:

CORPORATE MANAGEMENT	02/14/2020 DATE
STUDY DIRECTOR / PRINICPAL INVESTIGATOR	02-14-2020 DATE
N/A ASSOCIATE STUDY DIRECTOR / SUBINVESTIGATOR	N/A DATE
SPONSOR	2/14/2020 DATE
N/A IRB COMMITTEE CHAIR *	N/A DATE

* APPLICABLE: ☐ Yes ☒ No KB 02.14.2020
Study Director / Principal Investigator Initials

REVIEWED BY:

QUALITY ASSURANCE	02/14/2020 DATE

DEVIATION RECORDING FORM

STUDY NUMBER: 2001017-402 **DEVIATION NUMBER:** 01

STUDY TITLE: EVALUATION OF ONE TEST PRODUCT FOR ITS VIRUCIDAL PROPERTIES

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 Study Protocol lists the Lot # as X0106-18

DEVIATION FROM PROCEDURE [Include Date(s) of Deviation]: The correct Lot# X-106-18 was tested on 02/05/2020 and 02/19/2020

REASON FOR DEVIATION: This was a typographical error.

EFFECT ON OUTCOME: The correct lot number will be reported throughout the final report, and as such, there is no adverse effect on the final report.

REPORTED BY: Kelly Burningham

Kelly Burningham — 03-09-2020
TITLE: Study Director — DATE

APPROVAL SIGNATURES:

Kelly Burningham — 03-09-2020
①TITLE: — DATE

Maisha Brown — 03-09-2020
MANAGER/SUPERVISOR — DATE

Dan S Paul — 03-09-2020
CORPORATE MANAGEMENT — DATE

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

QUALITY ASSURANCE REVIEW

Danielle Gouveia — 03/09/2020
QUALITY ASSURANCE — DATE