

**BIO**SCIENCE  
LABORATORIES • INC

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November 25, 2009

FINAL REPORT #090620-450

**DETERMINATION OF THE ANTIVIRAL PROPERTIES OF A NOVEL ANTIMICROBIAL SOLUTION  
USED TO COAT POROUS SURFACES**

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Prepared for:

**INDUSCO DISTRIBUTION OF AMERICA, INC. (SPONSOR)**  
801 Maplewood Drive, #6  
Jupiter, Florida 33458

Prepared by:

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## TABLE OF CONTENTS

<u>SECTION</u>	<u>PAGE</u>
EXECUTIVE SUMMARY .....	3
1.0 TITLE .....	4
2.0 SPONSOR.....	4
3.0 TESTING FACILITY .....	4
4.0 STUDY DIRECTORS .....	4
5.0 PURPOSE OF STUDY .....	4
6.0 SCOPE .....	4
7.0 STUDY DATES .....	5
8.0 TEST MATERIALS .....	5
9.0 CHALLENGE VIRAL STRAIN .....	5
10.0 EQUIPMENT AND SUPPLIES .....	5
11.0 MEDIA .....	5
12.0 HOST CELL PREPARATION.....	5
13.0 TEST VIRUS PREPARATION.....	5
14.0 PREPARATION OF SURFACES .....	6
15.0 RESULTS - TABLES I THROUGH V .....	6
16.0 STATISTICAL ANALYSIS.....	12
17.0 TEST ACCEPTANCE CRITERIA.....	16
18.0 QUALITY ASSURANCE AUDITS/FINDINGS .....	16
19.0 LABORATORY PERSONNEL .....	16
20.0 QUALITY ASSURANCE PERSONNEL .....	17
21.0 DOCUMENTATION AND RECORD-KEEPING.....	17
22.0 ACCEPTANCE .....	18
INDEX OF ADDENDA.....	19

## EXECUTIVE SUMMARY

**FINAL REPORT** #090620-450

**TITLE:** DETERMINATION OF THE ANTIVIRAL PROPERTIES OF A NOVEL ANTIMICROBIAL SOLUTION USED TO COAT POROUS SURFACES

**SPONSOR:** INDUSCO DISTRIBUTION OF AMERICA, INC.  
801 Maplewood Drive, #6  
Jupiter, Florida 33458

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

**STUDY INITIATION DATE:** 09/09/09

**STUDY COMPLETION DATE:** 11/25/09

This study was designed to evaluate virucidal activity of surfaces treated with one test product versus Swine-like H1N1 Influenza A virus strain A/California/04/2009 (CDC ID #2009712047). The virucidal efficacy of the treated surfaces was determined by comparison with that of an untreated surface. The surfaces tested were white cloth treated with SIS 7200 AMP and untreated white cloth, each tested in three replicates. The test virus suspension was inoculated onto the test and control surfaces and dried at ambient temperature. The first group of the inoculated test and control surfaces was eluted with the appropriate elution solution immediately after drying. The suspension was serially diluted and plated onto Madin Darby Canis Kidney (MDCK [ATCC #CCL-34]) cells. The second group of the inoculated test and control surfaces was exposed for 30 minutes after drying. Following exposure, the virus was eluted, diluted, and plated onto MDCK cells.

The Test Product, SIS 7200 AMP Treated white cloth, reduced the infectivity of the test virus an average of **2.08 log<sub>10</sub>** (99.17%) after Zero time exposure (immediately after drying), and an average of **5.25 log<sub>10</sub>** (>99.99%) after a 30 minute exposure. The Control Product, untreated White Cloth produced average reductions of **1.67 log<sub>10</sub>** (97.86%) after Zero time exposure (immediately after drying), and **2.25 log<sub>10</sub>** (99.44%) after a 30 minute exposure.

Statistical analysis was performed using a two-factor Analysis of Variance (ANOVA) to evaluate differences in virucidal efficacy of the Test and Control Products. The log<sub>10</sub> reductions of the test virus population were used for analysis. The reduction produced by the Test Product at time Zero was not significantly different from that of the Control Product (untreated). The approximately equivalent recoveries produced by the Test and Control surfaces were due to the reduction of Influenza virus population due to drying. After 30 minutes of exposure, the reduction produced by SIS 7200 AMP treated surface was significantly greater by 3.00 log<sub>10</sub> than that of the untreated surface (p < 0.005). A 30-minute exposure of the epidemic strain of Influenza A H1N1 demonstrated significant virucidal activity of cloth treated with SIS 7200 AMP.

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**1.0**    **TITLE:**                    **DETERMINATION OF THE ANTIVIRAL PROPERTIES OF A NOVEL  
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**2.0**    **SPONSOR:**                    **INDUSCO DISTRIBUTION OF AMERICA, INC.**  
801 Maplewood Drive, #6  
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**3.0**    **TESTING FACILITY:**    **BIOSCIENCE LABORATORIES, INC.**  
300 N. Willson Avenue  
Bozeman, Montana 59715

**4.0**    **STUDY DIRECTORS:**  
  
Volha Dzyakanava, Ph.D. - Principal Study Director  
Kelly Burningham - Associate Study Director

**5.0**    **PURPOSE OF STUDY:**

This study was designed to evaluate the virucidal activity of a porous, treated surface when challenged with Swine-like H1N1 Influenza A virus strain A/California/04/2009 (CDC ID #2009712047), in comparison with that of an untreated control surface. The percent reduction and Log<sub>10</sub> reduction of the challenge strain were determined following zero and 30 minute exposures to the surfaces. The plating was performed in four replicates. 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:**

This study evaluated the virucidal efficacy of cloth surfaces treated with one test product versus Swine-like H1N1 Influenza A virus strain A/California/04/2009 (CDC ID #2009712047). The virucidal activity of the treated surfaces was determined by comparison with that of an untreated surface. The surfaces tested were white cloth treated with SIS 7200 AMP and untreated white cloth, each tested in three replicates. The test virus suspension was inoculated onto the test and control surfaces and dried at ambient temperature. The first group of the inoculated test and control surfaces was eluted with the appropriate elution solution immediately after drying. The suspension was serially diluted and plated onto Madin Darby Canis Kidney (MDCK [ATCC #CCL-34]) cells. The second group of the inoculated test and control surfaces was exposed for 30 minutes after drying. Following exposure, the virus was eluted, diluted, and plated onto MDCK cells. The Study Protocol, included as Addendum I of this Final Report, presents the study methodology in detail, as do the General Data Gathering Form (Form No. 91-L-002) in Addendum V of this Final Report. No deviations from the methodology described in the Study Protocol or from applicable BioScience Laboratories, Inc., Standard Operating Procedures occurred during the course of this evaluation.

**7.0**     **STUDY DATES:**

**STUDY INITIATION DATE:**           09/09/09  
**EXPERIMENTAL START DATE:**       10/02/09  
**EXPERIMENTAL END DATE:**         10/08/09  
**STUDY COMPLETION DATE:**        11/25/09

**8.0**     **TEST MATERIALS:**

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

**Test Surface:**                   SIS 7200 AMP Treated white cloth  
**Lot Number:**                   Not Provided  
**Expiration Date:**               Not Provided

**Control Surface:**               Control – Untreated white cloth  
**Lot Number:**                   Not Provided  
**Expiration Date:**               Not Provided

**9.0**     **CHALLENGE VIRAL STRAIN:**

Swine-like H1N1 Influenza A virus strain A/California/04/2009 (CDC ID #2009712047)

**10.0**    **EQUIPMENT AND SUPPLIES:**

The equipment and supplies used in this study are as described in the Study Protocol in Addendum I of this Final Report. Additional details are recorded on a Virology Equipment and Supplies Tracking Form (Form No. 07-L-011) in Addendum V of this Final Report.

**11.0**    **MEDIA:**

The growth media and diluting fluids used in this study are as described in the Study Protocol in Addendum I of this Final Report. Additional details are recorded on Virology Equipment and Supplies Tracking Forms (Form No. 07-L-011) in Addendum V of this Final Report.

**12.0**    **HOST CELL PREPARATION:**

Madin Darby Canis Kidney (MDCK [ATCC#CCL-34]) cells were maintained as monolayers in disposable cell culture labware and were used for the Virucidal Suspension Test of Swine-like H1N1 Influenza A virus strain A/California/04/2009 (CDC ID #2009712047). Prior to testing, host cell cultures were seeded onto the appropriate cell culture plates. Cell monolayers were sufficiently confluent and less than 48 hours old before inoculation with each virus. The growth medium (GM) and maintenance medium (MM) were 1X Minimum Essential Medium (MEM) with appropriate supplements.

**13.0**    **TEST VIRUS PREPARATION:**

The Swine-like H1N1 Influenza A virus strain A/California/04/2009 (CDC ID #2009712047) from BSLI high titer virus stock was used for this study. On the day of use, aliquots of the stock virus were removed from a -70°C freezer and thawed prior to use in testing.

**14.0 PREPARATION OF SURFACES:**

Treated and untreated surfaces were provided by the Sponsor. A minimum of six treated and six untreated surfaces were used for this evaluation.

**15.0 RESULTS - TABLES I THROUGH V:**

- 15.1 Table I presents the Initial Population and viral recoveries after a 0-minute exposure to the test product (SIS 7200 AMP Treated White Cloth) and the control product (Untreated White Cloth).
- 15.2 Table II presents the Initial Population and viral recoveries after a 30-minute exposure to the test product (SIS 7200 AMP Treated White Cloth) and the control product (Untreated White Cloth).
- 15.3 Table III presents the reductions of the Viral Initial Population after a 0-minute exposure to the test product (SIS 7200 AMP Treated White Cloth) and the control product (Untreated White Cloth).
- 15.4 Table IV presents the reductions of the Viral Initial Population after a 30-minute exposure to the test product (SIS 7200 AMP Treated White Cloth) and the control product (Untreated White Cloth).
- 15.5 Table V presents the reductions of the Viral Population after Zero time and 30 minute Exposures to the test product (SIS 7200 AMP Treated White Cloth) and the control product (Untreated White Cloth).

**TABLE I**

**Viral Recoveries after Zero Time Exposure to the Test Product (SIS 7200 AMP Treated White Cloth) and Control Product (Untreated White Cloth)**

Virus: Swine-like Influenza A H1N1 strain A/California/04/2009 CDC ID # 2009712047

Host Cell Line: MDCK Host Cell Line ATCC # CCL-34 Volume Plated per Well (mL): 1.0 mL

Dilution Plated	SIS 7200 AMP Treated White Cloth			Untreated White Cloth			Initial Population
	Replicate 1	Replicate 2	Replicate 3	Replicate 1	Replicate 2	Replicate 3	
-2	++++	++++	++++	++++	++++	++++	NT
-3	++++	++++	++++	++++	++++	++++	NT
-4	+++0	++++	++++	++++	++++	++++	++++
-5	+000	+000	+000	+000	+000	+000	++++
-6	0000	0000	0000	0000	0000	0000	++++
-7	0000	0000	0000	0000	0000	0000	+000
-8	NT	NT	NT	NT	NT	NT	0000
TCID <sub>50</sub> (log <sub>10</sub> )	4.50	4.75	4.75	5.00	5.25	5.00	6.75
Average TCID (log <sub>10</sub> )	4.67			5.08			NA
S <sub>N-1</sub>	0.144			0.144			NA

- + - CPE Present
  - 0 - CPE not detected
  - NA - Not Applicable
  - S<sub>N-1</sub> - Standard Deviation
- Standard Deviation Formula:

$$s_{N-1} = \sqrt{\frac{1}{N-1} \sum (x_i - \bar{x})^2}$$

**TABLE II**

**Viral Recoveries after 30 minute Exposure to the Test product (SIS 7200 AMP Treated White Cloth) and Control product (Untreated White Cloth)**  
 Virus: Swine-like Influenza A H1N1 strain A/California/04/2009 CDC ID # 2009712047  
 Host Cell Line: MDCK Host Cell Line ATCC # CCL-34 Volume Plated per Well (mL): 1.0 mL

Dilution Plated	SIS 7200 AMP Treated White Cloth			Untreated White Cloth			Initial Population
	Replicate 1	Replicate 2	Replicate 3	Replicate 1	Replicate 2	Replicate 3	
-2	0000	0000	0000	++++	++++	++++	NT
-3	0000	0000	0000	++++	++++	++++	NT
-4	0000	0000	0000	+++0	++++	++++	++++
-5	0000	0000	0000	0000	0000	+000	++++
-6	0000	0000	0000	0000	0000	0000	++++
-7	0000	0000	0000	0000	0000	0000	+000
-8	NT	NT	NT	NT	NT	NT	0000
TCID <sub>50</sub> (log <sub>10</sub> )	1.50*	1.50*	1.50*	4.25	4.50	4.75	6.75
Average TCID (log <sub>10</sub> )	1.50			4.50			NA
S <sub>N-1</sub>	0.00			0.25			NA

\* - Limit of Detection  
 +- CPE Present  
 0 - CPE not detected  
 NA - Not Applicable  
 S<sub>N-1</sub> - Standard Deviation  
 Standard Deviation Formula:

$$s_{N-1} = \sqrt{\frac{1}{N-1} \sum (x_i - \bar{x})^2}$$



**TABLE III**

**Reductions of Initial Viral Population after Zero Exposure Time to Test Product (SIS 7200 AMP Treated White Cloth) and Control Product (Untreated White Cloth)**

Virus: Swine-like Influenza A H1N1 strain A/California/04/2009 CDC ID # 2009712047

Host Cell Line: MDCK Host Cell Line ATCC # CCL-34 Volume Plated per Well (mL): 1.0 mL

	SIS 7200 AMP Treated White Cloth			Untreated White Cloth			Initial Population
	Replicate 1	Replicate 2	Replicate 3	Replicate 1	Replicate 2	Replicate 3	
Viral Recoveries TCID <sub>50</sub> (log <sub>10</sub> )	4.50	4.75	4.75	5.00	5.25	5.00	6.75
log <sub>10</sub> Reduction	2.25	2.00	2.00	1.75	1.50	1.75	NA
Average log <sub>10</sub> Reduction	2.08			1.67			NA
% Reduction	99.44	99.00	99.00	98.22	96.84	98.22	
Average % Reduction*	99.17%			97.86%			NA

+ - CPE Present

0 - CPE not detected

NA - Not Applicable

\* - Average % Reduction (calculated from average log<sub>10</sub> reduction) = 100-(1/ TCID<sub>50</sub> Reduction)\*100

**TABLE IV**

**Reductions of Initial Viral Population after Thirty minutes Exposure Time to Test Product (SIS 7200 AMP Treated White Cloth) and Control Product (Untreated White Cloth)**

Virus: Swine-like Influenza A H1N1 strain A/California/04/2009 CDC ID # 2009712047

Host Cell Line: MDCK Host Cell Line ATCC # CCL-34 Volume Plated per Well (mL): 1.0 mL

	SIS 7200 AMP Treated White Cloth			Untreated White Cloth			Initial Population
	Replicate 1	Replicate 2	Replicate 3	Replicate 1	Replicate 2	Replicate 3	
Viral Recoveries TCID <sub>50</sub> (log <sub>10</sub> )	1.50*	1.50*	1.50*	4.25	4.50	4.75	6.75
<b>log<sub>10</sub> Reduction</b>	<b>5.25</b>	<b>5.25</b>	<b>5.25</b>	<b>2.50</b>	<b>2.25</b>	<b>2.00</b>	NA
<b>Average log<sub>10</sub> Reduction</b>	<b>5.25 log<sub>10</sub></b>			<b>2.25 log<sub>10</sub></b>			NA
<b>% Reduction</b>	>99.99	>99.99	>99.99	99.68	99.44	99.00	NA
<b>Average % Reduction*</b>	<b>&gt;99.99%</b>			<b>99.44%</b>			NA

+ - CPE Present

0 - CPE not detected

NA - Not Applicable

\* - Average % Reduction (calculated from average log<sub>10</sub> reduction) = 100-(1/ TCID<sub>50</sub> Reduction)\*100

**TABLE V**

**Reductions of the Viral Population, Test versus Control, after Zero time and 30 minute Exposures to the Test Product (SIS 7200 AMP Treated White Cloth) and Control Product (Untreated White Cloth)**

Virus: Swine-like Influenza A H1N1 strain A/California/04/2009 CDC ID # 2009712047

Host Cell Line: MDCK Host Cell Line ATCC # CCL-34 Volume Plated per Well (mL): 1.0 mL

	Zero-time Exposure			30-minute Exposure		
	Rep. 1	Rep. 2	Rep. 3	Rep. 1	Rep. 2	Rep. 3
<b>log<sub>10</sub> Reduction*</b>	0.50	0.50	0.25	2.75	3.00	3.25
<b>Average log<sub>10</sub> Reduction</b>	<b>0.42 log<sub>10</sub></b>			<b>3.00 log<sub>10</sub></b>		
<b>% Reduction**</b>	68.38	68.38	43.77	99.82	99.90	99.94
<b>Average % Reduction***</b>	<b>61.98%</b>			<b>99.90%</b>		

\* - Log<sub>10</sub> Reduction = (log<sub>10</sub> TCID<sub>50</sub> of the Untreated Control) - (log<sub>10</sub> TCID<sub>50</sub> of the Test Product);

\*\* - % Reduction = 1 - (TCID<sub>50</sub> Test Product / TCID<sub>50</sub> Control) \* 100

\*\*\* - Average % Reduction (calculated from average log<sub>10</sub> reduction) = 100 - (1 / TCID<sub>50</sub> Reduction) \* 100

16.0 **STATISTICAL ANALYSIS – TABLE VI AND TABLE VII, FIGURE 1 THROUGH 3:**

The statistical model used in the analysis was a two-factor Analysis of Variance (ANOVA), as follows:

$$\hat{y} = A + B + (A \times B) + e$$

Where

$\hat{y}$  = Log<sub>10</sub> reduction

$A$  = Treatment

1, if Treated

2, if Untreated

$B$  = Exposure

1, if Time 0-minute exposure

2, if Time 30-minute exposure

$(A \times B)$  = Interaction of  $A$  and  $B$

$e$  = Error term

$\hat{y} = A + B + (A \times B) + e$  was modified to:

$$C3 = C1 + C2 + (C1 \times C2)$$

Where

$C3 = \hat{y}$  = Log<sub>10</sub> reduction

$C1$  = Treatment

$C2$  = Exposure

$(C1 \times C2)$  = Interaction

Both  $C1$  and  $C2$  were fixed (predetermined), not random. The analysis is presented in Table VI.

**TABLE VI**

General Linear Model: C3 versus C1, C2

Factor	Type	Levels	Values
C1 (Treatment)	Fixed	2	1, 2
C2 (Exposure)	Fixed	2	1, 2

Analysis of Variance for C3, using Adjusted Sum of Squares for Tests

Source	Degrees of Freedom	Sequential Sum of Squares	Adjusted Sum of Squares	Adjusted Mean Square <sup>1</sup>	F <sup>2</sup>	Probability <sup>3</sup>	Significant/Not Significant <sup>4</sup>
C1 (Treatment)	1	8.7552	8.7552	8.7552	336.20	0.000	Significant
C2 (Exposure)	1	10.5469	10.5469	10.5469	405.00	0.000	Significant
C1 × C2 (Interaction)	1	5.0052	5.0052	5.0052	192.20	0.000	Significant
Error	8	0.2083	0.2083	0.0260			
Total	11	24.5156					

$S = 0.161374$   $R - Sq(adj) = 98.83\%$

<sup>1</sup> The mean square is the Adjusted Mean Square divided by Degrees of Freedom.

<sup>2</sup> F statistic is the C1, C2, and (C1 × C2) divided by  $MS_{Error}$

<sup>3</sup> Probability Equation: For the first value, C1, Probability =  $(F \geq 336.20 \mid H_0 \text{ true}) \leq 0.000$ .

<sup>4</sup> The probability of the test being significant or not significant at  $\alpha = 0.05$ .

The model has an  $R_{adj}^2 = 98.83\%$ , which is more than adequate, with a variance ( $s^2$ ) = 0.260, and a standard deviation ( $S$ ) =  $\sqrt{0.260} = 0.161374$ , which is very tight.

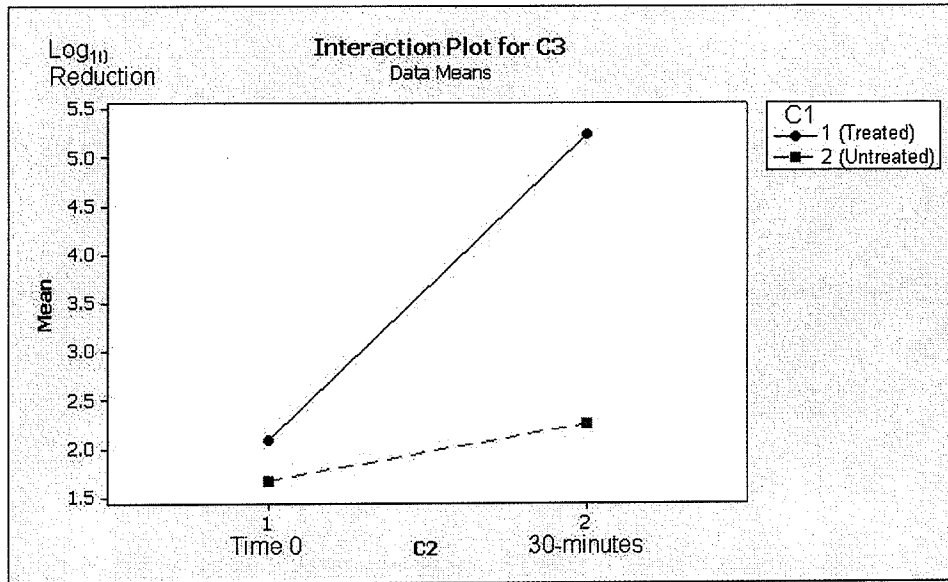
**First Test: Interaction (A × B)**

The interaction was significant ( $p < 0.000$ ), so we will evaluate it first.

$H_0$ : No interaction in present.

$H_A$ : Interaction is present.

Accept  $H_A$ ; the probability ( $F \geq 192.20 \mid H_0 \text{ true}) \leq 0.000$ . Interaction is present. Figure 1 provides a diagram of this interaction.



**Figure 1. Interaction of Treatment and Exposure.**

C1 – Treatment;  
 C2 – Exposure;  
 C3 – Log<sub>10</sub> Reduction

We see that at Time Zero, the log<sub>10</sub> reduction produced by the treated test surface was about 0.5 log<sub>10</sub> than that produced by the untreated control surface. After 30 minutes exposure time, the reduction produced by the test surface was greater than 5.0 log<sub>10</sub>, and that produced by the control surface was at about 2.0 log<sub>10</sub>. This is a difference of > 3 log<sub>10</sub>.

This is the interaction. The slope of the time-related graph of reduction produced by the treated surface is much greater than that for the untreated control. There is some killing of the virus on the treated surface at Time Zero, but it was far greater at the 30-minute time point. The reduction at the 30-minute time point on untreated control surface represents die-off of virus due to drying.

**Main Effects**

We must be careful in interpreting the main effects, due to the interaction.

$x_1$  = treatment  
 1, if treated  
 2, if untreated

$H_0$ : 1 = 2

$H_A$ : 1  $\neq$  2

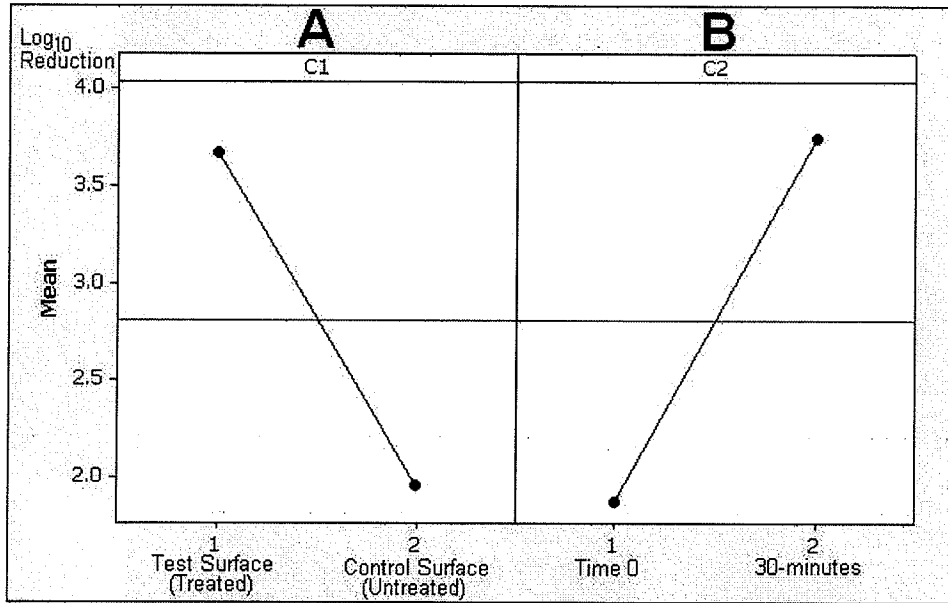
We accept  $H_A$ ; the effects of the two test surfaces are different. Probability ( $F \geq 336.20 \mid H_0 \text{ true}$ )  $\leq 0.000$ . Figure 2, Section A provides a graph of these findings.

$X_2$  = exposure  
 1 = Time 0  
 2 = 30-minute Exposure

$H_0$ : 1 = 2

$H_A$ : 1  $\neq$  2

We reject  $H_0$ , and accept  $H_A$ ; there is a difference. Probability ( $F \geq 405.00 \mid H_0 \text{ true}$ )  $\leq 0.000$ . Figure 2, Section B displays these findings.

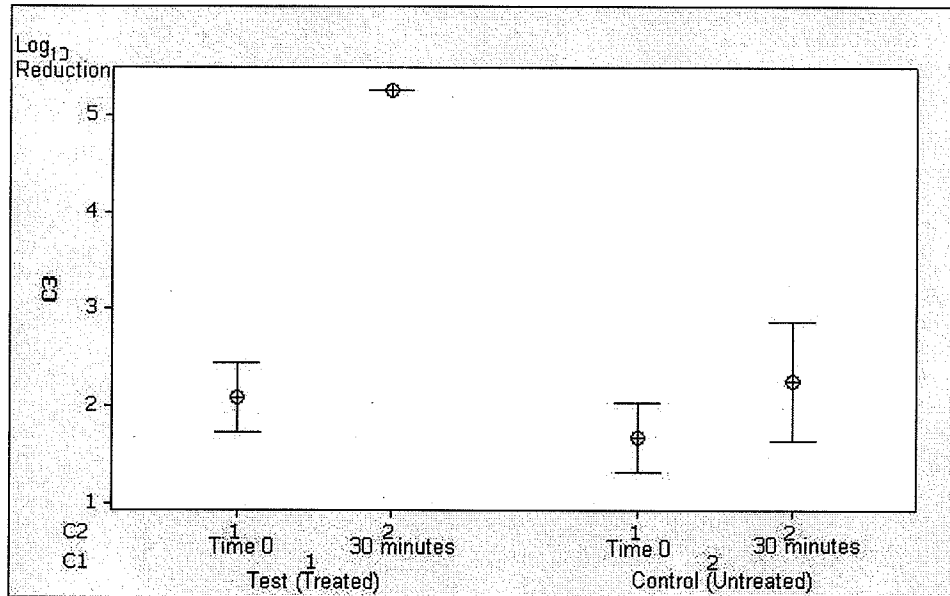


**Figure 2.** Main Effects Plot for log<sub>10</sub> Reductions – Data Means.

A – Treatment;  
B – Exposure

**95% Confidence Intervals for Treatments and Exposures**

A 95% confidence interval for the whole study is presented in Figure 3.



**Figure 3.** Interval Plot of Log<sub>10</sub> Reductions – 95% Confidence Interval for the Mean.

C1 – Treatment;  
C2 – Exposure;  
C3 – Log<sub>10</sub> Reduction

The test surface at Time Zero produced little reduction, but within 30 minutes, reduction was  $> 5 \log_{10}$ , which is significantly different. The populations recovered from the control surface at Times Zero and 30 minutes were equivalent, and also with population from the treated surface at Time Zero.

**Data**

Table VII presents the raw data used in the analysis.

**TABLE VII**

Data Display

Row	C1	C2	C3
1	1	1	2.25
2	1	1	2.00
3	1	1	2.00
4	2	1	1.75
5	2	1	1.50
6	2	1	1.75
7	1	2	5.25
8	1	2	5.25
9	1	2	5.25
10	2	2	2.50
11	2	2	2.25
12	2	2	2.00

C1 = Treatment  
 1, if Treated Test Surface  
 2, if Untreated Control Surface  
 C2 = Exposure  
 1, if Time 0  
 2, if 30-minute Exposure

**17.0 TEST ACCEPTANCE CRITERIA:**

A valid test requires that: 1) at least 4  $\log_{10}$  of TCID<sub>50</sub> be recovered from the Initial Population; 2) cells in the negative 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.

**18.0 QUALITY ASSURANCE AUDITS/FINDINGS:**

The Quality Assurance Unit (QAU) conducted in-phase audits 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 QAU performed an audit of the raw data and of the Final Report, in its entirety. No deviations from the methodology presented in the Protocol or from applicable BioScience Laboratories, Inc., Standard Operating Procedures occurred during the course of this evaluation.

**19.0 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.

PRINCIPAL STUDY DIRECTOR: Volha Dzyakanava, Ph.D.  
 Manager of Virology Laboratory

ASSOCIATE STUDY DIRECTOR: Kelly Burningham  
 Microbiologist



**LABORATORY PERSONNEL (Continued):**

Shelley Brown  
Laboratory Support Technician

Stephanie Scarff  
Laboratory Support Technician

Patricia Mays Suko  
Supervisor of Laboratory Support

Hillary Schmidt  
Microbiologist

**20.0 QUALITY ASSURANCE PERSONNEL:**

Scott D. Ferraro  
Manager of Quality Control

Brenon Savell  
Quality Assurance Associate/Product Handling

Amy L. Juhnke  
Manager of Quality Assurance/Document Control

Janis Smoke  
Manager of Regulatory Affairs/Employee Training

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

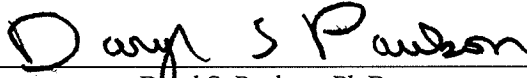
**21.0 DOCUMENTATION AND RECORD-KEEPING:**

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

22.0 **ACCEPTANCE:**

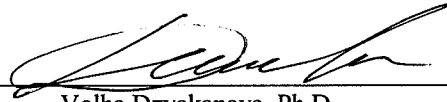
**BIOSCIENCE LABORATORIES, INC.**  
300 N. Willson Avenue  
Bozeman, Montana 59715

President  
And CEO:

  
Daryl S. Paulson, Ph.D.

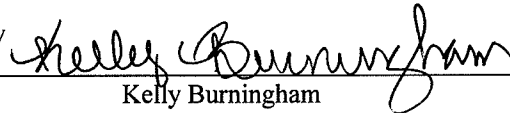
11-25-09  
Date

Principal Study  
Director:

  
Volha Dzyakanava, Ph.D.

11-25-09  
Study Completion Date

Associate Study  
Director:

  
Kelly Burningham

11-25-09  
Date

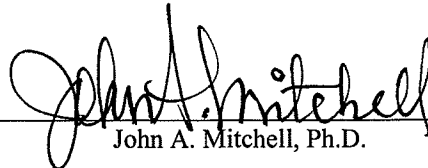
**QUALITY ASSURANCE STATEMENT:**

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:

<u>Phase</u>	<u>Date</u>
Product Testing	10/02/09
Data Audit	11/10/09
Final Report Review	11/25/09
Reports to Study Director and Management	11/12/09 and 11/25/09

This study was conducted in compliance with Good Laboratory Practices standards, as described by the FDA (21 CFR Part 58), with the following exception: test article preparations were not analyzed at BioScience Laboratories, Inc., to confirm chemical composition, concentration, purity, stability, or homogeneity.

Director of  
Quality  
Assurance:

  
John A. Mitchell, Ph.D.

11/25/09  
Date

## INDEX OF ADDENDA

- I Protocol #090620-450
- II Product Information
  - Product Receipt Log (Form No. 92-L-023)
  - Material Safety Data Sheet (MSDS)
  - Product-Tracking Forms (Form No. 93-L-029)
- III Tissue Culture Subculture Data Sheet (Form No. 01-L-006)
- IV Virucidal Test Evaluation
  - General Data Gathering Form (Form No. 91-L-002)
  - Virucidal Test Evaluation Forms (Form No. 03-L-017)
  - Virucidal Test Tracking Forms (Form No. 07-L-002)
- V General Records
  - Project Notes (Form No. 95-G-001)
  - Virology Equipment and Supplies Tracking Form (Form No. 07-L-011)
  - CO<sub>2</sub> Incubator Log Forms (Form No. 01-L-004)