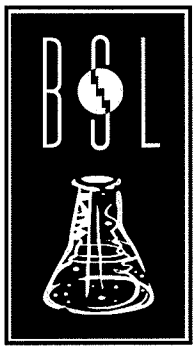

BIOSCIENCE
LABORATORIES•INC

July 10, 2009

FINAL REPORT #090452-402

EVALUATION OF ONE TEST PRODUCT FOR ITS ANTIVIRAL PROPERTIES AT THREE EXPOSURE TIMES USING AN IN-VITRO TIME-KILL METHOD

Prepared for:

STERLING NATURAL SCIENCE (SPONSOR)
84 Cutler Street U8
Warren, Rhode Island 02885

Prepared by:

BIOSCIENCE LABORATORIES, INC. (TESTING FACILITY)
300 N. Willson Avenue
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EXECUTIVE SUMMARY

This study was designed to evaluate the antiviral properties of one test product when challenged with Influenza A virus A/Swine/Iowa/15/30 (H1N1) (ATCC #VR-333) using a Virucidal Suspension Test (In-Vitro Time-Kill method). The percent and $\log_{10}$ reductions from the initial population of the viral strain were determined following exposure to the test product for 30 seconds, 1 minute, and 2 minutes. The test product was evaluated at a 90% (v/v) concentration.

The Test Product, Ag^2 Sterling Skin Sanitizer (Lot Number 041009-IP), reduced the infectivity of Influenza A H1N1 virus strain A/Swine/Iowa/15/30 (ATCC #VR-333) by 1.50 $\log_{10}$ (96.84% reduction) after a 30-second, 1.25 $\log_{10}$ (94.38% reduction) after a 1-minute, and 3.75 $\log_{10}$ (99.98% reduction) after a 2-minute exposure time.

July 10, 2009

FINAL REPORT #090452-402

1.0 TITLE: **EVALUATION OF ONE TEST PRODUCT FOR ITS ANTIVIRAL PROPERTIES AT THREE EXPOSURE TIMES USING AN IN-VITRO TIME-KILL METHOD**

2.0 SPONSOR: **STERLING NATURAL SCIENCE**
84 Cutler Street U8
Warren, Rhode Island 02885

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 antiviral properties of one test product when challenged with Influenza A virus A/Swine/Iowa/15/30 (H1N1) (ATCC #VR-333) using a Virucidal Suspension Test (In-Vitro Time-Kill method). The test product was evaluated at a 90% (v/v) concentration. 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 was designed to evaluate the antiviral properties of one test product when challenged with Influenza A H1N1 virus strain A/Swine/Iowa/15/30 (ATCC #VR-333) using a Virucidal Suspension Test (In-Vitro Time-Kill method). The percent and $\log_{10}$ reductions from the initial population of the viral strain were determined following exposure to the test product for 30 seconds, 1 minute, and 2 minutes. Plating was performed in four replicates. The Study Protocol, included as Addendum I of this Final Report, presents the study methodology, in detail, as does the General Data Gathering Form (Form No. 91-L-002) in Addendum V of this Final Report. 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.

7.0 STUDY DATES:

STUDY INITIATION DATE: 05/19/09

EXPERIMENTAL START DATE: 05/22/09

EXPERIMENTAL END DATE: 06/23/09

STUDY COMPLETION DATE: 07/10/09

8.0 TEST MATERIAL:

The test product evaluated was provided to the Testing Facility by the Study Sponsor, complete with appropriate documentation. 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, remained with the Sponsor. All documentation provided with the test product is included in Addendum II of this Final Report.

Test Product:	Ag^2 Sterling Skin Sanitizer
Lot Number:	041009-IP
Expiration Date:	05/2010

9.0 CHALLENGE VIRAL STRAIN:

The challenge viral strain (American Type Culture Collection [ATCC] Strain) evaluated was:

Influenza A virus A/Swine/Iowa/15/30 (H1N1) (ATCC #VR-333)

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 Virology Equipment and Supplies Tracking Forms (Form No. 07-L-011) in Addendum VI 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 VI of this Final Report.

12.0 HOST CELL PREPARATION:

Madin Darby Canis Kidney (MDCK [ATCC#CCL-34]) were maintained as monolayers in disposable cell culture labware and were used for the Virucidal Suspension Test of Influenza A H1N1 virus strain A/Swine/Iowa/15/30 (ATCC #VR-333). 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 the virus. The growth medium (GM) and maintenance medium (MM) were 1X Minimum Essential Medium (MEM) with appropriate supplements. Additional details are recorded on Tissue Culture Subculture Data Sheets (Form No. 01-L-006) in Addendum III of this Final Report.

13.0 TEST VIRUS PREPARATION:

The Influenza A H1N1 virus strain A/Swine/Iowa/15/30 (ATCC #VR-333) 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 NEUTRALIZATION TEST:

A Neutralization study of the test product was performed versus Influenza A H1N1 virus strain A/Swine/Iowa/15/30 (ATCC #VR-333), as outlined in the Study Protocol, to ensure that the neutralizing solution employed (Dey/Engley Neutralizing Broth [D/E Broth]) was effective in neutralizing the virucidal activity of the product. The neutralizing solution (D/E Broth) effectively neutralized the virucidal activity of the product and was shown to be non-toxic to the virus and cell culture. All data resulting from the Neutralization Assay are included in Addendum IV of this Final Report.

15.0 RESULTS - TABLE I:

Table I presents the Cytotoxity Control, the Neutralization Control, and the Cell Control data as well as the Virus Control infectivity ($TCID_{50}$), the post-exposure infectivity ($TCID_{50}$), and the log_{10} and percent reductions observed following exposures of Influenza A H1N1 virus strain A/Swine/Iowa/15/30 (ATCC #VR-333) to the Test Product, Ag^2 Sterling Skin Sanitizer (Lot Number 041009-IP)

TABLE I

Test Product: Ag^2 Sterling Skin Sanitizer
Virus / Strain: Swine Influenza A H1N1/A/Swine/Iowa/15/30 ATCC #VR-333
Host Cell Line: MDCK Host Cell Line ATCC #CCL-34 Volume Plated per Well: 1.0 mL
Neutralizer: D/E Neutralizing Broth

Dilution (- Log_{10})	Virus Control	Test exposure time			Cytotoxicity Control	Neutralization Control	Cell Control (negative control)
		30 seconds	1 minute	2 minutes			
							0000
-3	++++	++++	++++	000+	0000	++++	
-4	++++	++++	++++	0000	0000	++++	
-5	++++	+00+	+++0	0000	NT	++++	
-6	+++0	0000	0000	0000	NT	++++	
-7	000+	0000	0000	0000	NT	000+	
$TCID_{50}$	6.50 Log_{10}	5.00 Log_{10}	5.25 Log_{10}	2.75 Log_{10}	N/A	6.75 Log_{10}	
Log_{10} Reduction	N/A	**1.50 Log_{10}**	**1.25 Log_{10}**	**3.75 Log_{10}**	**N/A**		
Percent Reduction	N/A	**96.84%**	**94.38%**	**99.98%**			

\+ CPE (cytopathic/cytotoxic effect) present
0 CPE (cytopathic/cytotoxic effect) not detected
NT Not tested
N/A Not applicable

16.0 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 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, and 5) the test product be fully neutralized immediately after the timed exposure such that virus infectivity is not affected.

17.0 STATISTICAL ANALYSIS:

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

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
Stephanie Cebulla Laboratory Support Technician	Patricia Mays Suko Supervisor of Laboratory Support
Liv Graving Microbiologist	Stephanie Scarff Laboratory Support Technician

20.0 QUALITY ASSURANCE PERSONNEL:

Alicia Bogert Quality Assurance Associate/Product Handling	John A. Mitchell, Ph.D. Director of Quality Assurance
Scott D. Ferraro Manager of Quality Control	Janis Smoke Quality Assurance Associate
Amy L. Juhnke Manager of Quality Assurance/Document Control	

21.0 REFERENCES:

American Society of Testing and Materials (ASTM), E 1052-96 (2002), *Standard Test Method for Efficacy of Antimicrobial Agents Against Viruses in Suspension.*

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

23.0 ACCEPTANCE:

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

President And CEO: Daryl S. Paulson, Ph.D. — 07-10-09 Date

Principal Study Director: Volha Dzyakanava, Ph.D. — 07-10-09 Study Completion Date

Associate Study Director: Kelly Burningham — 07-10-09 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:

Phase	Date
Neutralization Assay	05/22/09
Product Testing	06/05/09
Data Audit	07/02/09
Final Report Review	07/10/09
Reports to Study Director and Management	05/22/09, 06/05/09, and 07/10/09

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. — 7/10/09 Date

INDEX OF ADDENDA