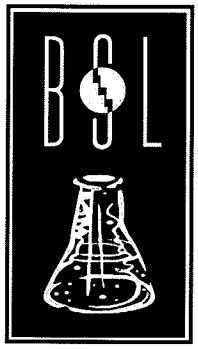

BIOSCIENCE
LABORATORIES•INC

September 30, 2009

FINAL REPORT #090818-402

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

Prepared for:

X3 LABS, INC. (SPONSOR)
35 Raglon Avenue, #106
Toronto, Ontario M6E2K7
Canada

Prepared by:

BIOSCIENCE LABORATORIES, INC. (TESTING FACILITY)
300 N. Willson Avenue
Bozeman, Montana 59715
(406) 587-5735

Mailing Address • P.O. Box 190 • Bozeman, MT 59771 - 0190
Shipping Address • 300 North Willson • Bozeman, MT 59715
Phone 406-587-5735 • FAX 406-586-7930 • Web Site: www.biosciencelabs.com • E-mail: biosci@biosciencelabs.com

TABLE OF CONTENTS

EXECUTIVE SUMMARY

This study was designed to evaluate the antiviral properties of one test product when challenged with Swine-like H1N1 Influenza A virus strain A/California/04/2009 (CDC ID #2009712047) using a Virucidal Suspension Test (In-Vitro Time-Kill method). The test product was evaluated at a 90% (v/v) concentration. 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 and 60 seconds.

The Test Product, X3: Clean Alcohol Free Hand Sanitizer (Lot Number 09368) reduced the infectivity of Swine-like H1N1 Influenza A virus strain A/California/04/2009 (CDC ID #2009712047) by 2.25 $\log_{10}$ (99.44% reduction) following a 30-second exposure and by 2.75 $\log_{10}$ (99.82% reduction) following a 60-second exposure.

September 30, 2009

FINAL REPORT #090818-402

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

2.0 SPONSOR: **X3 LABS, INC.**
35 Raglon Avenue, #106
Toronto, Ontario M6E2K7
Canada

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 Swine-like H1N1 Influenza A virus strain A/California/04/2009 (CDC ID #2009712047) using a Virucidal Suspension Test (In-Vitro Time-Kill Method). 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 Swine-like H1N1 Influenza A virus strain A/California/04/2009 (CDC ID #2009712047) using a Virucidal Suspension Test (In-Vitro Time-Kill method). The test product was evaluated at a 90% (v/v) concentration. 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 and 60 seconds. 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 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:	08/21/09
EXPERIMENTAL START DATE:	08/25/09
EXPERIMENTAL END DATE:	09/14/09
STUDY COMPLETION DATE:	09/30/09

8.0 TEST MATERIAL:

The test product evaluated was 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 product, as well as the retention of the test product, remained with the Sponsor.

Test Product:	X3: Clean Alcohol Free Hand Sanitizer
Lot Number:	09368
Expiration Date:	03/2011

9.0 CHALLENGE VIRAL STRAIN:

The challenge viral strain evaluated was:

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 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]) 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 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:

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 NEUTRALIZATION TEST:

A Neutralization Test of the Test Product was performed versus Swine-like H1N1 Influenza A virus strain A/California/04/2009 (CDC ID #2009712047), as outlined in the Study Protocol, to ensure that the neutralizing solution employed (Butterfield's Phosphate Buffer Solution with product neutralizers [BBP++]) was effective in neutralizing the virucidal activity of the product. The neutralizing solution (BBP++) effectively neutralized the virucidal activity of the test product and was shown to be non-toxic to the virus. All data resulting from the Neutralization test 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 Swine-like H1N1 Influenza A virus strain A/California/04/2009 (CDC ID #2009712047) to the Test Product, X3: Clean Alcohol Free Hand Sanitizer (Lot Number 09368).

TABLE I

Test Product: X3: Clean Alcohol Free Hand Sanitizer (Lot Number 09368)
Virus: Swine-like Influenza A H1N1/A/California/04/2009 (CDC #2009712047)
BSLI Lot 061809SinfH1N1/04/09
Host Cell Line: MDCK Host Cell Line ATCC #CCL-34 BSLI Lot #051208MDCK

Dilution (- Log_{10})	**Virus Control**	**Test exposure time**		**Cytotoxicity Control**	**Neutralization Control**	**Cell Control (negative control)**
		30 seconds	**60 seconds**			
						0000
-3	NT	++++*	++++*	++++	NT	
-4	++++	++++	++0+	0000	++++	
-5	++++	+000	0000	NT	++++	
-6	++++	0000	0000	NT	++++	
-7	++00	0000	0000	NT	0+0+	
-8	0000	NT	NT	NT	0000	
$TCID_{50}$	7.00 Log_{10}	4.75 Log_{10}	4.25 Log_{10}	N/A	7.00 Log_{10}	
Log_{10} Reduction	N/A	**2.25 Log_{10}**	**2.75 Log_{10}**	**N/A**		
Percent Reduction	N/A	**99.44%**	**99.82%**			

\+ 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. These criteria were met.

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
Shelley Brown Laboratory Support Technician	Stephanie Scarff Laboratory Support Technician
Patricia Mays Suko Supervisor of Laboratory Support	

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 Quality Assurance Associate/Product Handling
John A. Mitchell, Ph.D. Director of Quality Assurance	

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 — Daryl S. Paulson, Ph.D. — 09-30-09 — Date

Principal Study Director: Volha Dzyakanava, Ph.D. — 09-30-09 — Study Completion Date

Associate Study Director: Kelly Burningham — Kelly Burningham — 09-30-09 — 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	08/25/09
Product Testing	09/04/09
Data Audit	09/29/09
Final Report Review	09/29/09
Reports to Study Director and Management	08/26/09, 09/08/09, and 09/30/09

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 — John A. Mitchell, Ph.D. — 9/30/09 — Date

INDEX OF ADDENDA

I Protocol #090818-402

II Product Information
- Product Receipt Log (Form No. 92-L-023)
- Product-Tracking Forms (Form No. 93-L-029)

III Tissue Culture Subculture Data Sheets (Form No. 01-L-006)

IV Neutralization Evaluation
- General Data Gathering Form (Form No. 91-L-002) for Neutralization Test
- Virology Neutralization Evaluation Form (Form No. 07-L-005)
- Virucidal Test Tracking Form (Form No. 07-L-002)

V Virucidal Test Evaluation
- General Data Gathering Form (Form No. 91-L-002) for Virucidal Test Evaluation
- Virucidal Test Evaluation Form (Form No. 03-L-017)
- Virucidal Test Tracking Forms (Form No. 07-L-002)

VI Equipment Logs
- Virology Equipment and Supplies Tracking Forms (Form No. 07-L-011)
- CO_2 Incubator Log Form (Form No. 01-L-004)