April 13, 2020

FINAL REPORT #2003147-402

EVALUATION OF ONE TEST PRODUCT FOR ITS VIRUCIDAL PROPERTIES

Prepared for:

SARO SCIENCE (SPONSOR)
300 Highpoint Avenue
Portsmouth, Rhode Island 02871

Prepared by:

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TABLE OF CONTENTS

EXECUTIVE SUMMARY

STUDY NUMBER: **2003147-402**

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

SPONSOR: **SARO SCIENCE**
300 Highpoint Avenue
Portsmouth, Rhode Island 02871

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

STUDY INITIATION DATE: 03/20/2020

STUDY COMPLETION DATE: 04/13/2020

This study evaluated the virucidal properties of one test product when challenged with Human Coronavirus strain OC43 (ZeptoMetrix Corporation #0810024CF). 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. 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).

This study was designed to evaluate the virucidal properties of one test product versus Human Coronavirus strain OC43 (ZeptoMetrix Corporation #0810024CF) using a Virucidal Suspension test (In-Vitro Time-Kill method). The percent and $\log_{10}$ reduction from the initial population of the viral strain was determined following exposure to the test product for 5 minutes and 10 minutes. Plating was performed in four replicates.

Under the conditions of this evaluation Test Product #1, Hand Sanitizer (Lot Number: SA101) reduced the infectivity of Human Coronavirus strain OC43 by 2.75 $\log_{10}$ (99.82%) following a 5-minute exposure and by $\geq$ 4.00 $\log_{10}$ ($\geq$ 99.99%) following a 10-minute exposure.

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

SPONSOR: **SARO SCIENCE**
300 Highpoint Avenue
Portsmouth, Rhode Island 02871

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

3.0 STUDY DIRECTOR: Kelly Burningham

4.0 PURPOSE:

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. 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).

5.0 SCOPE:

This study was designed to evaluate the virucidal properties of one test product versus Human Coronavirus strain OC43 (ZeptoMetrix Corporation #0810024CF) using a Virucidal Suspension test (In-Vitro Time-Kill method). The percent and $\log_{10}$ reduction from the initial population of the viral strain was determined following exposure to the test product for 5 minutes and 10 minutes. Plating was performed in four replicates.

The Study Protocol, included as Addendum 1 of this Final Report, presents the study methodology, in detail. No deviations from the Study Protocol or from applicable Standard Operating Procedures occurred during the course of this evaluation.

6.0 STUDY DATES:

STUDY INITIATION DATE: 03/20/2020

EXPERIMENTAL START DATE: 03/27/2020

EXPERIMENTAL END DATE: 04/09/2020

STUDY COMPLETION DATE: 04/13/2020

7.0 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:	Hand Sanitizer
Lot Number:	SA101
Manufacture Date:	March 2020
Expiration Date:	March 2021

8.0 CHALLENGE VIRAL STRAIN:

Human Coronavirus (Betacoronavirus), strain OC43 (ZeptoMetrix Corp. #0810024CF)

9.0 HOST CELLS:

HCT-8 (ATCC #CCL-244; human colon adenocarcinoma, epithelial)

10.0 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.

11.0 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.

12.0 HOST CELL PREPARATION:

HCT-8 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.

13.0 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.

14.0 TEST PRODUCT PREPARATION:

The test product was used as received; tested at 90% (v/v) concentration.

15.0 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 + Test Product → Exposure → Neutralization → Dilution → Plating	4 per group
Virus Control	Virus + Diluent → Exposure → 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
Neutralizer Toxicity Control	Virus + Diluent → Neutralizer → Dilution → Plating	4 per group
Cell Culture Control	Maintenance medium	4 per group

16.0 RESULTS – TABLE 2:

16.1 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 5-minute and 10-minute exposure of Human Coronavirus strain OC43 (ZeptoMetrix Corp. #0810024CF) to Test Product #1, Hand Sanitizer; (Lot #SA101).

TABLE 2

Test Product #1: Hand Sanitizer (Lot #SA101)
Virus: Coronavirus strain OC43 (ZeptoMetrix #0810024CF)
Host Cell Line: HCT-8 (ATCC #CCL-244)
Volume Plated per Well: 1.0 mL

Dilution (- Log_{10})	Virus Control	Test		NTC	NC	CTC	CC
		5 minutes	10 minutes				
							0000
-2	NT	++++	0000	NT	NT	0000	N/A
-3	++++	000+	0000	++++	++++	0000	
-4	++++	0000	0000	++++	++++	0000	
-5	+0+0	0000	0000	0+++	0+++	NT	
-6	++00	0000	0000	++0+	0000	NT	
-7	0000	0000	0000	0000	0000	NT	
$TCID_{50}$ (log_{10})	5.50	2.75	≤1.50	6.00	5.25	≤1.50	
Log_{10} Reduction	N/A	**2.75**	**≥4.00**	N/A			
Percent Reduction		**99.82**	**≥99.99**				

\+ 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

17.0 STUDY CONCLUSIONS:

Under the conditions of this evaluation Test Product #1, Hand Sanitizer (Lot Number: SA101) reduced the infectivity of Human Coronavirus strain OC43 by 2.75 log_{10} (99.82%) following a 5-minute exposure and by ≥ 4.00 log_{10} (≥ 99.99%) following a 10-minute exposure.

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

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:

Kelly Burningham
Virologist

Rachel Byrd, M.S.
Microbiologist

Lisa Lehman
Senior Scientist

Aubrie Cornell
Laboratory Technician

Jared Montana, M.S.
Laboratory Technician

Mauri Erickson
Laboratory Technician

Terah Rash
Laboratory Technician

Kameron Kohn
Laboratory Technician

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

21.0 QUALITY ASSURANCE AND QUALITY CONTROL PERSONNEL:

Jeremy Duley
Systems Administrator/QC Specialist

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

Danielle Goveia
Quality Assurance Specialist

Renee LaFond, M.S.
Quality Assurance Specialist

Carl Schmidt
ISO Technical Manager (QC, 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: Kelly Burningham — Kelly Burningham

04-13-2020 — 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	03/27/2020	03/27/2020	03/31/2020
Data Audit	04/10/2020	04/13/2020	04/13/2020
Final Report Review	04/10/2020	04/13/2020	04/13/2020

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

Quality Assurance Specialist: Renee LaFond, M.S.

04/13/2020 — Date

ADDENDA

Protocol #2003147-402