SUMMARY OF RESULTS

The purpose of the study was to confirm the virucidal efficacy of BioProtect Plus (Lot No. 0011142012) against feline calicivirus (Strain F-9), ATCC VR-782, amended with a 5% soil load at a 5-minute contact time under room temperature conditions. The study results are detailed in Tables 1 to 6. The dried virus titer obtained for feline calicivirus as evident by observed viral cytopathic effects (CPE) was 5.75 $\log_{10}$ $TCID_{50}$ per 0.1 ml. Feline calicivirus dried film titers on duplicate test replicates were reduced to levels below assay detection limits ($\leq$1.50 $\log_{10}$ $TCLD_{50}$ per 0.1 ml) following exposure to the test substance (BioProtect Plus Lot No. 0011142012). Therefore, the average reduction in titer of feline calicivirus (amended with a 5% soil load) following the 10-minute exposure to one lot of BioProtect Plus (Lot No. 0011142012) was $\geq$ 4.25 $\log_{10}$. Cytotoxic effects were observed on CRFK host cells in the 10^{-1} dilution wells of the cytotoxicity and neutralization effectiveness controls, with none evident in the remaining dilutions (10^{-2} to 10^{-8}). Neutralization effectiveness control wells demonstrated viral CPE from dilutions 10^{-2} to 10^{-8}. No contamination was observed in any test or control wells.

RESULTS

Key: + = Virus recovered; 0 = Virus not recovered and/or no cytotoxicity observed; T = Toxicity observed

Table 1. Confirmatory Virucidal Effectiveness Test, Virus Stock Titer and Plate Recovery Control Data: Feline Calicivirus on CRFK Host Cell Monolayers

Dilution	Virus Stock Titer Control				Plate Recovery Control			
10^{-1}					+	+	+	+
10^{-2}					+	+	+	+
10^{-3}					+	+	+	+
10^{-4}					+	+	+	+
10^{-5}					+	+	+	+
10^{-6}	+	+	+	+	0	+	0	0
10^{-7}	+	+	+	+	0	0	0	0
10^{-8}	+	+	+	+	0	0	0	0
10^{-9}	+	+	+	+				
10^{-10}	0	0	0	0				
10^{-11}	0	0	0	0				
$TCID_{50}$ / 0.1 ml	9.50 $\log_{10}$				5.75 $\log_{10}$			

RESULTS (CONTINUED)

Key: + = Virus recovered; 0 = Virus not recovered and/or no cytotoxicity observed; T = Toxicity observed

Table 3. Virus-Test Data: Exposure of Feline Calicivirus (Amended With 5% Organic Soil) to BioProtect Plus (Lot No. 0011142012) Via Spray Device for a 10-Minute Contact Time

Dilution	Virus Test (Replicate No. 1)				Virus Test (Replicate No. 2)			
10^{-1}	T	T	T	T	T	T	T	T
10^{-2}	0	0	0	0	0	0	0	0
10^{-3}	0	0	0	0	0	0	0	0
10^{-4}	0	0	0	0	0	0	0	0
10^{-5}	0	0	0	0	0	0	0	0
10^{-6}	0	0	0	0	0	0	0	0
10^{-7}	0	0	0	0	0	0	0	0
10^{-8}	0	0	0	0	0	0	0	0
$TCLD_{50}$ / 0.1 ml	$\leq 1.50 \log_{10}$				$\leq 1.50 \log_{10}$			

RESULTS (CONTINUED)

Table 2. Plate Recovery Control: Calculation of the Tissue Culture Infectivity Dose at the 50% Endpoint Dilution ($TCID_{50}$)

Values				Accumulated Values			
Virus Dilution Inoculated	No. Infected / No. Inoculated	No. Infected	No. Not Infected	No. Infected	No. Not Infected	No. Infected / No. Inoculated	% Infected
10^{-1}	4/4	4	0	21	0	21/21	100
10^{-2}	4/4	4	0	17	0	17/17	100
10^{-3}	4/4	4	0	13	0	13/13	100
10^{-4}	4/4	4	0	9	0	9/9	100
10^{-5}	4/4	4	0	5	0	5/5	100
10^{-6}	1/4	1	3	1	3	1/4	25
10^{-7}	0/4	0	4	0	7	0/7	0
10^{-8}	0/4	0	4	0	11	0/11	0

The calculated $TCID_{50}$ of the Plate Recovery Control = 5.75 log_{10}.

RESULTS (CONTINUED)

Table 4. Feline Calicivirus-Test Data (Two Replicates): Calculation of the Tissue Culture Lethal Dose at the 50% Endpoint Dilution ($TCLD_{50}$)[a]

Values				Accumulated Values			
Virus Dilution Inoculated	No. I-T / No. Inoculated	No. I-T	No. Not I-T	No. I-T	No. Not I-T	No. I-T / No. Inoculated	% I-T
10^{-1}	8/8	8	0	8	0	8/8	100
10^{-2}	0/8	0	8	0	8	0/8	0
10^{-3}	0/8	0	8	0	16	0/16	0
10^{-4}	0/8	0	8	0	24	0/24	0
10^{-5}	0/8	0	8	0	32	0/32	0
10^{-6}	0/8	0	8	0	40	0/40	0
10^{-7}	0/8	0	8	0	48	0/48	0
10^{-8}	0/8	0	8	0	56	0/56	0

[a] "I-T": Wells identified as either infected (virus present) or cytotoxic.

The calculated average $TCLD_{50}$ of the two feline calicivirus test replicates:
$[(\leq 1.50 \log_{10} + \leq 1.50 \log_{10}) / 2] = \leq 1.50 \log_{10}$.

Therefore, Virus Inactivation = $TCID_{50} - TCLD_{50}$
$= 5.75 \log_{10} - \leq 1.50 \log_{10} = \geq 4.25 \log_{10}$

RESULTS (CONTINUED)

Key: + = Virus recovered; 0 = Virus not recovered and/or no cytotoxicity observed; T = Toxicity observed

Table 5. Cytotoxicity and Neutralization Effectiveness (Low Titer Feline Calicivirus) Control Data: BioProtect Plus (Lot No. 0011142012) Delivered via Spray Device

Dilution	Cytotoxicity Control				Neutralization Effectiveness			
10^{-1}	T	T	T	T	T	T	T	T
10^{-2}	0	0	0	0	+	+	+	+
10^{-3}	0	0	0	0	+	+	+	+
10^{-4}	0	0	0	0	+	+	+	+
10^{-5}	0	0	0	0	+	+	+	+
10^{-6}	0	0	0	0	+	+	+	+
10^{-7}	0	0	0	0	+	+	+	+
10^{-8}	0	0	0	0	+	+	+	+
$TCCD_{50}$ / 0.1 ml	1.50 $\log_{10}$							

Table 6. Cell Viability Control Data

Set	Results			
1	0	0	0	0
2	0	0	0	0

STUDY CONCLUSION

Two dried feline calicivirus films (Strain F-9), ATCC No. VR-782, amended with 5% soil were exposed via spray device to BioProtect Plus (Lot No. 0011142012) for a contact time of 10 minutes at room temperature. The evaluated test substance lot achieved complete inactivation of feline calicivirus in compliance with US EPA Product Performance Test Guidelines and virucidal efficacy label claims.

This study was carried out in compliance with the approved Protocol Number P1157. All experimental controls met the established acceptance criteria. Upon complete review of all study parameters and documentation by the Study Director, no adverse conditions were found to have affected the quality or integrity of the resulting data.

REFERENCES

1. Official Methods of Analysis of the AOAC International, Chapter 6, Disinfectants, Official Method 961.02 Germicidal Spray Products as Disinfectants, Current Edition. AOAC International, Suite 500, 481 North Frederick Avenue, Gaithersburg, MD 20877-2417.

2. U.S. Environmental Protection Agency. Antimicrobials Division, Office of Pesticide Programs. Confirmatory Virucidal Effectiveness Test Using Feline Calicivirus as Surrogate for Norovirus.

3. U.S. Environmental Protection Agency. Office of Chemical Safety and Pollution Prevention. Product Performance Test Guidelines. OCSPP 810.2200: Disinfectants for Use on Hard Surfaces – Efficacy Data Recommendations. September 4, 2012.

PROTOCOL

ANTIMICROBIAL TEST LABORATORIES

Confirmatory Virucidal Effectiveness Test Using Feline Calicivirus as Surrogate for Norovirus
Protocol Number: P1157
Page 1 of 7

Summary of parameters requested by the Study Sponsor, and incorporated into this Protocol by reference:

Test Substance

Date Received — 13 DEC 2012
Official Name — BioProtect Plus
Lot Number(s) — 0011142012 (Expires 14 NOV 2013)
Active Ingredient (1) — n-Alkyl (60% C_{14}, 30% C_{16}, 5% C_{12}, 5% C_{18}) dimethyl benzyl ammonium chloride (0.11%)
Active Ingredient (2) — n-Alkyl (68% C_{12}, 32% C_{14}) dimethyl ethyl benzyl ammonium chloride (0.11%)
Active Ingredient (3) — Octadecylaminodimethyltrihydroxysilyl propyl ammonium chloride (0.11%)
Form — Ready-to-Use

Test Parameters:

Test System (Virus) — Feline calicivirus (Strain F-9), ATCC No. VR-782
Number of Tests Comprising the Study — 2 (Two Carriers per One Lot of Test Substance)
Requested Test Substance Dilution — n/a
Diluent — n/a
Organic Soil Load — 5 ± 0.1%
Organic Soil Type — Fetal Bovine Serum (Heat-Inactivated)
Contact Time — 10 Minutes ± 10 Seconds
Test Temperature — Room Temperature
Test Subculture Medium — 2% FBS EMEM Containing Antibiotics
Neutralizer — Sephacryl (S-1000 SF) Gel Filtration Columns

Proposed Initiation Date — 05/FEB/2013
Proposed Completion Date — 19/FEB/2013

"I, the Study Sponsor, have read and understand the following protocol. By signing this protocol I am certifying that the information and parameters accurately describe the test(s) to be completed in accordance with US EPA Product Performance Test Guidelines OCSPP 810.2200, and Good Laboratory Practice Standards (GLP) defined by: 40 CFR Part 160. I have also read, understand and agree to the terms and conditions listed in the protocol."

RC Wall
Role: Study Sponsor
Name: Randy Wall
Company: PureShield, Inc.
Address: 1445 Jupiter Park Drive #11, Jupiter, FL 33458

30/1/13
Date (dd/mmm/yyyy)

Luisa Ikner
Luisa Ikner, Ph.D., Study Director, Antimicrobial Test Laboratories

05 FEB 2013
Study Initiation Date (dd/mmm/yyyy)

Antimicrobial Test Laboratories • 1304 W. Industrial Blvd • Round Rock, Texas 78681 • (512) 310-8378

I. Introduction

This document details the materials and procedure for evaluating the efficacy of a virucidal test substance delivered via spray device in accordance with US EPA Product Performance Test Guidelines OCSPP 810.2200: Disinfectants for Use on Hard Surfaces – Efficacy Data Recommendations, and Good Laboratory Practice Standards (GLP) as defined by 40 CFR Part 160. The methodology detailed herein is based on the Association of Official Analytical Chemicals (AOAC) International Germicidal Spray Products as Disinfectants Test (Official Method 961.02), with modifications for virucidal testing as appropriate, and the Confirmatory Virucidal Effectiveness Test Using Feline Calicivirus as Surrogate for Norovirus Protocol (US EPA Antimicrobials Division). This document also explains the terms and conditions of testing.

II. Purpose

The purpose of this study is to characterize and document the virucidal efficacy of a liquid test substance, BioProtect Plus (delivered via spray device), against feline calicivirus (a human norovirus surrogate).

III. Terms and Conditions

Prior to study initiation, Antimicrobial Test Laboratories must receive the approved and signed protocol, test substance and payment for the study. Studies are scheduled at Antimicrobial Test Laboratories' discretion. Changes to the signed, approved protocol will require amendment and may incur additional fees. Cancellation of the study any time after the protocol has been signed will result in a cancellation fee of at least 50% of the total study cost.

Antimicrobial Test Laboratories will repeat studies, free of charge, in the event of unintended protocol non-conformance that could be reasonably expected to affect the study outcome. If the neutralization system specified for a study is not adequate, the study will be deemed "inconclusive" and the Study Sponsor will be responsible for the cost of the study. In addition, the Study Sponsor is responsible for the cost of all studies performed to confirm the outcome of a previous study and for ensuring that the study will meet their regulatory objectives.

The Study Sponsor must obtain written consent from Antimicrobial Test Laboratories to publish its protocols, study reports, logo or employee names to the Internet, including to Sponsor's Company Webpage. Normal, non-Internet publication, use and display of these materials in business-to-business or business-to-customer discussions and transactions is generally acceptable.

IV. Test Substance Handling

Test substances are handled as follows:

- The test substance is stored at ambient (room) temperature and humidity under fluorescent lighting until used in the study.
- The test substance is shaken or otherwise mixed well immediately prior to use (if applicable).
- The test substance is handled safely in accordance with the chemical risks it may pose, stated on the MSDS or by the Study Sponsor during the course of pre-study communication.

Note: Test substance chemical characterization is to be the responsibility of the Study Sponsor, and the GLP study report will reflect such.

V. **Justification for the Selection of Test System (Microorganisms)**

The United States Environmental Protection Agency (US EPA) requires that specific antimicrobial claims made for antimicrobial pesticides sold in the United States be supported by relevant test systems (microorganisms) and validated (or Agency-evaluated) test methods.

VI. **Materials**

- Feline calicivirus (Strain F-9), ATCC No. VR-782, a non-enveloped virus.
- Crandell-Rees Feline Kidney (CRFK) Cells, ATCC No. CCL-94.
- Test/Cell Culture Medium: Eagle's Minimum Essential Medium (EMEM) supplemented with fetal bovine serum at a concentration of 2% (v/v). Antibiotic supplementation includes additions of the following to achieve the specified concentrations: 100 µg/ml Kanamycin Sulfate solution and Antibiotic-Antimycotic solution (100 units/ml Penicillin G, 100 µg/ml Streptomycin, and 0.25 µg/ml Amphotericin B).
- Sufficient quantity of sterile glass Petri dish carriers (100 x 15mm).
- Sufficient quantity of pre-equilibrated Sephacryl (S-1000 SF) columns for test substance neutralization.
- 0% FBS EMEM for dilution of virus stock and dilution tubes of test materials prior to assay.
- Sufficient quantity of serological pipets of the appropriate size and volume.
- PipetAid, or equivalent.
- Micropipette(s) and sterile micropipette tips containing aerosol barriers of suitable volumetric capacities.
- Sufficient quantity of sterile disposable cell scrapers.
- Appropriate number of multi-well cell culture trays containing permissive host cell monolayers prepared to suitable confluency.

VIII. **Procedure**

Preparation of Stock Virus

The feline calicivirus strain (F-9) to be used in this study is obtained from the American Type Culture Collection (ATCC) located in Manassas, Virginia. Viral stocks are readied by combining the supernatants from multiple cell culture flasks displaying cytopathic effect on ≥ 90% of the host cell monolayers. After subjection to several freeze-thaw cycles, the supernatants are centrifuged in order to remove cell debris. The supernatant is removed and the viruses pelleted using a PEG (polyethylene glycol) extraction. Further concentration and removal of lipids from the viral stocks is performed using Vertrel XF solution, and the stock is titered on the appropriate host cell line (CRFK). One milliliter aliquots are stored at approximately -70°C until the day of use, during which the appropriate number of stock aliquots are removed, thawed, and used promptly in the assay. Requested organic soil loads (heat-inactivated fetal bovine serum) are added directly to the stock virus to the percentage requested by the Study Sponsor.

Preparation of Virus Films

The bottom, inside surface of sterile, glass Petri dishes (100 x 15mm) are inoculated with 0.20 ml of virus stock (supplemented with the organic soil load as requested by the Study Sponsor) and spread over the entire area. The

virus films are exposed to ambient air for a minimum of 20 minutes until the surface appears to be visibly dry. The temperature, humidity, and drying time period are recorded.

Dried virus films are prepared and labeled according to the following designations:

- One Plate Recovery Control Carrier to determine the dried virus titer per exposure time requested.
- Two Virus Test Carriers per lot of test substance to determine the levels of infectious virus following exposure to the test substance at the contact time requested by the Study Sponsor.

Preparation of Sephacryl (S-1000 SF) Gel Filtration Columns

Sephacryl (S-1000 SF) columns are constructed and equilibrated using three separate volumes of phosphate-buffered saline (PBS) supplemented with 0.5 ± 0.1% (v/v) heat-inactivated fetal bovine serum. Centrifugation of the columns for approximately three minutes (1000 x *g*) is performed to clear any residual liquid from the column prior to use.

Exposure of Virus Films to the Test Substance, and Processing of Treated Virus Films

For each lot of test substance, two dried virus test films are treated via spray device by application of 3 to 5 sprays (distance of 6 to 8 inches) or until thoroughly wetted. The treated carriers are held for the contact time requested by the Study Sponsor (10 minutes ± 10 seconds). Sterile cell scrapers are used to mechanically detach the virus films from the glass Petri dish carriers, and the suspensions are pipetted into pre-equilibrated Sephacryl (S-1000 SF) columns upon closure of the study contact time for test substance neutralization. Syringe plungers are used to release the initial volumes of filtrate, followed by centrifugation (~3 minutes, 1000 x *g*) to retrieve any residual liquid. The filtrates (10^{-1}) are serially diluted (up to 10^{-8}) and applied in quadruplicate per dilution to host cell culture monolayers prepared to suitable confluency in multi-well trays.

Processing of the Plate Recovery Control Film

A Plate Recovery Control film is processed per exposure time requested by the Study Sponsor. A volume of cell culture maintenance medium (2% FBS EMEM with antibiotics) is applied to the control film equal to the volume of test substance delivered to the virus test film carriers. The control carrier is then held for the designated study contact time (10 minutes ± 10 seconds). All other test conditions and parameters (e.g. exposure temperature) are the same as for the test virus films. Upon termination of the exposure time, the virus control surface is abraded by a sterile cell scraper, and the virus suspension is pipetted into a Sephacryl (S-1000 SF) column. A syringe plunger is used to filter the majority of the virus suspension, followed by centrifugation (~3 minutes, 1000 x *g*) to retrieve any residual liquid. The filtrate (10^{-1}) is serially diluted (up to 10^{-8}) and applied in quadruplicate to host cell culture monolayers prepared to suitable confluency in multi-well trays. The Plate Recovery Control filtrate is assayed concurrently with Virus Test, Cytotoxicity Control, and Neutralization Effectiveness Control filtrates, in addition to the Virus Stock Titer Control.

Cytotoxicity Control

A glass Petri dish carrier (containing no virus film) is treated in the same manner with the test substance [3 to 5 sprays (distance of 6 to 8 inches at a 45° angle) or until thoroughly wetted], and held for the designated study contact time (10 minutes ± 10 seconds). The test substance is filtered through a Sephacryl (S-1000 SF) column.

The resulting filtrate (10^{-1}) is serially diluted (up to 10^{-8}) and inoculated onto test culture monolayers (quadruplicate per dilution) for assay in parallel with additional control and test filtrates from the same test substance lot.

Neutralization Effectiveness Control

A separate set of serial dilutions (1:10) is made from the Cytotoxicity Control filtrate generated from the submitted test substance lot to determine the neutralization effectiveness of the Sephacryl gel column system. Virus stock is diluted in order to add a low titer viral inoculum into each cytotoxicity filtrate dilution, followed by assay in quadruplicate per dilution with the aforementioned control and test filtrates.

Virus Stock Titer Control

The stock vial of virus is titered at the time of the cell culture infectivity assay in order to demonstrate the permissiveness of the host cell line (CRFK) to the test virus system (feline calicivirus). The virus stock is diluted ten-fold in 0% FBS EMEM. Selected dilutions are plated in quadruplicate onto CRFK host cell culture monolayers in multi-well trays, and assayed concurrently with Plate Recovery Control, Virus Test, Cytotoxicity Control, and Neutralization Effectiveness Control filtrates.

Cell Culture Infectivity Assay

Crandell-Rees Feline Kidney (CRFK) cells are the permissive host cell line for the feline calicivirus stock used during the study assay period. For both the test and control groups previously described, sample aliquots (0.1 ml) of each dilution are inoculated in replicates of four onto healthy monolayers prepared to suitable confluency in cell culture treated multi-well plates. Several cell viability control sets (also performed in quadruplicate) are dispersed throughout the assay trays, and receive an inoculum of test/cell culture medium only. The trays are incubated at 37 ± 2 °C (5 ± 1% CO_2) for a minimum of 30 minutes to facilitate virus-host cell adsorption. The trays may also be placed upon an orbital rotator during this incubation period, if feasible. Following incubation, each well receives 1.0 ± 0.2 ml of test/cell culture medium (2% FBS EMEM plus antibiotics). The cell culture assay trays are incubated at 37 ± 2 °C for five to seven days in a humidified CO_2 incubator. They are examined regularly, with changes to healthy monolayers including viral cytopathic effects (CPE), cytotoxicity, and contamination clearly documented as such changes are observed.

IX. Determination of Viral Titers

The Spearman-Karber Method is used to calculate the Plate Recovery Control titer ($TCID_{50}$), the viral titer following test substance exposure ($TCLD_{50}$), and the titer of host cell cultures exhibiting cytotoxicity following test substance exposure ($TCCD_{50}$). The $TCID_{50}$ (Tissue Culture Infectivity Dose) represents the endpoint dilution where 50% of the cell cultures exhibit cytopathic effects due to infection by the test virus. The dose required to kill 50% of the test viruses after the given exposure time is referred to as the Tissue Culture Lethal Dose ($TCLD_{50}$), and the endpoint dilution at which 50% of the host cell monolayers exhibit cytotoxicity is termed the Tissue Culture Cytotoxic Dose ($TCCD_{50}$). The $TCID_{50}$, $TCLD_{50}$, and $TCCD_{50}$ are determined according to the method of Spearman-Karber as follows:

-Log of 1st dilution inoculated – [(Sum of % mortality at each dilution / 100) – 0.5 x (logarithm of dilution)]

Calculation of Virus Inactivation Due to Test Substance Exposure

Plate Recovery Control Log_{10} $TCID_{50}$ – Average Virus-Test Substance Film Log_{10} $TCLD_{50}$ = Log_{10} Reduction of Virus Due to Inactivation by Test Substance

X. Reporting

1) Viral titers are reported as the $TCID_{50}$/$TCLD_{50}$ per unit volume of neutralized filtrate (e.g. $TCID_{50}$/0.1 ml). When no viral CPE is observed, viral titers will be expressed according to the appropriate limit of detection.
2) Cytotoxicity will be reported as the $TCCD_{50}$ per unit volume of neutralized filtrate (e.g. $TCCD_{50}$/0.1 ml). When toxic effects are not observed, cytotoxicity will be expressed according to the appropriate limit of detection.
3) The reduction in microorganisms on the test surfaces relative to the control surfaces will be calculated, and expressed as a log_{10} reduction.
4) The final report will contain various parameters related to the study, and include information concerning the type of test substance and date received, descriptions of the test system and host cell line employed, detailed descriptions of the methodology, calculated titers for all controls and experimental assay groups, results presented in tabular form, and an overall study conclusion.
5) Results are reported accurately and fully, in accordance with US EPA Product Performance Test Guidelines OCSPP 810.2200. A draft report will be provided for review by the Study Sponsor, if requested.

XI. Performance Criteria

The US EPA requires that the following measures are met to ensure the acceptability of virucidal efficacy data:

- A minimum of 4.00 log_{10} infectious viruses ($TCID_{50}$) is recovered from the plate recovery control film.
- Quantification of the plate recovery control titer, the virus titer following test substance exposure, cytotoxicity levels, and neutralization effectiveness controls is conducted at a minimum of four determinations per dilution for each assay system.
- The use of special methods used to increase the viral titer and further neutralize the test substance is disclosed.
- Viral cytopathic effects (CPE) are to be distinguishable from cytotoxic effects related caused by test substance exposure. If cytotoxicity is observed, a ≥3.00-log_{10} reduction in viral titer is confirmed past the level of cytotoxicity.
- In the absence of cytotoxicity, the product demonstrates complete inactivation of virus at all dilutions.
- The $TCLD_{50}$ values are calculated and provided for each test assay.
- The test results are reported as the reduction of the virus titer due to the activity of the test substance [$TCID_{50}$ of the plate recovery control less the $TCLD_{50}$ of the virus test carrier(s)] expressed as the logarithm to the base of 10 (log_{10}) and calculated by a statistical method (e.g. Spearman-Karber).
- Assay wells designated as "negative" controls be absent of infectivity, contamination, and cytotoxicity.

XI. Data and Sample Retention

- The study report and corresponding data sheets are held in the archives of Antimicrobial Test Laboratories for at least 2 years after the date of the final report and then may be destroyed. If the study is used by the Study Sponsor in support of a label claim, documentation may be returned to the Study Sponsor for archiving at Study Sponsor's expense.

- The test substance may be returned to the Study Sponsor at Study Sponsor's request and expense within 30 days of study completion. If the Study Sponsor does not request return of the sample, it will be destroyed >30 days after study completion.

XII. Quality Control

The study is conducted in accordance with Antimicrobial Test Laboratories' Quality Management System and will undergo a full quality assurance review. All protocol amendments are fully recorded and reported, as well as any deviations from the protocol.

XIII. References

1. Official Methods of Analysis of the AOAC International, Chapter 6, Disinfectants, Official Method 961.02 Germicidal Spray Products as Disinfectants, Current Edition. AOAC International, Suite 500, 481 North Frederick Avenue, Gaithersburg, MD 20877-2417.

2. U.S. Environmental Protection Agency. Antimicrobials Division, Office of Pesticide Programs. Confirmatory Virucidal Effectiveness Test Using Feline Calicivirus as Surrogate for Norovirus.

3. U.S. Environmental Protection Agency. Office of Chemical Safety and Pollution Prevention. Product Performance Test Guidelines. OCSPP 810.2200: Disinfectants for Use on Hard Surfaces – Efficacy Data Recommendations. September 4, 2012.