ACCURATUS
—LAB SERVICES—
THE ANTIMICROBIAL AUTHORITY

# FINAL STUDY REPORT

STUDY TITLE

Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

**Virus: Porcine Epidemic Diarrhea Virus**

PRODUCT IDENTITY

Atmosphere
Lot TC0501182 and Lot TC0501183

TEST GUIDELINE

OCSPP 810.2200

PROTOCOL NUMBER

ATM002032218.PEDV

AUTHOR

Matt Cantin, B.S.
Study Director

STUDY COMPLETION DATE

June 29, 2018

PERFORMING LABORATORY

Accuratus Lab Services
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

SPONSOR

Atmosphere Global LLC
55 West Goethe Unit 1241
Chicago, IL 60610

PROJECT NUMBER

A25624

## STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality, on any basis whatsoever, is made for any information contained in this document. I acknowledge that information not designated as within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C) and which pertains to a registered or previously registered pesticide is not entitled to confidential treatment and may be released to the public, subject to the provisions regarding disclosure to multinational entities under FIFRA 10(g).

Company: Atmosphere Global LLC

Company Agent: Mel Jones

Manager of Domestic and International Operations
Title

Signature Date: July 30, 2018

## GOOD LABORATORY PRACTICE STATEMENT

The study referenced in this report was conducted in compliance with U.S. Environmental Protection Agency Good Laboratory Practice (GLP) regulations set forth in 40 CFR Part 160.

Submitter: _____ Date: July 30, 2018
Mel Jones

Sponsor: _____ Date: July 30, 2018
Mel Jones

Study Director: _____ Date: 6-29-18
Matt Cantin, B.S.

## QUALITY ASSURANCE UNIT SUMMARY

Study: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

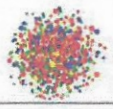
The objective of the Quality Assurance Unit is to monitor the conduct and reporting of non-clinical laboratory studies. This study has been performed in accordance to standard operating procedures and the study protocol. In accordance with Good Laboratory Practice regulation 40 CFR Part 160, the Quality Assurance Unit maintains a copy of the study protocol and standard operating procedures and has inspected this study on the date(s) listed below. Studies are inspected at time intervals to assure the integrity of the study. The findings of these inspections have been reported to Management and the Study Director.

| Phase Inspected | Date of Phase Inspection | Date Reported to Study Director | Date Reported to Management |
|---|---|---|---|
| Critical Phase Audit: Preparation of Test Substance | June 19, 2018 | June 19, 2018 | June 22, 2018 |
| Final Report | June 28, 2018 | June 28, 2018 | June 29, 2018 |

Quality Assurance Specialist: Cody Dam Date: 6/29/18



## TABLE OF CONTENTS



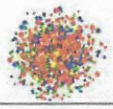


## STUDY PERSONNEL

STUDY DIRECTOR: Matt Cantin, B.S.

Professional Personnel Involved:

| | |
|---|---|
| Shanen Conway, B.S. | - Manager, Study Director Operations |
| Erica Flinn, B.A. | - Manager, Virology Laboratory Operations |
| Katherine A. Paulson, M.L.T. | - Lead Virologist |
| Miranda Peskar, B.S. | - Associate Virologist |





## STUDY REPORT

### GENERAL STUDY INFORMATION

**Study Title:** Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

**Project Number:** A25624

**Protocol Number:** ATM002032218.PEDV

**Sponsor:** Atmosphere Global LLC
55 West Goethe Unit 1241
Chicago, IL 60610

**Testing Facility:** Accuratus Lab Services
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

### TEST SUBSTANCE IDENTITY

**Test Substance Name:** Atmosphere

**Lot/Batch(s):** Lot TC0501182 and Lot TC0501183

**Test Substance Characterization**
Test substance characterization as to identity, strength, purity, stability and uniformity, as applicable, according to 40 CFR, Part 160, Subpart F [160.105], was documented prior to its use in the study. The Test Substance Certificate of Analysis Reports may be found in Attachments I-II.

### STUDY DATES

**Date Sample Received:** May 3, 2018
**Study Initiation Date:** June 5, 2018
**Experimental Start Date:** June 19, 2018 (Start time: 10:20 a.m.)
**Experimental End Date:** June 26, 2018 (End time: 10:05 a.m.)
**Study Completion Date:** June 29, 2018

### OBJECTIVE

The objective of this study was to evaluate the virucidal efficacy of a test substance for registration of a product as a virucide. The test procedure was to simulate the way in which the product is intended to be used. This method is in compliance with the requirements of and may be submitted to the U.S. Environmental Protection Agency (EPA), Health Canada and Australian Therapeutic Goods Administration (TGA).

## SUMMARY OF RESULTS

| | |
|---|---|
| Test Substance: | Atmosphere, Lot TC0501182 and Lot TC0501183 |
| Dilution: | 1:128 defined as 1 part test substance + 127 parts ≥200 ppm unsoftened tap water |
| Virus: | Porcine Epidemic Diarrhea Virus, Strain Colorado 2013 Isolate Obtained from National Veterinary Services Laboratories (NVSL), Ames, IA |
| Exposure Time: | 10 minutes |
| Exposure Temperature: | Room temperature (20.0°C) |
| Organic Soil Load: | 5% fetal bovine serum |
| Efficacy Result: | Two lots of Atmosphere (Lot TC0501182 and Lot TC0501183) met the performance requirements specified in the study protocol. The results indicate **complete inactivation** of Porcine Epidemic Diarrhea Virus under these test conditions as required by the U.S. EPA, Health Canada, and Australian Therapeutic Goods Administration (TGA). |

## TEST SYSTEM

1. Virus

The Colorado 2013 Isolate strain of Porcine Epidemic Diarrhea Virus used for this study was obtained from the National Veterinary Services Laboratories (NVSL), Ames, IA. The stock virus was prepared by collecting the supernatant culture fluid from 75-100% infected culture cells. The cells were disrupted and cell debris removed by centrifugation at approximately 2000 RPM for five minutes at approximately 4°C. The supernatant was removed, aliquoted, and the high titer stock virus was stored at ≤-70°C until the day of use. On the day of use, an aliquot of stock virus (ATS Labs Lot PED-62) was removed, thawed and maintained at a refrigerated temperature until used in the assay. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. The stock virus tested demonstrated cytopathic effects (CPE) typical of Porcine Epidemic Diarrhea Virus on Vero 76 cells.

2. Indicator Cell Cultures
Cultures of Vero 76 cells were originally obtained from the American Type Culture Collection, Manassas, VA (ATCC CRL-1587). The cells were propagated by Accuratus Lab Services personnel. The cells were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% $CO_2$. On the day of testing, the cells were observed as having proper cell integrity and confluency, and therefore, were acceptable for use in this study.

All cell culture documentation was retained for the cell cultures used in the assay with respect to source, passage number, growth characteristics, seeding densities and the general condition of the cells.

3. Test Medium
The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 2 µg/mL TPCK- trypsin, 10% (v/v) tryptose phosphate broth, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B.

## TEST METHOD

1. Preparation of Test Substance
Two lots of Atmosphere (Lot TC0501182 and Lot TC0501183) were tested at a 1:128 dilution defined as 1 part test substance + 127 parts ≥200 ppm unsoftened tap water (1.00 mL product + 127.0 mL water) as requested by the Sponsor. The test substance was in solution as determined by visual observation and used on the day of preparation. The prepared test substance was equilibrated to the exposure temperature prior to use.

The ≥200 ppm unsoftened tap water was titrated (at 211 ppm) and used on the day of testing.

2. Preparation of Virus Films
Films of virus were prepared by spreading 200 µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 30% until visibly dry (20 minutes).

3. Preparation of Sephadex Gel Filtration Columns
To reduce the cytotoxic level of the virus-test substance mixture prior to assay of virus, and/or to reduce the virucidal level of the test substance, virus was separated from the test substance by filtration through Sephadex LH-20 gel. On the day of testing, Sephadex columns were prepared by centrifuging the prepared Sephadex gel in sterile syringes for three minutes to clear the void volume. The columns were then ready to be used in the assay.

4. Input Virus Control (TABLE 1)
On the day of testing, the stock virus utilized in the assay was titered by 10-fold serial dilution and assayed for infectivity to determine the starting titer of the virus. The results of this control are for informational purposes only.

5. Treatment of Virus Films with the Test Substance (TABLE 1)
For each lot of test substance, one dried virus film was individually exposed to a 2.00 mL aliquot of the use dilution of the test substance and held covered for 10 minutes at room temperature (20.0°C). The virus films were completely covered with the test substance. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity.

6. Treatment of Dried Virus Control Film (TABLE 1)
One virus film was prepared as previously described (paragraph 2). The virus control film was exposed to 2.00 mL of test medium in lieu of the test substance and held covered for 10 minutes at room temperature (20.0°C). Just prior to the end of the exposure time, the virus control was scraped with a cell scraper and at the end of the exposure time the virus mixture was immediately passed through a Sephadex column in the same manner as the test virus (paragraph 5). The filtrate ($10^{-1}$ dilution) was then titered by 10-fold serial dilution and assayed for infectivity.

7. Cytotoxicity Controls (TABLE 2)
A 2.00 mL aliquot of the use dilution of each lot of the test substance was filtered through a Sephadex column and the filtrate was diluted serially in medium and inoculated into Vero 76 cell cultures. Cytotoxicity of the Vero 76 cell cultures was scored at the same time as the virus-test substance and virus control cultures.

8. Assay of Non-Virucidal Level of Test Substance (Neutralization Control) (TABLE 3)
Each dilution of the neutralized test substance (cytotoxicity control dilutions) was challenged with an aliquot of low titer stock virus to determine the dilution(s) of test substance at which virucidal activity, if any, was retained. Dilutions that showed virucidal activity were not considered in determining reduction of the virus by the test substance.

Using the cytotoxicity control dilutions prepared above, an additional set of indicator cell cultures was inoculated with a 200 µL aliquot of each dilution in quadruplicate. A 100 µL aliquot of low titer stock virus (approximately 16 infectious units) was inoculated into each cell culture well and the indicator cell cultures were incubated along with the test and virus control plates.

9. Infectivity Assays
The Vero 76 cell line, which exhibits cytopathic effect (CPE) in the presence of Porcine Epidemic Diarrhea Virus, was used as the indicator cell line in the infectivity assays. Cells in multiwell culture dishes were inoculated in quadruplicate with 200 µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C (36.4-37.0°C) in a humidified atmosphere of 5-7% $CO_2$ (5.7-6.0% $CO_2$) in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence or presence of CPE, cytotoxicity, and for viability.

10. Statistical Methods: Not applicable

## PROTOCOL CHANGES

**Protocol Amendments:**
To correct a typographical error on page 9, this protocol is amended to clarify the test substance dilution ratio is 1:128.

**Protocol Deviations:**
No protocol deviations occurred during this study.

## DATA ANALYSIS

### Calculation of Titers

Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber.

$$\text{- Log of 1st dilution inoculated} - \left[\left(\left(\frac{\text{Sum of \% mortality at each dilution}}{100}\right) - 0.5\right) \times (\text{logarithm of dilution})\right]$$

### Calculation of Log Reduction

Dried Virus Control $Log_{10}$ $TCID_{50}$ – Test Substance $Log_{10}$ $TCID_{50}$ = Log Reduction

## STUDY ACCEPTANCE CRITERIA

**U.S. EPA, Health Canada, and Australian TGA Submission**
A valid test requires 1) that at least 4 $\log_{10}$ of infectivity be recovered from the dried virus control film; 2) that when cytotoxicity is evident, at least a 3-log reduction in titer is demonstrated beyond the cytotoxic level; 3) that the cell controls be negative for infectivity.
**Note:** An efficacious product must demonstrate complete inactivation of the virus at all dilutions.

## RECORD RETENTION

### Study Specific Documents

All of the original raw data developed exclusively for this study shall be archived at Accuratus Lab Services, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121 for a minimum of five years following the study completion date. After this time, the Sponsor (or the Sponsor Representative, if applicable) will be contacted to determine the final disposition. The original data includes, but is not limited to, the following:

1. All handwritten raw data for control and test substances including, but not limited to, notebooks, data forms and calculations.
2. Any protocol amendments/deviation notifications.
3. All measured data used in formulating the final report.
4. Memoranda, specifications, and other study specific correspondence relating to interpretation and evaluation of data, other than those documents contained in the final study report.
5. Original signed protocol.
6. Certified copy of the final study report.
7. Study-specific SOP deviations made during the study.

### Test Substance Retention

The test substance will be discarded following study completion per Sponsor approved protocol. It is the responsibility of the Sponsor to retain a sample of the test substance.

## REFERENCES

1. Annual Book of ASTM Standards, Section 11 Water and Environmental Technology Volume 11.05 Pesticides, Antimicrobials, and Alternative Control Agents; Environmental Assessment; Hazardous Substances and Oil Spill Response, E1053-11.
2. American Society of Testing and Materials (ASTM). Standard Practice for Use of Gel Filtration Columns for Cytotoxicity Reduction and Neutralization, E1482-12 (Reapproved 2017).
3. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2000: General Considerations for Uses of Antimicrobial Agents, September 4, 2012.
4. 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.
5. Diagnostic Procedures for Viral, Rickettsial, and Chlamydial Infections. Lennette, E.H., Lennette, D.A. and Lennette, E.T. editors. Seventh edition, 1995.
6. Blackwell, J.H., and J.H.S. Chen. 1970. Effects of various germicidal chemicals on HEP-2 cell culture and Herpes simplex virus. J. AOAC 53:1229-1236.
7. Health Canada January 2014. Guidance Document – Disinfectant Drugs.
8. Health Canada January 2014. Guidance Document – Safety and Efficacy Requirements for Hard Surface Disinfectant Drugs.
9. Australian Therapeutic Goods Administration (TGA), February 1998. Guidelines for the Evaluation of Sterilants and Disinfectants.
10. Australian Therapeutic Goods Administration (TGA), February 1998. Therapeutic Goods Order No. 54: Standard for Disinfectants and Sterilants.
11. Australian Therapeutic Goods Administration (TGA), March 1997. Therapeutic Goods Order No. 54A: Amendment to Standard for Disinfectants and Sterilants (TGO 54).
12. Australian Therapeutic Goods Administration (TGA), July 2005. Draft Guidelines for the Evaluation of Household/Commercial and Hospital Grade Disinfectants.
13. Association of Official Analytical Chemists (AOAC) Official Method 960.09, Germicidal and Detergent Sanitizing Action of Disinfectants Method [Preparation of Synthetic Hard Water]. In Official Methods of Analysis of the AOAC, 2013 Edition.

## STUDY RESULTS

Results of tests with two lots of Atmosphere (Lot TC0501182 and Lot TC0501183), diluted 1:128 defined as 1 part test substance + 127 parts ≥200 ppm unsoftened tap water, exposed to Porcine Epidemic Diarrhea Virus in the presence of a 5% fetal bovine serum organic soil load at room temperature (20.0°C) for 10 minutes are shown in Tables 1-3. All cell controls were negative for test virus infectivity.

The titer of the input virus control was 5.00 $\log_{10}$. The titer of the dried virus control was 4.50 $\log_{10}$. Following exposure, test virus infectivity was not detected in the virus-test substance mixture for either lot at any dilution tested (≤0.50 $\log_{10}$). Test substance cytotoxicity was not observed in either lot at any dilution tested (≤0.50 $\log_{10}$). The neutralization control (non-virucidal level of the test substance) indicates that the test substance was neutralized at ≤0.50 $\log_{10}$ for both lots. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was ≥4.00 $\log_{10}$ for both lots.

## STUDY CONCLUSION

**Under the conditions of this investigation and in the presence of a 5% fetal bovine serum organic soil load, Atmosphere, diluted 1:128 defined as 1 part test substance + 127 parts ≥200 ppm unsoftened tap water, demonstrated complete inactivation of Porcine Epidemic Diarrhea Virus following a 10 minute exposure time at room temperature (20.0°C) as required by the U.S. EPA, Health Canada, and Australian Therapeutic Goods Administration (TGA).**

In the opinion of the Study Director, there were no circumstances that may have adversely affected the quality or integrity of the data.



## TABLE 1: Virus Controls and Test Results

### Effects of Atmosphere (Lot TC0501182 and Lot TC0501183) Following a 10 Minute Exposure to Porcine Epidemic Diarrhea Virus Dried on an Inanimate Surface

| Dilution | Input Virus Control | Dried Virus Control | Porcine Epidemic Diarrhea Virus + Lot TC0501182 | Porcine Epidemic Diarrhea Virus + Lot TC0501183 |
|---|---|---|---|---|
| Cell Control | 0 0 | 0 0 0 0 | 0 0 0 0 | 0 0 0 0 |
| $10^{-1}$ | + + | + + + + | 0 0 0 0 | 0 0 0 0 |
| $10^{-2}$ | + + | + + + + | 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 0 | 0 0 0 0 |
| $10^{-6}$ | 0 0 | 0 0 0 0 | 0 0 0 0 | 0 0 0 0 |
| $10^{-7}$ | 0 0 | NT | NT | NT |
| $TCID_{50}$/200 µL | $10^{5.00}$ | $10^{4.50}$ | $\leq 10^{0.50}$ | $\leq 10^{0.50}$ |

(+) = Positive for the presence of test virus
(0) = No test virus recovered and/or no cytotoxicity present
(NT) = Not tested

**TABLE 2: Cytotoxicity Control Results**

**Cytotoxicity of Atmosphere on Vero 76 Cell Cultures**

| Dilution | Cytotoxicity Control Lot TC0501182 | Cytotoxicity Control Lot TC0501183 |
|---|---|---|
| Cell Control | 0 0 0 0 | 0 0 0 0 |
| $10^{-1}$ | 0 0 0 0 | 0 0 0 0 |
| $10^{-2}$ | 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 |
| $TCD_{50}$/200 µL | $\leq 10^{0.50}$ | $\leq 10^{0.50}$ |

(0) = No test virus recovered and/or no cytotoxicity present

**TABLE 3: Neutralization Control Results**

**Non-Virucidal Level of the Test Substance (Neutralization Control)**

| Dilution | Test Virus + Cytotoxicity Control Lot TC0501182 | Test Virus + Cytotoxicity Control Lot TC0501183 |
|---|---|---|
| Cell Control | 0 0 0 0 | 0 0 0 0 |
| $10^{-1}$ | + + + + | + + + + |
| $10^{-2}$ | + + + + | + + + + |
| $10^{-3}$ | + + + + | + + + + |
| $10^{-4}$ | + + + + | + + + + |
| $10^{-5}$ | + + + + | + + + + |
| $10^{-6}$ | + + + + | + + + + |

(+) = Positive for the presence of test virus after low titer stock virus added (neutralization control)
(0) = No test virus recovered and/or no cytotoxicity present

Results of the non-virucidal level control indicate that the test substance was neutralized at a $TCID_{50}$/200 µL of ≤0.50 $log_{10}$ for both lots.

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## ATTACHMENT I: Certificate of Analysis – Lot TC0501182

ACCURATUS —LAB SERVICES— THE ANTIMICROBIAL AUTHORITY

# Certificate of Analysis

The analysis of this test substance was conducted in compliance with Good Laboratory Practice Standards as published in 40 CFR Part 160 as part of Accuratus Lab Services' Project Number: A25430.

EXACT COPY
INITIALS ll DATE 6-29-18

| | |
|---|---|
| Sponsor: | Atmosphere Global LLC<br>55 West Goethe Unit 1241<br>Chicago, IL 60610 |
| Test Facility: | Accuratus Lab Services<br>1285 Corporate Center Drive, Suite 110<br>Eagan, MN 55121 |
| Test Substance Name: | Atmosphere |
| Lot/Batch: | TC0501182 |
| Expiration Date: | September 1, 2020 |
| Protocol Number: | ATM002030818.CHR |
| Date of Analysis: | May 7, 2018 |

| Active Ingredient (Test) | Purity Result |
|---|---|
| Quaternary Ammonia | 6.91% |

Study Director Emily Breen Date: 05/28/18
Emily Breen, B.A.

The raw data generated during analysis have been reviewed by the Quality Assurance Unit. The raw data confirm the results as listed above.

Quality Assurance Specialist: Cody Dany Date: 5/23/18

Page 1 of 1



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## ATTACHMENT II: Certificate of Analysis – Lot TC0501183

# Certificate of Analysis

The analysis of this test substance was conducted in compliance with Good Laboratory Practice Standards as published in 40 CFR Part 160 as part of Accuratus Lab Services' Project Number: A25430.

Sponsor: Atmosphere Global LLC
55 West Goethe Unit 1241
Chicago, IL 60610

EXACT COPY
INITIALS LL DATE 6-29-18

Test Facility: Accuratus Lab Services
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

Test Substance Name: Atmosphere
Lot/Batch: TC0501183
Expiration Date: September 1, 2020
Protocol Number: ATM002030818.CHR
Date of Analysis: May 7, 2018

| Active Ingredient (Test) | Purity Result |
|---|---|
| Quaternary Ammonia | 6.88% |

Study Director: Emily Breen, B.A. Date: 05/23/18

The raw data generated during analysis have been reviewed by the Quality Assurance Unit. The raw data confirm the results as listed above.

Quality Assurance Specialist: Cody Barry Date: 5/23/18



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## AMENDMENT TO GLP TEST PROTOCOL

| | |
|---|---|
| **Amendment No.:** | 1 |
| **Effective Date:** | June 6, 2018 |
| **Sponsor:** | Atmosphere Global LLC<br>55 West Goethe Unit 1241<br>Chicago, IL 60610 |
| **Test Facility:** | Accuratus Lab Services<br>1285 Corporate Center Drive, Suite 110<br>Eagan, MN 55121 |
| **Protocol Title:** | Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces |
| **Protocol Number:** | ATM002032218.PEDV |
| **Project Number:** | A25624 |

EXACT COPY
INITIALS ll DATE 6-7-2018

**Modifications to Protocol:**

To correct a typographical error on page 9, this protocol is amended to clarify the test substance dilution ratio is 1:128.

Changes to the protocol are acceptable as noted.

Study Director

6-7-18
Date