**NON-GLP STUDY REPORT**

STUDY TITLE

Evaluation of the Virucidal Efficacy of a UV Device for Use on Inanimate Environmental Surfaces

**Virus: Human Coronavirus**

TEST DEVICE IDENTITY

BLUEMORPH UVC EMITTER

TRF NUMBER

BLU003032320.COR

AUTHOR

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STUDY COMPLETION DATE

May 27, 2020

PERFORMING LABORATORY

Analytical Lab Group-Midwest
1285 Corporate Center Drive, Suite 110
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SPONSOR

BlueMorph LLC
6318 Rocky Point Ct
Oakland, CA 94605

PROJECT NUMBER

A29600

This study was not performed under
EPA Good Laboratory Practice Regulations
(40 CFR Part 160)

# STUDY REPORT

## GENERAL STUDY INFORMATION

**Study Title:** Evaluation of the Virucidal Efficacy of a UV Device for Use on Inanimate Environmental Surfaces

**Project Number:** A29600

**TRF Number:** BLU003032320.COR

## TEST SUBSTANCE IDENTITY

**Test Devie Name:** BLUEMORPH UVC EMITTER

## STUDY DATES

**Date Sample Received:** March 31, 2020
**Study Initiation Date:** April 30, 2020
**Experimental Start Date:** May 8, 2020
**Experimental End Date:** May 18, 2020
**Study Completion Date:** May 27, 2020

## TEST PARAMETERS

**Carrier Type:** Stainless steel (1" x 1")
**Virus:** Human Coronavirus, ATCC VR-740, Strain 229E
**Exposure Time:** 6 minutes and 12 minutes
**Exposure Temperature:** Room temperature (18.0°C)
**Exposure Humidity:** 14.75%
**Organic Soil Load:** 1% fetal bovine serum
**Test Medium:** Minimum Essential Medium (MEM) supplemented with 2% (v/v) heat-inactivated fetal bovine serum, 100 units/mL penicillin, 10 µg/mL gentamicin, and 2.5 µg/mL amphotericin B
**Indicator Cell Cultures:** WI-38 (human lung) cells

## EXPERIMENTAL DESIGN

### Input Virus Control

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.

### Contamination of Carriers

For each replicate, a 100 µL aliquot of test virus was added to the surface of the carrier. The virus was air-dried at 21.0°C and 10.07% relative humidity until visibly dry (30 minutes).

### Test Exposure

Following the completion of drying, the carriers were placed vertically, at a distance of 2 meters from the test device. The device was operated per the instructions and turned on cold at the start of the exposure period. A calibrated timer was used during the exposure.

A digital UV meter was allowed to record at 1 minute intervals, at the same distance/time as the test.

| 6 Minute Exposure | |
|---|---|
| Exposure Time Point | Digital UVC Light Meter Reading (µW/cm$^2$) |
| 1 minute | 15 |
| 2 minute | 45 |
| 3 minute | 76 |
| 4 minute | 99 |
| 5 minute | 115 |
| 6 minute | 125 |

| 12 Minute Exposure | |
|---|---|
| Exposure Time Point | Digital UVC Light Meter Reading (µW/cm$^2$) |
| 1 minute | 22 |
| 2 minute | 39 |
| 3 minute | 77 |
| 4 minute | 105 |
| 5 minute | 124 |
| 6 minute | 137 |
| 7 minute | 147 |
| 8 minute | 153 |
| 9 minute | 156 |
| 10 minute | 157 |
| 11 minute | 158 |
| 12 minute | 159 |

### Recovery of Virus Following Exposure

Following exposure to the test device, a 1.0 mL aliquot of test medium was added to each carrier and was scraped with a cell scraper to resuspend the contents ($10^{-1}$ dilution). The test medium was collected and serial 10-fold dilutions were performed. Each dilution was then assayed for infectivity and/or cytotoxicity.

**Dried Virus Control**
The appropriate number of virus films (for each exposure time) were prepared as described previously and run in parallel to the test virus. Each virus control film was held uncovered in a sterile petri dish and exposed to the test medium for the same exposure time and at the same exposure temperature as the test films. A calibrated timer was used for timing the exposure and the actual temperature was recorded. Immediately following the Sponsor requested exposure, a 1.0 mL aliquot of test medium was added to the carrier and scraped with a cell scraper to resuspend the contents($10^{-1}$ dilution). The test medium was collected, serial 10-fold dilutions performed and each dilution was assayed for infectivity.

**Cytotoxicity Control**
A carrier was dried as above, however, an aliquot of test medium containing the requested organic soil load was used in lieu of virus. Following drying, the carrier was exposed to the test device in parallel with the test carriers (for the longest exposure time). Following exposure, the recoveries were the same as indicated above in testing. Serial 10-fold dilutions were performed and each dilution was assayed for cytotoxicity.

**Assay of Non-Virucidal Level of Test Substance (Neutralization Control)**
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, is retained. Dilutions that show virucidal activity will not be 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 100 µL aliquot of each dilution in quadruplicate. A 100 µL aliquot of low titer stock virus was inoculated into each cell culture well and the indicator cell cultures were incubated along with the test and virus control plates.

Per Sponsor's direction, the study was not required to be conducted under US EPA 40 CFR Part 160 or US FDA 21 CFR Part 58.

## CONCLUSION

**Under the conditions of this investigation and in the presence of a 1% fetal bovine serum organic soil load, the BLUEMORPH UVC EMITTER, demonstrated an average ≥4.00 $\log_{10}$ reduction in titer of Human Coronavirus on stainless steel carriers following a 6 minute exposure time at room temperature (18.0°C) and 14.75% relative humidity as compared to the average titer of the6 minute dried virus controls.**

**Under the conditions of this investigation and in the presence of a 1% fetal bovine serum organic soil load, the BLUEMORPH UVC EMITTER, demonstrated an average ≥4.00 $\log_{10}$ reduction in titer of Human Coronavirus on stainless steel carriers following a 12 minute exposure time at room temperature (18.0°C) and 14.75% relative humidity as compared to the average titer of the 12 minute dried virus controls.**

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

## STUDY RESULTS

**TABLE 1: Virus Controls**

| Dilution | Input Virus Control | Dried Virus Control (Stainless Steel Carriers) | | | |
|---|---|---|---|---|---|
| | | 6 minute exposure | | 12 minute exposure | |
| | | Replicate 1 | Replicate 2 | Replicate 1 | Replicate 2 |
| Cell Control | 0 0 | 0 0 0 0 | 0 0 0 0 | 0 0 0 0 | 0 0 0 0 |
| $10^{-1}$ | + + | + + + + | + + + + | + + + + | + + + + |
| $10^{-2}$ | + + | + + + + | + + + + | + + + + | + + + + |
| $10^{-3}$ | + + | + + + + | + + + + | + + + + | + + + + |
| $10^{-4}$ | + + | + + + + | + + + + | + + + + | + + + + |
| $10^{-5}$ | 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 + 0 0 |
| $10^{-7}$ | 0 0 | NT | NT | NT | NT |
| $TCID_{50}$/100 µL | $10^{5.00}$ | $10^{5.00}$ | $10^{4.50}$ | $10^{4.75}$ | $10^{4.50}$ |
| Average $TCID_{50}$/100 µL | NA | $10^{4.82}$ | | $10^{4.64}$ | |

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

**TABLE 2: Effects of BLUEMORPH UVC EMITTER Following a 6 Minute and 12 Minute Exposure to Human Coronavirus Dried on an Inanimate Surface**

| Dilution | Human Coronavirus + BLUEMORPH UVC EMITTER (Stainless Steel Carriers) | | | |
|---|---|---|---|---|
| | 6 minute exposure | | 12 minute exposure | |
| | Replicate 1 | Replicate 2 | Replicate 1 | Replicate 2 |
| Cell Control | 0 0 0 0 | 0 0 0 0 | 0 0 0 0 | 0 0 0 0 |
| $10^{-1}$ | 0 0 0 0 | 0 + + 0 | 0 0 0 0 | 0 0 0 + |
| $10^{-2}$ | 0 0 0 0 | 0 0 0 0 | 0 0 0 0 | 0 0 0 0 |
| $10^{-3}$ | 0 0 0 0 | 0 0 0 0 | 0 0 0 0 | 0 0 0 0 |
| $10^{-4}$ | 0 0 0 0 | 0 0 0 0 | 0 0 0 0 | 0 0 0 0 |
| $10^{-5}$ | 0 0 0 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 0 0 |
| $TCID_{50}$/100 µL | $\leq 10^{0.50}$ | $10^{1.00}$ | $\leq 10^{0.50}$ | $10^{0.75}$ |
| Average $TCID_{50}$/100 µL | $\leq 10^{0.82}$ | | $\leq 10^{0.64}$ | |
| Average Log reduction* | $\geq 4.00$ $\log_{10}$ | | $\geq 4.00$ $\log_{10}$ | |

(+) = Positive for the presence of test virus
(0) = No test virus recovered and/or no cytotoxicity present
(*) = Calculated using the corresponding dried virus control

**TABLE 2: Cytotoxicity Control and Neutralization Control**

| Dilution | Cytotoxicity Control BLUEMORPH UVC EMITTER (Stainless Steel Carrier) | Neutralization Control BLUEMORPH UVC EMITTER (Stainless Steel Carrier) |
|---|---|---|
| Cell Control | 0 0 0 0 | 0 0 0 0 |
| $10^{-1}$ | 0 0 0 0 | + + + + |
| $10^{-2}$ | 0 0 0 0 | + + + + |
| $10^{-3}$ | 0 0 0 0 | + + + + |
| $TCD_{50}$/100 µL | $\leq 10^{0.50}$ | See below |

(+) = Positive for the presence of test virus
(0) = No test virus recovered and/or no cytotoxicity present

Results of the non-virucidal level control (neutralization control) indicate that the test substance was neutralized at a $TCID_{50}$/100 µL of ≤0.50 $log_{10}$.

**PREPARED BY:**

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5-27-2020
Date