INNOVATIVE BIOANALYSIS
creating solutions | getting results

EFFICACY OF THE SIGNIFY UVCA210 UNIT AGAINST AEROSOLIZED SARS-COV-2

PROJECT: SIGNIFY - UVCA - SARS-COV-2

APPLICANT: SIGNIFY
PRODUCT: UVCA210 AIR DISINFECTION UNIT
MODEL NO: UVCA210
TRADEMARK: PHILIPS, ECOLINK, FAIL-SAFE, ALKCO, MAZDA, PILA & IRIS OHYAMA INC

CAP LIC NO: 8860298

CLIA LIC NO: 05D0955926

STATE ID: CLF 00324630

CHALLENGE ORGANISM(S):

SARS-COV-2 USA-CA1/2020

Medical Director

Dana Yee, M.D.

Testing Facility

Innovative Bioanalysis, Inc.

3188 Airway Ave Suite D

Costa Mesa, CA 92626

www.InnovativeBioanalysis.com

Email: info@innovativebioanalysis.com

Laboratory Project Number

1154

INNOVATIVE BIOANALYSIS
creating solutions | getting results

Table of Contents

INNOVATIVE BIOANALYSIS
creating solutions | getting results

Efficacy Study Summary

Study Title	EFFICACY OF THE SIGNIFY UVCA210 UNIT AGAINST AEROSOLIZED SARS-COV-2
Laboratory Project #	1154
Guideline:	Modified ISO standards as no international standards exist.
Testing Facility	Innovative Bioanalysis, Inc.
GLP Compliance	All internal SOPs and processes follow GCLP guidelines and recommendations.
Test Substance	SARS-CoV-2 USA-CA1/2020
Description	Signify provided the UVCA210 Air Disinfection device, a portable air purifier designed to be placed free-standing in a room to decrease the concentration of pathogens in the air. This in-vitro study aims to determine the effectiveness of the UVCA210 Air Disinfection unit against aerosolized SARS-CoV-2 USA-CA1/2020.
Test Conditions	The test was conducted in a sealed 10'x8'x8' chamber, which complied with BSL-3 standards. The temperature during all test runs was approximately 73 ±3°F, with relative humidity ranging between 31-34%. A starting concentration of 7.02×10^6 TCID50/mL SARS-CoV-2 in FBS-based viral media was nebulized into the room with mixing fans before collection. Air sample collections occurred after 0, 30, 45, and 60 minutes of device operation.
Test Results	Against SARS-CoV-2, the UVCA210 reduced an initial concentration of 7.02×10^6 TCID50/mL to 4.69×10^4 TCID50/mL after 30 minutes. Increased exposure time resulted in a higher reduction of aerosolized SARS-CoV-2 reaching below assay quantification limits represented by the value 1.20×10^2 TCID50/mL after 45 minutes of operation.
Control Results	A control test was conducted without the device, and samples were taken at the corresponding time points used for the challenge. The results displayed a natural viability loss over time in the chamber and were used as a comparative baseline to calculate net viral reduction.
Conclusion	The Signify UVCA210 air disinfection unit demonstrated a significant reduction of recoverable aerosolized SARS-CoV-2 compared to natural loss rates. The device achieved a 99.33% reduction at 30 minutes and a 99.998% reduction after 45 minutes.

INNOVATIVE BIOANALYSIS
creating solutions | getting results

Study Report

Study Title: EFFICACY OF THE SIGNIFY UVCA210 UNIT AGAINST AEROSOLIZED SARS-COV-2

Sponsor: Signify USA

Test Facility: Innovative Bioanalysis, Inc. 3188 Airway Ave Suite D, Costa Mesa, CA 92626

Device Testing: UVCA210 Air Disinfection Unit

Study Report Date: 10/04/2021
Experimental Start Date: 08/30/2021
Experimental End Date: 09/04/2021
Study Completion Date: 11/03/2021

Study Objective:

Signify provided the UVCA210 Air Disinfection unit for testing purposes to determine efficacy against viral pathogens. This study evaluated the effectiveness of the UVCA210 in its ability to reduce the viral strain referred to as SARS-CoV-2 USA-CA1/2020 within the air.

Test Method:

Bioaerosol Generation:

The nebulizer was filled with a 7.02 x 10^6 TCID50/mL viral media of SARS-CoV-2 USA-CA1/2020 and nebulized at a flow rate of 1mL/min with untreated local atmospheric air. The nebulizer's remaining viral stock volume was weighed to confirm that roughly the same amount was nebulized during each run. Bioaerosol procedures for the controls and viral challenges were performed in the same manner with corresponding time points and collection rates.

Bioaerosol Sampling:

This study used two probes for air sampling, each connected to a calibrated Gilian 10i vacuum device. Before use, the devices were inspected for functionality. The air sampler operated in conjunction with a removable sealed cassette and manually removed after each time point. Cassettes had a delicate internal filtration disc to collect viral samples, which was moistened with a viral suspension media to aid in the collection. The filtration disc from Zefon International, Lot# 24320, was used.

Test System Strains: SARS-CoV-2 USA-CA1/2020

The following reagent was deposited by the Centers for Disease Control and Prevention and obtained through BEI Resources, NIAID, NIH: SARS-Related Coronavirus 2, Isolate USA-CA1/2020, NR-52382.

Study Materials and Equipment:

Equipment Overview: The equipment arrived at the laboratory pre-packaged by the manufacturer and was inspected for damage upon arrival. Due to the closed design, no assessment was conducted on the inner components of the device. The device was powered on to confirm functionality before testing. Refer to the Appendix attached for the list of Signify-owned brands using the same device.

MANUFACTURER: Signify

MODEL: UVCA210 Air Disinfection Unit (Engineering Sample)

SIZE: 34.7cm x 34.6cm x 76cm

MAKE: (Refer to Appendix)

SERIAL #: N/A

Testing Layout:

Testing was conducted in a sealed 10'x8'x8' chamber per Biosafety Level 3 (BSL-3) standards. A nebulizing port connected to a programmable compressor system was located in the center of the 10' wall protruding 24" from the wall opposite the door. At each chamber corner, low-volume mixing fans (~30 cfm each) were positioned at 45-degree angles to ensure homogenous mixing of bioaerosol concentrations when nebulized into the chamber. The room was equipped with two probes positioned along the centerline at the same height as the unit's outlet, approximately 40 cm off the chamber floor. The device was placed on the floor in the center of the room. The chamber was visually inspected, pressure tested, and all internal lab systems and equipment were reviewed before testing.

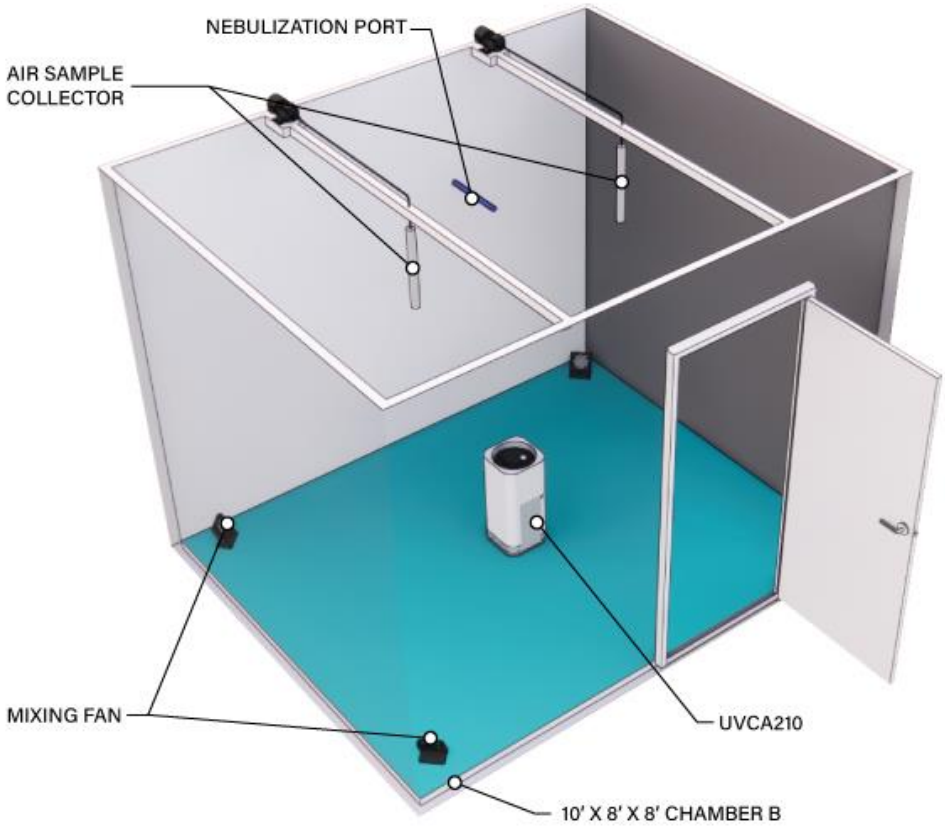


Figure 1. Room layout for control and experimental trial.

Test Method:

Exposure Conditions:

1. The temperature during all test runs was approximately 73 ±3°F, with relative humidity ranging between 31-34%.
2. Samples were collected after nebulization stopped for 10-minutes (T-0) at 30, 45, and 60 minutes.
3. Device fan speed was set on high.

Experimental Procedure:

1. Before the initial control test and following each trial, the testing area was decontaminated and prepped per internal procedures.
2. 5mL of 7.02 x 10^6 TCID50/mL of SARS-CoV-2 viral media was nebulized into the room via a dissemination port.
3. After nebulization, the device was turned on via remote control.
4. The device was turned off at the pre-determined time points for sample collection.
5. Air sampling collection was taken for 10-minutes from the start of sampling.
6. Sample cassettes were manually removed from the collection system and brought to an adjacent biosafety cabinet for extraction and placement into a viral suspension media.
7. All samples were sealed after collection and provided to lab staff for analysis after study completion.

Post Decontamination:

After testing, the UV system inside the testing chamber was activated for 30 minutes. After 30 minutes of UV exposure, a 30-minute air purge through the air filtration system was conducted. Test equipment was cleaned at the end of each day with a 70% alcohol solution. Collection lines were soaked in a bleach bath mixture for 30 minutes then rinsed repeatedly with DI water. The nebulizer and vacuum collection pumps were decontaminated with hydrogen peroxide mixtures.

Preparation of The Pathogen

Viral Stock: SARS-CoV-2 USA-CA1/2020 (BEI NR-52382)

Test	Specifications	Results
Identification by Infectivity in Vero 6 cells	Cell Rounding and Detachment	Cell Rounding and Detachment
Next-Generation Sequencing (NGS) of the complete genome using Illumina® iSeq™ 100 Platform	≥ 98% identity with SARS-CoV 2, isolate USA-CA1/2020 GenBank: MN994467.1	99.9% identity with SARS-CoV 2, isolate USA-CA1/2020 GenBank: MN994467.1
Approx. 940 Nucleotides	≥ 98% identity with SARS-CoV 2, strain FDAARGOS_983 isolate USA-CA1/2020 GenBank: MT246667.1	100% identity with SARS-CoV 2, strain FDAARGOS_983 isolate USA-CA1/2020 GenBank: MT246667.1
Titer by TCID50 in Vero E6 Cells by cytopathic effect	Report Results	2.8 X 10^5 TCID50 per mL in 5 days at 37°C and 5% CO_2
Sterility (21-Day Incubation)		
Harpos HTYE Broth, aerobic	No Growth	No Growth
Trypticase Soy Broth, aerobic	No Growth	No Growth
Sabourad Broth, aerobic	No Growth	No Growth
Sheep Blood Agar, aerobic	No Growth	No Growth
Sheep Blood Agar, anaerobic	No Growth	No Growth
Thioglycollate Broth, anaerobic	No Growth	No Growth
DMEM with 10% FBS	No Growth	No Growth
Mycoplasma Contamination		
Agar and Broth Culture	None Detected	None Detected
DNA Detection by PCR of extracted test article nucleic acid	None Detected	None Detected

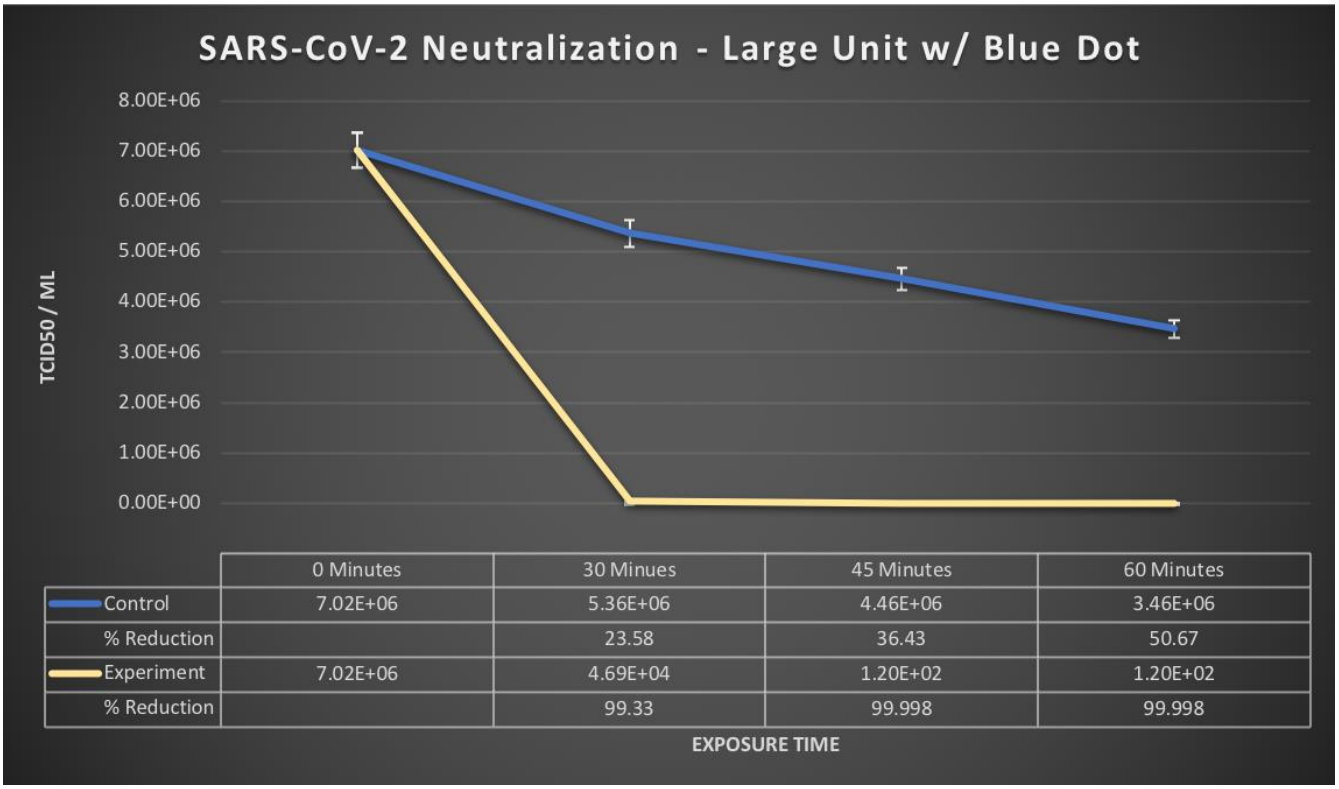
*The viral titer listed in the Certificate of Analysis is representative of the titer provided by BEI Resources. These viruses are grown on VeroE6 cells either in-house or at a partner lab to the concentrations listed within the experiment design.

Control Protocol

To accurately access the Signify UVCA210, a control was conducted without the device operating in the testing chamber. Control samples were taken in the same manner and at the corresponding time points used for the challenge trial to serve as a comparative baseline to assess the viral reduction when the device was operating.

Study Results

The results were plotted to compare the concentration of active SARS-CoV-2 collected at 30, 45, and 60 minutes of device operation. Controls displayed a natural viability loss without the device operating in the chamber for 60 minutes. At 30 minutes against aerosolized SARS-CoV-2, the device lowered a starting concentration of 7.02 x 10^6 TCID50/mL to 4.69 x 10^4 TCID50/mL. The concentration of SARS-CoV-2 decreased over time, reaching levels below limits of quantification represented as 1.20 x 10^2 TCID50/mL at 45 minutes and 60 minutes.



	0 Minutes	30 Minues	45 Minutes	60 Minutes
Control	7.02E+06	5.36E+06	4.46E+06	3.46E+06
% Reduction		23.58	36.43	50.67
Experiment	7.02E+06	4.69E+04	1.20E+02	1.20E+02
% Reduction		99.33	99.998	99.998

**As it pertains to data represented herein, the value of 1.2E+02 indicates a titer that is lower than the specified limit of quantitation. The limit of quantitation for this assay is 1.2E+02.

***As it pertains to data represented herein; the percentage error equates to an average of ±5% of the final concentration.

Conclusion

The Signify UVCA210 Air Disinfection unit demonstrated a significant ability to reduce active pathogen SARS-CoV-2 USA-CA1/2020 from the air. The device achieved a 99.33% reduction of active pathogen after 30 minutes and reached a 99.998% reduction after 45 minutes. Overall, UVCA210 showed the ability to reduce collectible pathogens in the air more rapidly than natural loss rates. The study focused on the impact the air purifier would have on a specific volume of space. Therefore, when applied to a different sized room, the results will scale and vary due to variables present, such as room size, occupancy rating, air movement, and more. Every effort was made to simulate a real-life situation and address constraints with the experimental design and execution while taking the proper precautions when working with a BSL-3 pathogen. These efforts are reflected in the meaningful recovery of the virus in the control test.

Appendix

List of Signify-owned brands using the same product, as provided by Signify.

Brand	Filter Type	Function	Product Name	Type Name	Color Options
Philips, Ecolink, Fail-Safe, Alkco, Pila, Mazda & Iris Ohyama Inc.	Non-HEPA	Air Disinfection	UVCA210 Air Disinfection unit	UVCA210	Gray & White

INNOVATIVE BIOANALYSIS
creating solutions | getting results

DocuSigned by:
Dana Yee
7D5A69A0907947B...

12/22/2021

Dana Yee M.D **Date**

Clinical Pathologist and Medical Director, Innovative Bioanalysis, Inc.

DocuSigned by:
Sam Kabbani
8B4B282DF4B34A3...

12/22/2021

Sam Kabbani, MS, BS, MT(ASCP), CLS **Date**

Chief Scientific Officer, Innovative Bioanalysis, Inc.

DocuSigned by:
Albert Brockman
06DF5C77A0D2400...

12/22/2021

Albert Brockman **Date**

Chief Biosafety Officer, Innovative Bioanalysis, Inc.

DocuSigned by:
Kevin Noble
5DE2797BAA78421...

12/21/2021

Kevin Noble **Date**

Laboratory Director, Innovative Bioanalysis, Inc.

Disclaimer

The Innovative Bioanalysis, Inc. ("Innovative Bioanalysis") laboratory is not certified or licensed by the United States Environmental Protection Agency and makes no equipment emissions claims pertaining to ozone or byproduct of any Signify device. Innovative Bioanalysis, Inc. makes no claims to the overall efficacy of any UVCA210 Air Disinfection Unit. The experiment results are solely applicable to the device used in the trial. The results are only representative of the experiment design described in this report. Innovative Bioanalysis, Inc. makes no claims as to the reproducibility of the experiment results given the possible variation of experiment results even with an identical test environment, viral strain, collection method, inoculation, nebulization, viral media, cell type, and culture procedure. Innovative Bioanalysis, Inc. makes no claims to third parties and takes no responsibility for any consequences arising out of the use of, or reliance on, the experiment results by third parties.