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EFFICACY OF THE ALLANSON UV-C CEILING FIXTURE AGAINST AEROSOLIZED SARS-COV-2

PROJECT: ALLANSON - UV-C CEILING FIXTURE - SARS-COV-2

PRODUCT: ALLANSON AIRGUARD C600

CAP LIC NO: 8860298

CLIA LIC NO: 05D0955926

STATE ID: CLF 00324630

CHALLENGE ORGANISM(S):

SARS-COV-2 USA-CA1/2020

Medical Director

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Testing Facility

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Laboratory Project Number

1117

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Efficacy Study Summary

Study Title	EFFICACY OF THE ALLANSON UV-C CEILING FIXTURE AGAINST SARS-COV-2
Laboratory Project #	1117
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	The Allanson UV-C Ceiling Fixture was designed to reduce airborne pathogens within an enclosed environment. This study evaluated the device's effectiveness to inactivate and reduce aerosolized SARS-CoV-2.
Test Conditions	The test was conducted in a sealed 10'x8'x8' bioaerosol chamber that complied with BSL-3 standards. The average temperature during all test runs was approximately 74.5 ±2°F, with a relative humidity of 50%. A 7.43×10^6 TCID50/mL of SARS-CoV-2 in viral media was nebulized into the room with mixing fans before collection. Air sample collections occurred at 0, 10, 20, and 30 minutes of device operation.
Test Results	Against SARS-CoV-2 with an initial concentration of 7.43×10^6 TCID50/mL, there was an observed reduction to 2.07×10^6 TCID50/mL after 10 minutes of the device being activated. Increased exposure time resulted in a higher reduction of aerosolized SARS-CoV-2 with a collected concentration of 4.27×10^5 TCID50/mL at 20 minutes and 1.20×10^2 TCID50/mL at 30 minutes.
Control Results	A control test was conducted without the device operating, and samples were taken at 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 viral reduction.
Conclusion	The Allanson UV-C Ceiling Fixture demonstrated observable reduction capabilities against aerosolized SARS-CoV-2 compared to natural loss rates, achieving a 99.998% reduction after 30 minutes of operation.

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Study Report

Study Title: EFFICACY OF THE ALLANSON UV-C CEILING FIXTURE AGAINST AEROSOLIZED SARS-COV-2

Sponsor: Allanson International, Inc.

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

Device Testing: Allanson AirGuard C600

Study Report Date: 11/15/2021
Experimental Start Date: 08/25/2021
Experimental End Date: 10/24/2021
Study Completion Date: 11/14/2021

Study Objective:

Allanson supplied the UV-C Ceiling Fixture for testing purposes to determine efficacy against viral pathogens. This study evaluated the effectiveness of the UV-C Ceiling Fixture 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 7.43 x 10^6 TCID50/mL suspension of viral media of SARS-CoV-2 and nebulized at a flow rate of 1 mL/min with untreated local atmospheric air. The nebulizer's remaining viral stock volume was weighed to confirm 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# 26338, 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

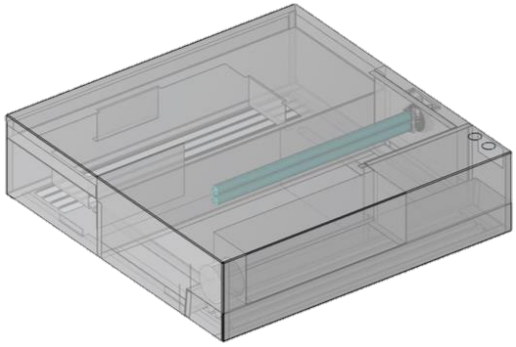
Equipment Overview: The equipment arrived at the laboratory pre-packaged by the manufacturer and was inspected for damage upon arrival. Due to the closed design, no assessment was conducted on the inner components of the device. The device was powered on to confirm functionality before testing. Per the manufacturer, the UV-C lamps had over 100 hours of usage, so no burn-in was performed before testing.

MANUFACTURER: Allanson International, Inc.

MODEL: AUVCCF600

SIZE: 23.75” x 23.75” x 6”

MAKE: AirGuard C600



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 (approximately 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 located approximately 6 feet off the chamber floor. The device was mounted in the center of the room as close to the ceiling as possible. The chamber was visually inspected, pressure tested, and all internal lab systems and equipment were reviewed before testing.

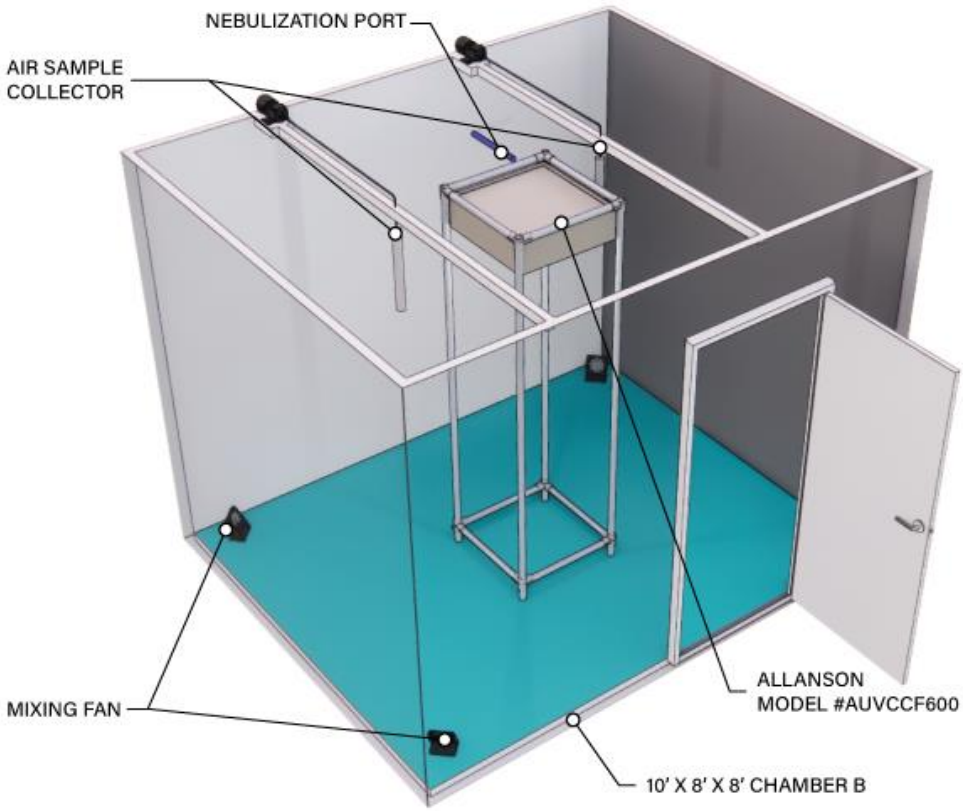


Figure 1. Room layout for control and experimental trial.

Control Protocol

A control group was conducted without the device operating in the testing chamber to assess the Allanson UV-C Ceiling Fixture accurately. 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.

Test Method

Exposure Conditions:

1. The temperature during all test runs was approximately 74.5 ±2°F with a relative humidity of 50%.
2. Samples were collected after nebulization stopped for 10-minutes (T-0) at 10, 20, and 30 minutes.

Experimental Procedure:

1. Before the initial control test and following each trial, the testing area was decontaminated and prepped per internal procedures.
2. 5 mL of a 7.43 x 10^6 TCID50/mL of SARS-CoV-2 viral media was nebulized via a dissemination port into the room.
3. After nebulization, the UV-C ceiling fixture was turned on via remote control.
4. At each predetermined time point, the device was turned off for sample collection.
5. Air sampling collections were set to 10-minute continuous draws at the point 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 each viral challenge test, the UV system inside the testing chamber was activated for 30 minutes. After 30 minutes of UV exposure, the air filtration system underwent a 30-minute air purge. 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.

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Certificate of Analysis

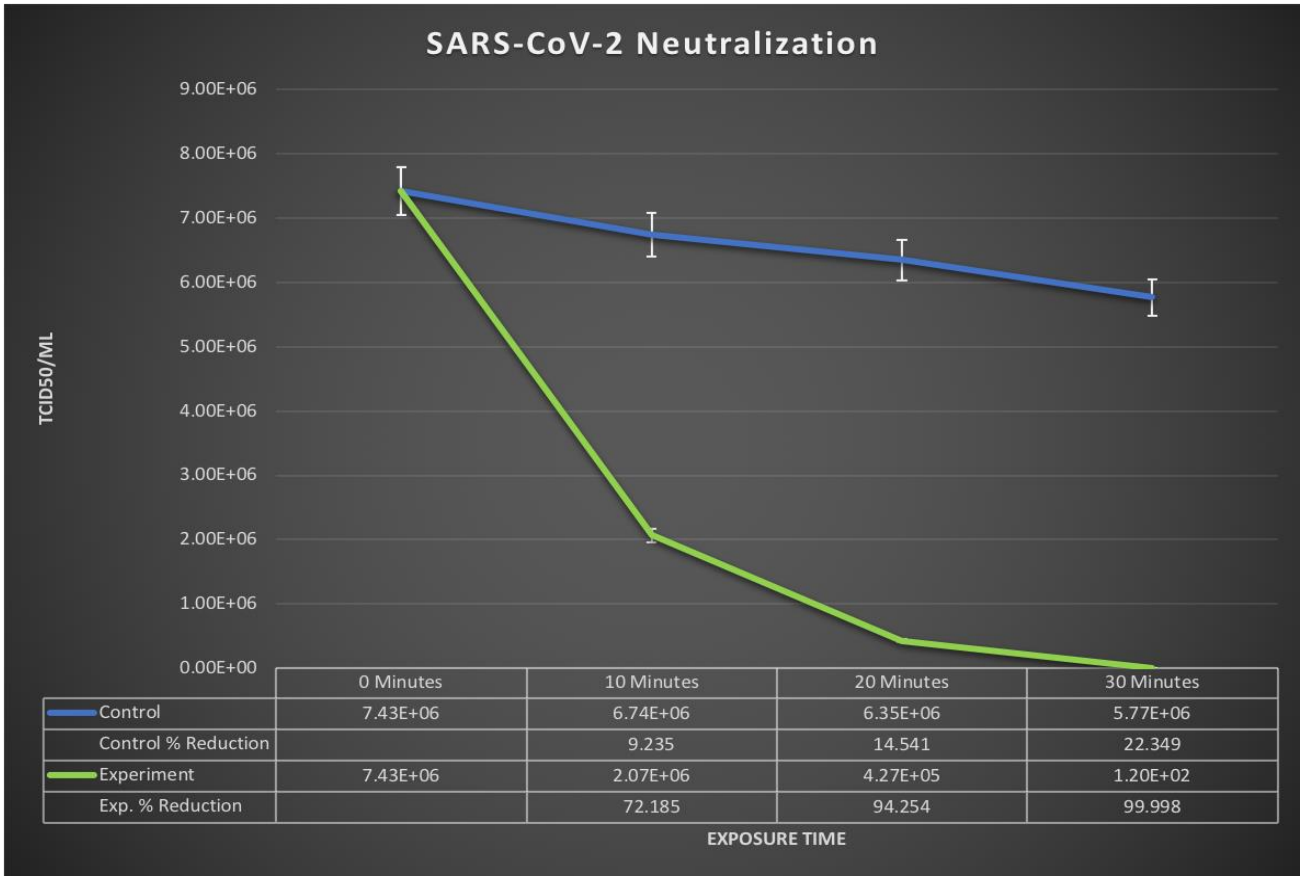
Viral Stock: SARS-CoV-2 USA-CA1/2020

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.

Study Results

Controls were plotted to show natural viability loss without the device operating in the chamber. Against SARS-CoV-2, the Allanson AirGuard C600 lowered a starting concentration of 7.43 x 10^6 TCID50/mL to 2.07 x 10^6 TCID50/mL at 10 minutes of operation. As aerosolized SARS-CoV-2 had more exposure to the device, the concentration of recoverable active SARS-CoV-2 decreased. Collectible SARS-CoV-2 was 4.27 x 10^5 TCID50/mL at 20 minutes and dropped to below quantification levels after 30 minutes.



	0 Minutes	10 Minutes	20 Minutes	30 Minutes
Control	7.43E+06	6.74E+06	6.35E+06	5.77E+06
Control % Reduction		9.235	14.541	22.349
Experiment	7.43E+06	2.07E+06	4.27E+05	1.20E+02
Exp. % Reduction		72.185	94.254	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 Allanson AirGuard C600 demonstrated the ability to significantly reduce aerosolized SARS-CoV-2 at all time points compared to the natural loss rate observed within the controlled setting. The device displayed a 72.18% reduction after 10 minutes of operation, which increased to 94.25% after 20 minutes. Furthermore, the UV-C Ceiling Fixture achieved a 99.998% reduction after 30 minutes. The study focused on the impact the UV-C Ceiling Fixture 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.

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