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AURA AIR - AIR PURIFIER AGAINST AEROSOLIZED SARS-COV-2

PROJECT: AURA AIR AEROSOL SARS-COV-2

PRODUCT: AURA AIR

CAP LIC NO: 8860298

CLIA LIC NO: 05D0955926

STATE ID: CLF 00324630

CHALLENGE ORGANISM(S):

SARS-COV-2 USA-CA1/2020

Dana Yee, M.D.

Medical Director

Study Completion Date

08/27/2021

Testing Facility

Innovative Bioanalysis, Inc.

3188 Airway Ave Suite D

Costa Mesa, CA 92626

www.InnovativeBioanalysis.com

Email: info@innovativebioanalysis.com

Laboratory Project Number

1116

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Efficacy Study Summary

Study Title	AURA AIR - AIR PURIFIER AGAINST AEROSOLIZED SARS-COV-2
Laboratory Project #	1116
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 Aura Air purification and disinfection system provided by Aura Air was designed as a wall or ceiling mount to filter and neutralize airborne pathogens within a room. This in-vitro study sought to determine the device's efficacy in reducing aerosolized SARS-CoV-2 in a controlled environment.
Test Conditions	The test was conducted in a sealed 10'x8'x8' chamber that complied with BSL-3 standards. The temperature during all test runs was approximately 77 ±2°F, with a relative humidity of 33%. A 6.32×10^6 TCID50/mL of SARS-CoV-2 in FBS-based viral media was nebulized into the room with mixing fans before collection. Air sample collections occurred at 0, 30, and 60 minutes of device operation.
Test Results	The test results displayed a more rapid reduction in viral concentration than the natural viability loss observed in the control data. Against SARS-CoV-2, after 30 minutes of operation, a 6.65×10^5 TCID50/mL of SARS-CoV-2 was recovered in the air and achieved a 1.20×10^2 TCID50/mL, indicating a titer lower than the limits of quantitation after 60 minutes.
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 wall-mounted Aura Air demonstrated a significant ability in reducing active SARS-CoV-2 in the air, as shown by the 99.998% reduction achieved after 60 minutes of device operation.

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Study Report

Study Title: AURA AIR – AIR PURIFIER AGAINST AEROSOLIZED SARS-COV-2

Sponsor: Aura Air

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

Device Testing: Aura Air

Study Report Date: 08/31/2021
Experimental Start Date: 07/13/2021
Experimental End Date: 08/03/2021
Study Completion Date: 08/27/2021

Study Objective:

Aura Air supplied a smart air device designed to potentially purify indoor air of viral and other pathogenic particles for testing purposes. This study aimed to measure the device's ability to purify air contaminated by, as well as inactivate SARS-CoV-2.

Test Method:

Bioaerosol Generation:

The nebulizer was filled with a 6.32 x 10^6 TCID50/mL of FBS-based viral media of SARS-CoV-2 USA-CA1/2020 and nebulized at a 1 mL/min flow rate 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:

There were 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. The unit utilizes a multi-cascade system containing filters and a UV-C LED to disinfect and purify the air. The device was powered on to confirm functionality before testing.

MANUFACTURER: Aura Smart Air Ltd.

MODEL: Aura Air Rev 1.0

SIZE: 15"x15"x6"

MAKE: Aura Air

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 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 connected to calibrated Gilian 10i vacuum devices positioned along the centerline and 6’ off the chamber floor for air sampling. The device was mounted in the center of the 10-foot wall opposite the dissemination port, approximately 5’ above the floor. The chamber was visually inspected, pressure tested, and all internal lab systems and equipment were reviewed before testing.

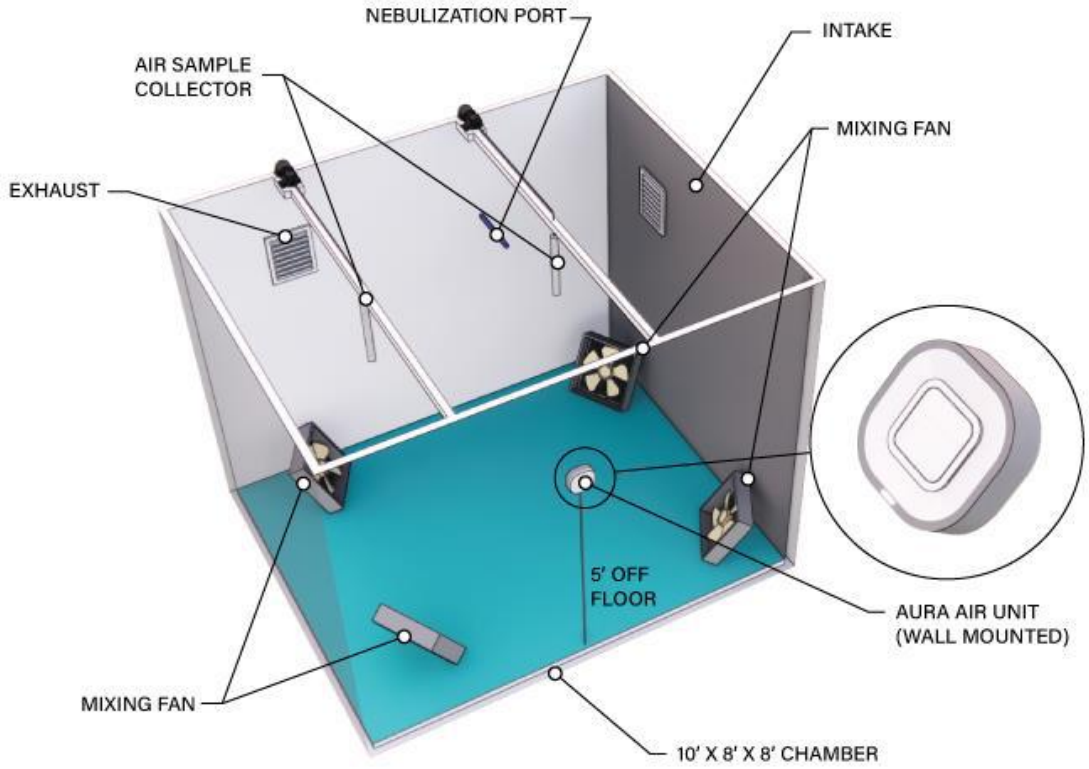


Figure 1. Room layout for control and experimental trial.

Test Method:

Exposure Conditions:

1. Before the initial control test and following each trial, the testing area was decontaminated and prepped per internal procedures.
2. The temperature during all test runs was approximately 77 ±2°F, with a relative humidity of 33%.
3. Samples were collected after nebulization stopped for 10-minutes (T-0) at 30 and 60 minutes.

Experimental Procedure:

1. 5 mL of a 6.32 x 10^6 TCID50/mL SARS-CoV-2 viral media was nebulized via a dissemination port into the room.
2. After nebulization, the wall mounted Aura Air unit was turned on via remote control.
3. At each predetermined time point, the device was turned off for sample collection.
4. Air sampling collections were set to 10-minute continuous draws at the point of sampling.
5. 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.
6. 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-C system inside the testing chamber was activated for 30 minutes. After 30 minutes of UV-C exposure, there was a 30-minute air purge through the air filtration system. 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.

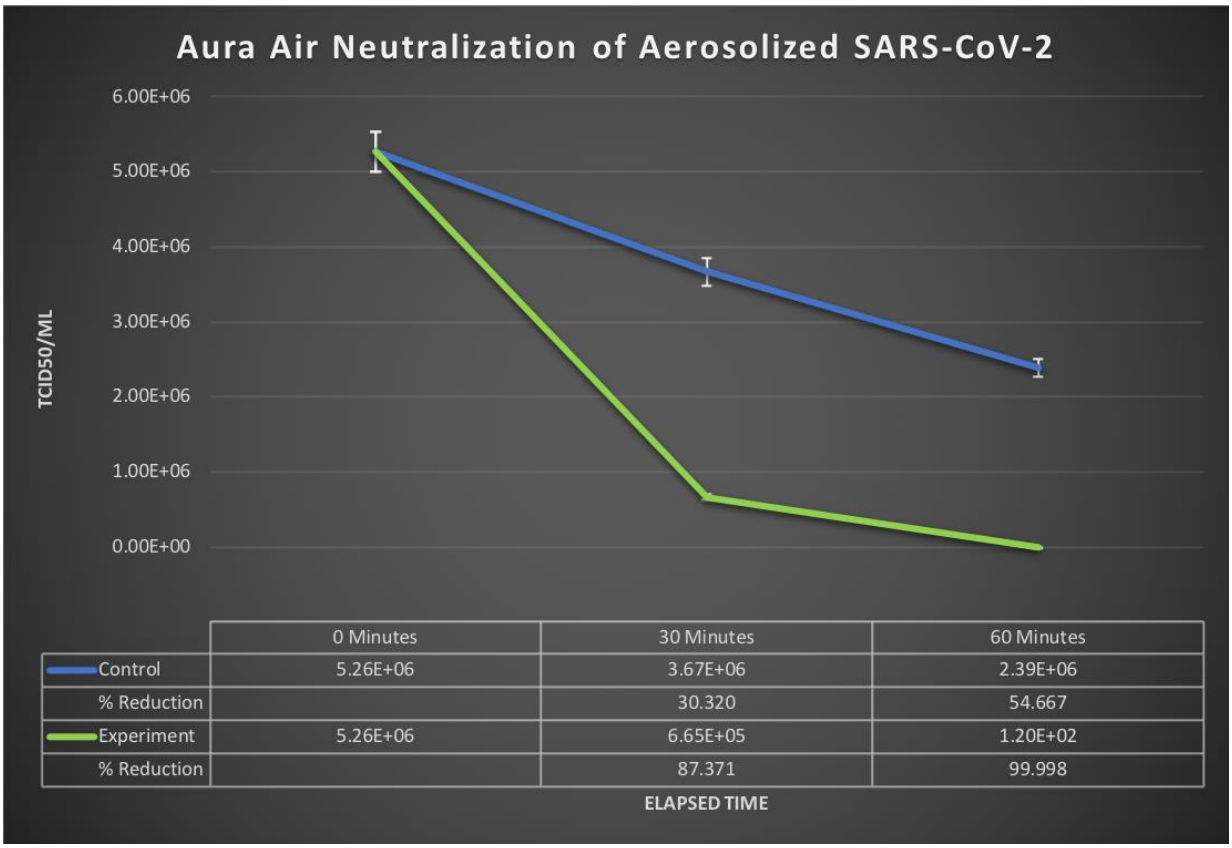
Control Protocol

A control was conducted without the device operating in the testing chamber to assess the Aura Air unit 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.

Study Results

The results were plotted, showing the amount of collectible active SARS-CoV-2 with and without the Aura Air operating over 60 minutes. The control displayed a natural viability loss over time, while the Aura Air displayed a more rapid reduction. Against SARS-CoV-2, 6.65 x 10^5 TCID50/mL of active SARS-CoV-2 was collected after 30 minutes of exposure, indicating an 87.37% reduction from a starting concentration of 5.26 x 10^6 TCID50/mL. After 60 minutes, the Aura Air achieved a loss greater than the quantitation limits, indicative of a 99.998% reduction.

RESULTS:



	0 Minutes	30 Minutes	60 Minutes
Control	5.26E+06	3.67E+06	2.39E+06
% Reduction		30.320	54.667
Experiment	5.26E+06	6.65E+05	1.20E+02
% Reduction		87.371	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 wall-mounted Aura Air device demonstrated the ability to significantly reduce concentrations of active SARS-CoV-2 from the air in a controlled environment. After 30 minutes of operation, the device achieved an 87.37% reduction. With a longer exposure time, the device reduced collectible SARS-CoV-2 to below quantitation limits, indicating a 99.998% reduction. The study focused on the impact the wall-mounted unit 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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DocuSigned by:
Dana Yee
7D5A69A0907947B...

9/15/2021

Dana Yee M.D **Date**

Clinical Pathologist and Medical Director, Innovative Bioanalysis, Inc.

DocuSigned by:
Sam Kabbani
8B4B282DF4B34A3...

9/14/2021

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

Chief Scientific Officer, Innovative Bioanalysis, Inc.

DocuSigned by:
Albert Brockman
06DF5C77A0D2400...

9/14/2021

Albert Brockman **Date**

Chief Biosafety Officer, Innovative Bioanalysis, Inc.

DocuSigned by:
Kevin Noble
5DF2797BAA78421...

9/14/2021

Kevin Noble **Date**

Laboratory Director, Innovative Bioanalysis, Inc.

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