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EFFICACY OF THE TADIRAN AIR CARE O2-1 AGAINST AEROSOLIZED SARS-COV-2

PROJECT: TADIRAN AIR CARE O2-1 - SARS-COV-2

PRODUCT: AIR CARE O2-1

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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Laboratory Project Number

1190

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Efficacy Study Summary

Study Title	EFFICACY OF THE TADIRAN AIR CARE O2-1 AGAINST AEROSOLIZED SARS-COV-2
Laboratory Project #	1190
Guideline:	Modified ISO standards as no test standards exist for this testing.
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 Tadiran Air Care O2-1 was designed to emit H_2O_2 molecules to decrease concentrations of pathogens in the air while operational. The Air Care O2-1 is built to the technologies of Air Care O2. This in vitro study sought to evaluate the device's ability to reduce aerosolized SARS-CoV-2 within a 1-meter cubed test box.
Test Conditions	The test was conducted in a sealed 1-m^3 test box located inside a BSL-3 chamber. The temperature during testing was approximately 76 ±4°F (24 ±2°C), with a relative humidity of 31 ±4%. The nebulizer was filled with the 7.02 x 10^6 Median Tissue Culture Infectious Dose per mL (TCID50/mL) in viral media and nebulized at a constant rate into the testing chamber. Air samples were collected 10 minutes after nebulization stopped (T-0) 30, 60, 90, 120, and 150 minutes after running the device.
Test Results	At 30 minutes, the Air Care O2 unit reduced the starting concentration from 7.02 x 10^6 TCID50/mL to 8.46 x 10^5 TCID50/mL. As time elapsed, the device consistently reduced collectible aerosolized SARS-CoV-2 as seen by the amount collected at 60 minutes (9.60 x 10^3 TCID50/mL) and 90 minutes (1.20 x 10^2 TCID50/mL).
Control Results	With the Air Care O2-1 unit not operating in the test environment, there was a 29.28% reduction at 60 minutes and a 69.74% reduction at 150 minutes. The results displayed a natural viability loss in the chamber and were used as a comparative baseline to calculate net viral reduction.
Conclusion	Overall, the Air Care O2-1 system as it was set up demonstrated observable ability to reduce aerosolized SARS-CoV-2 compared to natural loss rates. The device achieved the following reductions: 87.947% at 30 minutes, 99.863% at 60 minutes, and 99.998% at 90, 120 and 150 minutes of operation.

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Study Report

Study Title: EFFICACY OF THE TADIRAN AIR CARE O2-1 AGAINST AEROSOLIZED SARS-COV-2

Sponsor: Tadiran Consumer & Technology Products Ltd.

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

Device Testing: Air Care O2-1

Study Report Date: 11/15/2021
Experimental Start Date: 10/14/2021
Experimental End Date: 10/21/2021
Study Completion Date: 11/14/2021

Study Objective:

Tadiran provided the Air Care O2-1 for testing purposes to determine efficacy against viral pathogens. This study evaluated the effectiveness of the Air Care O2-1 at reducing 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 Median Tissue Culture Infectious Dose (TCID50) per mL viral media of SARS-CoV-2 and nebulized at a 1 mL/min flow rate with untreated local atmospheric air. The average particle size was approximately 0.8 µm. 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 three 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 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 from the manufacturer and was inspected for damage upon arrival. The system came with a power supply control box, preset fan, and internal components, all assembled and installed before arrival at the laboratory. The device was powered on to confirm functionality and safety before testing using the product setup procedure provided by the manufacturer. RKI air monitoring systems continuously sampled the air for O_3, H_2O_2, N_20 production to ensure safe working conditions for staff. No alarms for elevated O_3 were activated during testing. Air sampling for H_2O_2 was not designed for sub 50ppb measurements and is only a guideline.

MANUFACTURER: Tadiran Consumer & Technology Products Ltd.

MODEL: Air Care O2-1

SIZE: 4.98" x 4.05" x2.95"

MAKE: N/A

PN: 51619202400

Testing Layout:

Testing was conducted inside a sealed 1-m^3 test box located inside a BSL-3 room that followed BSL-3 standards. The chamber remained closed to prevent any air from entering and leaving the room during testing. The device with an attached preset fan was placed in the center of the test box on top of a support structure. A nebulizing port connected to a programmable compressor system was located behind and above the testing device, as seen in Figure 1. The test box was equipped with three probes positioned along the centerline of the top of the test chamber and protruded 10” down into the testing chamber. Before testing, the box and room were pressure tested and visually inspected for leaks. Also, all equipment required for testing underwent a function test to confirm proper working conditions.

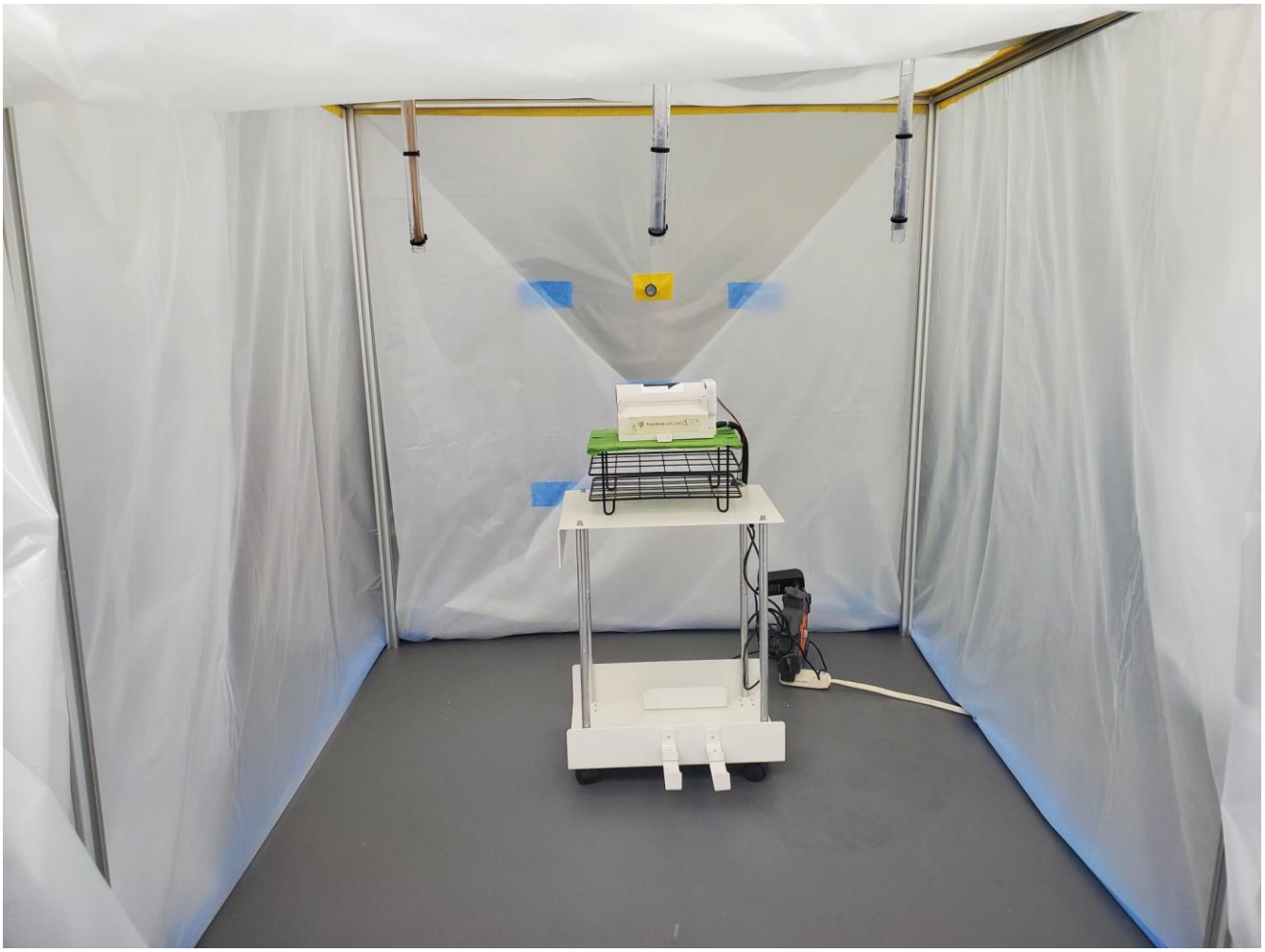


Figure 1. Testing layout for control and experimental trials.

Test Method:

Exposure Conditions:

1. The temperature during all test runs was approximately 76 ±4°F (24 ±2°C) with a relative humidity of 31 ±4%.
2. Samples were collected after nebulization stopped for 10-minutes (T-0) at 30, 60, 90, 120, and 150 minutes.

Experimental Procedure:

1. Before the initial control test and following each trial, the testing area was decontaminated and prepped per internal procedures.
2. 1 mL of a 7.02 x 10^6 TCID50/mL of SARS-CoV-2 viral media was nebulized via a dissemination port into the room.
3. After nebulization, the Air Care O2-1 unit 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 pooling 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, 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

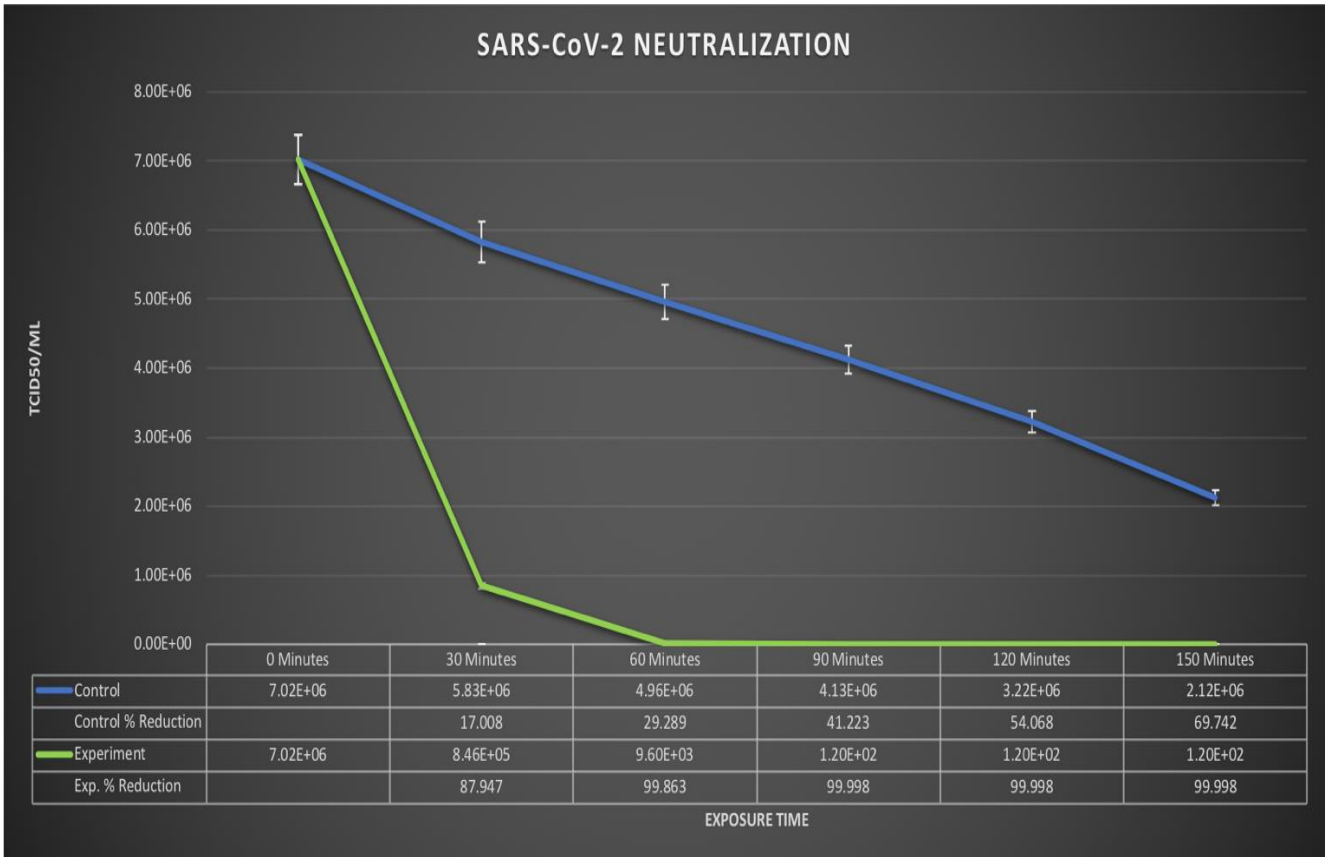
*The viral titer listed in the Certificate of Analysis is representative of the titer provided by BEI Resources. These viruses are grown on VeroE6 cells either in-house or at a partner lab to the concentrations listed within the experiment design.

Control Protocol

To accurately assess the Air Care O2-1 unit, a control group was conducted without the Air Care system running. 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

Controls displayed a natural viability loss within the testing environment for 150 minutes. At 30 minutes against aerosolized SARS-CoV-2, the device decreased a 7.02 x 10^6 TCID50/mL starting concentration to 8.46 x 10^5 TCID50/mL. The concentration of collectible SARS-CoV-2 decreased over time with 9.60 x 10^3 TCID50/mL at 60 minutes and reached below assay quantification levels after 90 minutes. The data showed that after 90 minutes of operation, the device achieved a 99.998% reduction.



	0 Minutes	30 Minutes	60 Minutes	90 Minutes	120 Minutes	150 Minutes
Control	7.02E+06	5.83E+06	4.96E+06	4.13E+06	3.22E+06	2.12E+06
Control % Reduction		17.008	29.289	41.223	54.068	69.742
Experiment	7.02E+06	8.46E+05	9.60E+03	1.20E+02	1.20E+02	1.20E+02
Exp. % Reduction		87.947	99.863	99.998	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; the percentage error equates to an average of ±5% of the final concentration.

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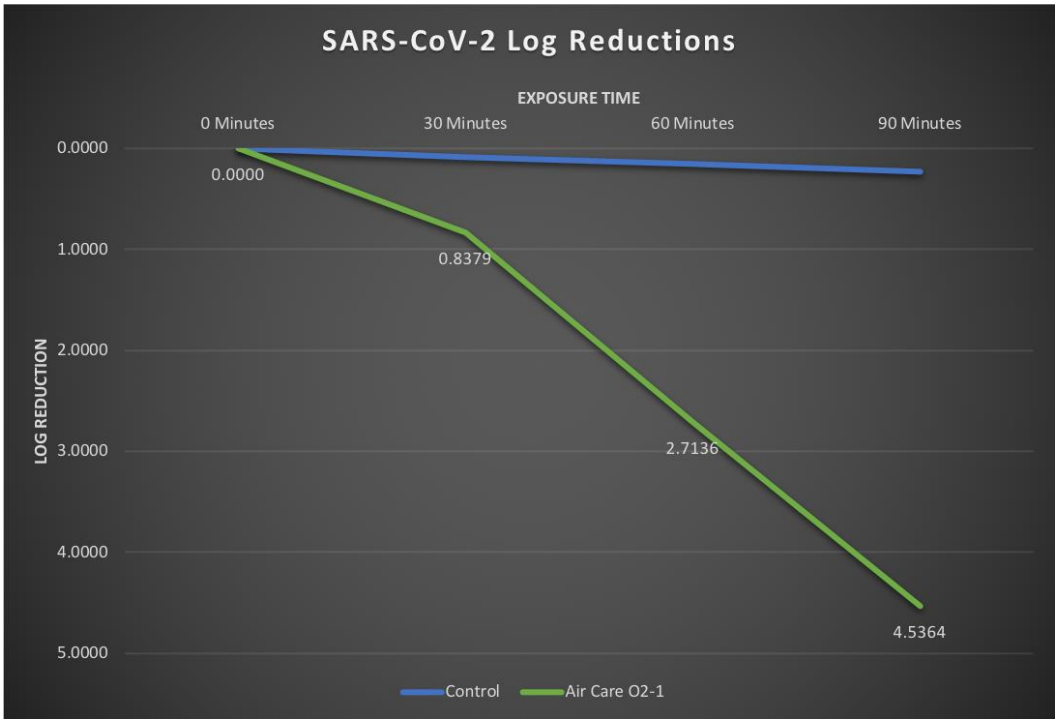
VIRAL VOLUME REDUCTION OF SARS-COV-2		
	Control	Air Care O2-1
0 Minutes	7.02E+06	7.02E+06
30 Minutes	5.83E+06	8.46E+05
60 Minutes	4.96E+06	9.60E+03
90 Minutes	4.13E+06	1.20E+02
120 Minutes	3.22E+06	1.20E+02
150 Minutes	2.12E+06	1.20E+02

VIRAL LOG REDUCTION OF SARS-COV-2		
	Control	Air Care O2-1
0 Minutes	0.0000	0.0000
30 Minutes	0.0810	0.8379
60 Minutes	0.1505	2.7136
90 Minutes	0.2308	4.5364



Conclusion

The Tadiran Air Care O2-1 demonstrated a consistently higher reduction of aerosolized SARS-CoV-2 USA-CA1/2020 within a 1-m^3 test box over 150 minutes compared to the natural loss rates observed during testing. The device achieved an 87.94% reduction after 30 minutes, 99.86% reduction after 60 minutes, and reached a 99.998% reduction after 90 minutes. As the test was designed to observe aerosol functions, it is unknown if any active pathogen remained on the surface areas inside the unit or the chamber walls. Furthermore, the study focused on the impact the Air Care O2-1 unit would have against an aerosolized pathogen in a specific volume of space. Therefore, when applied to a different size room, the results will scale and vary due to variables present, such as room size, air movement, and more. Every effort was made to simulate a replicable situation and address constraints with the experimental design and execution while taking the proper precautions when working with a BSL-3 pathogen.

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