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EFFICACY OF NOVAERUS DEFEND 400 AGAINST AEROSOLIZED SARS-COV-2

PROJECT: NOVAERUS DEFEND 400 AEROSOL SARS-COV-2

PRODUCT: DEFEND 400

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

1079

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Efficacy Study Summary

Study Title	EFFICACY OF NOVAERUS DEFEND 400 AGAINST AEROSOLIZED SARS-COV-2
Laboratory Project #	1079
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 Defend 400 unit was designed as a portable standalone air purifying unit for use in large environments and situations with a high risk of infection. This in-vitro study is being conducted to determine the efficacy of the Defend 400 device in reducing a known pathogen, SARS-CoV-2, in aerosol form when operating.
Test Conditions	The test was conducted in a 20'x8'x8' chamber that complied with BSL-3 standards. The temperature during all test runs was approximately 76 ±2°F (24.4 ±1.1°C), with a relative humidity of 33%. A 6.32×10^6 TCID50/mL of SARS-CoV-2 in viral suspension media was nebulized into the room with mixing fans before collection. Air sample collections occurred at 0, 15, and 45 minutes of device operation.
Test Results	The test results displayed a more rapid reduction in viral concentration than the natural viability loss rates observed. After 15 minutes of operation, the viral concentration decreased from a starting value of 6.32×10^6 TCID50/mL to 3.45×10^6, 3.19×10^6, and 3.00×10^6 TCID50/mL, averaging to approximately 3.21×10^6 TCID50/mL, a 49.20% reduction. With the device operating for 45 minutes, collectible SARS-CoV-2 decreased to an average of 8.76×10^3 TCID50/mL, a 99.86% reduction.
Control Results	A control test was conducted twice 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 Defend 400 demonstrated the ability to reduce the concentration of active SARS-CoV-2 from the air at a more rapid rate with an average of 49.20% reduction after 15 minutes and 99.86% after 45 minutes. A net reduction of 99.75% was achieved with the device operating for a total of the 45 minutes time point.

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Study Report

Study Title: EFFICACY OF NOVAERUS DEFEND 400 AGAINST AEROSOLIZED SARS-COV-2

Sponsor: WellAir

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

Device Testing: Novaerus Defend 400

Study Dates:

Study Report Date: 09/27/2021

Experimental Start Date: 08/23/2021

Experimental End Date: 08/27/2021

Study Objective:

WellAir supplied the Novaerus Defend 400 for testing purposes to determine efficacy against viral pathogens in the air. This study evaluated the effectiveness of the Defend 400 in its ability to reduce the viral strain referred to as SARS-CoV-2 USA-CA1/2020.

Test Method:

Bioaerosol Generation:

The nebulizer was filled with a 6.32 x 10^6 TCID50/mL viral suspension 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:

This study used four probes for air sampling, each connected to a calibrated Gilian 10i vacuum device. Before use, the equipment was 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 discs are manufactured by Zefon International.

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. All filters were installed before arrival at the laboratory. The device was powered on to confirm functionality before testing.

MANUFACTURER: Novaerus

MODEL: Defend 400

SIZE: N/A

MAKE: Novaerus

SERIAL #: 2004-2109-0001

Testing Layout:

Testing was conducted in a sealed 20'x8'x8' chamber following Biosafety Level 3 (BSL-3) standards. The room had a displacement volume of 1,280 cubic feet, approximately 36,245.56 liters of air. A nebulizing port connected to a programmable compressor system was located in the center of the 20' wall protruding 24" from the wall opposite the door. At each chamber corner, a low-volume mixing fan was positioned at 45-degree angles to ensure homogenous mixing of bioaerosol concentrations when nebulized into the chamber. The chamber was equipped with four probes, each connected to a calibrated Gilian 10i vacuum device positioned along the room's centerline and protruded down from the ceiling 24". The device was placed on the floor in the center of the testing chamber. The chamber was visually inspected, pressure tested, and all internal lab systems and equipment were reviewed before testing.

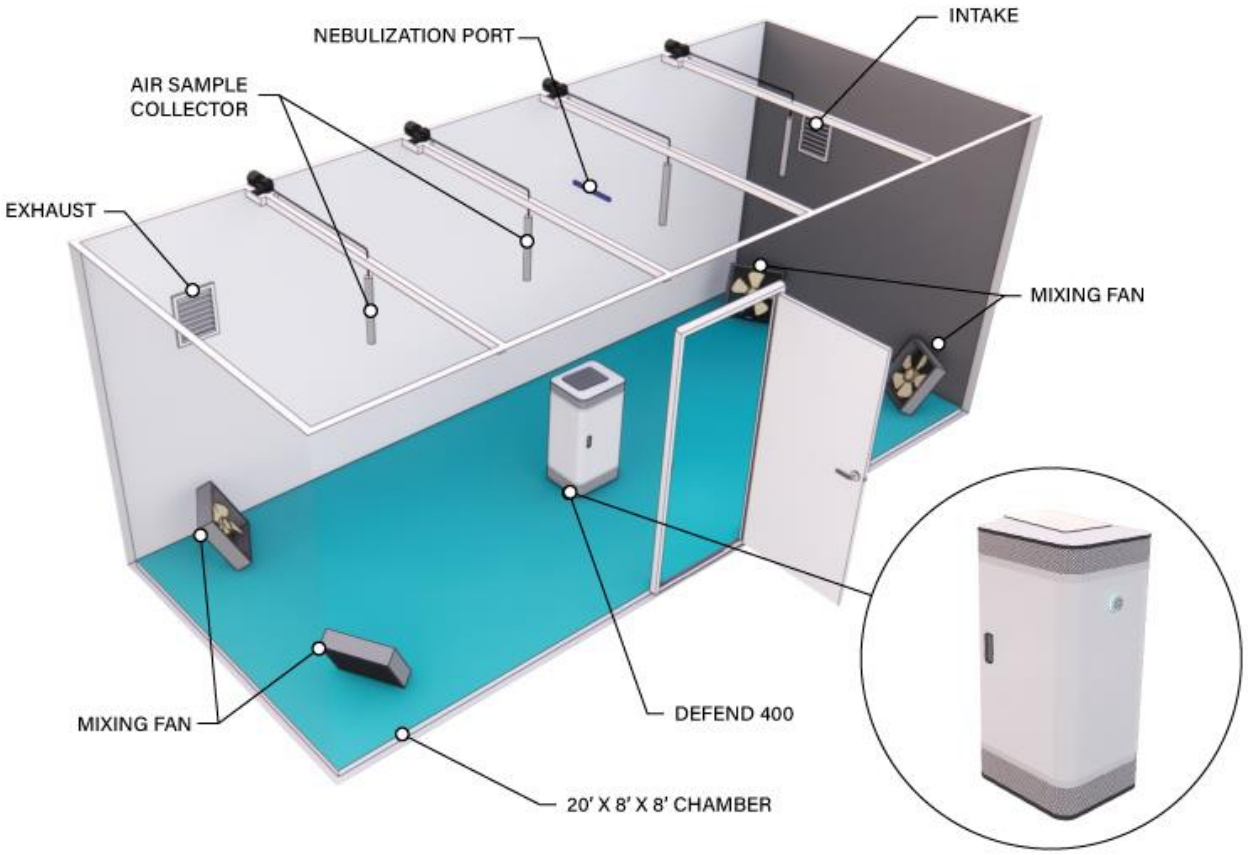


Figure 1. Room layout for control and experimental trial.

Test Method:

Exposure Conditions:

1. The temperature during all test runs was approximately 76 ±2°F (24.4 ±1.1°C), with a relative humidity of 33%.
2. Samples were collected after nebulization stopped (T-0) at the following time points with T equal to minutes: T-15 and T-45.
3. Controls were conducted in duplicate and viral challenge in triplicates using the same methodology.
4. Fan speed was set to high for all testing.

Nebulization:

1. Before the initial control test and following each trial, the testing area was decontaminated and prepped per internal procedures.
2. 10mL of 6.32 x 10^6 TCID50/mL SARS-CoV-2 viral media was nebulized via a dissemination port into the room.
3. After nebulization, the Novaerus Defend 400 system was turned on via remote control with the fan setting on high.
4. The device was turned off at the pre-determined time points for sample collection.
5. The sample cassettes were manually removed from the collection system after each control run and each air pass challenge and pooled.
6. Upon cassette removal after each challenge, cassette sets were taken to an adjacent biosafety cabinet for extraction and placement into viral suspension media.

Post Decontamination:

After each viral challenge test, the UV system inside the testing chamber was activated for 30 minutes as part of the decontamination process. After 30 minutes of UV exposure, there was a 30-minute air purge through the air filtration system. All 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.

Control Protocol

To accurately assess the Novaerus Defend 400, a control was conducted in duplicate. Control samples were taken 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.

Preparation of The Pathogen

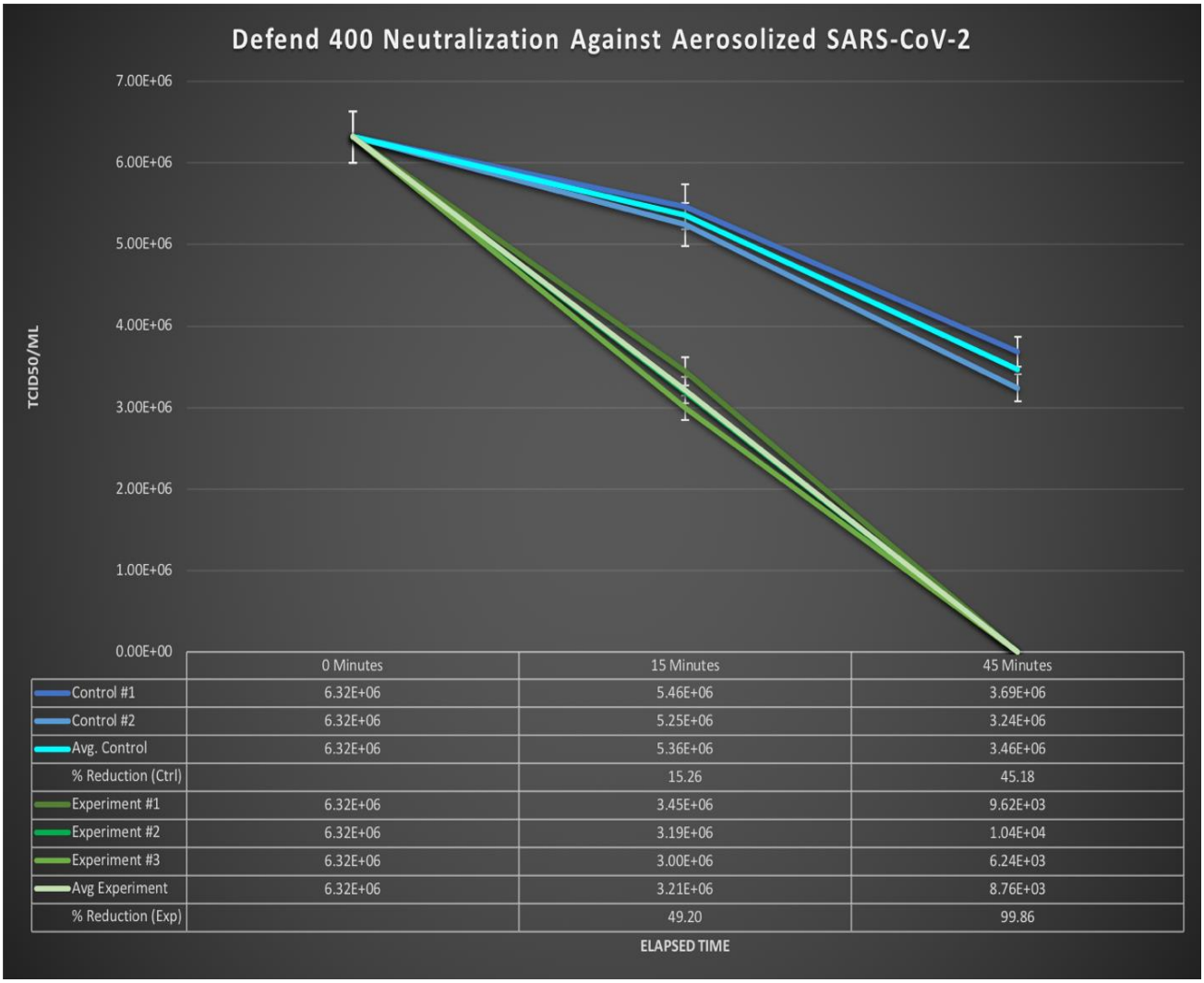
Viral Stock: SARS-CoV-2 USA-CA1/2020 (BEI NR-52382)

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.

Study Results

The plotted results show the concentration of active SARS-CoV-2 collected with and without the Defend 400 over 45 minutes. The control data displayed a natural viability loss over time in the chamber. The device was observed to have decreased an initial concentration of 6.32 x 10^6 TCID50/ml to 3.45 x 10^6, 3.19 x 10^6, and 3.00 x 10^6 TCID50/mL, averaging to approximately 3.21 x 10^6 TCID50/mL after 15 minutes of operation. After 45 minutes, the observed viral concentration dropped to an average of 8.76 x 10^3 TCID50/mL, indicative of a 99.86% reduction.



	0 Minutes	15 Minutes	45 Minutes
Control #1	6.32E+06	5.46E+06	3.69E+06
Control #2	6.32E+06	5.25E+06	3.24E+06
Avg. Control	6.32E+06	5.36E+06	3.46E+06
% Reduction (Ctrl)		15.26	45.18
Experiment #1	6.32E+06	3.45E+06	9.62E+03
Experiment #2	6.32E+06	3.19E+06	1.04E+04
Experiment #3	6.32E+06	3.00E+06	6.24E+03
Avg Experiment	6.32E+06	3.21E+06	8.76E+03
% Reduction (Exp)		49.20	99.86

**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.

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Defend 400 Neutralization Against SARS-CoV-2			
Time (min)	**0**	**15**	**45**
Control 1	6.32E+06	5.46E+06	3.69E+06
Control 2	6.32E+06	5.25E+06	3.24E+06
Test 1	6.32E+06	3.45E+06	9.62E+03
Test 2	6.32E+06	3.19E+06	1.04E+04
Test 3	6.32E+06	3.00E+06	6.24E+03
Control AVG	6.320E+06	5.355E+06	3.465E+06
Test AVG	6.320E+06	3.213E+06	8.753E+03
Net Reductions	0.00%	-40.00%	-99.75%

Conclusion:

The Novaerus Defend 400 demonstrated the ability to reduce concentrations of aerosolized SARS-CoV-2 from the air significantly. An average 49.20% reduction was observed after 15 minutes in the sealed, controlled environment. After 45 minutes of exposure, the Defend 400 achieved an average of 99.86% reduction, a net reduction of 99.75%. The device showed a consistent ability to reduce collectible pathogen significantly faster than natural loss rates. 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 testing chamber walls.

Furthermore, the study focused on the impact the device would have on a specific volume of space. Therefore, when applied to a different size room, the results will scale and vary. Every effort was made to simulate a real-life situation and address constraints with the experimental designs 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 controls.

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