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EFFICACY OF THE TADIRAN AIROW 3 INSTALLED INTO THE TADIRAN SUPREME 10 MINI SPLIT AGAINST SARS-COV-2

PROJECT: TADIRAN AIROW 3 AEROSOL - SARS-COV-2

PRODUCT: TADIRAN AIROW 3 (INSTALLED INTO SUPREME 10 MINI SPLIT)

CAP LIC NO: 8860298

CLIA LIC NO: 05D0955926

STATE ID: CLF 00324630

CHALLENGE ORGANISM(S):

SARS-COV-2 USA-WA1/2020

Study Completion Date:

09/01/2022

Medical Director

Dana Yee, M.D.

Testing Facility

Innovative Bioanalysis, Inc.

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Laboratory Project Number

1275

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Table of Contents

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Efficacy Study Summary

Study Title	EFFICACY OF THE TADIRAN AIROW 3 INSTALLED INTO TADIRAN SUPREME 10 MINI SPLIT AGAINST SARS-COV-2
Laboratory Project #	1275
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-WA1/2020
Description	Tadiran provided a AIROW 3 installed into a Supreme 10 mini split for testing. Per the manufacturer, the mini split with the AIROW 3 was designed to provide temperature control while reducing pathogen concentrations within a room. The study aims to test and quantify the unit's efficacy in lowering active aerosolized SARS-CoV-2 USA-WA1/2020 in a controlled environment.
Test Conditions	Testing was conducted in an 11' x 6.5' x 8' chamber following BSL-3 standards. The temperature during testing was approximately 74 ±2°F, with a relative humidity of 40%. A 6.86×10^6 TCID50/mL of SARS-CoV-2 in suspension media was nebulized into the room with mixing fans before collection. Each test was completed as a 90-minute continuous run with air sample collections at 0, 30, 60, and 90 minutes of device operation with 10-minute air sampling.
Test Results	The experiment showed a more rapid reduction in viral concentration than the natural viability loss observed in the controls. The AIROW 3 installed into a Supreme 10 mini split decreased from a 6.86×10^6 TCID50/mL starting concentration to 1.02×10^6 TCID50/mL after 30 minutes. Increased operation time resulted in a higher observed reduction with a 1.53×10^3 TCID50/mL of recovered active SARS-CoV-2 after 60 minutes and 1.20×10^2 TCID50/mL after 90 minutes, indicating a titer below assay quantitation.
Control Results	Control testing was conducted with the device turned off, and samples were taken at the corresponding time points used for the challenge. The control results displayed an 85.36% viability loss after a 90-minute continuous run. The data was used as a comparative baseline to calculate viral reduction.
Conclusion	The AIROW 3 installed into a Supreme 10 mini split demonstrated the ability to reduce active SARS-CoV-2 in the air, as shown by the 85.20% (0.83 log reduction) gross reduction at 30 minutes, 99.98% reduction at 60 minutes, and reaching at least a 99.998% (4.76 log) reduction after 90 minutes.

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Study Report

Study Title: EFFICACY OF THE TADIRAN AIROW 3 INSTALLED INTO TADIRAN SUPREME 10 MINI SPLIT AGAINST 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: AIROW 3 installed into a Supreme 10 mini split

Study Dates:

Study Report Date: 09/08/2022

Experimental Start Date: 08/03/2022

Experimental End Date: 08/04/2022

Study Completion Date: 09/01/2022

Study Objective:

The AIROW 3 installed into a Supreme 10 mini split was provided by Tadiran and designed to decrease concentrations of pathogens within the air while operation. This in-vitro study sought to evaluate the unit's ability to reduce aerosolized SARS-CoV-2 USA-WA1/2020.

Test Method:

Bioaerosol Generation:

Nebulization occurred using a Blaustein Atomizing Module (BLAM), as shown in Figure 1, with a pre-set PSI and computer-controlled liquid delivery system. Before testing, the nebulizer was checked for proper functionality by nebulizing the solution without the test virus to confirm the average particle size distribution of approximately 0.8 µm. See Table 1 and Appendix B for particle distribution specifics from sampling of aerosolized solution in the test chamber. The nebulizer was filled with 6.86 x 10^6 TCID50/mL of SARS-CoV-2 in suspension media and nebulized at a flow rate of 1mL/min with untreated local atmospheric air. After nebulization, the nebulizer's remaining viral stock volume was visually confirmed and weighed to confirm the volume nebulized was equivalent within accepted tolerances for each run. Bioaerosol procedures for the controls and viral challenges were performed in the same manner with corresponding time points and collection rates.

Figure 1: BLAM Nebulizer

Table 1: Particle Size Distribution Table

	Number Particle Size	Surface Particle Size	Mass Particle Size
Median (µm)	0.783	1.2	2.66
Mean (µm)	0.911	2	4.56
Geo. Mean (µm)	0.845	1.43	2.98
Mode (µm)	0.723	0.777	12
Geo. St. Dev.	1.42	2.06	2.57
Total Conc.	2.45e+03(#/cm³)	7.22e+03(µm²/cm³)	2.38(mg/m³)

Bioaerosol Sampling:

This study used two probes for air sampling, each connected to a calibrated Gilian 10i vacuum device and set at a standard flow of 5.02L/min with a 0.20% tolerance. Sample collection volumes were set to 10-minute draws per time point, which allowed for approximately 50 liters of air collection per collection port. The air sampler operated with a removable sealed cassette and was manually removed after each sampling time point. A customized, sealed channel was created above the chamber for easy access to the sample collection system for cassette removal. The channel allowed for manual removal of sample cassettes after each time point without needing to enter the room. Cassettes (Fig. 2) had a delicate internal filtration disc to collect virus samples, which was moistened with a viral suspension media to aid collection. Filtration discs from Zefon International, Lot# 29114, were used for testing. All sample discs were pooled into one collection tube at each time point to provide an average across the two sampling locations.

Figure 2: Sensidyne 37mm directional air flow sample cassette.

Test System Strains: SARS-CoV-2 USA-WA1/2020

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-WA1/2020, NR-52281.

TCID50 Procedure:

Materials and Equipment:

- Certified Biological Safety Cabinet
- Micropipette and sterile disposable aerosol resistant tips—20uL, 200uL, 1000uL
- Inverted Microscope
- Tubes for dilution
- Hemocytometer with coverslip
- Cell media for infection
- Growth media appropriate for the cell line
- 0.4% Trypan Blue Solution
- Lint-free wipes saturated with 70% isopropyl alcohol
- CO_2 Incubator set at 37°C or 34°C, or other temperature as indicated

Procedure:

1. One day before infection, prepare 96 well dishes by seeding each well with Vero E6 cells in DMEM plus fetal bovine serum, 4mM Glutamine, and antibiotics.
2. On the day of infection, make dilutions of virus samples in PBS.
3. Make a series of dilutions at 1:10 of the original virus sample. Fill the first tube with 2.0mL PBS and the subsequent tubes with 1.8mL.
4. Vortex the viral samples, then transfer 20uL of the virus to the first tube, vortex, and discard tip.
5. With a new tip, serial dilute subsequent tips transferring 200uL.

Additions of virus dilutions to cells:

1. Label the lid of a 96-well dish by drawing grid lines to delineate quadruplicates, number each grid to correspond to the virus sample, and label the rows of the plate for the dilution, which will be plated.
2. Include four (4) negative wells on each plate which will not be infected.
3. Remove all but 0.1mL of media from each well by vacuum aspiration.
4. Starting from the most dilute sample, add 0.1mL of virus dilution to each of the quadruplicate wells for that dilution.
5. Infect four wells per dilution, working backward.
6. Allow the virus to absorb into the cells at 37°C for 2 hours.
7. After absorption, remove the virus inoculum. Start with the most dilute and work backward.
8. Add 0.5mL infection medium to each well, being careful not to touch the wells with the pipette.
9. Place plates at 37°C and monitor CPE using the inverted microscope over a period of 1 to 4 weeks.
10. Record the number of positive and negative wells.

Study Materials and Equipment:

Equipment Overview: The equipment (Fig. 3) arrived at the laboratory pre-packaged from the manufacturer and was inspected for damage upon arrival. The module came pre-installed in the Supreme 10 mini split upon arrival. Due to the closed design, no assessment was conducted on the inner components of the device. The test device was powered on to confirm functionality and safety before testing.

UNIT

MANUFACTURER: Tadiran

MODEL: TADIRAN SUPREME 10 (2021)

SIZE: 88.9 cm x 21.2 cm x 29.4 cm

SERIAL #: 63229995490

TECHNOLOGY

MANUFACTURER: Tadiran

NAME: AIROW 3

SIZE: 4.25” x 1.14” x 1.89”

SERIAL #: 00096173 0120

Figure 3: The Supreme 10 mini split (top) and the installed AIROW 3 module (bottom) as tested.

Testing Layout:

Testing was conducted in a sealed 11’x 6.5’x 8’ chamber per Biosafety Level 3 (BSL3) standards. The overall dimensions of the test chamber provided a displacement volume of 572 ft^3 (approximately 16,197.20 L) of air. The room remained closed to prevent any air from entering and leaving the room during testing. A nebulizing port connected to a programmable compressor system was located in the center of the 11 ft wall protruding 24 inches from the wall opposite the door. At each chamber corner, low-volume mixing fans (approx. 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 for air sampling positioned along the room's centerline and located six feet off the chamber floor. The device was mounted in the center of the chamber at the height of approximately 6.5 ft off the floor and operated only on fan speed. The chamber was visually inspected and pressure tested, and all internal lab systems and equipment were reviewed before testing.

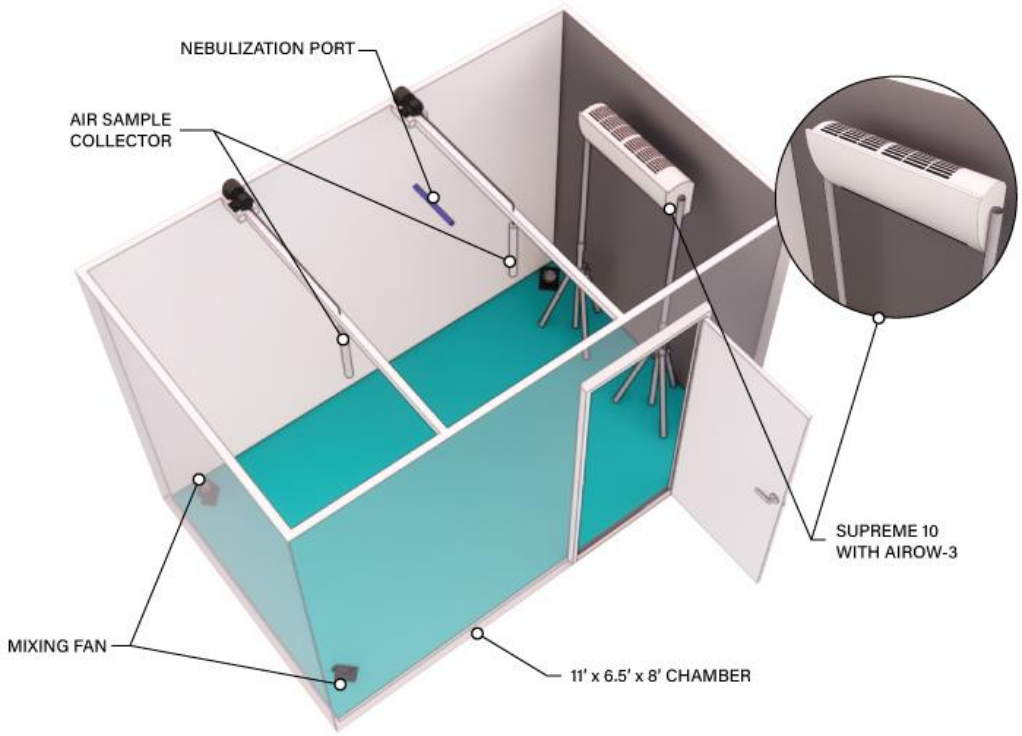

Figure 4: Room layout for control and experimental testing.

Control Protocol:

Control testing was conducted with the device turned off in the testing chamber to accurately assess the AIROW 3 installed into a Supreme 10 mini split. 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 Procedures:

Exposure Conditions:

1. The temperature during all test runs was approximately 74 ±2°F with a relative humidity of 40%.
2. The Supreme 10 with the AIROW 3 were turned on the night before and ran for 14 hours before testing.
3. The Supreme 10 mini split ran in fan mode without temperature controls.
4. Each test was conducted as a 90-minute continuous run with air sample collections at 0, 30, 60, 90, and 90 minutes.

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 a 6.86 x 10^6 TCID50/mL SARS-CoV-2 viral media was nebulized via a dissemination port into the room.
3. After nebulization, the AIROW 3 installed into a Supreme 10 mini split was turned on via remote control.
4. Air sampling collections were set to 10-minute continuous draws at the point of sampling.
5. Sample cassettes were manually removed through a sealed channel 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 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 and 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-WA1/2020 (BEI NR-52281)

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-WA1/2020 GenBank: MN985325.1	99.9% identity with SARS-CoV 2, isolate USA-WA1/2020 GenBank: MN985325.1
Sequencing of Species-Specific Region (~ 930 nucleotides)	≥ 98% identity with SARS-CoV-2, isolate USA-WA1/2020 GenBank: MN985325.1	100% identity with SARS-CoV 2, isolate USA-WA1/2020 GenBank: MN985325.1
(~ 930 nucleotides)	≥ 98% identity with SARS-CoV-2, strain FDAARGOS_983 isolate USA-WA1/2020 GenBank: MT246667.1	100% identity with SARS-CoV-2, strain FDAARGOS_983 isolate USA-WA1/2020 GenBank: MT246667.1
Titer by TCID50 in Vero E6 Cells by Cytopathic Effect	Report Results	1.6 X 10^6 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, aerobic	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 results were plotted (Fig. 5) to display collectible active SARS-CoV-2 with and without the AIROW 3 installed into a Supreme 10 mini split operating in the chamber. The controls showed natural loss of aerosolized SARS-CoV-2 for 90 minutes under controlled conditions. After 30 minutes of device operation, a starting concentration of 6.86 x 10^6 TCID50/mL SARS-CoV-2 decreased to 1.02 x 10^6 TCID50/mL. After 60 minutes, 1.53 x 10^3 TCID50/mL SARS-CoV-2 was recovered. The data showed increased device operational time resulted in higher reductions of active aerosolized pathogens, as demonstrated by the device achieving a 4-log reduction with an observed titer of 1.20 x 10^2 TCID50/mL after 90 minutes. The value 1.20 x 10^2 TCID50/mL represents a recovered viral concentration below the assay quantitation limit. See Appendix C for the $\log_{10}$ reduction graph and table.

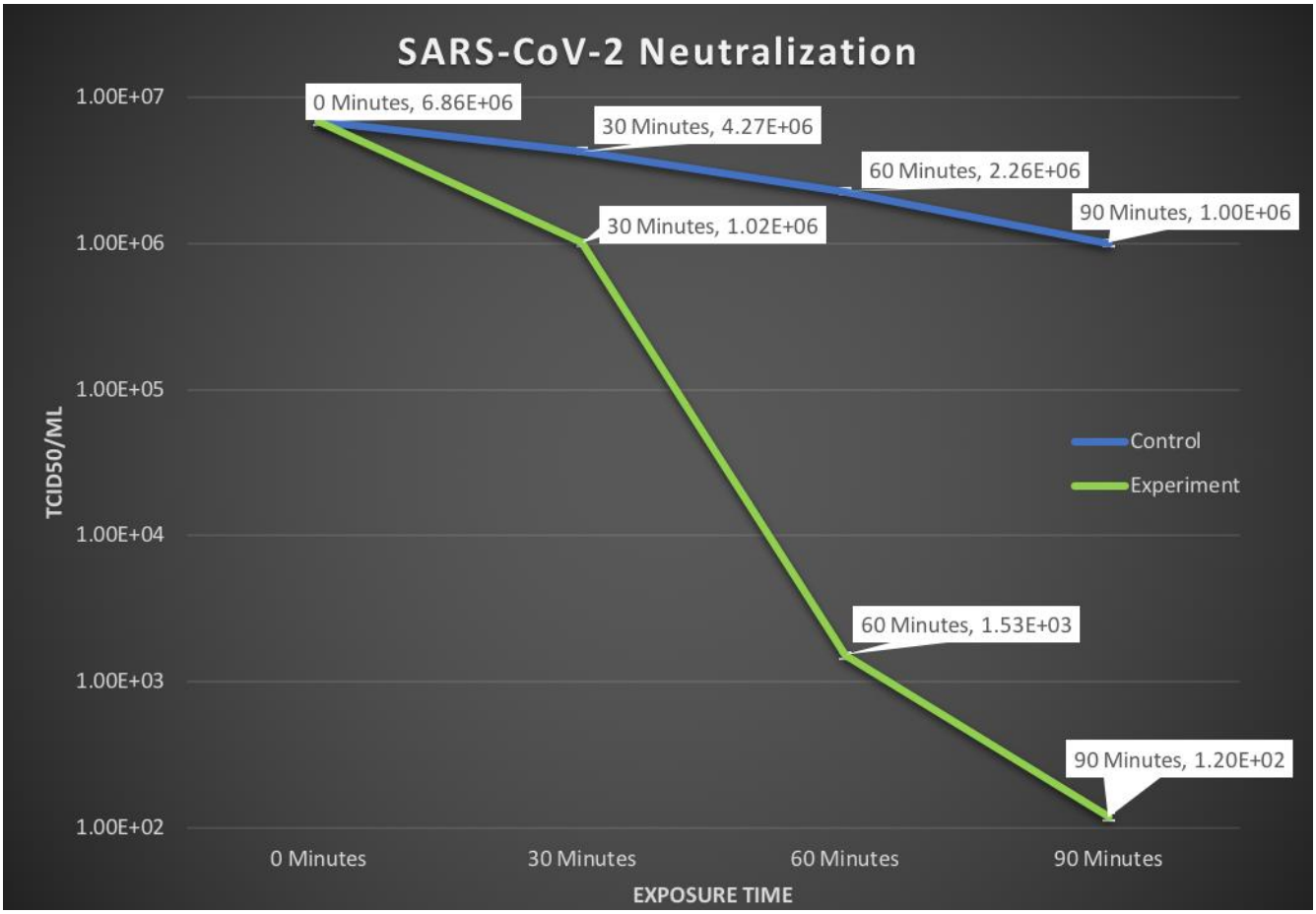

Figure 5: SARS-CoV-2 neutralization using the AIROW 3 installed into a Supreme 10 mini split for 90 minutes under controlled conditions.

***As it pertains to data represented herein, the value of 1.20E+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.*

Table 2: Results Data and Calculated Percentage Reductions

Time (min)	**0**	**30**	**60**	**90**
Control (TCID50/mL)	6.86E+06	4.27E+06	2.26E+06	1.00E+06
% Gross Reduction – Control		-37.82%	-67.01%	-85.361%
Experiment (TCID50/mL)	6.86E+06	1.02E+06	1.53E+03	1.20E+02
% Gross Reduction – Experiment		-85.20%	-99.98%	-99.998%
% Net Reduction		**-76.19%**	**-99.93%**	**-99.988%**

Conclusion:

The AIROW 3 installed into a Supreme 10 mini split demonstrated the ability to reduce active, aerosolized SARS-CoV-2 across all time points compared to the natural loss rate observed in the temperature-controlled room. After 30 minutes, the device displayed an 85.20% gross reduction of active SARS-CoV-2. With more prolonged exposure, the device has more time to interact with the air reducing the amount of pathogen recovered, as shown by the 99.98% gross reduction observed after 60 minutes and achieving at least a 99.998% gross reduction at 90 minutes.

When aerosolizing and collecting said pathogens, some variables cannot be fully accounted for, namely, placement of pathogen, collection volume, collection points, drop rate, surface saturation, viral destruction upon collection, viral destruction on aerosolization, and possibly others. Every effort was made to address these constraints with the design and execution of the trials. And these efforts are reflected in the meaningful recovery of the virus in the control test.

Considering the variables, the AIROW 3 installed into a Supreme 10 mini split achieved a measurable reduction at each time point (T-30, T-60, and T-90). The results observed were consistent with the manufacturer's claim that the device can decrease concentrations of active pathogens within the room. Overall, under controlled conditions, the AIROW 3 installed into a Supreme 10 mini split resulted in a 0.83 log reduction of SARS-CoV-2 at 30 minutes and achieved at least a 4.76 log reduction at 90 minutes.

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12/16/2022

Dana Yee M.D **Date**

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12/15/2022

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APPENDIX A: Glossary of Terms

CAP: The College of American Pathologists (CAP), the leading organization of board-certified pathologists, serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. A laboratory can pursue a higher level of quality by becoming accredited by The College of American Pathologists (CAP).

CLIA: The Clinical Laboratory Improvement Amendments of 1988 (CLIA) are federal regulations for the United States-based clinical laboratories to provide industry standards for testing human samples for diagnostic purposes.

COA: A Certificate of Analysis refers to an authenticated document that is issued by BEI or ATCC Quality Assurance Department that ascertains that a product has met its predetermined pathogen specifications and preparations.

DMEM: Dulbecco's Modified Eagle Medium (DMEM) is a widely used basal medium for supporting the growth of many different mammalian cells.

FBS: Fetal bovine serum (FBS) is derived from the blood drawn from a bovine fetus via a closed collection system at the slaughterhouse. Fetal bovine serum is the most widely used serum supplement for the in vitro cell culture of eukaryotic cells. This is because it has an extremely low level of antibodies and contains more growth factors, allowing for versatility in many different cell culture applications.

The globular protein, bovine serum albumin (BSA), is a major component of fetal bovine serum. The rich variety of proteins in fetal bovine serum maintains cultured cells in a medium where they can survive, grow, and divide.

Because it is a biological product, FBS is not a fully defined media component and varies in composition between batches. As a result, serum-free and chemically defined media (CDM) have been developed to minimize the possibility of transferring adventitious agents. However, the effectiveness of serum-free media is limited, as many cell lines still require serum to grow, and many serum-free media formulations can only support the growth of narrowly defined types of cells.

LLOQ: The ULOQ and LLOQ are the highest and lowest standard curve points that can still be used for quantification; they are the values below and above which, respectively, quantitative results may be obtained with a specified degree of confidence, or the highest/lowest concentration of an analyte that can be accurately measured. Together, the ULOQ and LLOQ define the range of quantification for the assay. Limits of quantitation are matrix, method, and analyte-specific and can be calculated as follows:

Equation 1.

(Calculation used in Q-View): ULOQ & LLOQ = Highest or Lowest Standard, respectively, with a %backfit of 120%-80%, a %CV of < 30%, and a positive mean pixel intensity difference between it and the negative control.

Equation 2.

(Commonly used in science to estimate the LLOQ): LLOQ = (Mean negative control pixel intensity) + 10 * (StDev of negative control pixel intensities).

PBS: Phosphate buffered saline (PBS) is a pH-adjusted blend of ultrapure-grade phosphate buffers and saline solutions which, when diluted to a 1X working concentration, contains 137mM NaCl, 2.7mM KCl, 8mM Na_2HPO_4, and 2mM KH_2PO_4.

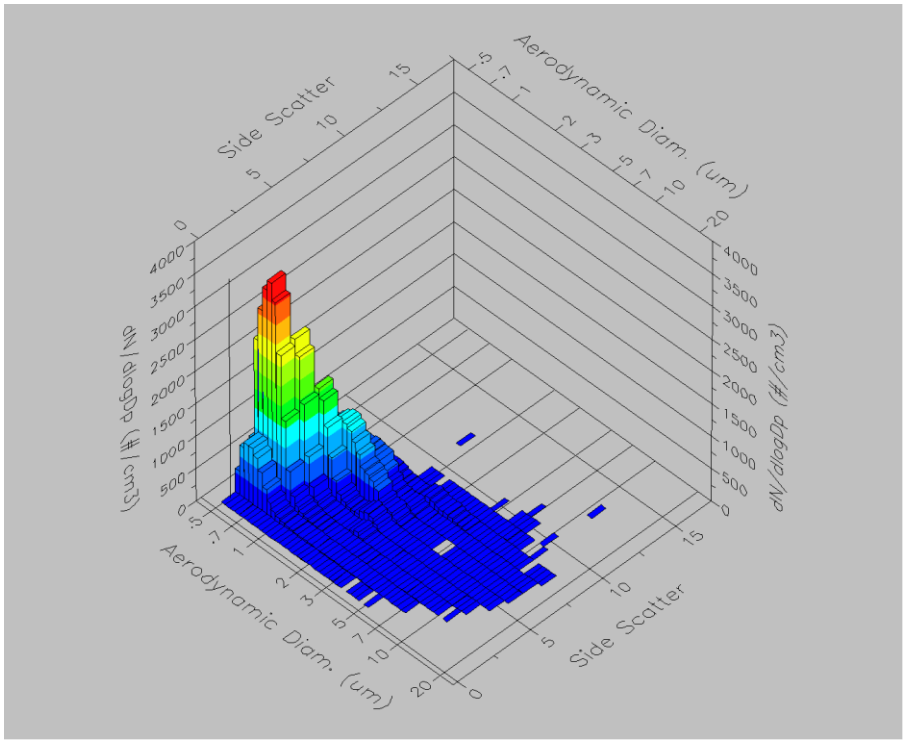
TCID50/mL: The number of infectious virus particles is frequently quantified using the Median Tissue Culture Infectious Dose (TCID50) assay. The assay works by adding a serial dilution of the virus sample to cells in a 96-well plate format. The cell type is specifically selected to show a cytopathic effect (CPE), i.e., morphological changes upon infection with the virus or cell death. After an incubation period, the cells are inspected for CPE or cell death, and each well is classified as infected or not infected. Colorimetric or fluorometric readouts are also possible, which can increase assay sensitivity. The dilution, at which 50% of the wells show a CPE, is used to calculate the TCID50 of the virus sample. Virus titer is expressed as TCID50/mL. See Appendix D for Spearman-Karber method calculation details.

VERO/E6: Vero cells are a lineage of cells used in cell cultures. Vero E6, also known as Vero C1008 (ATCC No. CRL-1586) This line is a clone from Vero 76. Vero E6 cells show some contact inhibitions making these cells suitable for propagating viruses that replicate slowly.

APPENDIX B: Particle Size Distribution

The TSI Aerodynamic Particle Sizer® (APS™) 3321 spectrometer is a device designed to collect high-resolution, real-time aerodynamic measurements of particles from 0.5 to 20 microns. The APS was used during pre-study testing and validation for particle dispersion with the Blaustein Atomizing Module (BLAM) bioaerosol generating nebulizer. Testing with the BLAM generating nebulizer was conducted over an extensive period of time to confirm and validate particle distribution. Setup, suspension solution, and all test equipment were the same as used in this viral study.

	Number Particle Size	Surface Particle Size	Mass Particle Size
Median (µm)	0.783	1.2	2.66
Mean (µm)	0.911	2	4.56
Geo. Mean (µm)	0.845	1.43	2.98
Mode (µm)	0.723	0.777	12
Geo. St. Dev.	1.42	2.06	2.57
Total Conc.	2.45e+03(#/cm³)	7.22e+03(µm²/cm³)	2.38(mg/m³)



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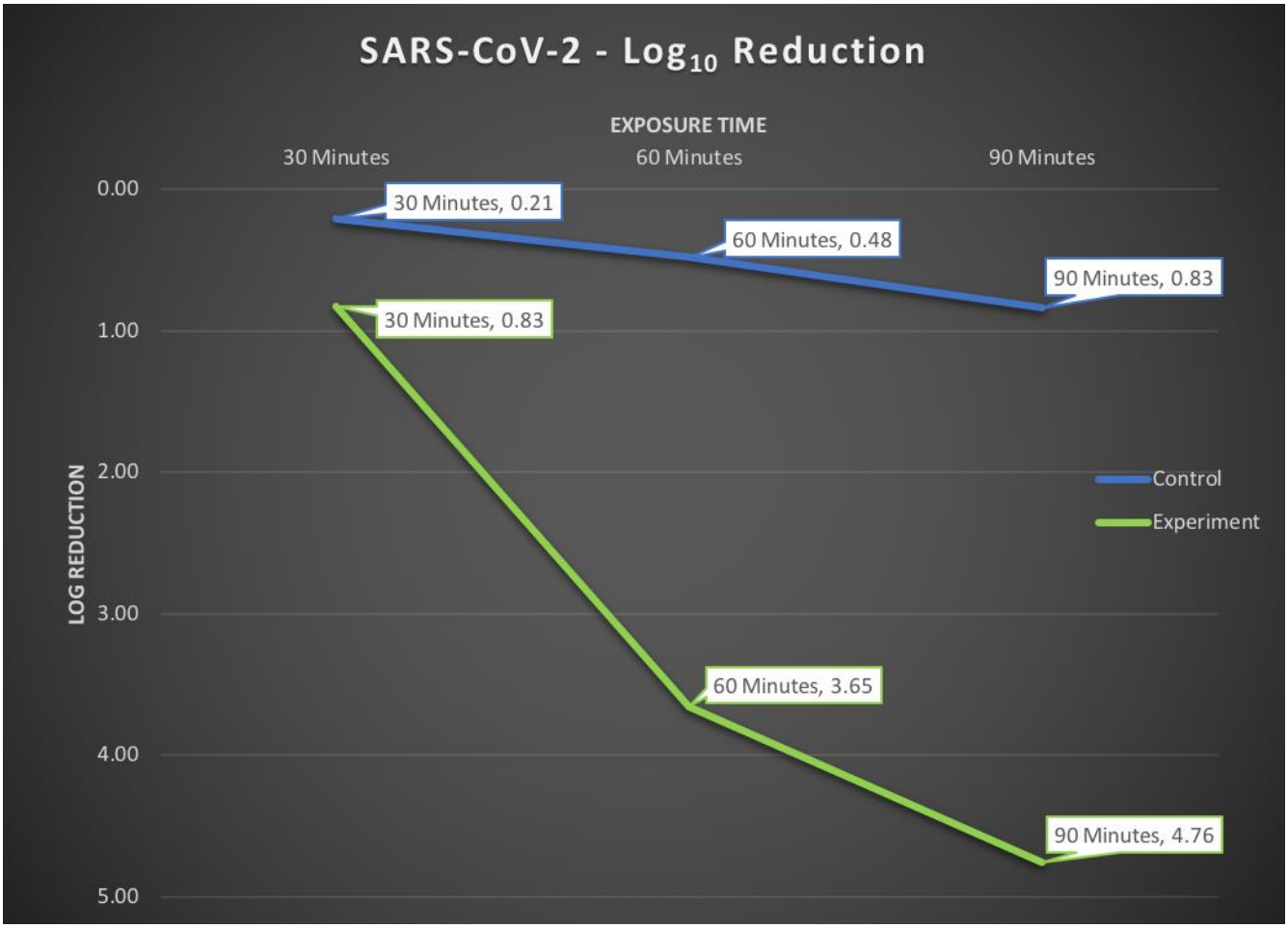
APPENDIX C: Additional Results Graph – Log_{10} Reduction



Time (min)	30	60	90
Control (TCID50/mL)	4.27E+06	2.26E+06	1.00E+06
Log Reduction – Control	0.21	0.48	0.83
Experiment (TCID50/mL)	1.02E+06	1.53E+03	1.20E+02
Log Reduction – Experiment	0.83	3.65	4.76

APPENDIX D: Calculation Equations

Spearman-Karber TCID50 calculation method:

$$\log_{10} 50\% \text{ endpoint dilution} = -(x_0 - \frac{d}{2} + d\sum\frac{r_i}{n_i})$$

x_0 = $\log_{10}$ of the reciprocal of the highest dilution (lowest concentration) at which all animals are positive
d = $\log_{10}$ of the dilution factor
n_i = number of animals used in each dilution (after discounting accidental deaths)
r_i = number of positive animals (out of n_i)
Summation is started at dilution x_0.

Percent Reduction calculation:

$$\text{Percent Reduction} = \frac{(A - B)}{A} \times 100$$

A = initial number of viable microorganisms
B = final number of viable microorganisms

Log Reduction calculation:

$$\text{Log Reduction} = \log_{10}\left(\frac{A}{B}\right)$$

A = initial number of viable microorganisms
B = final number of viable microorganisms

APPENDIX E: Equipment Calibration Certificates

SENSIDYNE
Industrial Health & Safety Instrumentation

Sensidyne Certificate of Performance
Gilian 10i Sampling Pumps

This document certifies that the product below performs in accordance with factory specifications. Sensidyne's volumetric test equipment is traceable to NIST. Sensidyne, LP is an ISO 9001:2015 registered company.

Gilian 10i Assembly, P/N 610-1501-01-R
Serial Number 20220202003 Month of Manufacture: February 2022

Set Flow L/min	Set BP Inches H2O	Acceptable Minimum L/min	Acceptable Maximum L/min	Pass = √ Fail = X
4	2	3.800	4.200	√
	25	3.800	4.200	√
	50	3.800	4.200	√
8	2	7.600	8.400	√
	10	7.600	8.400	√
	22	7.600	8.400	√
10	2	9.500	10.500	√
	6	9.500	10.500	√
	12	9.500	10.500	√

Technician Stamp 10

091-1015-01rC

SENSIDYNE
Industrial Health & Safety Instrumentation

Sensidyne Certificate of Performance
Gilian 10i Sampling Pumps

This document certifies that the product below performs in accordance with factory specifications. Sensidyne's volumetric test equipment is traceable to NIST. Sensidyne, LP is an ISO 9001:2015 registered company.

Gilian 10i Assembly, P/N 610-1501-01-R
Serial Number 20220202002 Month of Manufacture: February 2022

Set Flow L/min	Set BP Inches H2O	Acceptable Minimum L/min	Acceptable Maximum L/min	Pass = √ Fail = X
4	2	3.800	4.200	√
	25	3.800	4.200	√
	50	3.800	4.200	√
8	2	7.600	8.400	√
	10	7.600	8.400	√
	22	7.600	8.400	√
10	2	9.500	10.500	√
	6	9.500	10.500	√
	12	9.500	10.500	√

Technician Stamp 10

091-1015-01rC

SENSIDYNE
Industrial Health & Safety Instrumentation

Sensidyne Certificate of Performance
Gilian 10i Sampling Pumps

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Gilian 10i Assembly, P/N 610-1501-01-R
Serial Number 20220202001

Month of Manufacture: February 2022

Set Flow L/min	Set BP Inches H2O	Acceptable Minimum L/min	Acceptable Maximum L/min	Pass = √ Fail = X
4	2	3.800	4.200	√
	25	3.800	4.200	√
	50	3.800	4.200	√
8	2	7.600	8.400	√
	10	7.600	8.400	√
	22	7.600	8.400	√
10	2	9.500	10.500	√
	6	9.500	10.500	√
	12	9.500	10.500	√

Technician Stamp 10

091-1015-01rC

APPENDIX F: BEI Resources - Certificate of Authenticity

b|e|i RESOURCES
SUPPORTING INFECTIOUS DISEASE RESEARCH

Product Information Sheet for NR-52281

SARS-Related Coronavirus 2, Isolate USA-WA1/2020

Catalog No. NR-52281

For research use only. Not for human use.

Contributor:
Centers for Disease Control and Prevention, Atlanta, Georgia, USA

Manufacturer:
BEI Resources

Product Description:
Virus Classification: *Coronaviridae*, *Betacoronavirus*
Species: Severe acute respiratory syndrome-related coronavirus 2 [Note: This virus was originally deposited to BEI Resources as 2019 Novel Coronavirus, but subsequently named SARS-CoV-2 by the International Committee on Taxonomy of Viruses (ICTV). Please note that the depositor's original nomenclature was used on the product label.]
Isolate: USA-WA1/2020
Original Source: Severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2), isolate USA-WA1/2020 was isolated from an oropharyngeal swab from a patient with a respiratory illness who had recently returned from travel to the affected region of China and developed clinical disease (COVID-19) in January 2020 in Washington, USA.[1]
Comments: Under the nomenclature system introduced by GISAID (Global Initiative on Sharing All Influenza Data), SARS-CoV-2, isolate USA-WA1/2020 is assigned lineage A and GISAID clade S using Phylogenetic Assignment of Named Global Outbreak LINeages (PANGOLIN) tool.[2,3,4] The complete genome of SARS-CoV-2, USA-WA1/2020 has been sequenced (the isolate - GenBank: MN985325 and GISAID: EPI_ISL_404895 and after one passage in Vero cells - GenBank: MT020880). The complete genome of SARS-CoV-2, USA-WA1/2020 has been sequenced after four passages in Vero cells in collaboration with Database for Reference Grade Microbial Sequences (FDA-ARGOS; GenBank: MT246667).

In December 2019, an outbreak of a respiratory illness (COVID-19) began in Wuhan, Hubei Province, China. The outbreak is associated with a seafood market and although environmental samples from the market are positive for the novel coronavirus, an association with a particular animal has not been determined.[5] SARS-CoV-2 was isolated and appears to be less virulent than other recently emerged coronaviruses (SARS and MERS-CoV). The sequences of several isolates have been deposited with GSAID.

Material Provided:
Each vial contains approximately 0.5 mL of cell lysate and supernatant from *Cercopithecus aethiops* kidney cells infected with SARS-CoV-2, isolate USA-WA1/2020.

Note: If homogeneity is required for your intended use, please purify prior to initiating work.

Packaging/Storage:
NR-52281 was packaged aseptically in screw-capped plastic cryovials. The product is provided frozen and should be stored at -60°C or colder immediately upon arrival. For long-term storage, the vapor phase of a liquid nitrogen freezer is recommended. Freeze-thaw cycles should be avoided.

Growth Conditions:
Host: *Cercopithecus aethiops* kidney cells (Vero E6; ATCC® CRL-1586™)
Growth Medium: Eagle's Minimum Essential Medium containing Earle's Balanced Salt Solution, non-essential amino acids, 2 mM L-glutamine, 1 mM sodium pyruvate and 1.5 g/L of sodium bicarbonate supplemented with 2% fetal bovine serum and 100 µg/mL Penicillin/Streptomycin solution (optional) and 2.5 µg/mL Amphotericin B (optional), or equivalent
Infection: Cells should be 70% to 80% confluent
Incubation: 2 to 5 days at 37°C and 5% CO_2
Cytopathic Effect: Cell rounding and sloughing

Citation:
Acknowledgment for publications should read "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-WA1/2020, NR-52281."

Biosafety Level: 3
Appropriate safety procedures should always be used with this material. Laboratory safety is discussed in the following publication: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington, DC: U.S. Government Printing Office, 2009; see www.cdc.gov/biosafety/publications/bmbl5/index.htm.

Disclaimers:
You are authorized to use this product for research use only. This product is not intended for human use.

Use of this product is subject to the terms and conditions of the Emergency Use Simple Letter Agreement (EUSLA) and the BEI Resources Material Transfer Agreement (MTA). The MTA is available on our Web site at www.beiresources.org.

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Use Restrictions:

SARS-CoV-2 materials provided by BEI Resources under the EUSLA are made available for any legitimate purpose, including commercial purposes as long as they are to rapidly prevent, detect, prepare for, and respond to, the spread or transmission of the 2019 SARS-CoV-2. Any further transfer of the original material or any unmodified progeny must be done under the terms of the EUSLA, documented as described above and you must notify BEI Resources of each subsequent transfer. Any new materials made by you that are not the original material or unmodified progeny are excluded from this requirement and you are free to share and commercialize those as your materials.

References:

1. Harcourt, J., et al. "Severe Acute Respiratory Syndrome Coronavirus 2 from Patient with 2019 Novel Coronavirus Disease, United States" Emerg. Infect. Dis. 26 (2020): 1266-1273. PubMed: 32160149.
2. GISAID
3. Rambaut, A., et al. "A Dynamic Nomenclature Proposal for SARS-CoV-2 Lineages to Assist Genomic Epidemiology." Nat. Microbiol. (2020): doi: 10.1038/s41564-020-0770-5. PubMed: 32669681.
4. Daniele, M. and F. M. Giorgi. "Geographic and Genomic Distribution of SARS-CoV-2 Mutations." Front. Microbiol. (2020): doi.org/10.3389/fmicb.2020.01800.
5. Gralinski, L. E. and V. D. Menachery. "Return of the Coronavirus: 2019-nCoV." Viruses 12 (2020): 135. PubMed: 31991541.

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