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EFFICACY OF THE PURIFI LABS™ IAI-100 AGAINST AEROSOLIZED SARS-COV-2 DELTA VARIANT

PROJECT: PURIFI IAI-100 AEROSOL SARS-COV-2 DELTA VARIANT

PRODUCT: PURIFI LABS™ IAI-100

CAP LIC NO: 8860298

CLIA LIC NO: 05D0955926

STATE ID: CLF 00324630

CHALLENGE ORGANISM (S):

SARS-COV-2 DELTA VARIANT

Dana Yee, M.D.

Medical Director

Study Completion Date

8/9/2021

Testing Facility

Innovative Bioanalysis, Inc.

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Laboratory Project Number

1122

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Efficacy Study Summary

Study Title	EFFICACY OF THE PURIFI LABS™ IAI-100 AGAINST AEROSOLIZED SARS-COV-2 DELTA VARIANT
Laboratory Project #	1122
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 Delta Variant
Description	PuriFi Labs™ provided a PuriFi IAI-100 Generator, a commercially available HVAC mounted disinfection device for installation and used in central heating and ventilating systems. The in vitro study evaluates the efficacy of the IAI-100 against aerosolized SARS-CoV-2 Delta variant.
Test Conditions	A modified HVAC system housing the device located in a 20'x8'x8' BSL-3 chamber was used for testing. The temperature during testing was 77 ± 2°F, with a relative humidity of 41%. Bioaerosol was generated using a nebulizer filled with 1.24×10^7 TCID50/mL SARS-CoV-2 Delta variant in FBS-based media. Air samples were collected after 0, 14, 29, and 59 minutes of exposure to the operating device.
Test Results	The device continually reduced the active SARS-CoV-2 Delta variant more rapidly than natural loss rates. At 59 minutes of operation, a concentration below the specified limit of quantitation was achieved.
Control Results	A static control and airflow control run was conducted and plotted to show a natural loss rate over 59 minutes. The static control simulates the device on standby while the airflow control replicates a running HVAC system. The data was used to assess the device's ability to reduce aerosolized pathogens.
Conclusion	The PuriFi Labs™ IAI-100 demonstrated a consistent and progressive reduction of active aerosolized SARS-CoV-2 Delta variant. After 59 minutes of exposure, a 99.999% total reduction was achieved, indicative of a 5-log reduction.

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Study Report

Study Title: EFFICACY OF THE PURIFI LABS™ IAI-100 AGAINST AEROSOLIZED SARS-COV-2 DELTA VARIANT

Sponsor: PuriFi Labs™

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

Device Testing: IAI-100

Study Report Date: 08/09/2021
Experimental State Date: 07/17/2021
Experimental End Date: 07/17/2021
Study Completion Date: 08/09/2021

Study Objective:

An ionization device, IAI-100, was provided by PuriFi Labs™ for testing to evaluate the efficacy of the device against an aerosolized virus, SARS-CoV-2 Delta variant.

Test Method:

Bioaerosol Generation:

The nebulizer was filled with a (1.24×10^7 TCID50 per mL) FBS-based viral media of SARS-CoV-2 Delta variant and nebulized at a flow rate of 1mL/min with untreated local atmospheric air. For this experiment, fans were used to thoroughly mix 15 mL of aerosolized viral media into the environment to replicate a room containing a high viral load. Bioaerosol procedures for the controls and viral challenges were performed in the same manner with corresponding time points and collection rates.

Bioaerosol Sampling:

Four probes connected to a calibrated Gilian 10i vacuum device set at a standard flow of 5.02L/min with a 0.20% tolerance were inspected for functionality before being used. Sample collection volumes were set to 10-minute draws per time point. The air sampler operated in conjunction with a removable sealed cassette and manually removed after each sampling 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. Filtration discs from Zefon International, Lot# 24320, were used for testing.

Test System Strains: SARS-CoV-2 Delta Variant

Study Materials and Equipment:

Equipment Overview: The equipment arrived at the laboratory pre-packaged from the manufacturer and was inspected for damage upon arrival. Before starting the challenge, the PuriFi Labs™ IAI-100 unit was operated for 1 hour in a dry run to confirm correct operations. Positive and negative ion levels were measured using two Alpha Labs AIC2 devices with an average generation of 2,200 ± 500 ions per cubic centimeter.

MANUFACTURER: PuriFi Labs™

MODEL: IAI-100

DIMENSIONS: 12” x 8.5” x 14” (with antenna)

MAKE: PuriFi Generator

SERIAL #: 9454935D9913

Testing Layout:

Testing was conducted in a 20'x8'x8' sealed chamber per Biosafety Level 3 (BSL3) standards. The overall dimensions of the test chamber provided a displacement volume of 1,280 cubic feet and approximately 36,245.56 liters of air. 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 four probes for air sampling positioned along the centerline of the room and protruded down from the ceiling 24". A nebulizing port connected to a programmable compressor system was located in the center of the 20' wall protruding 24" from the wall. The chamber was visually inspected, pressure tested, and all internal lab systems and equipment were reviewed before testing.

A modified HVAC system with an air handler box housing the PuriFi Labs™ IAI-100 device was used. The air handling box was located downstream from a fan unit and was situated in one corner of the room with a vertical stack of ducting. The duct traveled along the ceiling of the chamber creating an internal duct line with two diffusers in the room's centerline, as shown in Figure 1. The modified HVAC system made an airflow of approximately eight air changes per hour through the circular ducting.

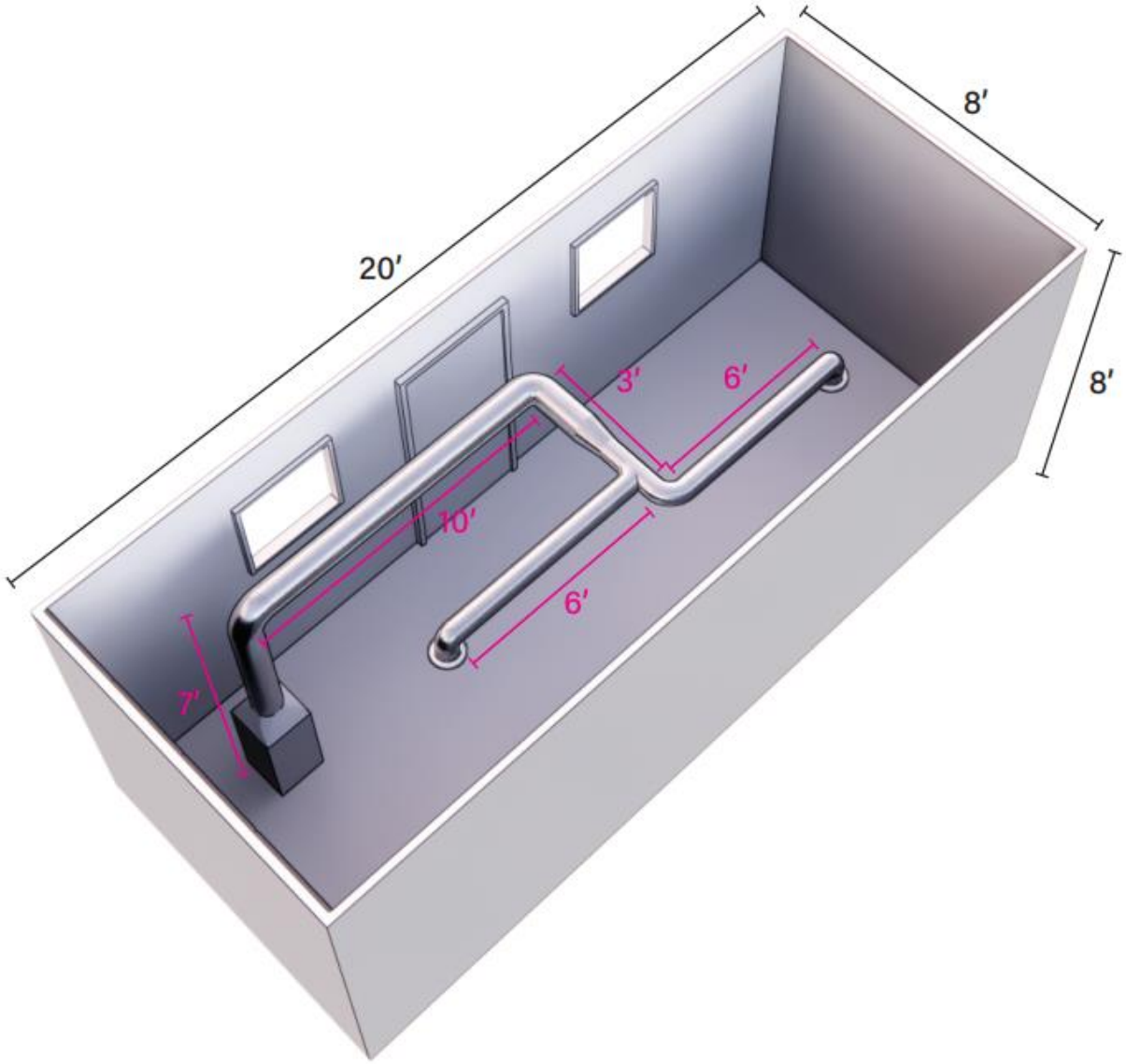


Figure 1. Room layout for the control and experimental trials.

Test Method:

Exposure Conditions:

1. The temperature during all test runs was approximately 77 ±2°F with a relative humidity of 41%. Testing conditions were taken in two sections of the chamber to confirm a deviation of less than ±3%.
2. Testing time points were as follows, with T equal to minutes: T-0, T-14, T-29, and T-59.

Experimental Procedures:

1. Before the initial control test and following each trial run, the testing area was decontaminated and prepped per internal procedures.
2. Test conditions were a "Hot Start" scenario where the ion and modified internal HVAC system were turned on 15 minutes before the introduction of the pathogen.
3. A SARS-CoV-2 Delta variant stock of 1.24×10^7 TCID50/mL in FBS media was nebulized into the sealed environment via the dissemination port.
4. Air sampling collection occurred after nebulization ceased for the challenges and control test.
5. After each run, sample cassettes were manually removed from the collection system and taken to an adjacent biosafety cabinet to be pooled.

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. 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.

Preparation of The Pathogen

Viral Stock: SARS-CoV-2 Delta Variant (BEI NR-55611)

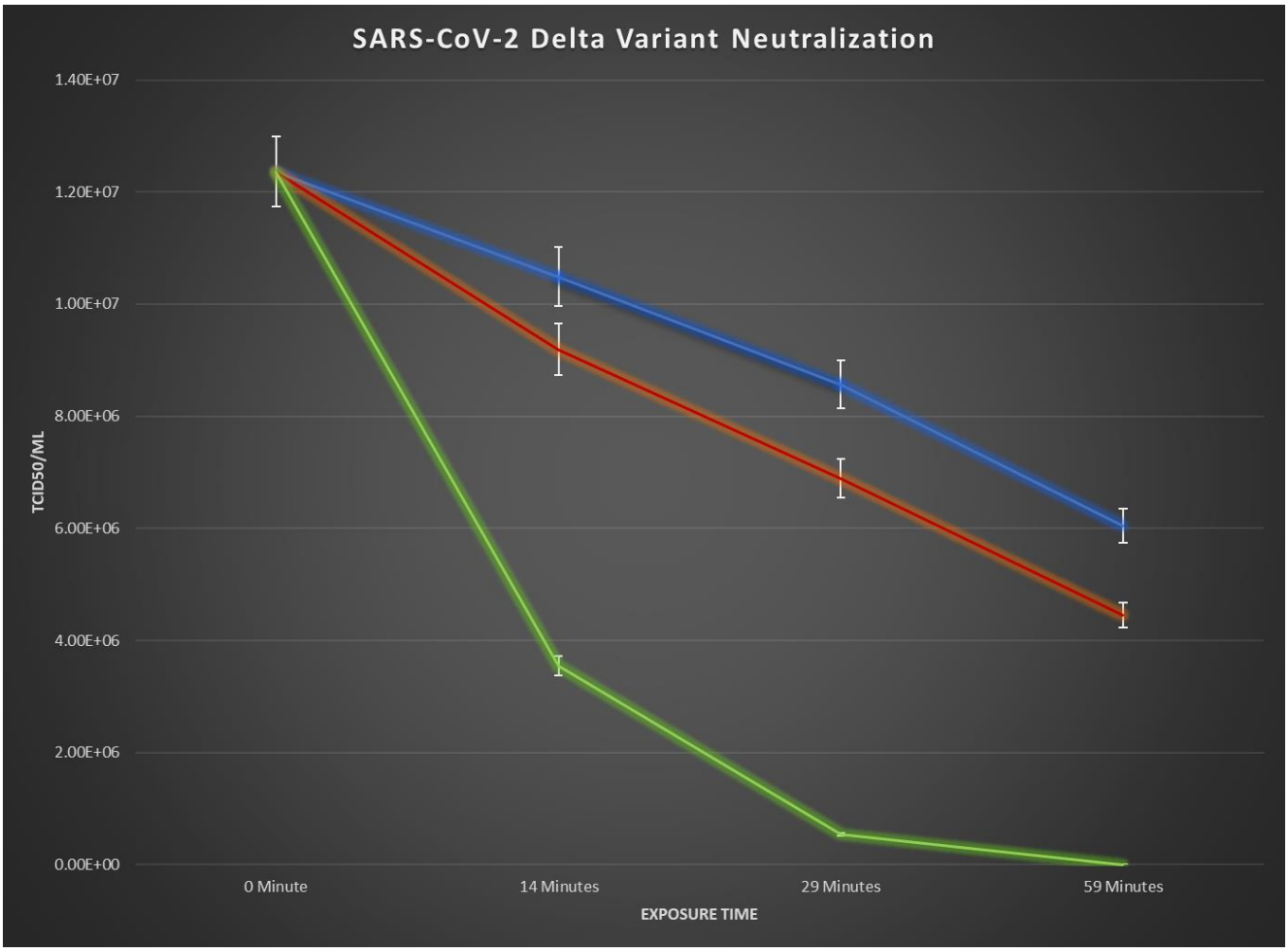
Test	Specifications	Results
Identification by Infectivity in Calu-3 Cells	Cell rounding and detachment	Cell rounding and detachment
Next-Generation Sequencing (NGS) of Complete Genome Using Illumina® iSeq™ 100 Platform	≥ 98% identity with SARS-CoV-2, hCoV-19/USA/PHC658/2021 depositor sequence	99.99% identity with SARS-CoV-2, hCoV-19/USA/PHC658/2021 depositor sequence
Titer by $TCID_{50}$ Assay in Calu-3 Cells by Cytopathic Effect	Report Results	6.5 X 10^5 $TCID_{50}$ per mL^2
Sterility (21-Day Incubation)		
Harpo's 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 represents the titer provided by BEI Resources.

Control Protocol

To accurately assess the IAI-100, a static decay control and an airflow control were conducted without the device operating in the testing chamber. The static decay control was performed to simulate an HVAC system in standby mode, and the airflow control acts as an active HVAC system without an air purification device. The collection was taken at corresponding time points used for the challenge trial, in the same manner, to serve as a comparative baseline to assess aerosolized viral reduction when the device was operating.

Study Results



**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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VIRAL VOLUME REDUCTION OF SARS-COV-2 (SCIENTIFIC)			
	Static Control	**Airflow Control**	**PuriFi**
0 Minutes	1.24E+07	1.24E+07	1.24E+07
14 Minutes	1.05E+07	9.19E+06	3.55E+06
29 Minutes	8.56E+06	6.89E+06	5.47E+05
59 Minutes	6.05E+06	4.45E+06	1.20E+02

VIRAL VOLUME REDUCTION OF SARS-COV-2 (NUMERICAL)			
	Static Control	**Airflow Control**	**PuriFi**
0 Minutes	12,400,000	12,400,000	12,400,000
14 Minutes	10,500,000	9,190,000	3,550,000
29 Minutes	8,560,000	6,890,000	547,000
59 Minutes	6,050,000	4,450,000	120

VIRAL LOG REDUCTION OF SARS-COV-2			
	Static Control	**Airflow Control**	**PuriFi**
0 Minutes	0.000	0.000	0.000
14 Minutes	0.072	0.130	0.543
29 Minutes	0.161	0.255	1.355
59 Minutes	0.312	0.445	5.014

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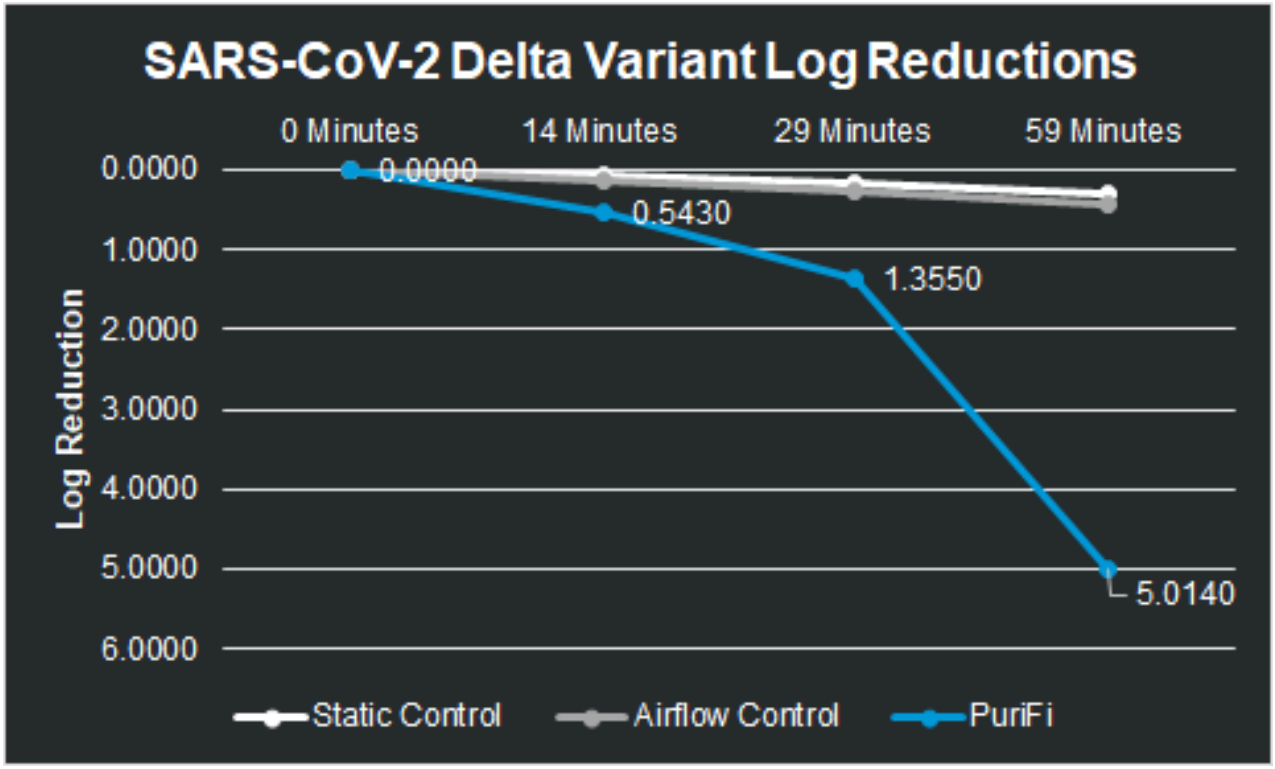
PURIFI VIRAL INACTIVATION OF SARS-COV-2			
	PuriFi vs Static Control	**PuriFi vs Airflow Control**	**PuriFi Total Reduction**
0 Minutes	0.00%	0.00%	0.00%
14 Minutes	66.19%	61.37%	71.37%
29 Minutes	93.61%	92.06%	95.59%
59 Minutes	99.998%	99.997%	99.999%



Conclusion:

The PuriFi Labs™ IAI-100 device performed to manufacturer specifications and demonstrated a consistent progressive reduction of the active virus at 14 minutes, 29 minutes, and 59 minutes of exposure in aerosol form. The amount of active SARS-CoV-2 Delta variant in the atmosphere was reduced over the control samples by approximately 99.998% vs the static control and 99.997% vs the airflow control, with a total reduction of 99.999%.

When aerosolizing pathogens 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 on 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 virus in the control test.

Considering the variables, there was a measurable amount of reduction achieved by the PuriFi Labs™ IAI-100 device at each of the T-14, T-29, and T-59 time points. The decline in air was consistent with the manufacturer's claims that the device can decrease the concentration of active pathogens in the air. Overall, the PuriFi Labs™ IAI-100 device showed efficacy in reducing SARS-CoV-2 from the air samples collected.

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