INNOVATIVE BIOANALYSIS
creating solutions | getting results

EFFICACY OF THE GPS-FC48-AC™ AGAINST SARS-COV-2 DELTA VARIANT

PROJECT: GPS AEROSOL SARS-COV-2 -DELTA

TECHNOLOGY: Needle Point Bipolar Ionization (NPBI™)

DEVICE: GPS-FC48-AC™

CAP LIC NO: 8860298

CLIA LIC NO: 05D0955926

STATE ID: CLF 00324630

CHALLENGE ORGANISM (S):

SARS-COV-2 DELTA VARIANT

Medical Director

Dana Yee, M.D.

Study Completion Date

9/20/2021

Study Revision Date:

4/4/22

Testing Facility

Innovative Bioanalysis, Inc.

3188 Airway Ave Suite D

Costa Mesa CA, 92626

www.InnovativeBioanalysis.com

Email: info@innovativeBioanalysis.com

Laboratory Project Number

1159

INNOVATIVE BIOANALYSIS
creating solutions | getting results

Table of Contents

EFFICACY OF THE GPS-FC48-AC™ AGAINST SARS-COV-2 DELTA VARIANT 1
Efficacy Study Summary 3
Study Report 4
Study Title: 4
Sponsor: 4
Test Facility: 4
Device Testing: 4
Study Dates: 4
Study Objective: 4
Test Method: 4
Test System Strains: 4
Study Materials and Equipment: 5
Test Method: 7
Control Protocol 9
Study Results 10
Conclusion: 11
Disclaimer 12

INNOVATIVE BIOANALYSIS
creating solutions | getting results

Efficacy Study Summary

Study Title	EFFICACY OF THE GPS-FC48-AC™ AGAINST SARS-COV-2 DELTA VARIANT
Laboratory Project #	1159
Guideline:	No standard exists; GLP and modified ISO standards were used.
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	The GPS-FC48-AC™ device is commercially available and designed to be installed in the ductwork of an HVAC system to reduce the concentration of bacteria and pathogens when operational. Testing was conducted on the device to evaluate the effectiveness of the GPS-FC48-AC™ unit in reducing aerosolized SARS-CoV-2 Delta Variant.
Test Conditions	The test was conducted in a sealed 20'x8'x8' chamber that complied with BSL-3 standards. The temperature during testing was 77 ± 2°F, with a relative humidity of 32%. A 7.02 x 10^6 TCID50/mL of SARS-CoV-2 Delta Variant in FBS-based viral media was nebulized into the room with mixing fans before collection. Air sample collections occurred at 0, 15, 30, 45, and 60 minutes of exposure to the operating device.
Test Results	The device decreased concentration of the SARS-CoV-2 Delta Variant from 7.02 x 10^6 TCID50/mL* to 4.86 x 10^4 TCID50/mL after 60 minutes. The device consistently reduced the infective SARS-CoV-2 Delta Variant at each time point faster than natural loss rates.
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 GPS FC48-AC™ demonstrated an overall capability to reduce aerosolized SARS-CoV-2 Delta Variant at each time point faster than the control or natural decay rate of infectious virus. After 60 minutes of operation, a 99.30% reduction in active airborne SARS-CoV-2 Delta Variant in the air was observed.

INNOVATIVE BIOANALYSIS
creating solutions | getting results

Study Report

Study Title: EFFICACY OF THE GPS-FC48-AC™ AGAINST SARS-COV-2 DELTA VARIANT

Sponsor: Global Plasma Solutions

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

Device Testing: GPS FC48-AC™

Study Dates:
Study Report Date: 09/22/2021
Study Report Revision Date: 04/04/2022
Experimental Start Date: 08/19/2021
Experimental End Date: 08/27/2021
Study Completion Date: 09/20/2021

Study Objective:

An ionization unit, GPS-FC48-AC™, was provided by Global Plasma Solutions 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 7.02 x 10^6 TCID50 per mL viral suspension media of SARS-CoV-2 Delta Variant and nebulized at a flow rate of 1mL/min for 10 min with untreated local atmospheric air. Upon each completion, the nebulizer's remaining viral stock volume was weighed to confirm that roughly the same amount (+/- .2g) 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:

Four probes, each 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 with a removable sealed cassette and was 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. The filtration disc from Zefon International, Lot# 24320, was used.

Test System Strains: SARS-CoV-2 Delta Variant

Study Materials and Equipment:

Equipment Overview: The GPS-FC48-AC™ equipment arrived at the laboratory pre-packaged from the manufacturer and was inspected for damage upon arrival. Before starting the challenge, the GPS-FC48-AC™ was operated for 1 hour in a dry run to confirm correct operations.

MANUFACTURER: Global Plasma Solutions

MODEL: GPS-FC48-AC™

TECHNOLOGY: NPBI™

SIZE: N/A

SERIAL #: N/A

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. The device was placed in the room's centerline, mounted on a movable scaffolding against the wall and elevated six feet above the ground, depicted in Figure 1. A variable-speed fan was placed behind the GPS-FC48-AC™ to create the necessary airflow to produce the required concentration of negative ions.

At each chamber corner, low-volume mixing fans moving at approximately 120 cfm were positioned at 45-degree angles to ensure homogenous mixing of bioaerosol concentrations when nebulized into the chamber. Four air sampling probes were 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. Due to the nature of ions, there were fluctuations of concentrations around the entire room. Ion readings were taken from multiple points in the room before aerosol testing. The chamber was visually inspected, pressure tested, and all internal lab systems and equipment were reviewed before testing.

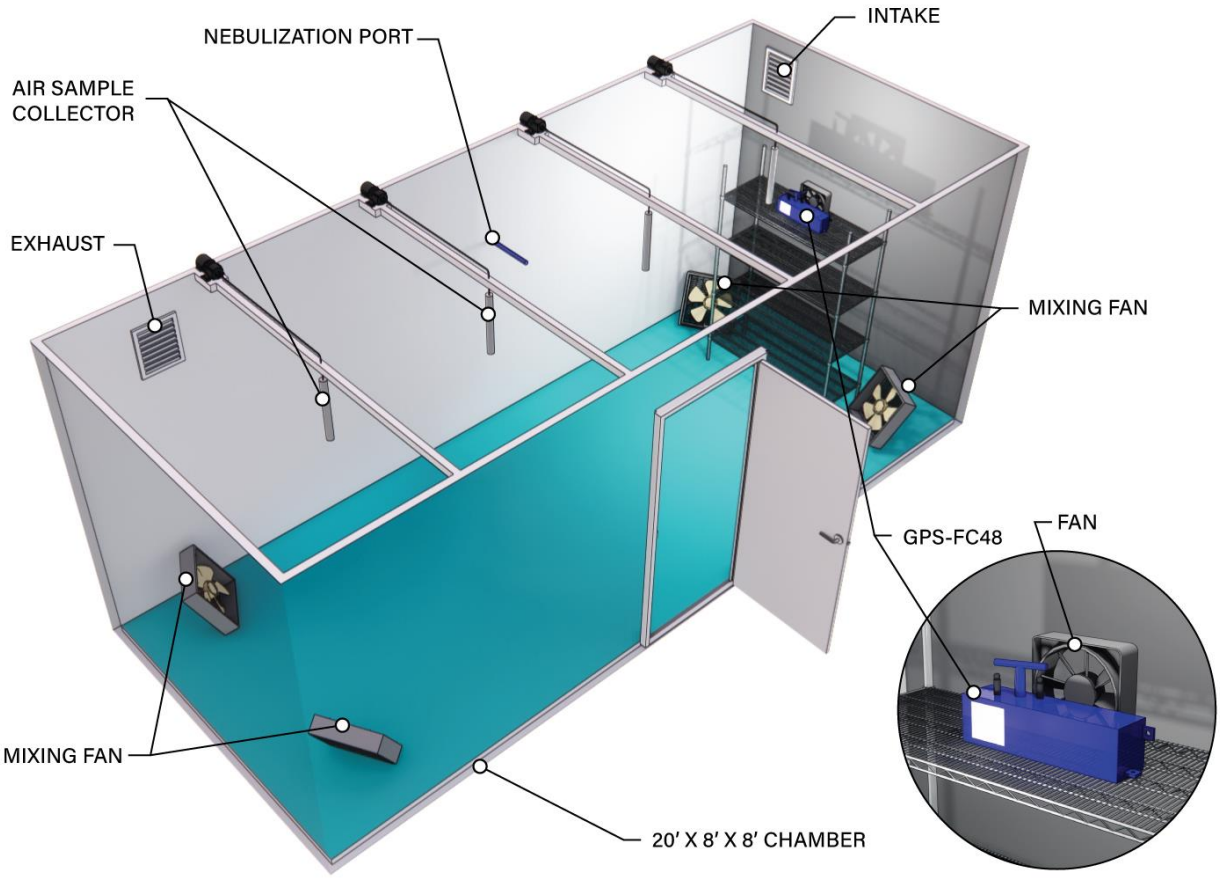


Figure 1. Room layout for control and experimental testing.

Test Method:

Exposure Conditions:

1. The temperature during all test runs was 77 ±2°F with a relative humidity of 32%.
2. Testing time points were as follows, with T equal to minutes: T-0, T-15, T-30, T-45, and T-60.

Nebulization:

1. Before the initial control test and following each trial run, the testing area was decontaminated and prepped per internal procedures.
2. The four low volume mixing fans were turned on prior to starting nebulization.
3. 10 mL of 7.02 x 10^6 TCID50/mL* of SARS-CoV-2 Delta Variant viral media was nebulized into the sealed environment via the dissemination port.
4. After nebulization, the GPS-FC48-AC™ device was turned on via remote control and allowed to run for the duration of the testing time point as outlined in previous section.
5. At the end of each time point the device was turned off and air samples were collected.
6. Air sampling collection was set to 10-minute continuous draws immediately after the NPBI device and mixing fans were turned off.
7. Sample cassettes were manually removed from the collection system and taken to an adjacent biosafety cabinet to be pooled.
8. 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 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.

*The viral titer listed in the Certificate of Analysis represents the titer provided by BEI Resources.

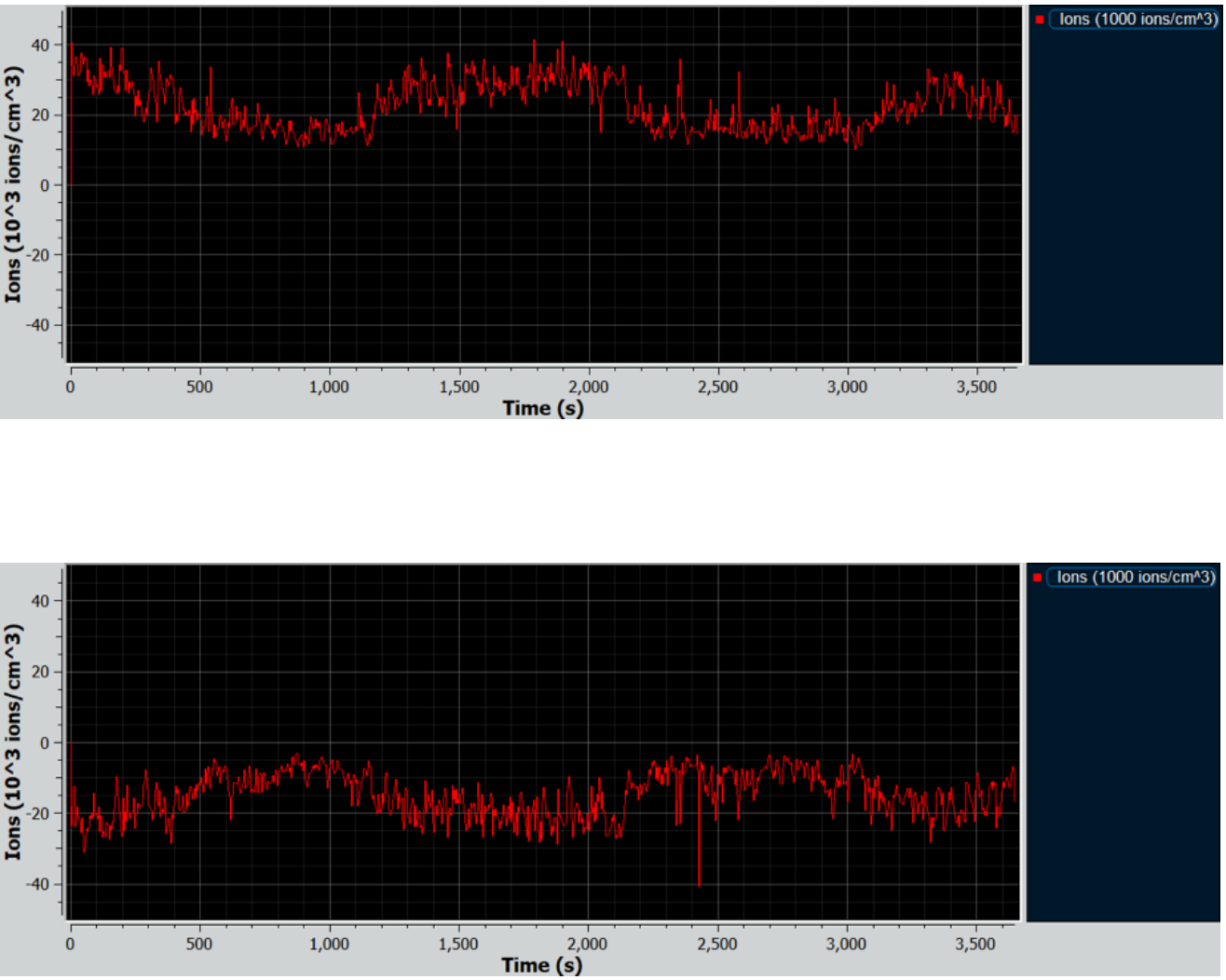


Figure 2. GPS-FC48™ positive (top) and negative (bottom) ion concentration recordings over time when operating during dry testing.

Preparation of The Pathogen

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

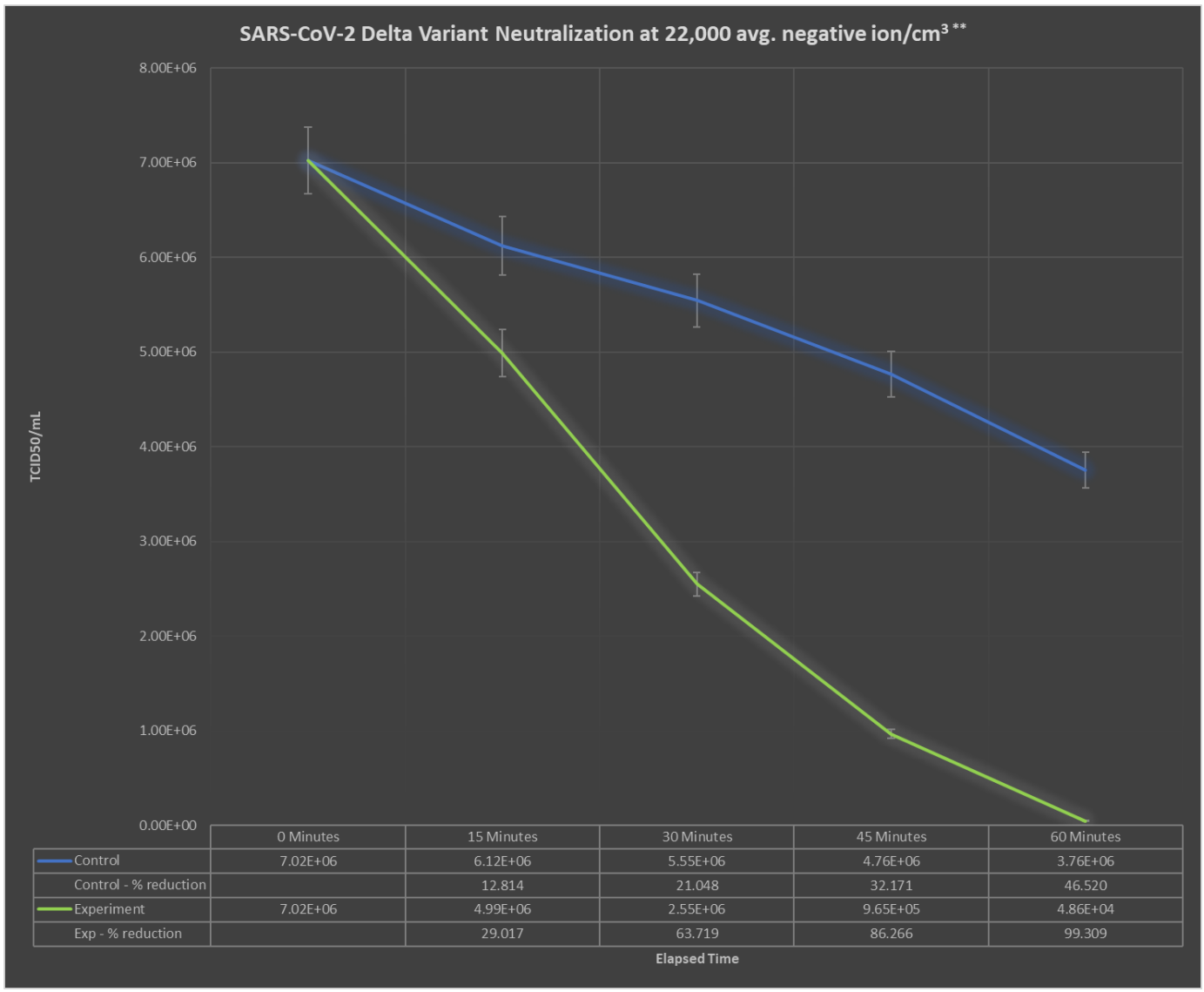
Test	Specifications	Results
Identification by Infectivity in Calu-3 Cells	Cell rounding and detachment	Cell rounding and detachment
Next-Generation Sequencing (NGS) of Complete Genome Using Illumina® iSeq™ 100 Platform	≥ 98% identity with SARS-CoV-2, hCoV-19/USA/PHC658/2021 depositor sequence	99.99% 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

Control Protocol

To accurately assess the GPS-FC48-AC™, a control was conducted without the device operating in the testing chamber. 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

The graph below shows the number of collectible SARS-CoV-2 Delta Variant with and without the GPS-FC48-AC™ ionizer operating over 60 minutes. The control plotted shows a natural viability loss over time. Against SARS-CoV-2 Delta, 4.99 x 10^6 TCID50/mL was collected after 15 minutes of exposure. After 30 minutes, 2.55 x 10^6 TCID/mL of collectible SARS-CoV-2 Delta indicating a 63.71% reduction. In the span of 60 minutes, the GPS-FC48-AC™ reduced a starting concentration of 7.02 x 10^6 TCID50/mL to 4.86 x 10^4 TCID50/mL, achieving a 99.30% reduction.



	0 Minutes	15 Minutes	30 Minutes	45 Minutes	60 Minutes
Control	7.02E+06	6.12E+06	5.55E+06	4.76E+06	3.76E+06
Control - % reduction		12.814	21.048	32.171	46.520
Experiment	7.02E+06	4.99E+06	2.55E+06	9.65E+05	4.86E+04
Exp - % reduction		29.017	63.719	86.266	99.309

**As it pertains to data represented herein, the percentage error equates to an average of ±5% of the final concentration.

Conclusion:

The GPS-FC48-AC™ ionizer demonstrated the ability to reduce aerosolized SARS-CoV-2 Delta Variant in a sealed controlled environment consistently over the defined test time periods. The device reduced 99.30% of active virus after 60 minutes of exposure, calculated based on the 4.86×10^4 TCID50/mL of active SARS-CoV-2 Delta Variant collected. Some variables cannot be fully accounted for when working with microorganisms and collecting said microorganisms, namely, placement of microorganisms, collection volume, collection points, surface saturation, microorganism destruction on collection, 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 microorganisms in the control test.

INNOVATIVE BIOANALYSIS
creating solutions | getting results

DocuSigned by:
Dr. Dana Yee MD.
52F0012FC10C43F...

4/5/2022

Dana Yee M.D **Date**

Clinical Pathologist and Medical Director, Innovative Bioanalysis, Inc.

DocuSigned by:
Sam Kabbani
8B4B282DE4B34A3...

4/5/2022

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

Chief Scientific Officer, Innovative Bioanalysis, Inc.

DocuSigned by:
Albert Brockman
42751B72F2FE40A...

4/5/2022

Albert Brockman **Date**

Chief Biosafety Officer, Innovative Bioanalysis, Inc.

DocuSigned by:
Kevin Noble
5DF2797BAA78421...

4/5/2022

Kevin Noble **Date**

Laboratory Director, Innovative Bioanalysis, Inc.

Disclaimer

The Innovative Bioanalysis, Inc., LLC. ("Innovative Bioanalysis") laboratory is not certified or licensed by the United States Environmental Protection Agency and makes no equipment emissions claims pertaining to ozone, hydrogen peroxide gas, reactive oxygen species, volatile organic compounds, or byproduct of any device. Innovative Bioanalysis, Inc. makes no claims to the overall efficacy of any device. The experiment results are solely applicable to the device used in the trial. The results are only representative of the experiment design described in this report. Innovative Bioanalysis, Inc. focuses heavily of variable mitigation as it pertains to our experiments and uses several proprietary methods of culturing pathogens and recovering experiment samples. Tests conducted in the same manner with attention to all experimental variables should come within a margin of error to the results stated within this report. Innovative Bioanalysis, Inc. makes no claims to third parties and takes no responsibility for any consequences arising out of the use of, or reliance on, the experiment results by third parties.