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EFFICACY OF THE AURA TECHNOLOGIES ION BAR MARK IV AGAINST STREPTOCOCCUS PNEUMONIAE (STREP)

PROJECT: AURA TECHNOLOGIES – ION BAR – STREP

PRODUCT: AURA Ion Bar™ Mark IV

CAP LIC NO: 8860298

CLIA LIC NO: 05D0955926

STATE ID: CLF 00324630

CHALLENGE ORGANISM(S):

Streptococcus Pneumoniae (STREP)

STUDY COMPLETION DATE:

09/18/2023

Medical Director:

Dana Yee, M.D.

Testing Facility:

Innovative Bioanalysis, Inc.

3188 Airway Ave Suite D

Costa Mesa, CA 92626

www.InnovativeBioanalysis.com

Email: info@innovativebioanalysis.com

Laboratory Project Number:

1394S

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Efficacy Study Summary

Study Title	EFFICACY OF THE AURA TECHNOLOGIES ION BAR MARK IV AGAINST STREP
Laboratory Project #	1394S
Guideline	Custom design based on ASHRAE and ISO principles as no international standards exist.
Testing Facility	Innovative Bioanalysis, Inc.
GLP Compliance	All internal SOPs and processes follow GCLP guidelines and recommendations per the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Regulations Standards and Certification: Laboratory Requirements (42 CFR 493) and the College of American Pathologists (CAP) All Common Checklist.
Test Substance	Streptococcus Pneumoniae (STREP)
Description	The AURA Technologies AURA Ion Bar™ Mark IV s an overhead airflow curtain system with an integrated negative ion generator. The AURA Ion Bar™ Mark IV is typically mounted above a doorway or portal, creating a high-negative-air-ion germicidal partition between the air masses on each side of the threshold. The germicidal partition is intended to eliminate or significantly reduce the transfer of airborne particles between the air masses and to kill or inactivate pathogens in the air and on surfaces proximate to the doorway or portal. This in-vitro study consists of aerosol and surface testing to determine the efficacy of the AURA Ion Bar™ Mark IV against Streptococcus Pneumoniae (STREP).
Test Conditions	Testing was conducted in a sealed 20 ft (~6.1 m) x 8 ft (~2.44 m) x 8 ft (~2.44 m)) chamber that complied with Biological Safety Level 3 (BSL-3) standards per NIH guidelines. The temperature was approximately 71 °F ± 2 °F (~21.7 °C ± 1.1 °C), with a relative humidity of 35 %. A simulated wall with a doorway/portal was constructed such that the chamber was partitioned into two 10 ft (~3.05 m) x 8 ft (~2.44 m) x 8 ft (~2.44 m) sections. The AURA Ion Bar™ Mark IV was mounted above the doorway, approximately 7 ft (2.15 m) above the floor, on the "clean" side of the door. A 4.77×10^4 CFU/mL of STREP in a Phosphate Buffered Saline (PBS) solution was nebulized for aerosol testing. Nebulization occurred 5 ft (~1.52 m) above the floor, 1.5 ft (~0.46 m) away from the doorway and pointed towards the door while air samples were collected at the same distance from the clean side for 2 minutes.

Test Results	During aerosol testing, the germicidal barrier blocked an average of ≥ 99.999 % (5 log) of active STREP from entering through the simulated door opening during device operation, which was quantified as no growth.
Control Results	Control testing was conducted for each subtest with the device fan and ionizer off and samples were taken at the corresponding time points used for each challenge. The results displayed a natural viability loss and served as a comparative baseline to calculate bacterial reduction and evaluate device efficacy.
Conclusion	The AURA Technologies AURA Ion Bar™ Mark IV demonstrated significant efficacy as a germicidal partition, reducing the transfer of STREP aerosols to no growth below quantification limits (≥ 99.999 %) after 2 minutes.

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Study Report

Study Title: EFFICAFY OF THE AURA TECHNOLOGIES ION BAR MARK IV AGAINST STREP

Sponsor: AURA Technologies, LLC.

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

Device Testing: AURA Ion Bar™ Mark IV

Study Dates:

Study Report Date: 9/18/2023

Experimental Start Date: 7/26/2023

Experimental End Date: 8/6/2023

Study Completion Date: 9/15/2023

Study Objective:

AURA Technologies supplied the AURA Ion Bar™ Mark IV for testing purposes to determine efficacy against Streptococcus Pneumoniae (Strep). This study evaluated the effectiveness of the AURA Ion Bar™ Mark IV in its ability to reduce the pathogen strain referred to as Streptococcus Pneumoniae (Strep).

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. A calibrated nebulizer is used to check for proper functionality by nebulizing a solution without the test bacteria to confirm the average particle size distribution of approximately 0.8 um. See Table 1 and Appendix B for particle distribution specifics from sampling of aerosolized solution from the functionality particle testing prior to this study.

Figure 1: BLAM Nebulizer

The nebulizer was filled with a 4.77×10^4 CFU/mL of STREP in suspension media and nebulized at a flow rate of 1mL/min with untreated local atmospheric air. After nebulization, the nebulizer's remaining bacterial stock volume was weighed to confirm that approximately the same amount was nebulized during each run. Bioaerosol procedures for the controls and bacterial challenges were performed in the same manner with corresponding time points and collection rates.

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 four probes connected to calibrated Gilian 10i vacuum devices set at a standard flow of 5.00 L/min with a 0.20% tolerance and were inspected for functionality before being used. Air sample volume collections were confirmed with a Gilian Gilibrator 2 SN-200700-12 and a high flow bubble generator SN-2009012-H with calibrations performed in September 2020. Sample collection volumes were set to 10-minute draws per time point. The air sampler operated with a removable sealed cassette and manually removed after each time point. The 37 mm cassettes and filtration disc, Lot # 26338, used for testing was manufactured by Zefon International Inc. The delicate internal filtration disc used to collect bacterial samples was moistened with a bacterial suspension media to aid in the collection.

Test System Strains: Streptococcus Pneumoniae, Strain Type 1, Lot # 70053013 (ATCC 12344)

Colony Forming Unit (CFU) Assay Procedure:

Materials and Equipment:

- Certified Biological Safety Cabinet
- CO_2 Incubator set at 37 °C or 34 °C, or other temperature as indicated
- Inverted Microscope
- Micropipette and sterile disposable aerosol resistant tips—20uL, 200uL, 1000uL
- Tubes for dilution
- Growth media appropriate for bacterial growth
- Overlay medium
- Lint-free wipes saturated with 70 % isopropyl alcohol

Procedure:

1. Prepare a series of 1:10 dilutions of the bacterial sample in sterile distilled water filling each tube with 9.0 mL distilled water. Vortex the test sample, then transfer 1.0 mL of the bacteria to the first tube, vortex, and discard tip.
2. With a new tip, serial dilute the subsequent sample transferring 1.0 mL.
3. Inoculate the labeled empty Petri dish with each diluted sample, using one plate per dilution.
4. Pour overlay medium into the Petri dish, ensuring aseptic techniques are used to prevent contamination.
5. Gently swirl the plate to mix culture and medium. Ensure that the medium covers the plate evenly and does not slip over the edge of the dish.
6. Wait 10 minutes to allow time for the agar to set.
7. Seal and incubate in the appropriate conditions to allow for bacterial growth, which may vary depending on the microorganism being cultured.
8. Record the number of colonies observed for each dilution. A log drop should be noted between serial dilutions and will vary by 10 % for every 100 colonies counted when comparing sample replicates.
9. Identify the bacterial dilution factor that yields 30 to 300 colonies per dish. Calculate Bacteria Titer by counting the number of colonies formed on the plate. Then use the following formula to determine the titer (CFU/mL) of the bacteria stock:

$$\text{No. of colonies}/(D \times V) = \text{CFU/mL}$$

D = Dilution factor
V = Volume of culture plated on to dish

Sample calculation:

- An average of 50 colonies formed in the 1:10,000 dilution wells
- Volume of culture added: 0.2mL

$$\frac{50}{10^{-4} \times 0.2} = 2.50 \times 10^{6} \text{ CFU/mL}$$

Study Materials and Equipment:

Equipment Overview: The equipment (Fig. 2) arrived at the laboratory pre-packaged by the manufacturer and was inspected for damage upon arrival. Due to the closed design, no assessment was conducted on the inner components of the device. The device was powered on to confirm functionality before testing. Two Alpha Lab AIC2 ion polarity meters confirmed average ion concentrations of ~960,000 negative ions/cm^3 in the doorway six inches above the ground. Ion air sampling was taken every few inches along the width of the doorway to confirm all sections were producing negative ions.

MANUFACTURER: AURA Technologies, LLC.

MODEL: Mark IV pre-production prototype

MAKE: AURA Blue

SERIAL #: NA

Figure 2. AURA Ion Bar™ Mark IV

Testing Layout:

All testing was conducted in a sealed 220 ft (~6.1 m) x 8 ft (~2.44 m) x 8 ft (~2.44 m) chamber following BSL-3 standards. The room had a displacement volume of 1,280 ft^3 (36,245.56 L) of air. The chamber remained closed to prevent any air from entering and leaving the room during testing.

A nebulizing port connected to a programmable compressor system was set 5 ft (~1.52 m) off the floor and 1.5 ft (~0.46 m) from the simulated door opening during aerosol testing; air samples were collected 5 ft (~1.52 m) off the floor and 1.5 ft (~0.46 m) inside the simulated doorway. The AURA Ion Bar™ Mark IV was positioned to replicate the device mounted above a door, clear of any obstructions.

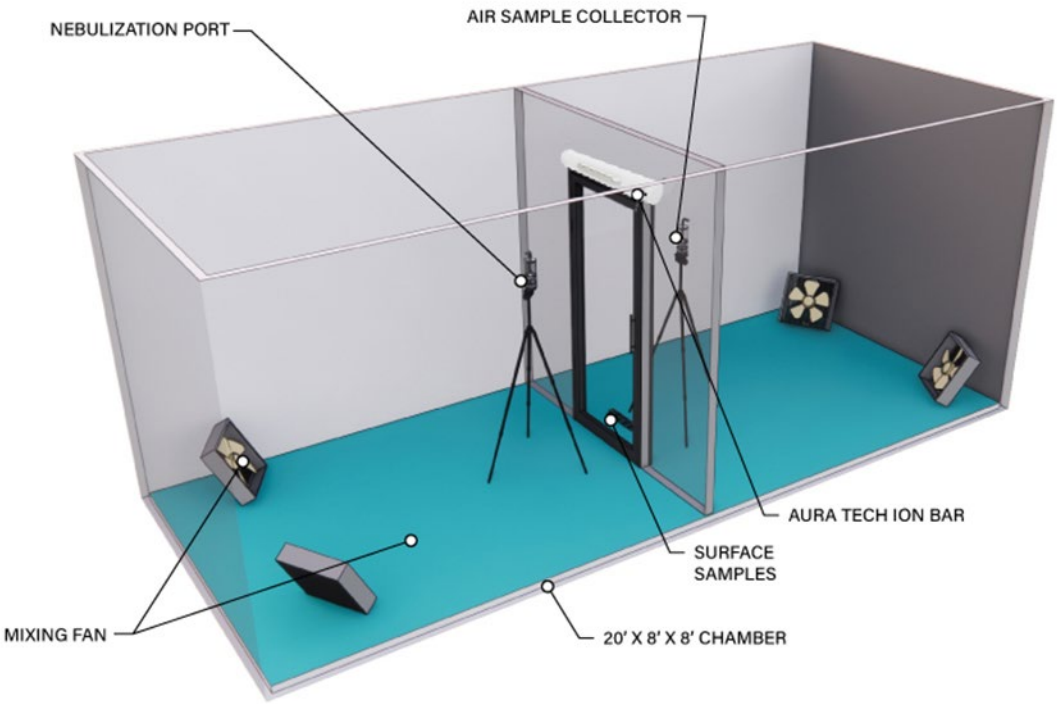


Figure 3. Testing layout for control and experimental trials.

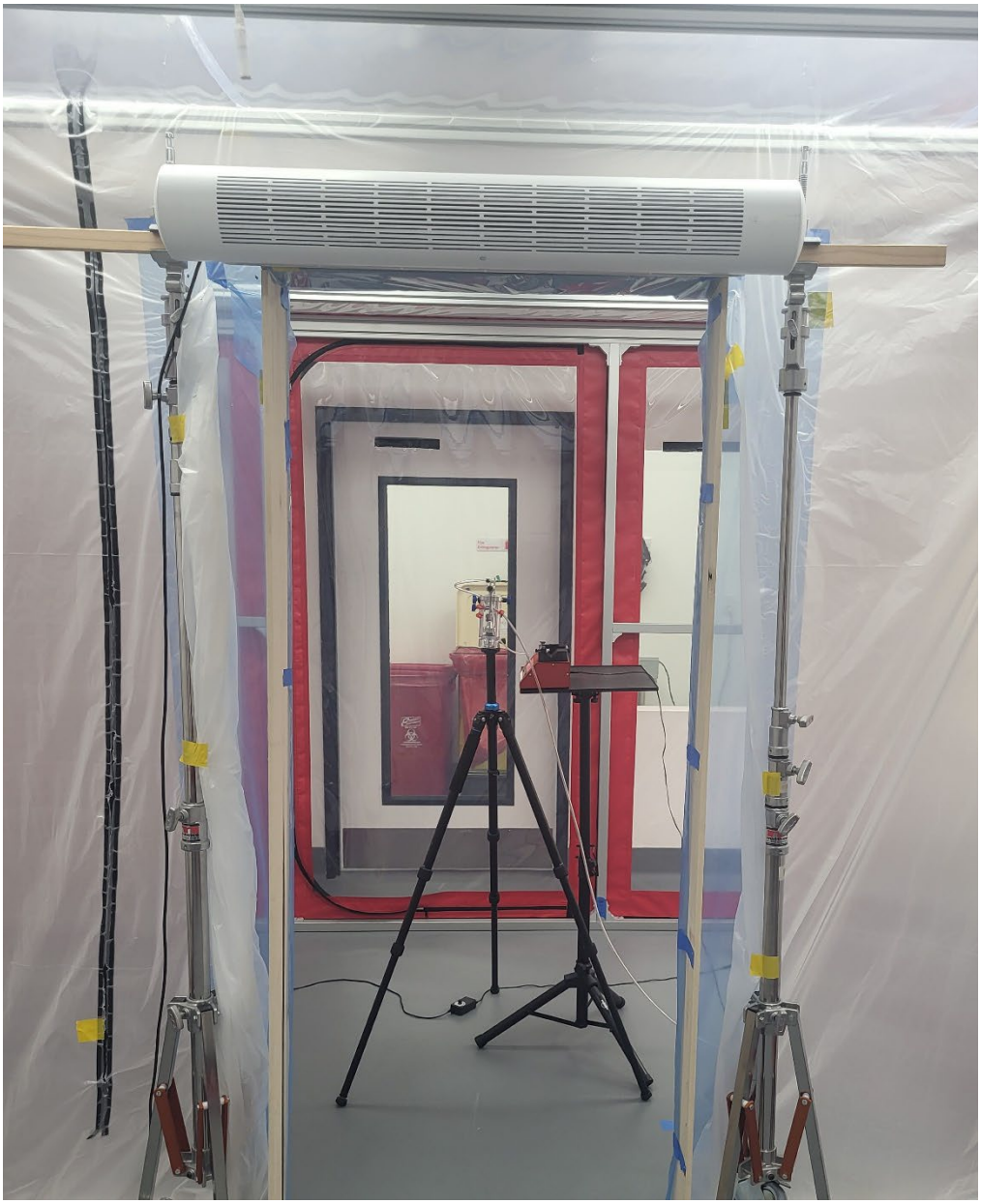


Figure 4. Testing setup.

Test Method:

General Testing Conditions:

1. Before the initial control test and following each trial run, the testing area was decontaminated and prepped per internal procedures.
2. The AURA Ion Bar™ Mark IV ran for the duration of testing unless stated otherwise.
3. The temperature during all test runs was approximately 71 °F ± 2 °F (~21.7 °C ± 1.1 °C) with a relative humidity of 35 %.

Exposure Conditions:

1. Test sample collection occurred between 0 to 2 minutes and was conducted in triplicate.
2. Nebulization of bacterial pathogen occurred at the height of 5 ft (~1.52 m) and distance of 1.5 ft (~0.46 m) outside the simulated door opening.
3. Collection occurred 5 ft (~1.52 m) off the floor and 1.5 ft (~0.46 m) from the simulated doorway on the chamber's inside (clean) side.

Experimental Procedures:

1. 2 mL of 4.77×10^4 CFU/mL STREP bacterial media was nebulized from 0 to 2 minutes to distribute stock into the room.
2. Air samples were taken for 2 minutes with the Gilian 10i programmable vacuum devices.
3. The sample cassettes were manually removed from the collection system after each run.
4. Upon cassette removal after each run, cassette sets were taken to an adjacent biosafety cabinet for extraction and placement into bacterial suspension media.
5. All samples were sealed and provided to lab staff for analysis after study completion.

Post Decontamination:

After each bacterial challenge test, the UV system inside the testing chamber was activated for 30 minutes. After 30 minutes of UV exposure, the air filtration system underwent a 30-minute air purge. All test equipment was cleaned with a 70 % isopropyl alcohol solution at the end of each day. 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:

A control was conducted for aerosol testing with the fan and ionizer off to assess the AURA Ion Bar™ Mark IV accurately. Control samples were taken in the same manner and at the corresponding time points used for the challenge trials to serve as a comparative baseline to assess the net bacterial reduction when the device was operating.

Preparation of The Pathogen

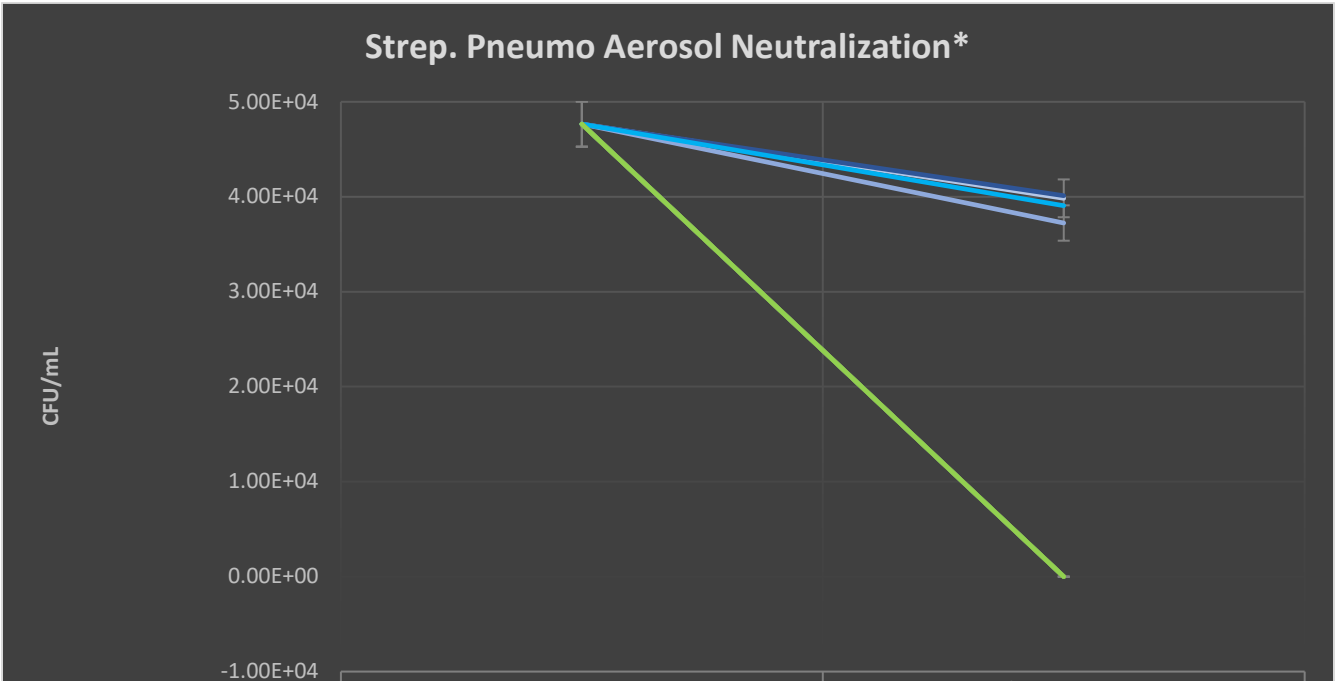
Bacterial Stock: *Streptococcus pyogenes* Strain Type 1 (ATCC 12344, Lot#: 70053013)

TEST	SPECIFICATIONS	RESULTS
Gram stain and cell morphology (Visual observation method)	Gram stain (when applicable) and cell morphology are consistent with the organism being tested.	Gram-positive, non-motile cocci in pairs and long chains
Colony description (Visual observation method)	Colony description is consistent with the organism being tested.	Circular, entire, smooth, low convex, and translucent
Purity (Visual observation method)	Sample material is inoculated onto non-selective media. Cultures are examined macroscopically and microscopically after incubation. Cultures show no evidence of aberrant growth.	No evidence of aberrant growth
Viability (confluency plate) (Visual observation method)	Sample material is viable.	Confluent growth on dilution plate, $>10^4$ cfu/vial
Viability (titer) (Titer method)	Sample material is checked for titer. Results are reported.	2.4×10^8 cfu/vial; Tested on 15Jul2022
Phenotypic testing	Sample material is evaluated with a defined battery of phenotypic tests including evaluation by bioMérieux VITEK 2 Compact. Results are consistent with the organism being tested.	99% identification to *Streptococcus pyogenes* using bioMérieux VITEK 2 Compact
Genotypic testing	Sample material is evaluated by 16S ribosomal gene sequencing. Results are consistent with the organism being tested.	Matches GenBank accession AB023575

*The Certificate of Analysis represents the titer provided by BEI Resources. See Appendix E for more details.

Study Results

Aerosol testing was conducted to determine any pass-through of aerosolized STREP through the AURA Ion Bar™ Mark IV air curtain within 2 minutes of device operation. From the inside of the air barrier, the concentration of active STREP collected at 2 minutes from three test runs were all no growth. The presence of STREP indicated about 0.003% of nebulized STREP passed through the barrier after 2 minutes resulting in a ≥ 99.999 % reduction of nebulized STREP on the protected side. The control observed an 84.18 % pass-through of nebulized STREP after 2 minutes with the AURA Ion Bar™ Mark IV fan and ionizer off.



	Starting Concentration	Final Concentration
Control 1	4.77E+04	3.98E+04
Control 2	4.77E+04	3.72E+04
Control 3	4.77E+04	4.01E+04
Ctrl (avg.)	4.77E+04	3.91E+04
Ctrl (avg.) % Reduction		18.03
Experiment 1	4.77E+04	0.00E+00
Experiment 2	4.77E+04	0.00E+00
Experiment 3	4.77E+04	0.00E+00
Experiment (avg.)	4.77E+04	0.00E+00
Exp (avg.) % Reduction		100.00

* The percentage error equates to an average of ±5% of the final concentration.

Conclusion:

The AURA Ion Bar™ Mark IV demonstrated a significant ability to neutralize Streptococcus Pneumoniae (Strep) from entering the chamber with the test unit running. Aerosolized Streptococcus Pneumoniae (Strep) transfer was significantly restricted through the AURA Ion Bar™ Mark IV germicidal partition with no STREP growth after 2 minutes from a starting concentration of 4.77×10^4 CFU/mL; equivalently, $\geq$ 99.999 % (5 log) of active pathogen. Overall, the AURA Ion Bar™ Mark IV utilized a combination of methods (laminar air curtain and negative ion generation) to reduce the transfer of pathogens through a doorway/portal if installed correctly.

It should be noted that testing was designed to observe the ability of AURA Ion Bar™ Mark IV (controlled airflow and ionizing function ability) to reduce potential exposure to a pathogen. The study focused on the AURA Ion Bar™ Mark IV being mounted above a doorway without obstructions. Air moves differently in all spaces, and human interactions within the environment can change subtle airflow movements. Every effort was made to simulate a real-life situation and address constraints with experimental design and execution while taking the proper precautions when working with a BSL-3 pathogen.

DocuSigned by:
Dr. Dana Yee M.D.
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10/16/2023

Dana Yee M.D **Date**

Clinical Pathologist and Medical Director, Innovative Bioanalysis, Inc.

DocuSigned by:
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10/16/2023

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

Chief Scientific Officer, Innovative Bioanalysis, Inc.

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Albert Brockman **Date**

Chief Biosafety Officer, Innovative Bioanalysis, Inc.

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10/16/2023

Kevin Noble **Date**

Laboratory Director, Innovative Bioanalysis, Inc.

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).

CFU/mL: A CFU or colony-forming unit is a unit for measuring microorganism concentration in a test sample. The total count of observable colonies on an agar plate is multiplied with the dilution factor to provide the resulting CFU/mL.

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.

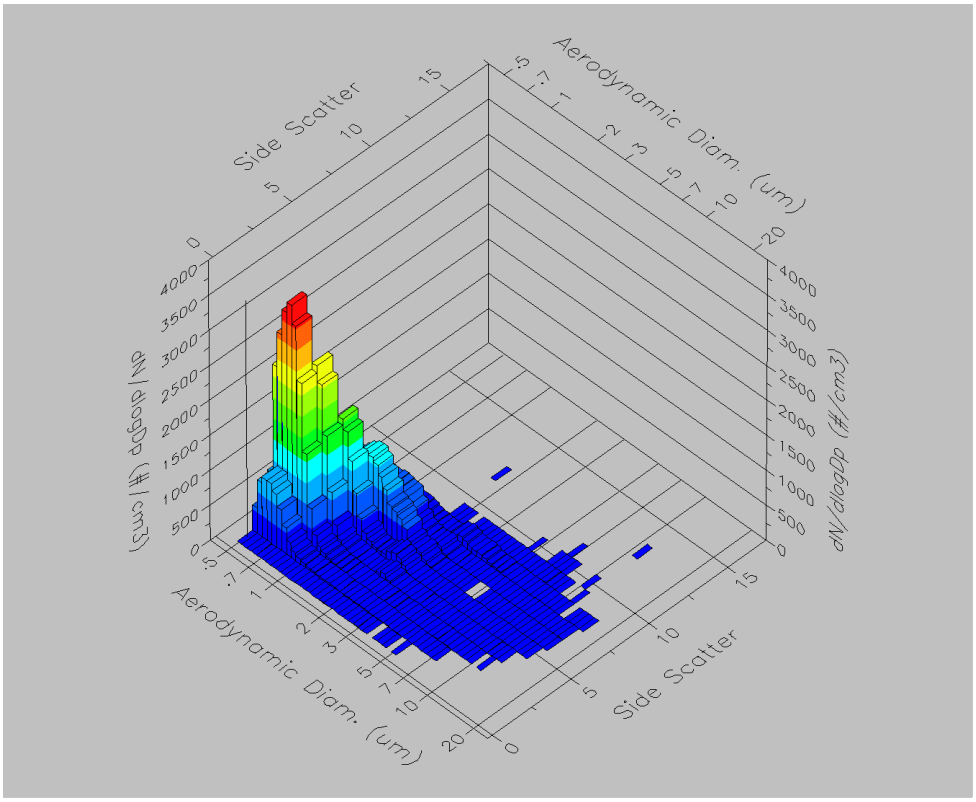
(Commonly used in science to estimate the LLOQ): LLOQ = (Mean negative control pixel intensity) + 10 * (StDev of negative control pixel intensities).

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 137 mM NaCl, 2.7 mM KCl, 8 mM Na_2HPO_4, and 2 mM KH_2PO_4.

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 functionality testing and validation for particle dispersion with the Blaustein Atomizing Module (BLAM) bioaerosol-generating nebulizer. All test equipment, suspension solution, and setup were the same as what was used in this bacterial 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)



APPENDIX C: Calculation equations

CFM/mL calculation method:

No. of colonies/(D × V) = CFU/mL

D = Dilution factor
V = Volume of culture plated on to dish

Percent Reduction calculation:

Percent Reduction = (A-B) * 100 / A

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

Log Reduction calculation:

Log Reduction = $\log_{10}(A/B)$

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

APPENDIX D: 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

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 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 25 50	3.800 3.800 3.800	4.200 4.200 4.200	√ √ √
8	2 15 22	7.600 7.600 7.600	8.400 8.400 8.400	√ √ √
10	2 8 12	9.500 9.500 9.500	10.500 10.500 10.500	√ √ √

Technician Stamp 10

091-1015-01rC

APPENDIX E: BEI Resources - Certificate of Authenticity

ATCC®

CERTIFICATE OF ANALYSIS

ATCC® Number: 12344™
Lot Number: 70053013

Organism: *Streptococcus pyogenes* Strain Type 1
Fill Volume: 0.25 mL
Note: If material is in lyophilized format, the fill volume denotes the volume filling into the vial prior to drying.
Product Format: Bacterial cells suspended in an appropriate cryoprotectant
Expiration Date: 31MAY2027
Storage Conditions: 2°C to 8°C for freeze-dried cultures

Test / Method	Specification	Result
Gram stain and cell morphology (Visual observation method)	Gram stain (when applicable) and cell morphology are consistent with the organism being tested.	Gram-positive, non-motile cocci in pairs and long chains
Colony description (Visual observation method)	Colony description is consistent with the organism being tested.	Circular, entire, smooth, low convex, and translucent
Purity (Visual observation method)	Sample material is inoculated onto non-selective media. Cultures are examined macroscopically and microscopically after incubation. Cultures show no evidence of aberrant growth.	No evidence of aberrant growth
Viability (confluency plate) (Visual observation method)	Sample material is viable.	Confluent growth on dilution plate, $>10^4$ cfu/vial
Viability (titer) (Titer method)	Sample material is checked for titer. Results are reported.	2.4×10^8 cfu/vial; Tested on 15Jul2022
Phenotypic testing	Sample material is evaluated with a defined battery of phenotypic tests including evaluation by bioMérieux VITEK® 2 Compact. Results are consistent with the organism being tested.	99% identification to *Streptococcus pyogenes* using bioMérieux VITEK® 2 Compact
Genotypic testing	Sample material is evaluated by 16S ribosomal gene sequencing. Results are consistent with the organism being tested.	Matches GenBank accession AB023575

Jo Salisbury
Digitally signed by Jo Salisbury
Date: 2022.07.27 12:38:10 -04'00'
Quality Assurance Specialist; Quality Assurance

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

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Manassas, VA 20110-2209 USA
www.atcc.org

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Fax: 703-365-2750
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or contact your local distributor

- Page 1 of 2 -

Template Doc ID: 31194 Template Revision: 6 Template Effective Date: 02/21/2020

ATCC®

CERTIFICATE OF ANALYSIS

ATCC® Number: 12344™

Lot Number: 70053013

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

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