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EFFICACY OF THE 12" CIRCULAR PLASMA CEILING LIGHT AGAINST AEROSOLIZED SARS-COV-2

PROJECT: 12" CIRCULAR PLASMA CEILING LIGHT – SARS-COV-2

PRODUCT: 12" CIRCULAR PLASMA CEILING LIGHT

CAP LIC NO: 8860298

CLIA LIC NO: 05D0955926

STATE ID: CLF 00324630

CHALLENGE ORGANISM:

SARS-COV-2 USA-CA1/2020

STUDY COMPLETION DATE:

05/21/2022

Medical Director

Dana Yee, M.D.

Testing Facility

Innovative Bioanalysis, Inc.

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Laboratory Project Number

1242-12

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Table of Contents

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Efficacy Study Summary:

Study Title	EFFICACY OF THE 12” CIRCULAR PLASMA CEILING LIGHT AGAINST AEROSOLIZED SARS-COV-2
Laboratory Project #	1242
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 12" Circular Plasma Ceiling Light provided by ETI Solid State Lighting (Zhuhai) Ltd was designed as a hybrid lighting solution that combines lighting with a disinfection system. The device was designed to be mounted to a ceiling and aid in reducing pathogen concentrations in the air. This study sought to determine the device's efficacy in lowering active aerosolized SARS-CoV-2 in a controlled environment.
Test Conditions	Testing was conducted in a 10’x8’x8’ chamber following BSL-3 standards. The temperature during testing ranged between 74-75°F, with a relative humidity of 36-37%. A 9.27×10^6 TCID50/mL of SARS-CoV-2 in suspension media was nebulized into the room with mixing fans before collection. Air sample collections occurred at 0, 120, and 240 minutes of device operation.
Test Results	The test results displayed observable reduction rates compared to the natural viability loss observed in the controls. The 12" Circular Plasma Light reduced active SARS-CoV-2 to approximately 4.03×10^2 TCID50/mL after 120 minutes and reached below the limit of assay quantitation after 240 minutes, indicated by the value of 1.20×10^2 TCID50/mL.
Control Results	Control testing was conducted in duplicate 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 viral reduction.
Conclusion	The 12" Circular Plasma Ceiling Light demonstrated the ability to reduce active SARS-CoV-2 in the air, as shown by the 99.996% gross reduction after 120 minutes.

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Study Report:

Study Title: EFFICACY OF THE 12" CIRCULAR PLASMA CEILING LIGHT AGAINST AEROSOLIZED SARS-COV-2

Sponsor: ETI Solid State Lighting, Inc.

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

Device Testing: 12" Circular Plasma Ceiling Light (model number: 559031###, 558121###) *
(Note: The first ## maybe 00-99 represents different LED color temperature and the last # maybe 0-9 or blank for internal use. The two models are the same except model name and color of indicator light are different.)

Study Dates:

Study Report Date: 05/19/2022

Experimental Start Date: 05/04/2022

Experimental End Date: 05/06/2022

Study Completion Date: 05/21/2022

Study Objective:

ETI Solid State Lighting (Zhuhai) Ltd supplied the 12" Circular Plasma Ceiling Light for testing to determine efficacy against viral pathogens. The study evaluated the effectiveness of the 12' Circular Plasma Ceiling Light in its ability to reduce the viral strain referred to as SARS-CoV-2 USA-CA1/2020 within the air.

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 present to confirm the average particle size distribution. The nebulizer was filled with 9.27 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 weighed to confirm 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.

Figure 1: BLAM Nebulizer

** Note: The 12" Circular Plasma Ceiling Light tested did not include a model number. The model # listed was provided by ETi Solid State Lighting, Inc. with supporting ETL report documentation as included in Appendix A.*

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. Cassettes had a delicate internal filtration disc (Fig. 2) to collect virus samples, which was moistened with a virus suspension media to aid in the collection. Filtration discs from Zefon International, Lot# 28875, were used for testing. At each time point, all the sample discs were pooled into one collection tube to provide an average across the four sampling locations.

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

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.

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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 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. No product label indicating the name, model or serial number were found on the device. The device was powered on to confirm functionality before testing. Ion generation was confirmed using two Alpha Lab AIC2 ion polarity meters placed inside the room while the units were operating. The average ion concentration at the recorded point was approximately 57,000 ions/cm^3. It should be noted that due to the nature of ions, there would be fluctuations in concentrations around the entire room.

MANUFACTURER: ETI Solid State Lighting (Zhuhai) Ltd

PRODUCT: 12" Circular Plasma Ceiling Light

SIZE: 12” x 12” x 2.65”

SERIAL #: N/A

Figure 3. 12” Circular Plasma Ceiling Light unit as tested.

Testing Layout:

Testing was conducted in a sealed 10’x8’x8’ chamber per Biosafety Level 3 (BSL3) standards. The overall dimensions of the test chamber provided a displacement volume of 640 ft^3 (approximately 18,122.78 liters) of air. The chamber remained closed during testing, with no air entering or leaving the room. A nebulizing port connected to a programmable compressor system was located in the center of the 10-ft wall protruding 24-inches from the wall. 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. Two devices were mounted in the chamber's centerline as close to the ceiling as possible and positioned 5 ft apart, as shown in Figure 4. The devices were set on high for all testing. The chamber was visually inspected, and pressure tested, and all internal lab systems and equipment were reviewed before testing.

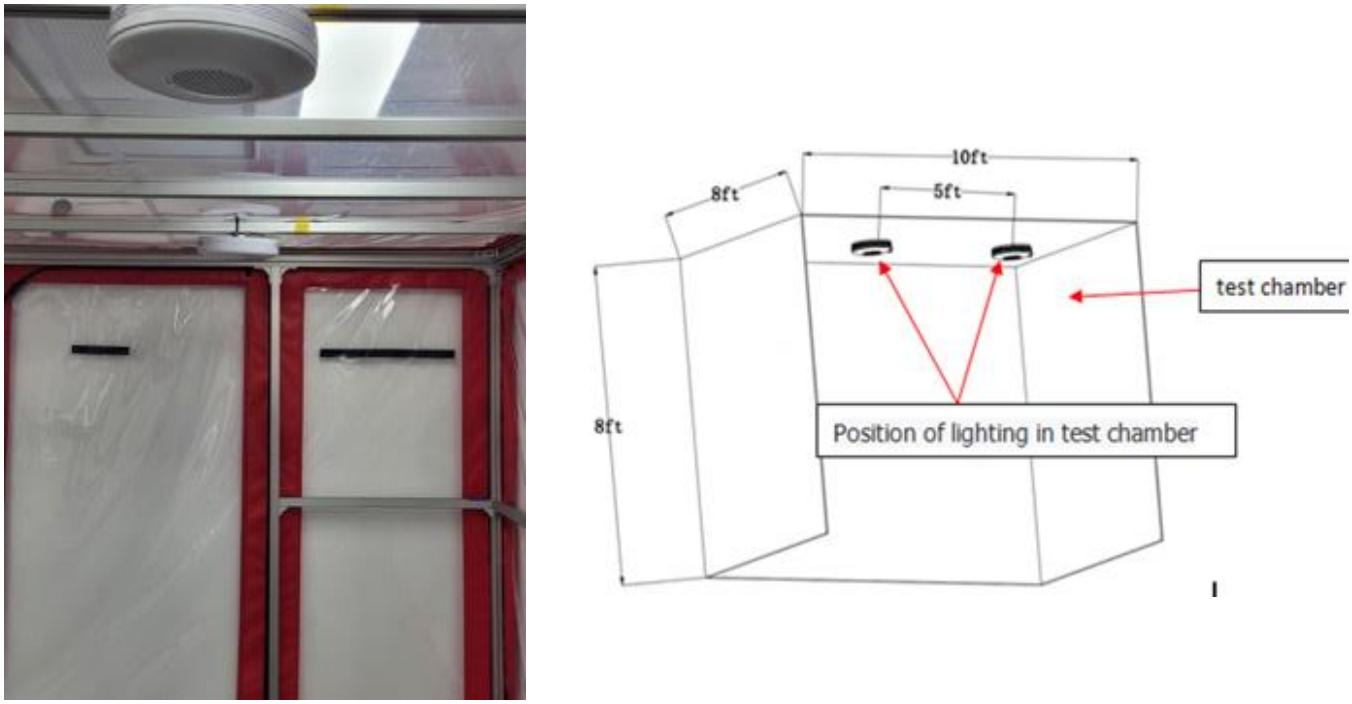

Figure 4. 12" Circular Plasma Ceiling Light positioning in the testing chamber.

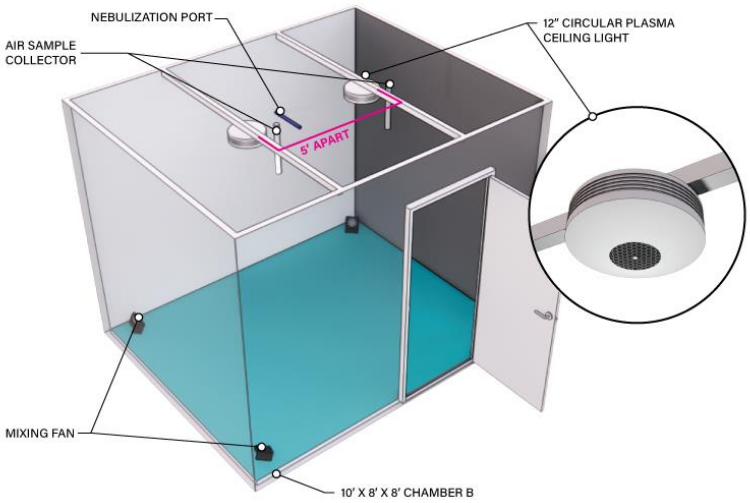

Figure 5. 3D model of the testing layout for control and experimental trials.

Control Protocol:

Control testing was conducted in duplicate without the device operating in the testing chamber to assess the 12" Circular Plasma Ceiling Light accurately. 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 74-75°F, with a relative humidity of 36-37%.
2. The device fan speed was set at High for all testing.
3. Testing time points were as follows, with T equal to minutes: T-0, T-120, and T-240.
4. Two controls and three viral challenges were conducted using the same methodology.

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 9.27 x 10^6 TCID50/mL SARS-CoV-2 in suspension media was nebulized via a dissemination port into the room.
3. After nebulization (T-0), the circular ceiling light was turned on via remote control.
4. At each predetermined time point, the device was turned off for sample collection.
5. Air sampling collections were set to 10-minute continuous draws at the point of sampling.
6. Sample cassettes were manually removed from the collection system and brought to an adjacent biosafety cabinet for extraction and placement into a viral suspension media.
7. 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, 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 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-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.

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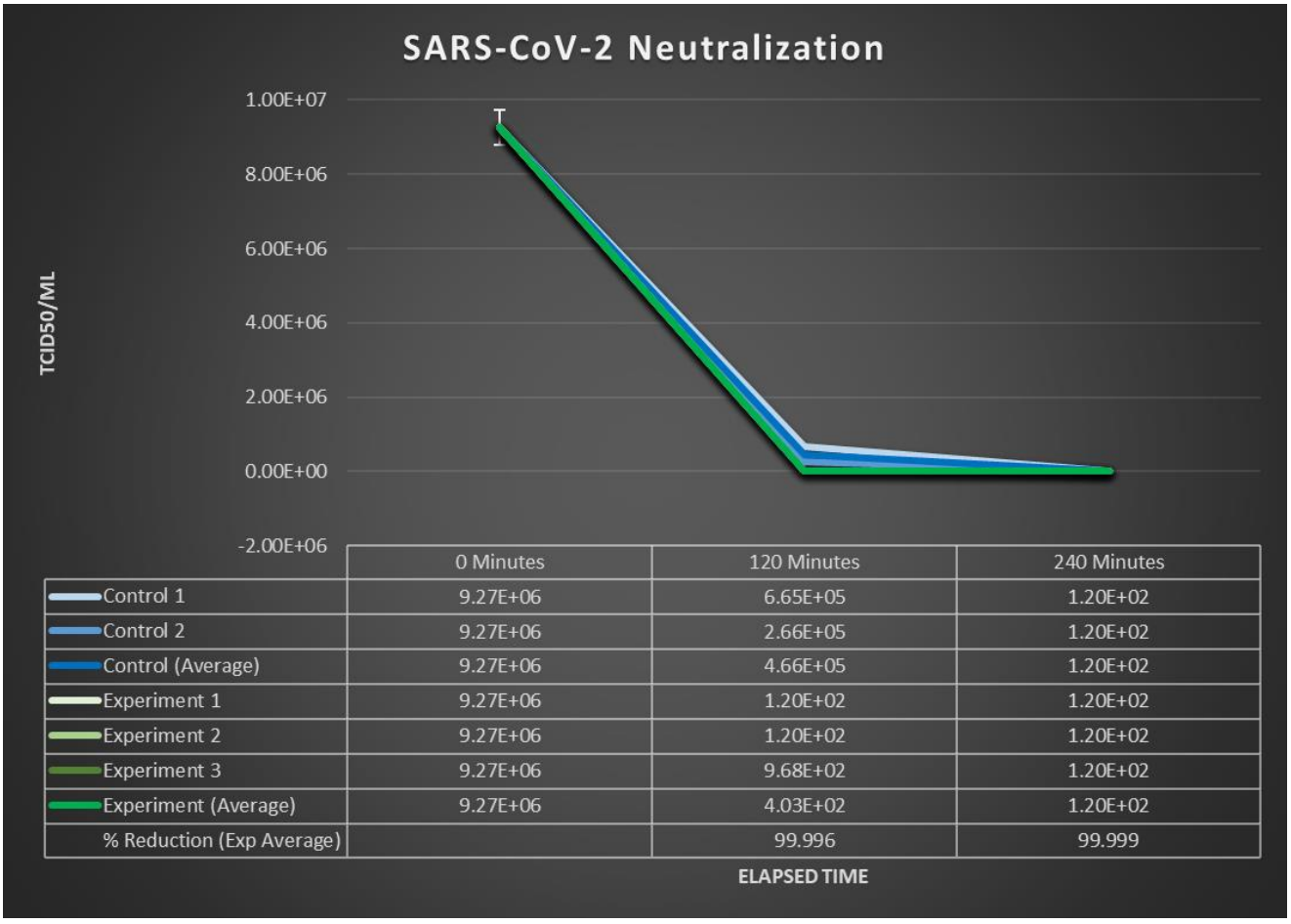
Study Results:

The graph below displayed recoverable active SARS-CoV-2 with and without the 12" Circular Plasma Ceiling Light operating under controlled conditions. The controls showed a natural loss of aerosolized SARS-CoV-2 within the chamber and low recoverable active SARS-CoV-2 at 240 minutes. Across three trials, the device reduced a starting concentration of 9.27 x 10^6 TCID50/mL of SARS-CoV-2 to 1.20 x 10^2, 1.20 x 10^2, and 9.68 x 10^2 TCID50/mL averaging approximately 4.03 x 10^2 TCID50/mL after 120 minutes. After 240 minutes of operation, the device reduced active SARS-CoV-2 to below the assay quantitation limits, represented by 1.20 x 10^2 TCID50/mL.



	0 Minutes	120 Minutes	240 Minutes
Control 1	9.27E+06	6.65E+05	1.20E+02
Control 2	9.27E+06	2.66E+05	1.20E+02
Control (Average)	9.27E+06	4.66E+05	1.20E+02
Experiment 1	9.27E+06	1.20E+02	1.20E+02
Experiment 2	9.27E+06	1.20E+02	1.20E+02
Experiment 3	9.27E+06	9.68E+02	1.20E+02
Experiment (Average)	9.27E+06	4.03E+02	1.20E+02
% Reduction (Exp Average)		99.996	99.999

*** 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.

Conclusion:

The 12" Circular Plasma Ceiling Light demonstrated the ability to reduce active, aerosolized SARS-CoV-2 slightly faster than the natural loss rate observed in the controlled environment. The device achieved an average 99.996% gross reduction of active SARS-CoV-2 compared to the 94.97% viability loss in the controls after 120 minutes. At 120 minutes, the control and experimental trials observed low concentrations of recoverable active SARS-CoV-2 with a 99.999% loss in the controls and with the device.

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 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 12" Circular Plasma Ceiling Light achieved measurable reduction. The results observed were consistent with the manufacturer's claim that the device can decrease concentrations of active pathogens. Overall, the device successfully reduced active SARS-CoV-2 in the air by 99.996% after 120 minutes under controlled conditions.

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7/14/2022

Kevin Noble **Date**

Laboratory Director, Innovative Bioanalysis, Inc.

Appendix A: Model Number Documentation (ETL Report 220114009GZU-001)

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Listing Constructional Data Report (CDR)

1.0 Reference and Address			
Report Number	220114009GZU-001	Original Issued: 14-Mar-2022	Revised: None
Standard(s)	Luminaires [UL 1598:2021 Ed.5+R:18Jun2021] Luminaires [CSA C22.2#250.0:2021 Ed.5+U1]		
Applicant	ETI Solid State Lighting (Zhuhai) Ltd.	Manufacturer 1	**ETI Solid State Lighting (Zhuhai) Ltd.**
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Report No. 220114009GZU-001 Page 2 of 32 Issued: 14-Mar-2022
ETI Solid State Lighting (Zhuhai) Ltd. Revised: None

2.0 Product Description	
Product	Fixed luminaire with ionizer
Brand name	ETI, Silentaire, Cleanaire, NVC, Cleanaire pro, Blue Halo
Description	The products covered by this report are LED fixed luminaires equiped with ionizer suitable for damp location use.
Models	558121, 559031; followed by zero to three characters.
Model Similarity	The model name suffix letters "XXX", where the first and the second "X=0-9" denotes color temperature, the last "X=0-9" denotes different manufacture factory. The two models have the same electrical and mechanical construction except for the indicated LED color.
Ratings	Input: 120-277VAC, 50/60Hz, 17W, 100 pcs non-replaceable LEDs, Φ305*93mm.
Other Ratings	Ta=45℃.

See Full ETL Report for more luminaire specific details.