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STAPHYLOCOCCUS AUREUS ON SURFACE EFFICACY TESTING

PROJECT: GPS SURFACE *S. Aureus*

TECHNOLOGY: Needle Point Bipolar Ionization (NPBI™)

DEVICE: GPS-FC48-AC™

CAP LIC NO: 8860298

CLIA LIC NO: 05D0955926

STATE ID: CLF 00324630

CHALLENGE ORGANISM:

STAPHYLOCOCCUS AUREUS ROSENBACH

Dana Yee, M.D.

Medical Director

Study Completion Date:

6/14/2021

Study Revision Date:

3/22/22

Testing Facility:

Innovative Bioanalysis, Inc.

3188 Airway Ave Suite D

Costa Mesa CA, 92626

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Laboratory Project Number:

1034-S.A.

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Efficacy Study Summary

Study Title	*STAPHYLOCOCCUS AUREUS* (*S. AUREUS*) SURFACE EFFICACY TESTING
Laboratory Project #	1034-S.A.
Guideline:	No standard exists; GCLP 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	*Staphylococcus aureus* Rosenbach
Description	The GPS-FC48-AC™ device housing NPBI™ technology is commercially available and designed to be installed in the ductwork of an HVAC system to reduce the concentration of certain viruses and bacteria on surfaces and potentially in the air while operational. Testing was conducted on the device to evaluate the effectiveness of the NPBI™ technology in reducing a known bacterium, *Staphylococcus aureus,* on a surface.
Test Conditions	The test was conducted in an airtight 20'x8'x8' chamber with a redundant negative pressure system connected to HEPA filters and an in-duct UV-C system. The temperature during testing was 72 ± 2°F, with a relative humidity of 47%. Surface samples were collected after 0, 15, 30, 45, and 60 minutes of exposure to the operating device.
Test Results	The GPS-FC48-AC™ device housing NPBI™ technology reduced the initial *Staph. aureus* concentration of 26,400 CFU/mL to 15,128 CFU/mL after 45 minutes of exposure to the device. After 60 minutes of operation, the amount of viable *S. aureus* decreased to 1,846 CFU/mL. Ion concentrations were measured during testing with an average over the 60 minutes of 14,000 negative ions per cm^3
Control Results	A decrease from 26,400 to 21,864 CFU/mL was observed after 60 minutes. The results showed a natural loss rate over 60 minutes and were used to assess NPBI™ technology's ability to reduce *S. aureus*.
Conclusion	Against *Staphylococcus aureus*, the NPBI™ technology demonstrated a higher reduction rate with the technology in operation. A 93.00% reduction in active *S. aureus* after 60 minutes of exposure compared to a 17.18% reduction in control.

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Study Report

Study Title: *STAPHYLOCOCCUS AUREUS* (*S. AUREUS*) SURFACE EFFICACY TESTING

Sponsor: Global Plasma Solutions

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

Technology Tested: NPBI™

Device Tested: GPS-FC48-AC™

Study Dates:

Study Report Date: 06/14/2021
Study Report Revision Date: 03/22/2022
Experimental Start Date: 04/12/2021
Experimental End Date: 04/15/2021
Study Completion Date: 06/14/2021

Study Objective:

An ionization unit, GPS-FC48-AC™ containing NPBI™ technology, was provided by Global Plasma Solution for testing to determine the surface efficacy against *Staphylococcus aureus.*

Test Method:

Five dishes (one per time point) were inoculated with 26,400 CFU/mL of *Staph. aureus* Rosenbach for the control and viral challenges. After each time point, the sample was taken to the adjacent biosafety hood, where it was swabbed and rinsed. Swabs were sealed and analyzed by the staff after the study was completed.

Test System Strains: *Staphylococcus aureus*, NCTC 8532 [IAM 12544, R. Hugh 2605]

ATCC #: 12600

Staphylococcus aureus (S. aureus), strain NCTC 8532 [IAM 12544, R. Hugh 2605] nt. Bull. Bacteriol. Nomencl. Taxon. 8: 154, 1958. Hugh R, Ellis MA. The neotype strain for Staphylococcus epidermidis (Winslow and Winslow 1908), Evans 1916. Int. J. Syst. Bacteriol. 18: 231-239, 1968. Skerman VB, et al. Approved lists of bacterial names. Int J Syst Bacteriol 30: 225-420, 1980. GP2 MicroPlate. Biolog. Staphylococcus aureus and staphylococcal enterotoxins. Washington, DC: American Public Health Association; APHA APHA2001-39, 2001

Study Materials and Equipment:

Equipment Overview: The GPS-FC48-AC™ device housing NPBI™ technology 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™

SERIAL #: N/A

Testing Layout:

Testing was conducted in a 20'x8'x8' controlled chamber per Biosafety Level 3 (BSL3) standards. Sample dishes were placed on a stainless-steel table approximately 35 inches above the ground opposite from the device. Two Alpha Labs AIC2 ion meters were positioned behind the sample dishes to monitor positive and negative ion concentrations. During testing, ion measurements were taken directly above the samples to confirm consistent readings, as shown in Figure 2. The device was mounted on a movable scaffolding against the wall at an elevated position 74 inches above the ground. A variable-speed fan was placed behind the GPS-FC48-AC™ to create the necessary airflow to produce the required concentration of negative and positive ions. The chamber was visually inspected and pressure tested, and all internal lab systems and equipment were reviewed before testing.

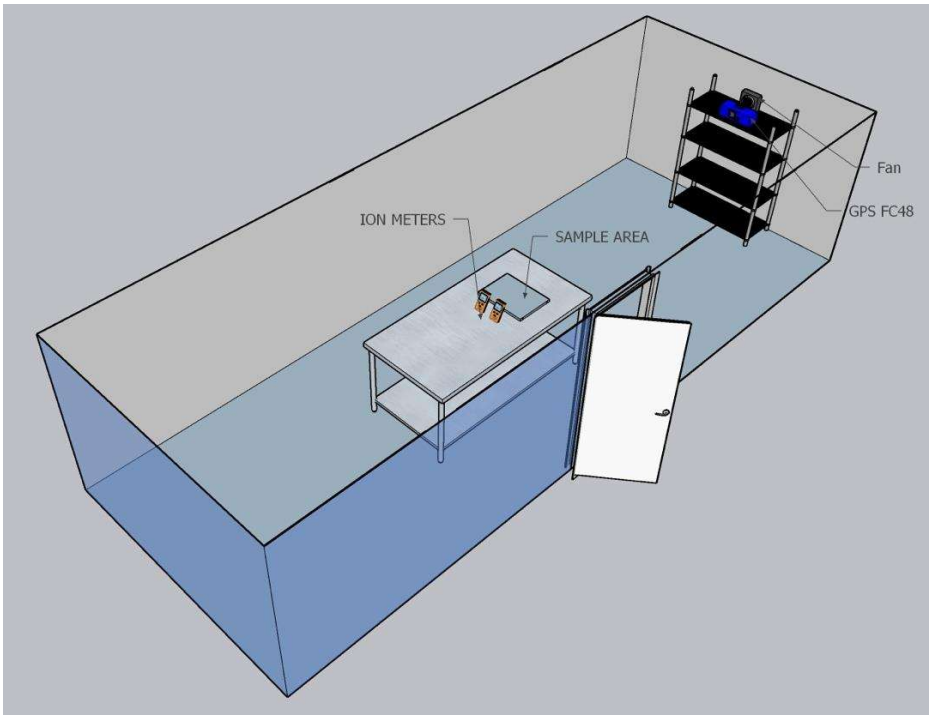

Figure 1. Room layout for the control and experimental trials.

Test Method:

Exposure Conditions:

1. Temperatures taken during all test runs ranged from 72°F to 74°F with a relative humidity of 47%.
2. Surface samples were collected at the following time points after exposure to the device: 0, 15, 30, 45, and 60 minutes.

Experimental Procedure

1. Before the initial control test and after each run, the chamber was decontaminated and prepped per internal procedures.
2. The GPS-FC48-AC™ device housing NPBI™ technology was turned on prior to the start of testing at the 0-minute time point.
3. Inoculated dishes of *S. aureus* Rosenbach labeled with time point designation were placed on a stainless-steel table.
4. A swab and rinse were performed on each sample dish and cultured to determine recovery and efficacy.
5. All swabs were sealed after collection and provided to lab staff for analysis after study completion.
6. After the testing, the UV system inside the lab was activated for 30 minutes.
7. After 30 minutes of UV exposure, all test equipment was cleaned with a 70% alcohol solution.

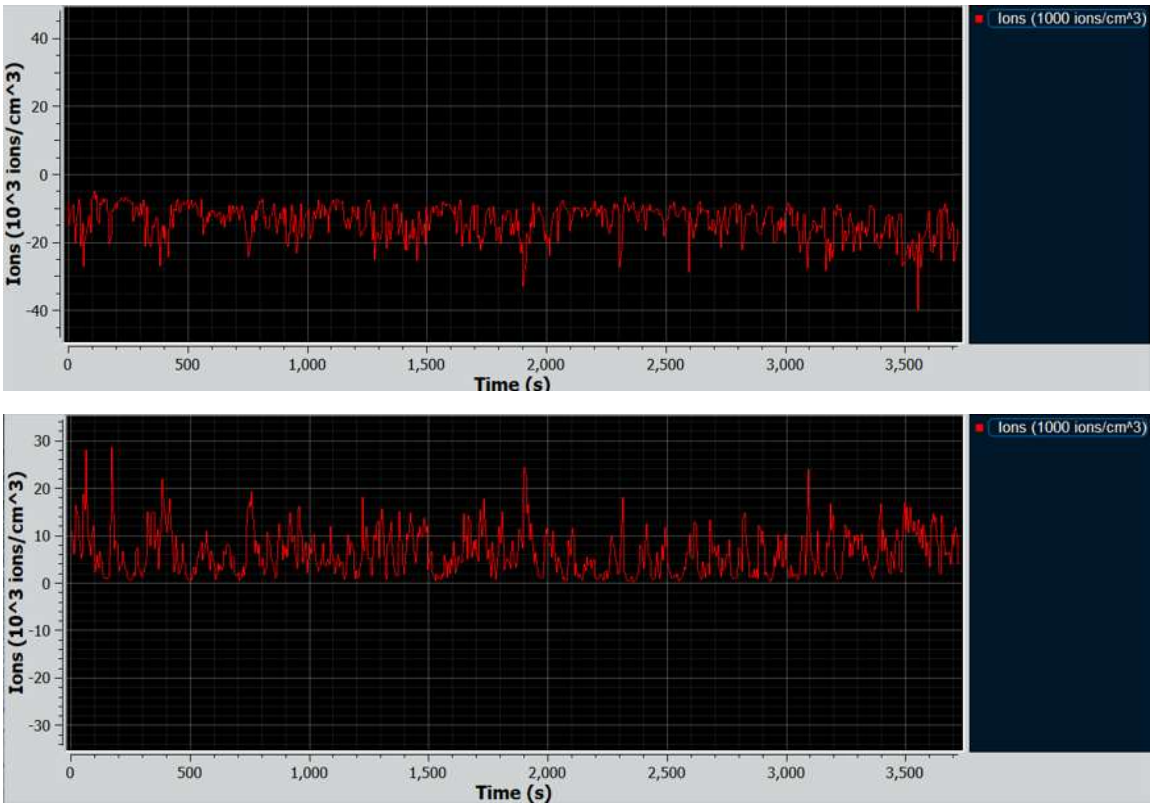

Figure 2. Device ion concentration recordings while in operation during testing.

Preparation of The Pathogen

Staphylococcus aureus was cultured by plating the organism on Blood Agar and incubated at 37°C for 24 hours. A single isolate colony was harvested and introduced to a nutrient broth and allowed to incubate at 37°C for an additional 24 hours. This process was replicated several times to reach higher concentrations of the organism and to be able to represent a potential for a greater log reduction. Upon completion of the incubation period, bacteria were harvested and rinsed three times in phosphate-buffered saline. A 1 to 10 dilution was made by removing 1 mL of inoculated nutrient broth and adding 9 mL of phosphate-buffered saline. This solution was further diluted to a final concentration of 1:100.

MATERIALS AND EQUIPMENT:

- Certified Biological Safety Cabinet
- Micropipette and sterile disposable aerosol resistant tips—20uL, 200 uL, 1000uL
- Microscope
- Tubes for dilution
- Hemocytometer with a coverslip
- Nutrient Broth
- Blood Agar
- 10 uL Inoculation Loops
- CO_2 Incubator set at 34°C

Control Protocol

To accurately assess the GPS-FC48-AC™ device housing NPBI™ technology 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 the bacterial reduction when the device was operating.

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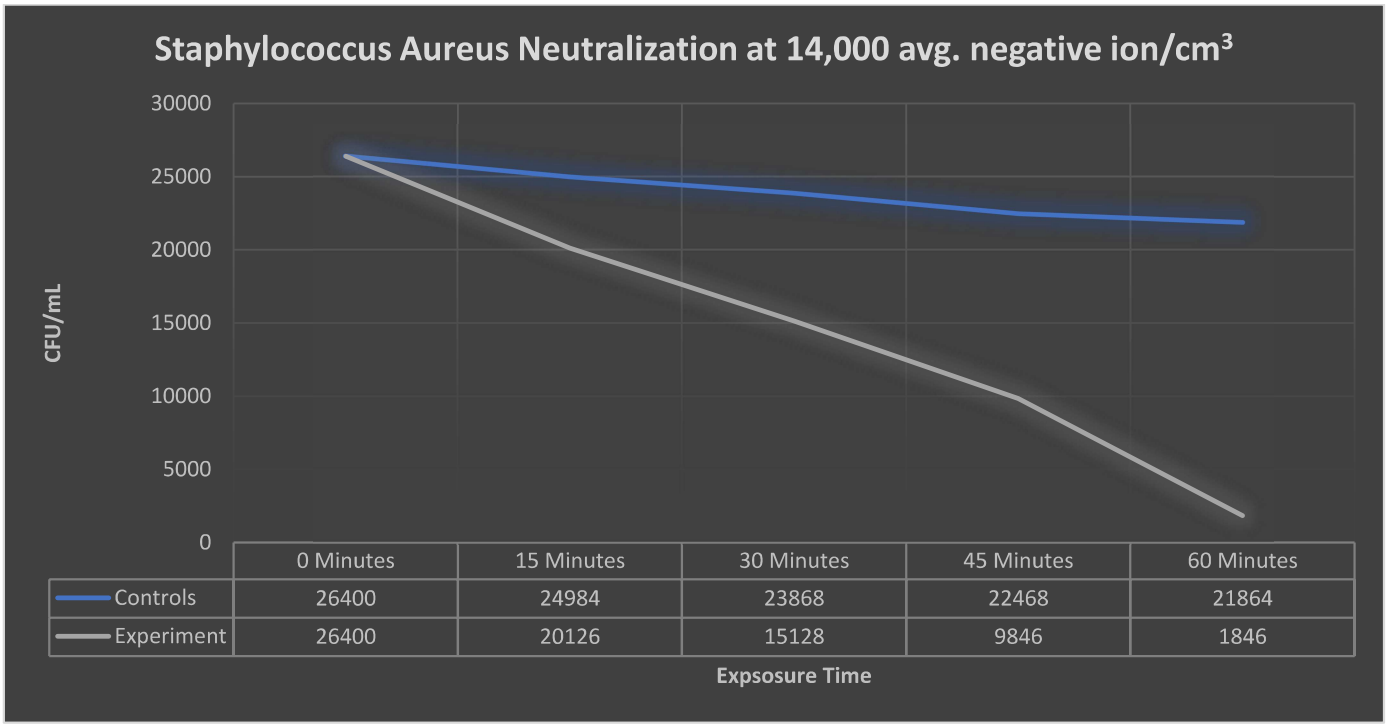
Study Results



Conclusion:

The GPS-FC48-AC™ device housing NPBI™ technology demonstrated the ability to reduce active *S. aureus* on a surface. The results showed a higher rate of reduction than the natural loss of viability in the control group. A 93.00% reduction of the organism was achieved after 60 minutes of device operation. Ion concentrations were measured during testing with an average over the 60 minutes of 14,000 negative ions per cm^3.

Considerations:

When working with microorganisms and collecting said microorganisms, some variables cannot be fully accounted for, 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.

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