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# METHICILLIN-RESISTANT *S. AUREUS* ON SURFACE EFFICACY TESTING

**PROJECT: GPS SURFACE *MRSA***

TECHNOLOGY: Needle Point Bipolar Ionization

DEVICE: GPS-FC48-AC™

CAP LIC NO: 8860298

CLIA LIC NO: 05D0955926

STATE ID: CLF 00324630

**CHALLENGE ORGANISM (S):**

NR-41877 *STAPHYLOCOCCUS AUREUS*, M0055 (MRSA)

**Dana Yee, M.D.**

Medical Director

**Study Completion Date:**

6/14/2021

**Testing Facility**

Innovative Bioanalysis, Inc.

3188 Airway Ave Suite D

Costa Mesa CA, 92626

www.InnovativeBioanalysis.com

Email: info@innovativeBioanalysis.com

**Laboratory Project Number**

1034-M

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# Table of Contents

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## Efficacy Study Summary

| | |
|---|---|
| **Study Title** | METHICILLIN-RESISTANT *S. AUREUS* (MRSA) SURFACE EFFICACY TESTING |
| **Laboratory Project #** | 1034-M |
| **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** | NR-41877 *Staphylococcus aureus*, M0055 (MRSA) |
| **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 bacterial strain, MRSA, 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 active *Staphylococcus aureus*, M0055 from a starting concentration of 42,000 CFU/mL to 20,468 CFU/mL after 30 minutes. With the device operating for 60 minutes, collectible MRSA dropped to 3,985 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** | Methicillin-resistant *S. aureus* (MRSA) was observed to decrease from 42,000 to 32,864 CFU/mL after 60 minutes of exposure. The results for the controls were plotted to show a natural rate of loss over 60 minutes and used to assess the NPBI™ technology's ability to reduce MRSA on surfaces. |
| **Conclusion** | Using the NPBI™ technology, MRSA was reduced at a more rapid rate than in a controlled setting without the device over 60 minutes with a 90.51% reduction in active *S. aureus*, M0055 with the technology. |

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# Study Report

Study Title: METHICILLIN-RESISTANT *S. AUREUS* (MRSA) SUSPENSION 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 Report Date: 6/14/2021
Experimental State Date: 4/12/2021
Experimental End Date: 4/16/2021
Study Completion Date: 6/14/2021

## Study Objective:

An ionizing device, GPS-FC48-AC™ containing NPBI™ technology, was provided by Global Plasma Solution for testing to determine the surface efficacy against a known strain of bacteria, Methicillin-resistant *S. aureus* (MRSA).

## Test Method:

Five dishes (one per time point) were inoculated with 42,000 CFU/mL of MRSA 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: NR.41877 *Staphylococcus aureus*, M0055 (MRSA)

*Staphylococcus aureus* (*S. aureus*) strain M0055 was isolated in 2003.

"The following reagent was obtained through BEI Resources, NIAID, NIH: *Staphylococcus aureus*, Strain M0055 (MRSA), NR-41877."

## Study Materials and Equipment:

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.

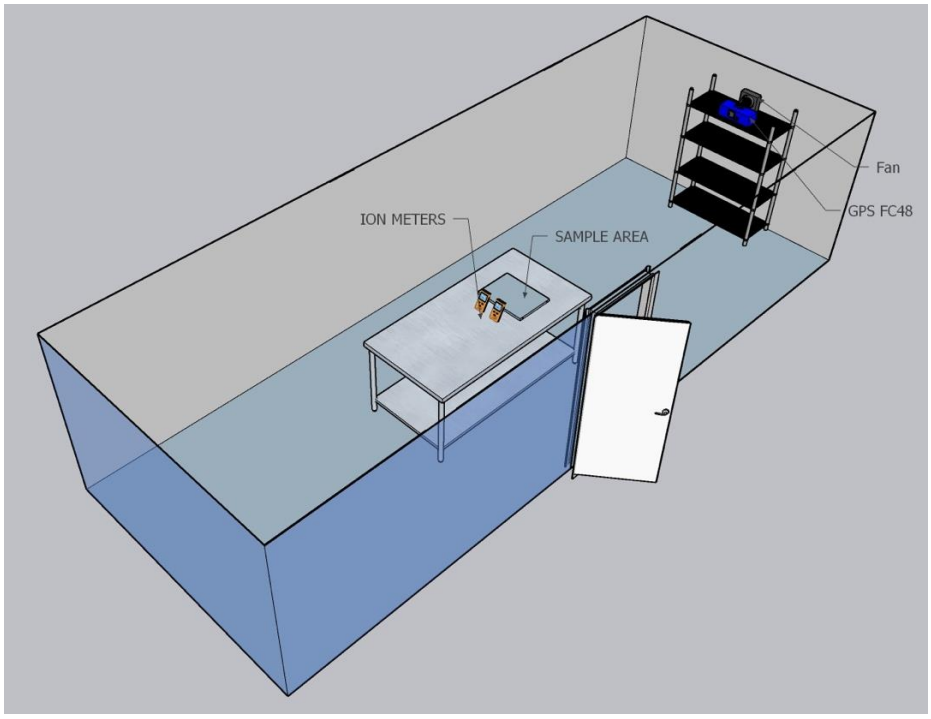


Figure 1. Room layout for the control and experimental trials.

## Test Method:

**Exposure Conditions:**

1. Temperatures taken during all test runs ranged from 72°F to 73°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*, M0055 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.

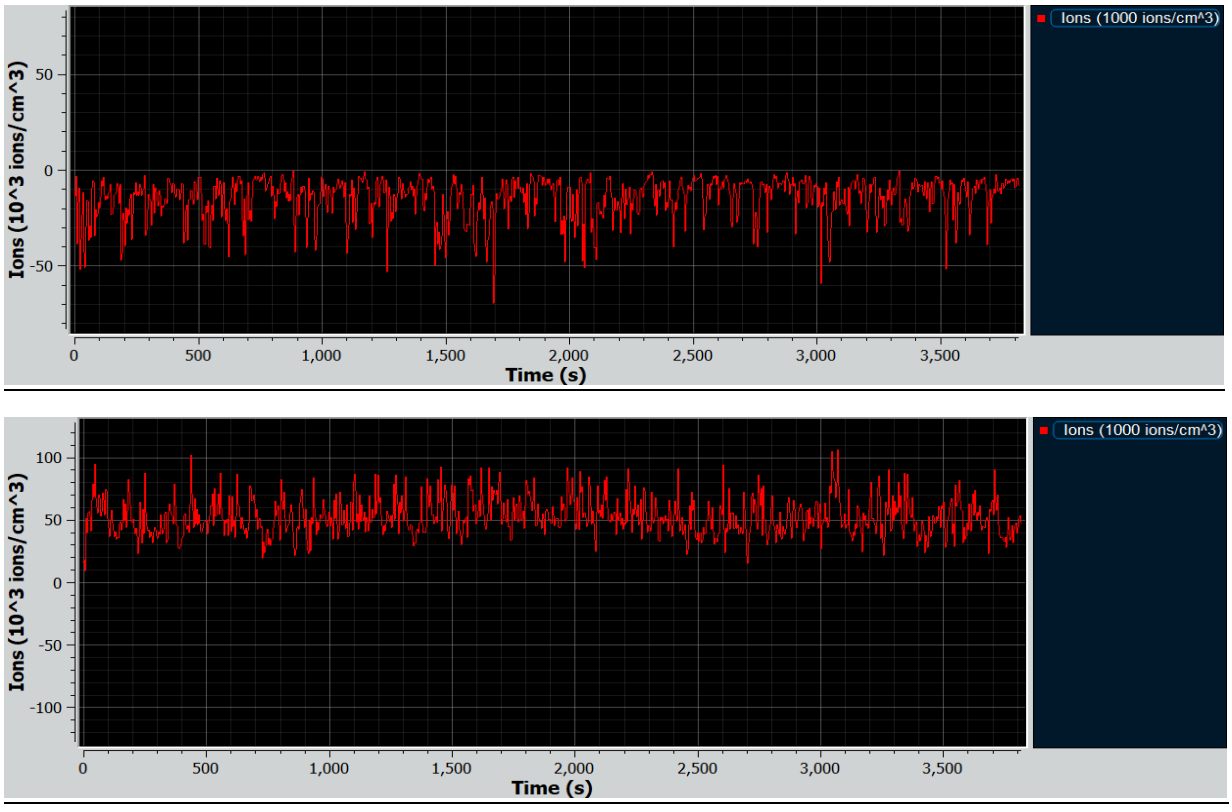


Figure 2. Device ion concentration recordings while in operation during testing.

**Preparation of The Pathogen**

BEI Resources Catalog number NR-41877 (CoA attached) Methicillin-Resistant *S. Aureus* was cultured by plating the thawed broth on BHIS Agar and incubated at 34°C with 5% $CO_2$ for 48 hours. Colonies were harvested and introduced to a Tryptic Soy Broth and allowed to incubate at 34°C for an additional 48 hours. 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 Tryptic Soy 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
- Tryptic Soy Broth
- BHIS 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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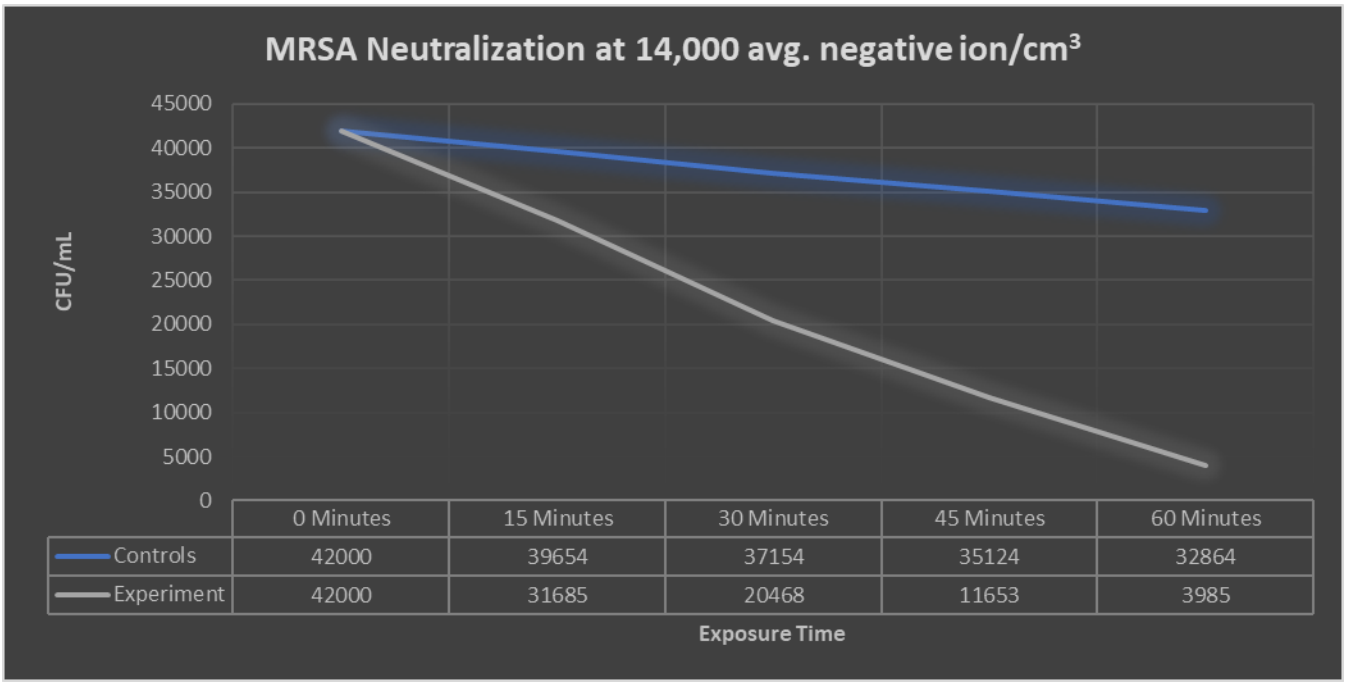
## Study Results




## Conclusion:

The GPS-FC48-AC™ device housing NPBI™ technology showed a noticeable impact on the test samples under the specific testing parameters. In a closed environment with a defined negative and positive ion density, the equipment demonstrated a 90.51% reduction of active MRSA on a surface after 60 minutes of exposure. Ion concentrations were measured during testing with an average over the 60 minutes of 14,000 negative ions per $cm^3$. Overall, the technology showed the capability of reducing surface pathogen MRSA at a higher rate than the natural loss observed in control.

## 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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DocuSigned by:
Dana Yee
7D5A69A0907947B...

8/24/2021

**Dana Yee M.D** **Date**

**Clinical Pathologist and Medical Director, Innovative Bioanalysis, Inc.**

DocuSigned by:
Sam Kabbani
8B4B282DF4B34A3...

8/24/2021

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

**Chief Scientific Officer, Innovative Bioanalysis, Inc.**

DocuSigned by:
Albert Brockman
06DF5C77A0D2400...

8/24/2021

**Albert Brockman** **Date**

**Chief Biosafety Officer, Innovative Bioanalysis, Inc.**

DocuSigned by:
Kevin Noble
5DF2797BAA78421...

8/24/2021

**Kevin Noble** **Date**

**Laboratory Director, Innovative Bioanalysis, Inc.**

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