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SARS - CoV - 2 Neutralization by Needlepoint Bipolar Ionization, Powered by GPS

CLIENT: ACA/IAE

PROJECT: Needlepoint Bipolar Ionization "NPBI™" applied to COVID19

PRODUCT: ACA-RN-0001 and ACA4800GU-1, Powered by GPS DM48 - AC NPBI™ Technology
CAP LIC NO: 9501843
CLIA LIC NO: 05D1064850

SAMPLE RECEIVED: 05/21/2020
START DATE: 05/27/2020
REPORT DATE: 06/02/2020
CHALLENGE VIRUS: SARS-CoV-2

EXPERIMENTAL SUMMARY:

Single RE22 control chambers set on a table with pressure verification seals. Internal working dimensions 16.5"W x 9"H x 12"D for a total cubic footage of 1.031. Under initial observation it was determined to seal the unit completely with no intake or exhaust port. Control ionization counts were performed prior to initial test. Testing and control were conducted in an average ambient temperature of 72.6 degrees Fahrenheit.

A singular fan unit was set up at a 45-degree angle to the two ionization units affixed to the testing chamber. The initial control fan speed was measured at an average of 870 Ft/m. At these airflow speeds the initial ionization saturation counts were taken so adjustment could be made to lower or raise ionization levels depending on the testing parameters needed. Under the original control section, the primary fan was set 10 inches away from ion production unit A and the average air flow speed past the ion producing nodes was 250Ft/m

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Under the original control section, the primary fan was set 13 inches away from ion production unit B and the average air flow speed past the ion producing nodes was 240Ft/m. Initial observations indicated large fluctuations of ions throughout the interior of the testing chamber based in the airflow. With unit B running the Ion count fluctuated from 800 thousand ions per cubic centimeter in the center of the testing chamber directly below the ionization unit to 152 thousand ions per cubic centimeter at the exterior edges of the testing chamber.

Initial observations indicated large fluctuations of ions throughout the interior of the testing chamber based in the airflow. With unit A running the Ion count fluctuated from 1.8 million ions per cubic centimeter in the center of the testing chamber directly below the ionization unit to 600 thousand ions per cubic centimeter at the exterior edges of the testing chamber.

The ion density in an open space as a function of the air flow velocity can be found in the chart below, the ion counts are in the thousands (x1,000).

	1	***2***	***3***
Airflow (ft/min)	230	330	380
Distance (ft)	**Ion Count (*x1000*)**		
4	630	1100	1400
7	250	240	380
11	92	143	170
15	21	40	arc
19	6	24	arc
24	6	18	9
46			5

After control samples were completed for saturation levels a slower moving fan was introduced to lessen the airflow across the Ionization nodes to reduce the overall Ion concentration levels to something more similar to conditions found inside a standard aircraft when running the ion cleaning system. Based on historical observations the standard Ion count inside aircrafts was 10,000 – 50,000 ions per cubic centimeter. With the slower fan speed and slightly altered angle the average negative ion count inside the test chamber was reduced to an average of 27 thousand per cubic centimeter for the viral testing phase.

A continuous ion density measuring sensor was used in the viral test chamber during the viral sample testing. The overall ion counts were measured and logged for the duration of the test. The average Ion count within the testing chamber at point of viral placement was -27.2307 (+/– 10,000) cm3. Viral cultures added to test chamber in independent sealable dishes. The NPBI device ran for 30 minutes during the initial test. Each viral sample was sealed at a pre-determined time. Sample A sealed up after 10 minutes of Ion exposure. Sample B sealed after 15 minutes of ion exposure. Sample C sealed up after 30 min of Ion exposure. After final sample was sealed the samples were removed from testing chamber and transferred to the lab staff for further testing.

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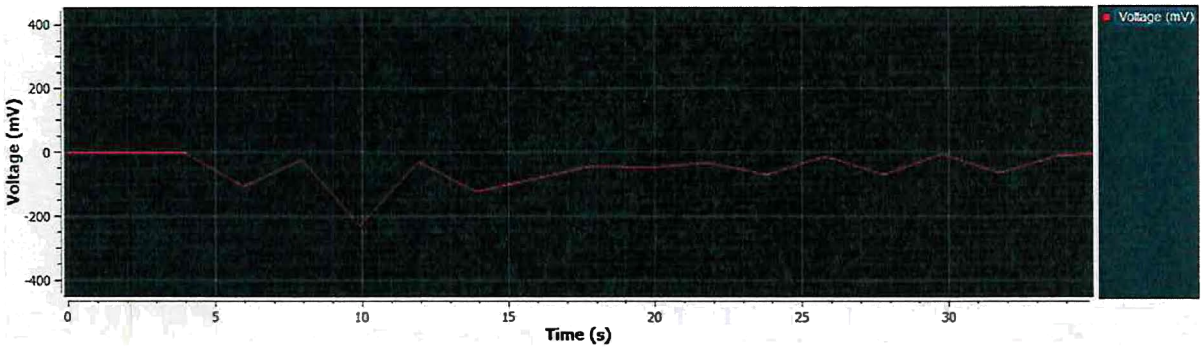
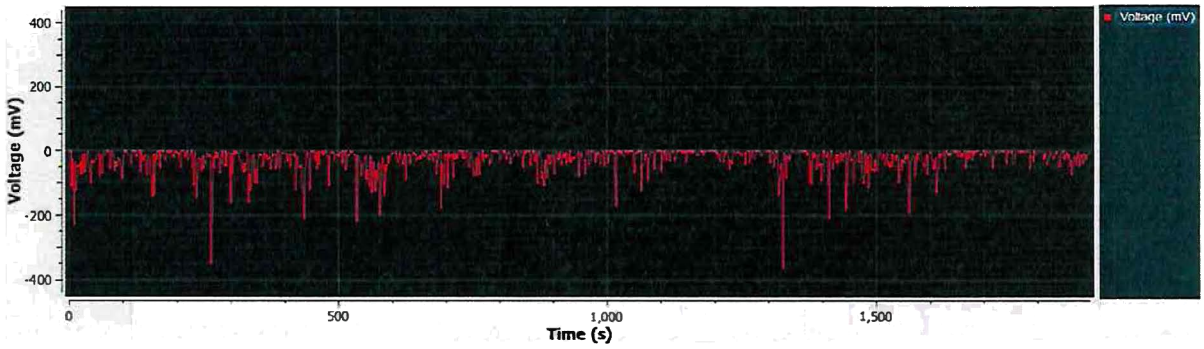
Below are the readouts for the measured ionization levels, the first chart shows the ion levels for the test every minute. The second chart is a readout showing the continuous ionization levels in the test chamber for the duration of the test.





Upon confirmation of a safety review, multiple sets of tests are recommended whereby the virus is aerosolized in a 8x20x8 contamination pod for large scale control testing.

PROCEDURE:

VIRUS: SARS-CoV-2

Nasopharyngeal swabs were collected on day 4 post symptom onset, placed in 2–3 mL of viral transport medium, used for molecular diagnosis, and frozen. Vero CCL-81 cells were cultured in Dulbecco minimal essential medium (DMEM) supplemented with heat-inactivated fetal bovine serum (5% or 10%) and antibiotics/antimycotics. For isolation, limiting dilution, and passage 1 of the virus, 50 µL of serum-free DMEM was pipetted into columns 2–12 of a 96-well tissue culture plate. Then 100 µL of clinical specimens pipetted into column 1 and serially diluted 2-fold across the plate. Then trypsinized and resuspended Vero cells in DMEM containing 10% fetal bovine serum, 2× penicillin/streptomycin, 2× antibiotics/antimycotics, and 2× amphotericin B at a concentration of 2.5×10^5 cells/mL. 100 µL of cell suspension added directly to the clinical specimen dilutions and mixed gently by pipetting. The inoculated cultures were grown in a humidified 37°C incubator in an atmosphere of 5% CO_2 and observed for cytopathic effects (CPEs) daily.

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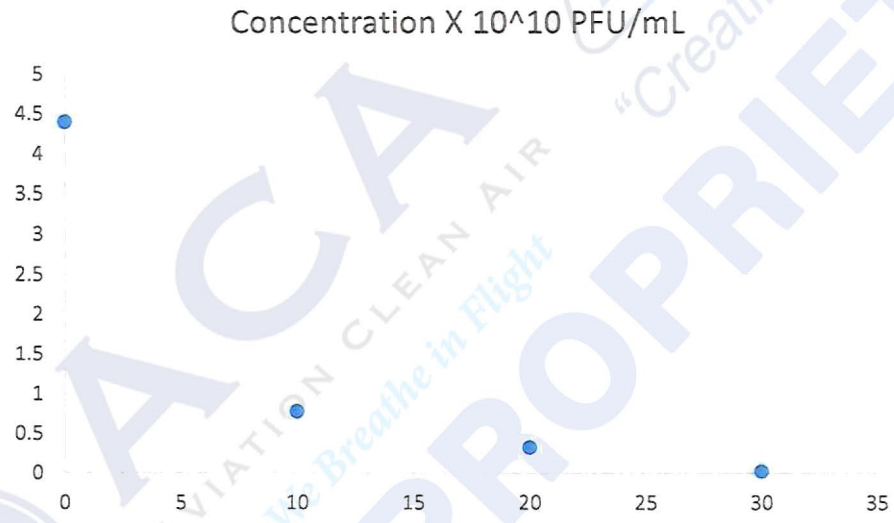
INNOCULATION OF THE TEST CARRIER:

Sterile sealable dishes were coated with 1 mL viral suspension containing samples with a viral titer of 4.4 X 10^10 PFU/mL crude SARS-CoV-2 virus. Using the Poisson distribution, one would determine the TCID50 value would be equivalent to roughly .7 X PFU/mL or 3.8 X 10^10 TCID50/mL

EFFICACY TESTING:

Viral media with a known concentration of Plaque Forming Units was applied to a sterile static dish composed of polystyrene plastic and individually sealable and exposed to bipolar ionization for a period of 10, 15, and 30 minutes. Swabs were taken of all plates and cultured by the same means as the original nasopharyngeal swab culture. Based on viral titrations it was determined that at 10 minutes 84.2 % of the virus was inactivated, at 15 minutes 92.6% of the virus was inactivated, and at 30 minutes 99.4% of the virus was inactivated.



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CONCLUSIONS/OBSERVATIONS:

Based on the results listed above, it can be determine that hydrolysis via positively charged hydrogen ions binding to peplomers of the SARS-CoV-2 virus can render 99.4 % or viral particles are inactivated on a stagnant surface at 30 minutes. The ionization technology allows for the saturation of hemagglutinin with hydroxyl groups effectively inactivating the hemagglutinin receptors and rendering the virus ineffective and eliminating its ability to bind to and infect cells. Initial testing has demonstrated that needlepoint biopolar ionization has the ability to neutralize pathogens, namely SARS-CoV-2, on a static surface. Further studies are required for reproducibility testing as well as variation in environment and environmental factors.

Disclaimer:

03 JUN 2020

Dr. Dana Yee M.D Medical Director **Date**

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06/06/2020 11:52:25 am

06/03/2020

Sam Kabbani, MS, BS, MT(ASCP), CLS **Date**
Chief Scientific Officer, Innovative Bioanalysis

6/02/2020

Albert Brockman
Director of Biosafety, Lead Biosafety Officer **Date**

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