PuriFi Labs
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SARS-CoV-2 Neutralization by PuriFi Bipolar Cold-Plasma Ionization

TEST LAB: Innovative Bioanalysis
CLIENT: PuriFi Labs
PROJECT: PuriFi Bipolar Cold-Plasma Ionization applied to SARS-CoV-2
PRODUCT: PuriFi IAI-100
SERIAL NO: 9454935D9913
SAMPLE RECEIVED: 11/12/2020
START DATE: 11/20/2020
REPORT DATE: 12/04/2020
CHALLENGE VIRUS: SARS-CoV-2

ABSTRACT:

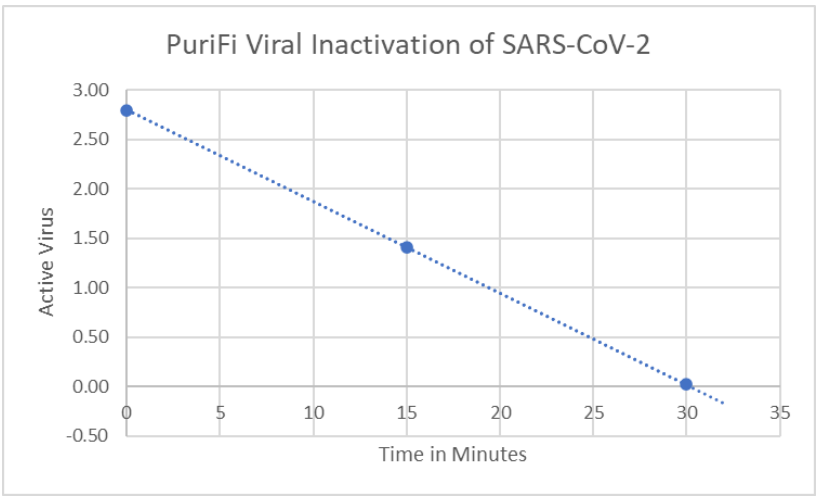
This biosafety test was an in vitro research study designed to study the pathogen deactivation performance of the PuriFi Labs IAI-100 Air Purification Unit (APU) for installation and use in central Heating, Ventilating, and Air Conditioning (HVAC) systems. The PuriFi technology is designed to produce positive and negative ions during active operation, through its patented bipolar cold plasma energy core and 0^2 catalyst. According to previous research, there are initial indications that positive and negative ions can inactivate viral pathogens in ambient air and on surfaces, depending on the species and lifecycle of ions produced. This biosafety test was used to determine PuriFi's static inactivation performance on SARS-CoV-2 at typical HVAC system fan speeds and to establish baseline performance, prior to performing additional tests.

OBSERVATIONS:

The PuriFi system provided statistically consistent viral inactivation performance throughout the test. Between the time points of 0 and 15 minutes, there was an average viral inactivation of 3.30% per minute, totaling 49.5% viral inactivation at the 15-minute time point. Between the time points of 15 and 30 minutes, there was an average viral inactivation of 3.17% per minute, totaling 97% viral inactivation at the 30-minute time point, thereby providing an average viral decay rate of 3.23% per minute through the first 30 minutes of the study.

No additional time point samples were taken until the 60-minute mark, at which point, the viral decay rate had already achieved **99.994% viral inactivation** (>4 Log Reduction).

Based on the statistically consistent viral inactivation performance of this system during the study, it has been demonstrated that the PuriFi technology provided statistically consistent deactivation rates of ≥3.23% per minute on SARS-CoV-2 in a biosafety environment designed to represent central HVAC system airflow dynamics.



BIOSAFETY TEST PARAMETERS:

One PuriFi IAI-100 APU was duct mounted to the top left side of a controlled biosafety hood which measures 36”x36”x72”. A variable speed fan was installed upstream of the PuriFi device to provide airflow across the device and throughout the test chamber. A HEPA filtered exhaust duct was mounted to the opposite end of the chamber to safely simulate supply and exhaust airflow dynamics typically seen in central HVAC systems. During testing, the air temperature was monitored along with the humidity. Air temperature was approximately 71 degrees and relative humidity was 48%.

Prior to each inactivation test, a control sample was run without the ionization system operating. Controls were performed for each time point in the biosafety test. Controls were treated in the same fashion as viral challenge test. Viral challenge and control time point samples were taken at 15 minutes, 30 minutes, and 60 minutes.

Glass slides used for control and viral challenge were inoculated with a known concentration of viral media through a sterile pipette. Glass slides with control samples were placed in the center of the biosafety hood and collected at the appropriate time point. Glass slides were rinsed in a 50mL tube and provided to lab staff for sampling.

Viral challenge glass slides were placed in the center of the bio-safety environment, away from the direct downward airflow derived from the chamber’s variable speed fan. For the viral challenge, the fan was activated and the PuriFi device was turned on at the 0-minute time point (cold-start). The same fan speed was used for the 15-minute, 30-minute, and 60-minute time points.

It is important to note that in typical indoor environments, an APU installed in a central HVAC system, such as PuriFi, would be actively operating prior to any contamination event that occurs within the environment the APU is serving. However, due to the procedural constraints of this biosafety environment, it was not possible to simulate that type of “hot-start” scenario at this time.

TESTING PROCEDURE:

TEST	SPECIFICATIONS	RESULTS
Identification by Infectivity in Vero 6 cells	Cell Rounding and Detachment	Cell Rounding and Detachment
Next Generation Sequencing (NGS) of 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% CO2
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

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

VIRAL STOCK: SARS-CoV-2 USA-CA1/2020 (BEI NR-52382)

INNOCULATION OF THE TEST CARRIER:

Surface inoculation consisted of applying exactly 1 ml of viral media to each coupon with a calibrated Eppendorf pipette utilizing filtered pipette tips. Coupons were standard sterile 25mm x 75mm slides. Once applied, the media was spread thin using a disposable spatula and allowed to dry for 10 minutes.

EFFICACY TEST RESULTS:

The PuriFi system provided statistically consistent viral inactivation performance throughout the test. Between the time points of 0 and 15 minutes, there was an average viral inactivation of 3.30% per minute, totaling 49.5% viral inactivation at the 15-minute time point. Between the time points of 15 and 30 minutes, there was an average viral inactivation of 3.17% per minute, totaling 97% viral inactivation at the 30-minute time point, thereby providing an average viral decay rate of 3.23% per minute through the first 30 minutes of the study.

No additional time point samples were taken until the 60-minute mark, at which point, the viral decay rate had already achieved **99.994% viral inactivation** (>4 Log Reduction).

Based on the statistically consistent viral deactivation performance of this system during the study, it has been demonstrated that the PuriFi technology provided statistically consistent deactivation rates of ≥3.23% per minute on SARS-CoV-2 in a biosafety environment designed to represent central HVAC system airflow dynamics.

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SARS-CoV-2 Neutralization by PuriFi Bipolar Cold-Plasma Ionization

CLIENT: PuriFi Labs
PROJECT: PuriFi Bipolar Cold-Plasma Ionization applied to COVID-19
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ABSTRACT:

This biosafety test was an in vitro research study designed to study the pathogen deactivation performance of the PuriFi Labs IAI – 100 Air Purification Unit (APU). The PuriFi system tested is designed for installation and use in central heating, ventilating and air conditioning systems (HVAC). The PuriFi technology is designed to produce positive and negative ions during operation. The primary goal of the biosafety test is to confirm baseline functionality of the PuriFi™ labs purification unit in a controlled environment. According to previous research, there are initial indications that negative and positive ions can inactive viral pathogens in the air and on surfaces. The bio safety test is to determine a level of functionality of devices prior to more complex testing environments.

BIOSAFETY TEST PARAMETERS.

One PuriFi IAI-100 APU was duct mounted to the top left side of a controlled biosafety hood which measures 36”x36”x72”. A variable speed fan was installed upstream of the PuriFi device to provide airflow across the device and throughout the test chamber. A HEPA filtered exhaust duct was mounted to the opposite end of the chamber to safely simulate supply and exhaust airflow dynamics typically seen in central HVAC systems. During testing, the air temperature was monitored along with the humidity. Air temperature was approximately 71 degrees and relative humidity was 48%.

Prior to each inactivation test, a control sample was run without the ionization system operating. Controls were performed for each time point in the biosafety test. Controls were treated in the same fashion as viral challenge test. Viral challenge and control time point samples were taken at 15 minutes, 30 minutes, and 60 minutes.

Glass slides used for control and viral challenge were inoculated with a known concentration of virus suspended in viral media via a sterile pipette. Glass slides with control samples were placed in the center of the biosafety hood and collected at the appropriate time point. Glass slides were rinsed in a 50mL tube and provided to lab staff for sampling.

Viral challenge glass slides were placed in the center of the bio-safety environment, away from the direct downward airflow derived from the chamber’s variable speed fan. For the viral challenge, the fan was activated and the PuriFi device was turned on at the 0-minute time point (cold-start). The same fan speed was used for the 15-minute, 30-minute, and 60-minute time points.

It is important to note that in typical indoor environments, an APU installed in a central HVAC system, such as PuriFi, would be actively operating prior to any contamination event that occurs within the environment the APU is serving. However, due to the procedural constraints of this biosafety environment, it was not possible to simulate that type of “hot-start” scenario at this time.

INNOVATIVE BIOANALYSIS
creating solutions | getting results

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VIRAL STOCK: SARS-CoV-2 USA-CA1/2020 (BEI NR-52382)

INNOCULATION OF SURFACE SAMPLES

Surface inoculation consisted of applying exactly 1 ml of viral media to each coupon with a calibrated Eppendorf pipette utilizing filtered pipette tips. Coupons were standard sterile 25mm x 75mm slides. Once applied, the media was spread thin using a disposable spatula and allowed to dry for 10 minutes.

OBSERVATIONS:

Viral test samples were provided to laboratory staff for comparison of the control samples to the viral challenge samples and to determine a baseline efficacy of the system.

The PuriFi system provided consistent viral inactivation performance throughout the test. There was an observed 49.5% viral inactivation at the 15-minute time point. At the 30 minutes sampling point a 97% viral inactivation was observed.

No additional time point samples were taken until the 60-minute mark, at which point, the viral decay rate had already achieved **99.994% viral deactivation** (>4 Log Reduction).

Based on the consistent viral deactivation performance of this system in a controlled environment, it has been demonstrated that the PuriFi technology provided consistent deactivation rates. The biosafety environment was designed to represent similar airflow dynamics as a central HVAC system. Under similar test conditions, similar results can be expected.

A.Brockman

Chief Bio Safety Officer