STUDY TITLE

Assessment of IONaer 7000 Ion Generator to reduce Pathogen Levels on Hard, Non-porous Environmental Surfaces: Testing with Human Respiratory Coronavirus 229E (ATCC VR-740)

TEST ORGANISM

Coronavirus 229E (ATCC VR-740):
Host:
L-132 cells

TEST PRODUCT IDENTITY

IONaer 7000 Ion Generator Carrier

TEST Method

Modified Quantitative Disk Carrier Test Method (ASTM 2197)

AUTHOR

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STUDY COMPLETION DATE

April/14/20

PERFORMING LABORATORY

CREM Co. Labs. Units 1-2, 3403 American Dr., Mississauga, Ontario, Canada L4V 1T4

SPONSOR

Clean Air EXP

STUDY NUMBER

CAE200306-02

STUDY PERSONNEL

STUDY DIRECTOR: Bahram. Zargar, PhD

PROFESSIONAL PERSONNEL INVOLVED: Sepideh Khoshnevis, MSc

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title:	Assessment of IONaer 7000 Ion Generator to reduce Pathogen levels on Hard, Non-porous Environmental Surfaces: Testing with Human Respiratory Coronavirus 229 E(ATCC VR-740)
Study Number:	CAE200306-02
Sponsor	Clean Air EXP
Testing Facility	CREM Co Labs Units 1-2, 3403 American Drive, Mississauga, ON, Canada

TEST SUBSTANCE IDENTITY

Test Substance Name: IONaer 7000 Ion Generator

STUDY DATES

Date Device Received:
Study initiation date: March/03/06
Experimental Start Date: March/03/20
Experimental End Date: April/15/20
Study Completion Date: April/19/20

TEST SYSTEM

1. Test Microorganism

Coronavirus 229E (ATCC VR-740): Coronavirus 229E is an enveloped virus in the genus Coronavirus. Members of this genus can cause acute and potentially fatal respiratory infections such as SARS-1, SARS-2 (19-nCOV) and the Middle-East Respiratory Syndrome (MERS). Unlike coronavirus 229E, handling of SARS-1, SARS-2 and MERS requires Biosafety Level 3 facilities. Therefore, Coronavirus 229E is frequently used as a surrogate for them to assess the activity of different technologies for infection prevention and control (IPAC).

2. Host Cell Line

L-132 cells were used as hosts to support the replication and quantitation of 229E.

The cells were seeded into 12-well multi-well cell culture plates containing modified Eagle's medium (MEM) supplemented with 10% fetal bovine serum (FBS) and maintained at 36±1°C in a humidified atmosphere of 5% CO_2. Efficacy test was performed when the cell monolayer reached >90% confluency.

Preparation of Test Inocula
To prepare the virus for inoculation, the virus stock was mixed directly with the soil load (5% FBS). Dilution of the mixture was prepared using normal Saline.

The aerobiology chamber

The details of our aerobiology chamber have been published before (Sattar et al., 2016). Briefly, the chamber (26 m^3) was built to comply with the guidelines from the U.S. Environmental Agency (U.S. EPA 2012). A glove-box on one side of the chamber permitted the handling of the required items without breaching the containment barrier. A muffin fan (Nidec Alpha V, TA300, Model AF31022-20; 80 mm X 80 mm, with an output of 0.17 cubic meters/minute) inside the chamber enabled the uniform mixing of the air inside it. Between uses, fresh air was used to flush out the chamber of any residual airborne microbes.

Environmental monitoring: The air temperature (22±2°C) and RH (50±5%) inside the chamber were measured and recorded using a remote-sensing device (RTR-500 Datalogger).

TEST METHOD

1. **Preparation of Test Substance**
   1-cm diameter disks of brushed stainless steel 304 (AISI SS304) were used as the carriers in this test.

2. **Test Procedure**

A quantitative test system to closely simulate the field-application of the environmental surface decontamination process (modified quantitative carrier test – Tier 2 or QCT-2 (ASTM 2197)) was applied. The protocol was adapted to assess IONaer 7000 Ion Generator for surface decontamination.

Each disk received 10 uL of virus inoculum with a soil load (5% FBS). The disks were left inside an operating biosafety cabinet (BSC) for one hour to dry. The control disks for 30 min contact time were placed in a separate Petri dish and the Petri dishes were sealed with M3 tape. The Petri dishes containing test carriers and control carrier were placed on the floor of a sealed aerobiology chamber (26 m^3) in front of the access gloves. The IONaer 7000 Ion Generator was already installed in the chamber close to the access gloves. The fan of aerobiology chamber was turned on 30 minutes before testing and humidity was set to 50±5%. The exposure time was calculated from the moment that the test machine was turned on. Two test carriers and two control carriers were then removed from aerobiology chamber using the transport chamber (without breaking the sealing) and eluted at the contact time (30 min). The eluates were assayed for viable virus.

OBJECTIVE

To assess the ability of the IONaer 7000 Ion Generator to inactivate coronavirus 229E (ATCC VR-740) on the hard, non-porous surfaces.

Test Device:	IONaer 7000 Ion Generator
Room Temperature	Ambient temperature (22±2ºC)
Relative Humidity (RH):	50±5%

DATA ANALYSIS

Calculation of Log_{10} Reduction

Log_{10} Reduction = Log_{10} of average PFU from control carriers – log_{10} of average PFU the test carriers.

STUDY ACCEPTANCE CRITERIA

No product acceptance criterion was specified for this range-finding study.

TEST RESULTS

The initial challenge on each carrier was 5.18 log_{10} PFU. Table 1 show the result of log_{10} reduction for 30 min contact times. In this test, one hour drying time was considered. There is no significant difference between the log reductions in the exposure times (30 min). The device demonstrate 0.83 Log_{10} reduction (85.2% reduction).

Table 1: Virucidal Efficacy of polymer coating technology against Human Respiratory Coronavirus 229E (ATCC VR-740) at 30 min contact time

Log_{10} Reductions in PFU	**Percent Reduction**
0.83	85.2

APPENDIX

Result of efficacy test on polymer coating technology at 30 min contact time against *Human Respiratory Coronavirus 229E (ATCC VR-740)*.

Contact Time	30 minutes					
Dilution	C1	C2	C3	T1	T2	T3
10^{-0}	TNTC	TNTC	TNTC	40,39,38	25,25,19	34,30,37
10^{-1}	10,17,13	14,11,11	14,19,19	4,3,3	2,2,1	4,3,4
10^{-2}	1,1,1	1,1,1	1,1,1	0,0,0	0,0,0	0,0,0
10^{-3}	0,0,0	0,0,0	0,0,0	0,0,0	0,0,0	0,0,0