CONFIDENTIAL ABBREVIATED FINAL REPORT

SPONSOR: Novaerus Inc.

SPONSOR CONTACT: Christy Mocny and Sandeep Kalelkar, Ph.D.

STUDY TITLE: Evaluation of Inactivation of Airborne Bacteria Using an Air Purification Device

STUDY IDENTIFICATION: MicroBioTest Project No. 914-101,102,103,104 &106

TEST AGENT NAME	LOT NO.	RECEIVED DATE	DS NO.
Novaerus NV-900 Air Purifier	EG1R1151901012/15 00888	01/20/16	G34

ACTIVE INGREDIENT(S): Plasma field

CHALLENGE ORGANISM(S): *Methicillin Resistant Staphylococcus aureus,* ATCC 33591

EXPOSURE TIME(S): 10 minutes, 20 minutes, 60 minutes, 120 minutes and 240 minutes

CONTACT TEMPERATURE: Ambient (20-21C)

OVERVIEW OF TESTING CONDITIONS / EXPERIMENTAL DESIGN: Multiple conditions were tested using a single device inside the chamber. The test device is an air purification device based on plasma technology. Each unit is approx. 36.5cm h x 36.5 cm w x 11.5 cm d. The device was placed into an air chamber approximately $1m^3$ size.

The challenge bacteria was aerosolized using a six-jet collision nebulizer under high pressure air and introduced into the chamber. Immediately, at T = 0 min, the test device and one or more fans inside the chamber were turned on via power switches outside the chamber. The aerosolized bacteria was delivered for 10 minutes. After, the air input was turned off; the test device and the fans were left on for the specified contact time to allow sufficient air processing by the device. Then the device and fans were turned off; and the air inside the chamber was drawn into an air sampler (Anderson Sampler) using a vacuum. The bacteria particles in the air were captured by the semi-solid media on the collection dish inside the Anderson sampler.

After the test round of air collection, a "clean" air (containing no bacteria) was injected into the chamber while the downstream vacuum is left on, to allow a thorough collection of the air into the Anderson sampler. Then the chamber was opened and the stage inside the Anderson Sampler was flushed with media to recover residual bacteria particles that remained on the surface of the stage. The flush media and the semi-solid media from the collection dish were combined, liquefied and assayed to determine the amount of surviving bacteria using standard culture culturing procedures.

The Bacteria Input Control (BIC) runs were performed similarly but without the test device, with or without holding for the contact time, in a singlet run (n=1). The bacteria levels in the presence and absence of the test device were compared to determine the inactivation efficacy by the test device against aerosolized Methicillin Resistant *Staphylococcus aureus*.

Clean air was flushed through the chamber while the downstream vacuum was on for at least 15 minutes between the runs to avoid bacteria carry-over.

RESULTS

Results and data are presented in Tables 1 - 4. The challenge microorganism was confirmed by Gram stain and colony morphology to be consistent with Methicillin Resistant *Staphylococcus aureus*. All sterility controls exhibited no growth.

Enumeration is expressed as colony-forming units (CFU)/mL. Log_{10} reductions (presented in Table 4) were calculated using the following equation:

$$Log_{10}(\text{Average Bacterial Input Counts Control}) - Log_{10}(\text{Test Results}) = Log_{10}\ \text{Reduction}$$

RESULTS (continued)

Table 1

Test Results

Expressed as Average Colony Forming Units (CFU) per mL and Log_{10}

Lot: EG1R1151901012/1500888			
Study Number	Contact Time	CFU/mL	Log_{10}
914-101	10 minutes	1.4×10^4	4.15
914-102	20 minutes	2.2×10^3	3.34
914-103	60 minutes	1.4×10^2	2.15
914-104	120 minutes	7.2×10^1	1.86
914-106	240 minutes	1.0×10^0	0

Table 2

Bacterial Input Counts (with contact time) Control Results

Expressed as Average Colony Forming Units (CFU) per mL and Log_{10}

Non Active Test Device with Contact Time			
Study Number	Contact Time	CFU/mL	Log_{10}
914-101	10 minutes	2.2×10^4	4.34
914-102	20 minutes	1.9×10^4	4.28
914-103	60 minutes	2.4×10^4	4.38
914-104	120 minutes	1.1×10^4	4.04
914-106	240 minutes	1.2×10^4	4.08

RESULTS (continued)

Table 3

Bacterial Input Counts (without contact time) Control Results

Expressed as Average Colony Forming Units (CFU) per mL and Log_{10}

Study Number	CFU/mL	Log_{10}
914-101	2.5×10^4	4.40
914-102	2.6×10^4	4.41
914-103	2.5×10^4	4.40
914-104	2.3×10^4	4.36
914-106	2.4×10^4	4.38

Table 4

Log_{10} Reductions

Non Active Test Device with Contact Time				
Study Number	Contact Time	Log_{10} BIC Control Result	Log_{10} Test Result	Log_{10} Reduction
914-101	10 minutes	4.40	4.15	0.25
914-102	20 minutes	4.41	3.34	1.07
914-103	60 minutes	4.40	2.15	2.25
914-104	120 minutes	4.36	1.86	2.50
914-106	240 minutes	4.38	0	4.38

CONCLUSIONS

The bacterial reduction for the test materials are presented in Table 4. All of the controls met the criteria for a valid test. These conclusions are based on observed data.

Travis R. Farley
Study Director

5/19/16
Date