BIOLOGICAL INACTIVATION OF ARCALUX HEALTH RISK MANAGEMENT SYSTEM (HRMS)

FINAL REPORT

PROTOCOL NO. AER 09112013 Rev 4

LABORATORY PROJECT ID # 13017604

Organism: *MRSA BAA 44*

Contact time: 1 hr., 4hr, 8 hr. and 24 hr.

SPONSOR

ARCALUX

SUBMITTED BY

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BIOLOGICAL INACTIVATION OF ARCALUX HEALTH RISK MANAGEMENT SYSTEM (HRMS)

COMPLIANCE STATEMENT

Information on the structure and activation of Arcalux HRMS system resides with the sponsor of the study.

QAU STATEMENT

TITLE: Biological Inactivation of Arcalux Health Risk Management System (HRMS)

PROTOCOL	AER 09112013 Rev 4
LAB PROJECT	**13017604**
EVALUATION STUDY	Study IV
TEST DATE	11.19.2013
DATE QAU INSPECTED	11.21.2013
DATE REPORTED	11.21.2013

STUDY OBJECTIVES

Evaluate the inactivation efficiency of the HRMS system in terms of % reduction or Log reduction of microorganism in a simulated room in the same manner as the critical care facility areas in hospital settings. The system is designed to operate quietly with 100% disinfection while delivering highly purified air. The protocol described herein determines the inactivation efficiency of the system against spore forming and vegetative bacteria which represents a wide range of applications.

The test was conducted based on the EPA protocol "Biological Inactivation Efficiency by HVAC In-Duct Ultraviolet Light Systems". The Quality Assurance Unit of Aerobiology Laboratory has inspected the lab project # 13017604 in compliance with the current GLP Regulations and the reported results accurately reflect the raw data.

INTRODUCTION

This report describes the procedure and results of the biological inactivation efficiency of HRMS system during an increased challenge of aerosoled inoculum of clinically relevant microorganisms. A medical grade nebulizer is used to deliver the accurate and consistent number of pathogens into the simulated room. The HRMS system is turned on for specified contact time during which the aerosolized microorganism comes in contact with the UV system resulting in reduction and release of purified air into the room. This test procedure is developed for a challenge level of greater than 10^6 colony forming units (CFU), which provides 1000 times higher challenge than would be expected in normal surrounding. This method employed the fundamentals of the EPA method "Biological Inactivation Efficiency by HVAC In-Duct Ultraviolet Light Systems".

JUSTIFICATION

The surface air sampler (SAS) or impactor provides advantages over other methods for test because it can simulate inhalation of aerosoled contaminants at controlled air flow rate. The SAS pulls in 500L of air which is represented as 219 impaction holes on the media placed within the SAS. High volume of air causes multiple impactions which skews the data interpretation. The use of medical grade delivery nebulizer allows a high concentration of aerosol challenge to be aerosolized into the room. The actual count of challenging microorganism is predetermined by colony count, while the volume of the challenge aerosol is tightly controlled by monitoring the air flow and air pressure through the nebulizer. Aerosols are self-contained and they do not pose any bio-safety concerns.

DESCRIPTION OF TEST PROCEDURE

Sample conditioning and calibration

The Zipwall® is constructed as per manufacture instruction. The spacing of the poles is based on the movement of air in the room. The air flow is typical for commercial air space environment. Four glove box areas are specified in the Zipwall® room for nebulizer placement and for three SAS samplers. The Arcalux HRMS is installed in the ceiling as per instructions and plugged in. At nominal design airflow of 50 cfm, with a MERV 6 filter and a UV lamp, the HRMS emits 15 watts of UV radiation at 253.7 nm. The SAS and the nebulizer are placed at the appropriate glove box. The SAS will operate at the flow rate of 100 lpm for 5 minutes for a total of 500 L.

Challenge phase

Unplug the HRMS system. Connect nebulizer to the PARI compressor. An appropriate media plate is also placed in each of the SAS. Add 8ml of inoculum to the sterile nebulizer. Attach the nebulizer to the connector and to the hose of the PARI compressor. Set timer for 15 minute. Turn on PARI compressor. The nebulizer aerosolizes the inoculum and the compressor is turned off after 15 min. The SAS are turned on for 5 min for sample collection. Three sets of samples are taken outside the simulated clean room using to SAS at 5 min to verify contamination of outside air by the indicator organism.

Contact time

The HRMS system is turned on after the baseline samples are taken. Samples are taken after the contact times of 1hr, 4 hr, 8 hr and 24 hr during which the aerosolized inoculum comes in contact with HRMS system.

Recovery phase

After sampling at specified time intervals, the plates are then placed in the incubator at 35°C for 24 hrs to recover the challenge microorganism.

Plate count / Result recording

Examine plates after 24 hours for growth, and colony count. If necessary, incubate plates for an additional 24 hours. After the colonies have grown, choose countable plate. Record control counts to determine the accuracy of the challenge and the inhibitory efficiency of the HRMS system. The raw colony counts are compared to the 219-hole surface air sampler (SAS) positive hole correction chart to get positive hole corrected colony count for the respective samples. (Attachment 1). The No growth sample is assumed to be <1 colony forming unit per sample and cfu/m^3 of air will be less than <2 cfu/ m^3 per analysis.

TEST MATERIALS

Testing Area (Room area)	8ft x9ft x10ft
Equipment Source	Arcalux (HRMS system)
Equipment	Surface air sampler (SAS)
Date Received	10.21.13
Start Date	11.19.13
Lab study completion date	11.21.13
Report Issue Date	11.21.13

TESTS CONDITIONS

Test Matrix	6 samples
Organism	*MRSA BAA 44*
Inoculum	10^6 cfu/ml
Media	Tryptic Soy Agar with 5% sheep blood
Set up	Protocol no. 09112013 Rev 4 (Diagram 1)
Challenge Device	Nebulizer Pro NEB ULTRA II
Delivery Time	15 min
Challenge Volume	8ml
Internal Control	Pre-samples taken outside and inside the Zipwall room
"Base line"	Immediately after aerosolisation for 15 min with HRMS off
Contact time	1 hr, 4hr, 8 hr, and 24hr
Incubator	35°C
Recovery	24hr in Incubator at 35°C

CALCULATION - LOG REDUCTION

1. Conversion raw count to colony forming units per cubic meter (cfu/m3).

- Raw count converted to positive hole corrected value using the SAS (219-Hole impactor correction table).

- Minimum reporting limits (MRL): 1000 divided by the volume of air collected by SAS (500 L). The MRL (detection limit) for the testing will be <2cfu/m^3 of air.

- Total colony forming units per cubic meter (cfu/m3): positive hole corrected count x MRL

2. Log reduction were calculated using following equation:
   Log reduction = Log (Avg of Baseline – Avg for each specified contact time)

3. All statistical analysis were calculated using MS Excel static package.

The data and results of log recovery are represented in Table 1 and Table 2 respectively.

RESULTS

TABLE 1: RECOVERY OF MRSA AT DIFFERENT TIME INTERVALS

SAS	TIME										
	Baseline (cfu*)	Pos. hole**	cfu/m³	1HR** (cfu)	cfu/ m³	4HR** (cfu)	cfu/ m³	8HR** (cfu)	cfu/ m³	24HR** (cfu)	cfu/m³
SAS 1	168	317	634	3	6	1	2	1	2	1	2
	125	185	370	1	2	1	2	1	2	1	2
	168	317	634	1	2	1	2	1	2	1	2
SAS 2	219	1307	2614	1	2	1	2	1	2	1	2
	200	530	1060	2	4	1	2	1	2	1	2
	196	489	978	1	2	1	2	1	2	1	2
SAS 3	176	354	708	1	2	1	2	1	2	1	2
	152	258	516	3	6	1	2	1	2	1	2
	219	1307	2614	1	2	1	2	1	2	1	2

*** Positive corrected value as per the 219-hole SAS value chart**

****colony forming units**

***** NG assumed to be <1 cfu for raw count per plate and calculated as <2 for cfu/m3 of air.**

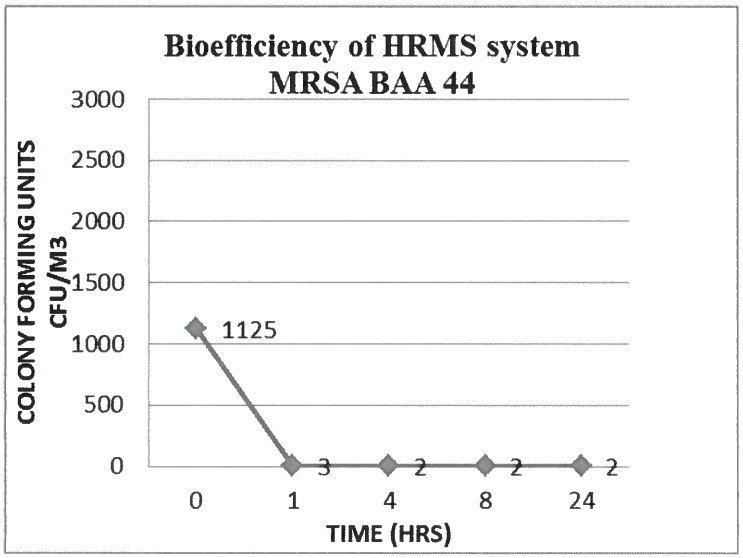

TABLE 2:

STATISTICAL ANALYSIS AND LOG REDUCTION AT EACH TIME INTERVAL FOR MRSA

SAS	TIME				
	Baseline (cfu/m3)	1 HR (cfu/m3)	4 HR (cfu/m3)	8HR (cfu/m3)	24 HR (cfu/m3)
SAS 1	634	6	2	2	2
	370	2	2	2	2
	634	2	2	2	2
SAS 2	2614	2	2	2	2
	1060	4	2	2	2
	978	2	2	2	2
SAS3	708	2	2	2	2
	516	6	2	2	2
	2614	2	2	2	2
Average	1125	3	2	2	2
Log Red		2.56	2.75	2.75	2.75
% Red		**99.7**	**99.8**	**99.8**	**99.8**

CONCLUSION

The baseline samples showed growth of *MRSA* and after the specified contact time of 1 hr., 4hr,8 hr. and 24 hr. with the Arcalux HRMS system on, the samples showed complete reduction in the colony count. The samples taken after 48hrs showed no *MRSA* indicating complete elimination of the target organism that was aerosolized into the simulated room for 15 minute.

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