ATS實驗室最終報告-豬藍耳病病毒

ATS LABS

FINAL STUDY REPORT

STUDY TITLE

Evaluation of Antiviral Activity of UV Illumination/Hydroxyl Generator

Virus: Porcine Respiratory & Reproductive Syndrome virus

PRODUCT IDENTITY

Odorox Mobile Disinfection Unit (MDU Hydroxyl Generator)

AUTHOR

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STUDY COMPLETION DATE

April 9, 2009

PERFORMING LABORATORY

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SPONSOR

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PROJECT NUMBER

A07349

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Evaluation of Antiviral Activity of UV Illumination/Hydroxyl Generator

Project Number: A07349

TRF Number: SPS01122208.PRRS

TEST SUBSTANCE IDENTITY

Test Substance Name: Odorox Mobile Disinfection Unit (MDU Hydroxyl Generator)

STUDY DATES

Date Sample Received: September 30, 2008
Study Initiation Date: January 28, 2009
Experimental Start Date: February 11, 2009
Experimental End Date: February 20, 2009
Study Completion Date: April 9, 2009

SUMMARY OF TEST PARAMETERS

Dilution: Ready to use (RTU)

Virus: Porcine Respiratory & Reproductive Syndrome virus (PRRS), Strain NVSL, obtained from the University of Kentucky

Exposure Times: 3 hours, and 6 hours

Exposure Temperature: Room temperature (24.0°C) in a humidified atmosphere of 55%

Organic Soil Load: 1% fetal bovine serum

Test Medium: Minimum Essential Medium (MEM) supplemented with 5% heat-inactivated fetal bovine serum, 100 units/mL penicillin, 10 µg/mL gentamicin, and 2.5 µg/mL amphotericin B.

Indicator Cell Cultures: MARC-145

Test Carrier: 100 x 15 mm sterile, glass petri dish representing a hard, non-porous surface

EXPERIMENTAL DESIGN

An incubator (approximately 35" x 26" x 76.5") was prepared for testing by turning off all applicable fans and heat sources, allowing the incubator to equilibrate to room temperature. The Odorox Mobile Disinfection Unit (MDU Hydroxyl Generator) was placed into the incubator; the unit was powered on and was allowed to run for two hours and twenty one minutes prior to placing the test carriers in the incubator.

For each exposure time assayed, a 0.2 mL aliquot of virus was inoculated onto the bottom of two glass petri dishes and allowed to dry. The prepared carriers were placed within the incubator for the requested 3 and 6 hour exposure times at 24.0°C in a relative humidity of 55%. The glass petri dishes were placed with the lids removed so that the virus film was fully exposed. Following the 3 and 6 hour exposure times, the carriers were neutralized using a 2.00 mL aliquot of test medium per carrier and each carrier was assayed individually for viral infectivity. Appropriate virus, test substance cytotoxicity, and neutralization controls were run concurrently.

Two additional dried virus control carriers were neutralized immediately after drying for the zero time control. The average titer of the two zero time control carriers, was used to calculate the average percent and log reductions for the corresponding carrier type following each exposure time.

STUDY CONCLUSION

Under these test conditions, Odorox Mobile Disinfection Unit (MDU Hydroxyl Generator) demonstrated an average percent reduction in viral titer of Porcine Respiratory & Reproductive Syndrome virus dried onto a hard carrier (glass) surface of 49.9% following a 3 hour exposure time and a 97.9% reduction following a 6 hour exposure time at 24.0°C as compared to the average titer of the zero time control. The log reductions in viral titer were 0.30 $\log_{10}$ and 1.68 $\log_{10}$, respectively.

In the opinion of the Author, there were no circumstances that may have affected the quality or integrity of the data. This study was performed following ATS Labs' Standard Operating Procedures (SOPs) and internal quality systems.

STUDY RESULTS

TABLE 1: Results of Porcine Respiratory & Reproductive Syndrome Virus (PRRS) Dried on Hard Carrier (Glass) Surface (Zero Time Control)

Dilution	Zero Time Control	
	Hard Carrier (Glass) Surface	
	Replicate # 1	Replicate # 2
Cell Control	0 0 0 0	0 0 0 0
10^{-1}	+ + + +	+ + + +
10^{-2}	+ + + +	+ + + +
10^{-3}	+ + + +	+ + + +
10^{-4}	0 0 + 0	0 0 + 0
10^{-5}	0 0 0 0	0 0 0 0
10^{-6}	0 0 0 0	0 0 0 0
10^{-7}	0 0 0 0	0 0 0 0
$TCID_{50}$/0.1 mL	$10^{3.75}$	$10^{3.75}$
Average $TCID_{50}$/0.1 mL	$10^{3.75}$	

(+) = Positive for the presence of test virus
(0) = No test virus recovered and/or no cytotoxicity present

TABLE 2: Results of Porcine Respiratory & Reproductive Syndrome Virus Dried on a Hard Carrier (Glass) Surface Following 3 and 6 Hour Exposure Times

Dilution	Dried Virus Control (Hard Surface)			
	3 Hour Exposure Time		6 Hour Exposure Time	
	Replicate # 1	Replicate # 2	Replicate # 1	Replicate # 2
Cell Control	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10^{-1}	+ + + +	+ + + +	+ + + +	+ + + +
10^{-2}	+ + + +	0 + + +	0 + + 0	0 + + +
10^{-3}	+ + 0 +	0 0 0 0	0 0 0 0	0 0 0 0
10^{-4}	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10^{-5}	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10^{-6}	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10^{-7}	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
$TCID_{50}$/0.1 mL	$10^{3.25}$	$10^{2.25}$	$10^{2.0}$	$10^{2.25}$
Average $TCID_{50}$/0.1 mL	$10^{2.99}$		$10^{2.14}$	

(+) = Positive for the presence of test virus
(0) = No test virus recovered and/or no cytotoxicity present

TABLE 3: Effects of Odorox Mobile Disinfection Unit (MDU Hydroxyl Generator) to Porcine Respiratory & Reproductive Syndrome virus (PRRS) Dried on a Hard Carrier (Glass) Surface

Dilution	PRRS + Odorox Mobile Disinfection Unit (MDU Hydroxyl Generator)			
	3 Hour Exposure Time		6 Hour Exposure Time	
	Replicate # 1	Replicate # 2	Replicate # 1	Replicate # 2
Cell Control	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10^{-1}	+ + + +	+ + + +	+ + + +	+ + + +
10^{-2}	0 0 0 +	+ + + +	0 + 0 0	0 + + +
10^{-3}	0 0 0 0	+ + + +	0 0 0 0	0 0 0 0
10^{-4}	0 0 0 0	0 0 + 0	0 0 0 0	0 0 0 0
10^{-5}	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10^{-6}	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10^{-7}	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
$TCID_{50}$/0.1 mL	$10^{1.75}$	$10^{3.75}$	$10^{1.75}$	$10^{2.25}$
Average $TCID_{50}$/0.1 mL	$10^{3.45}$		$10^{2.07}$	
Average Log Reduction	0.30 log_{10}		1.68 log_{10}	
Average Percent Reduction	49.9%		97.9%	

TABLE 4: Cytotoxicity Control and Neutralization Control

Dilution	Cytotoxicity Control	Neutralization Control
	Hard Surface	Hard Surface
Cell Control	0 0 0 0	0 0 0 0
10^{-1}	0 0 0 0	+ + + +
10^{-2}	0 0 0 0	+ + + +
10^{-3}	0 0 0 0	+ + + +
TCD_{50}/0.1 mL	$\leq 10^{0.5}$	See below

(+) = Positive for the presence of test virus
(0) = No test virus recovered and/or no cytotoxicity present

Results of the non-virucidal level control indicate that the test substance was neutralized at a $TCID_{50}$ of ≤ 0.5 log_{10}.

PROFESSIONAL PERSONNEL INVOLVED:

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