ATS LABS

NON-GLP STUDY REPORT

STUDY TITLE

Evaluation of Antiviral Activity of UV Illumination/Hydroxyl Generator

Virus: Influenza A virus

PRODUCT IDENTITY

Odorox Mobile Disinfection Unit (MDU Hydroxyl Generator)

AUTHOR

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STUDY COMPLETION DATE

February 27, 2009

PERFORMING LABORATORY

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PROJECT NUMBER

A07348

EXACT COPY
INITIALS KMR DATE 2/23/09

STUDY REPORT

GENERAL STUDY INFORMATION

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

Project Number: A07348

TRF Number: SPS01122208.FLUA

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 18, 2009
Study Completion Date: February 27, 2009

SUMMARY OF TEST PARAMETERS

Dilution: Ready to use (RTU)
Virus: Influenza A virus, ATCC VR-544, Strain Hong Kong
Exposure Time: 3 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 1% heat-inactivated fetal bovine serum, 100 units/mL penicillin, 10 µg/mL gentamicin, and 2.5 µg/mL amphotericin B.
Indicator Cell Cultures: Rhesus monkey kidney (RMK) cells
Test Carriers: 1 inch x 1 inch fabric (plain cotton weave) representing a soft, porous surface and 100 x 15 mm 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 two fabric carriers and 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 fabric carriers were allowed to hang freely, while 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, for each carrier type, were neutralized immediately after drying for the zero time control. The average titer of the two zero time control carriers, for each carrier type, was used to calculate the average percent and log reductions for the corresponding carrier type following each exposure time.

STUDY CONCLUSION

Hard (Glass) Surface
Under these test conditions, Odorox Mobile Disinfection Unit (MDU Hydroxyl Generator) demonstrated an average percent reduction in viral titer of Influenza A virus of 99.98% following a 3 hour exposure time and a ≥99.997% reduction following a 6 hour exposure time at 24.0°C as compared to the average titer of the corresponding zero time control. The log reductions in viral titer were 3.7 $\log_{10}$ and ≥4.5 $\log_{10}$, respectively.

Soft (Fabric) Surface
Under these test conditions, Odorox Mobile Disinfection Unit (MDU Hydroxyl Generator) demonstrated an average percent reduction in viral titer of Influenza A virus of 99.9994% following a 3 hour exposure time and a ≥99.9997% reduction following a 6 hour exposure time at 24.0°C as compared to the average titer of the corresponding zero time control. The log reductions in viral titer were 5.25 $\log_{10}$ and ≥5.5 $\log_{10}$, 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 Influenza A Dried on Hard (Glass) and Soft (Fabric) Surfaces (Zero Time Control)

Dilution	Zero Time Control			
	Hard Carrier (Glass) Surface		Soft Carrier (Fabric) Surface	
	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}	+ + + +	+ + + +	+ + + +	+ + + +
10^{-3}	+ + + +	+ + + +	+ + + +	+ + + +
10^{-4}	+ + + +	+ + + +	+ + + +	+ + + +
10^{-5}	0 0 + +	+ 0 + 0	0 0 0 0	+ + + +
10^{-6}	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	$10^{5.0}$	$10^{5.0}$	$10^{4.5}$	$10^{6.25}$
Average $TCID_{50}$/0.1 mL	$10^{5.0}$		$10^{6.0}$	

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

TABLE 2: Results of Influenza A 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}	+ + + +	+ + + +	+ + + +	0 + + 0
10^{-2}	+ + + +	+ + + +	+ 0 0 0	0 0 0 0
10^{-3}	+ 0 0 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	$10^{2.75}$	$10^{2.5}$	$10^{1.75}$	$10^{1.0}$
Average $TCID_{50}$/0.1 mL	$10^{2.6}$		$10^{1.5}$	

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

TABLE 3: Results of Influenza A Virus Dried on a Soft Carrier (Fabric) Surface Following 3 and 6 Hour Exposure Times

Dilution	Dried Virus Control (Soft 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}	+ + + +	+ + + +	+ + + +	+ + + +
10^{-3}	+ + + +	+ + + +	0 + + +	0 0 0 0
10^{-4}	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	$10^{3.5}$	$10^{4.25}$	$10^{3.25}$	$10^{2.5}$
Average $TCID_{50}$/0.1 mL	$10^{4.0}$		$10^{3.0}$	

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

TABLE 4: Effects of Odorox Mobile Disinfection Unit (MDU Hydroxyl Generator) to Influenza A Virus Dried on a Hard Carrier (Glass) Surface

Dilution	Influenza A virus + 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}	0 + 0 0	+ + + 0	0 0 0 0	0 0 0 0
10^{-2}	0 0 + 0	0 0 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
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	$10^{1.0}$	$10^{1.5}$	$\leq 10^{0.5}$	$\leq 10^{0.5}$
Average $TCID_{50}$/0.1 mL	$10^{1.3}$		$\leq 10^{0.5}$	
Average Log Reduction	3.7 Log_{10}		$\geq$4.5 Log_{10}	
Average Percent Reduction	99.98%		≥99.997%	

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

TABLE 5: Effects of Odorox Mobile Disinfection Unit (MDU Hydroxyl Generator) to Influenza A Virus Dried on a Soft Carrier (Fabric) Surface

Dilution	Influenza A virus + 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}	+ 0 0 0	0 0 0 +	0 0 0 0	0 0 0 0
10^{-2}	0 0 0 0	0 0 0 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
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	$10^{0.75}$	$10^{0.75}$	$\leq 10^{0.5}$	$\leq 10^{0.5}$
Average $TCID_{50}$/0.1 mL	$10^{0.75}$		$\leq 10^{0.5}$	
Average Log Reduction	5.25 Log_{10}		$\geq$5.5 Log_{10}	
Average Percent Reduction	99.9994%		≥99.9997%	

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

TABLE 6: Cytotoxicity and Neutralization Control Results

Dilution	Cytotoxicity Control		Neutralization Control	
	Hard Surface	Soft Surface	Hard Surface	Soft Surface
Cell Control	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10^{-1}	0 0 0 0	0 0 0 0	+ + + +	+ + + +
10^{-2}	0 0 0 0	0 0 0 0	+ + + +	+ + + +
10^{-3}	0 0 0 0	0 0 0 0	+ + + +	+ + + +
TCD_{50}/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	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 $\log_{10}$ for both surface types.

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