

**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

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INITIALS *KR* DATE *2/27/09*

## 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  $\geq 99.997\%$  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  $\geq 4.5 \log_{10}$ , 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  $\geq 99.9997\%$  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  $\geq 5.5 \log_{10}$ , 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 <sup>-1</sup>	++++	++++	++++	++++
10 <sup>-2</sup>	++++	++++	++++	++++
10 <sup>-3</sup>	++++	++++	++++	++++
10 <sup>-4</sup>	++++	++++	++++	++++
10 <sup>-5</sup>	0 0 ++	+ 0 + 0	0 0 0 0	++++
10 <sup>-6</sup>	0 0 0 0	0 0 0 0	0 0 0 0	0 +++
10 <sup>-7</sup>	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
TCID <sub>50</sub> /0.1 mL	10 <sup>5.0</sup>	10 <sup>5.0</sup>	10 <sup>4.5</sup>	10 <sup>6.25</sup>
Average TCID <sub>50</sub> /0.1 mL	10 <sup>5.0</sup>		10 <sup>6.0</sup>	

(+) = 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 <sup>-1</sup>	++++	++++	++++	0+++
10 <sup>-2</sup>	++++	++++	+000	0000
10 <sup>-3</sup>	+000	0000	0000	0000
10 <sup>-4</sup>	0000	0000	0000	0000
10 <sup>-5</sup>	0000	0000	0000	0000
10 <sup>-6</sup>	0000	0000	0000	0000
10 <sup>-7</sup>	0000	0000	0000	0000
TCID <sub>50</sub> /0.1 mL	10 <sup>2.75</sup>	10 <sup>2.5</sup>	10 <sup>1.75</sup>	10 <sup>1.0</sup>
Average TCID <sub>50</sub> /0.1 mL	10 <sup>2.6</sup>		10 <sup>1.5</sup>	

(+) = 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 <sup>-1</sup>	++++	++++	++++	++++
10 <sup>-2</sup>	++++	++++	++++	++++
10 <sup>-3</sup>	++++	++++	0+++	0000
10 <sup>-4</sup>	0000	0+++	0000	0000
10 <sup>-5</sup>	0000	0000	0000	0000
10 <sup>-6</sup>	0000	0000	0000	0000
10 <sup>-7</sup>	0000	0000	0000	0000
TCID <sub>50</sub> /0.1 mL	10 <sup>3.5</sup>	10 <sup>4.25</sup>	10 <sup>3.25</sup>	10 <sup>2.5</sup>
Average TCID <sub>50</sub> /0.1 mL	10 <sup>4.0</sup>		10 <sup>3.0</sup>	

(+) = 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 <sup>-1</sup>	0 + 0 0	+ + + 0	0 0 0 0	0 0 0 0
10 <sup>-2</sup>	0 0 + 0	0 0 0 +	0 0 0 0	0 0 0 0
10 <sup>-3</sup>	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10 <sup>-4</sup>	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10 <sup>-5</sup>	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10 <sup>-6</sup>	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10 <sup>-7</sup>	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
TCID <sub>50</sub> /0.1 mL	10 <sup>1.0</sup>	10 <sup>1.5</sup>	≤10 <sup>0.5</sup>	≤10 <sup>0.5</sup>
Average TCID <sub>50</sub> /0.1 mL	10 <sup>1.3</sup>		≤10 <sup>0.5</sup>	
Average Log Reduction	3.7 Log <sub>10</sub>		≥4.5 Log <sub>10</sub>	
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 <sup>-1</sup>	+ 0 0 0	0 0 0 +	0 0 0 0	0 0 0 0
10 <sup>-2</sup>	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10 <sup>-3</sup>	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10 <sup>-4</sup>	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10 <sup>-5</sup>	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10 <sup>-6</sup>	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10 <sup>-7</sup>	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
TCID <sub>50</sub> /0.1 mL	10 <sup>0.75</sup>	10 <sup>0.75</sup>	≤10 <sup>0.5</sup>	≤10 <sup>0.5</sup>
Average TCID <sub>50</sub> /0.1 mL	10 <sup>0.75</sup>		≤10 <sup>0.5</sup>	
Average Log Reduction	5.25 Log <sub>10</sub>		≥5.5 Log <sub>10</sub>	
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 <sup>-1</sup>	0 0 0 0	0 0 0 0	++++	++++
10 <sup>-2</sup>	0 0 0 0	0 0 0 0	++++	++++
10 <sup>-3</sup>	0 0 0 0	0 0 0 0	++++	++++
TCD <sub>50</sub> /0.1 mL	≤10 <sup>0.5</sup>	≤10 <sup>0.5</sup>	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<sub>50</sub> of ≤0.5 log<sub>10</sub> for both surface types.

**PROFESSIONAL PERSONNEL INVOLVED:**

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