

STUDY TITLE

Evaluation of Antimicrobial Activity of UV Illumination/Hydroxyl Generator

Test Organisms:

Staphylococcus aureus (ATCC 6538)
Escherichia coli (ATCC 11229)
Pseudomonas aeruginosa (15442)

PRODUCT IDENTITY

Odorox Mobile Disinfection Unit Hydroxyl Generator

AUTHOR

Scott R. Steinagel, B.S.
Manager, Microbiology Laboratory Operations

STUDY COMPLETION DATE

January 21, 2009

PERFORMING LABORATORY

ATS Labs
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

SPONSOR

Safety Performance Solutions, Inc.
3908 Kingston Drive
Bismarck, ND 58503

PROJECT NUMBER

A07207

EXACT COPY
INITIALS KR DATE 1/22/09

STUDY REPORT

GENERAL STUDY INFORMATION

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

Project Number: A07207

TRF Number: SPS01120908.CUST.1

TEST SUBSTANCE IDENTITY

Test Substance Name: Odorox Mobile Disinfection Unit Hydroxyl Generator

STUDY DATES

Date Sample Received: September 30, 2008

Study Initiation Date: January 5, 2009

Experimental Start Date: January 12, 2009

Experimental End Date: January 14, 2009

Study Completion Date: January 21, 2009

Test Organism	ATCC #	Culture Medium	Subculture Plate Medium
<i>Staphylococcus aureus</i>	6538	Synthetic Broth	Tryptic Soy Agar + 5% Sheep's blood (BAP)
<i>Escherichia coli</i>	11229	Synthetic Broth	
<i>Pseudomonas aeruginosa</i>	15442	Nutrient Broth	

The microorganisms used in this study were obtained from the American Type Culture Collection (ATCC), Manassas, Virginia.

Test Exposure: 4 hours, 8 hours, and 12 hours
Exposure Temperature: Room temperature (25.0-30.3°C).
Number of Carriers Tested/lot: Duplicate carriers per exposure time utilizing two carrier types, 1" x 1" stainless steel and 1" x 1" cotton fabric
Soil Load Description: No organic soil load required
Neutralizing Subculture Medium: Lethen Broth with 0.07% Lecithin and 0.5% Tween 80

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 Hydroxyl Generator was placed into the incubator; the unit was powered on and was allowed to run for 72 minutes prior to placing the carriers in the incubator. Duplicate test carriers, per carrier type, per test organism, per exposure time point were inoculated with a dried film of test culture and were placed within the incubator. Fabric carriers were allowed to hang freely, while stainless steel carriers were exposed within Petri dishes with the dish lids fully ajar. Following a 4 hour, 8 hour and 12 hour exposure, the carriers were neutralized, mixed and assayed for survivors. Side by side fabric and stainless steel quantitation control carriers were inoculated and dried as in the test. Individual control carriers were neutralized immediately after drying (time zero). Additionally, duplicate control carriers were exposed for 4 hours, 8 hours and 12 hours, as in the test, at 20±5°C and 50-70% relative humidity. Appropriate purity, carrier sterility, and neutralizing subculture medium sterility controls were performed. Percent and log₁₀ reductions were determined for the test carriers as compared to the quantitation control carriers.

TABLE 1: CONTROL RESULTS

Type of Control		Results		
		<i>Staphylococcus aureus</i> (ATCC 6538)	<i>Escherichia coli</i> (ATCC 11229)	<i>Pseudomonas aeruginosa</i> (ATCC 15442)
Purity Control		Pure	Pure	Pure
Neutralizing Subculture Medium Sterility Control		No Growth		
Carrier Sterility Control	Stainless Steel	No Growth		
	Cotton Fabric	No Growth		

TABLE 2: EVALUATION OF QUANTITATION CONTROL CARRIER DATA
(TIME ZERO)

Test Organism	Carrier type	CFU/carrier	Log ₁₀
<i>Staphylococcus aureus</i> (ATCC 6538)	Stainless Steel	2.72 x 10 ⁶	6.435
	Cotton Fabric	6.4 x 10 ⁴	4.81
<i>Escherichia coli</i> (ATCC 11229)	Stainless Steel	3.00 x 10 ⁵	5.477
	Cotton Fabric	4.6 x 10 ⁴	4.66
<i>Pseudomonas aeruginosa</i> (ATCC 15442)	Stainless Steel	2.70 x 10 ⁶	6.431
	Cotton Fabric	5.8 x 10 ⁴	4.76

CFU = Colony Forming Unit

**TABLE 3: EVALUATION OF QUANTITATION CONTROL CARRIER DATA
(FOLLOWING EXPOSURE)**

Test Organism	Carrier type	Time Point	Average CFU/carrier	Average Log ₁₀
<i>Staphylococcus aureus</i> (ATCC 6538)	Stainless Steel	4 hours	3.15×10^6	6.498
		8 hours	3.78×10^6	6.578
		12 hours	2.63×10^6	6.420
	Cotton Fabric	4 hours	7.2×10^4	4.86
		8 hours	2.2×10^4	4.35
		12 hours	5.68×10^4	4.754
<i>Escherichia coli</i> (ATCC 11229)	Stainless Steel	4 hours	5.48×10^4	4.739
		8 hours	2.71×10^4	4.433
		12 hours	1.3×10^4	4.10
	Cotton Fabric	4 hours	3.1×10^3	3.49
		8 hours	2.1×10^3	3.32
		12 hours	2.36×10^3	3.373
<i>Pseudomonas aeruginosa</i> (ATCC 15442)	Stainless Steel	4 hours	1.7×10^6	6.22
		8 hours	5.6×10^5	5.75
		12 hours	4.33×10^5	5.636
	Cotton Fabric	4 hours	1.6×10^4	4.20
		8 hours	1.3×10^4	4.10
		12 hours	1.0×10^4	4.02

CFU = Colony Forming Unit

TABLE 4: EVALUATION OF TEST CARRIER DATA

Test Substance	Test Organism	Carrier type	Exposure Time	Average CFU/carrier	Average Log ₁₀
Odorox Mobile Disinfection Unit Hydroxyl Generator	<i>Staphylococcus aureus</i> (ATCC 6538)	Stainless Steel	4 hours	1.67×10^5	5.224
			8 hours	3.93×10^3	3.594
			12 hours	$< 2 \times 10^1$	< 1.3
		Cotton Fabric	4 hours	$< 2 \times 10^1$	< 1.3
			8 hours	$< 2 \times 10^1$	< 1.3
			12 hours	$< 2 \times 10^1$	< 1.3
	<i>Escherichia coli</i> (ATCC 11229)	Stainless Steel	4 hours	$< 2 \times 10^1$	< 1.3
			8 hours	$< 2 \times 10^1$	< 1.3
			12 hours	$< 2 \times 10^1$	< 1.3
		Cotton Fabric	4 hours	$< 2 \times 10^1$	< 1.3
			8 hours	$< 2 \times 10^1$	< 1.3
			12 hours	$< 2 \times 10^1$	< 1.3
	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	Stainless Steel	4 hours	$< 2 \times 10^1$	< 1.3
			8 hours	$< 2 \times 10^1$	< 1.3
			12 hours	$< 2 \times 10^1$	< 1.3
		Cotton Fabric	4 hours	$< 2 \times 10^1$	< 1.3
			8 hours	$< 2 \times 10^1$	< 1.3
			12 hours	$< 2 \times 10^1$	< 1.3

CFU = Colony Forming Unit

**TABLE 5: RELATIVE ORGANISM REDUCTION AS COMPARED TO SIDE BY SIDE
QUANTITATION CONTROL CARRIERS**

Test Substance	Test Organism	Carrier type	Exposure Time	Percent Reduction	Log ₁₀ Reduction
Odorox Mobile Disinfection Unit Hydroxyl Generator	<i>Staphylococcus aureus</i> (ATCC 6538)	Stainless Steel	4 hours	94.7%	1.274
			8 hours	>99.8%	2.984
			12 hours	>99.999%	>5.1
		Cotton Fabric	4 hours	>99.9%	>3.6
			8 hours	>99.9%	>3.1
			12 hours	>99.9%	>3.5
	<i>Escherichia coli</i> (ATCC 11229)	Stainless Steel	4 hours	>99.9%	>3.4
			8 hours	>99.9%	>3.1
			12 hours	>99.8%	>2.8
		Cotton Fabric	4 hours	>99.4%	>2.2
			8 hours	>99.0%	>2.0
			12 hours	>99.2%	>2.4
	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	Stainless Steel	4 hours	>99.99%	>4.9
			8 hours	>99.99%	>4.5
			12 hours	>99.99%	>4.3
Cotton Fabric		4 hours	>99.8%	>2.9	
		8 hours	>99.8%	>2.8	
		12 hours	>99.8%	>2.7	

**TABLE 6: OVERALL ORGANISM REDUCTION AS COMPARED TO TIME ZERO
QUANTITATION CONTROL CARRIERS**

Test Substance	Test Organism	Carrier type	Exposure Time	Percent Reduction	Log ₁₀ Reduction
Odorox Mobile Disinfection Unit Hydroxyl Generator	<i>Staphylococcus aureus</i> (ATCC 6538)	Stainless Steel	4 hours	93.9%	1.211
			8 hours	>99.8%	2.841
			12 hours	>99.999%	>5.1
		Cotton Fabric	4 hours	>99.9%	>3.5
			8 hours	>99.9%	>3.5
			12 hours	>99.9%	>3.5
	<i>Escherichia coli</i> (ATCC 11229)	Stainless Steel	4 hours	>99.99%	>4.2
			8 hours	>99.99%	>4.2
			12 hours	>99.99%	>4.2
		Cotton Fabric	4 hours	>99.9%	>3.4
			8 hours	>99.9%	>3.4
			12 hours	>99.9%	>3.4
	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	Stainless Steel	4 hours	>99.999%	>5.1
			8 hours	>99.999%	>5.1
			12 hours	>99.999%	>5.1
Cotton Fabric		4 hours	>99.9%	>3.5	
		8 hours	>99.9%	>3.5	
		12 hours	>99.9%	>3.5	

ANALYSIS

Odorox Mobile Disinfection Unit Hydroxyl Generator, demonstrated a 94.7% (1.274 log₁₀) relative reduction on stainless steel and greater than a 99.9% (>3.6 log₁₀) relative reduction on cotton fabric for *Staphylococcus aureus* (ATCC 6538) following a 4 hour exposure period, greater than a 99.8% (2.984 log₁₀) relative reduction on stainless steel and greater than a 99.9% (>3.1 log₁₀) relative reduction on cotton fabric for *Staphylococcus aureus* (ATCC 6538) following an 8 hour exposure period, and greater than a 99.999% (>5.1 log₁₀) relative reduction on stainless steel and greater than a 99.9% (>3.5 log₁₀) relative reduction on cotton fabric for *Staphylococcus aureus* (ATCC 6538) following a 12 hour exposure period, as compared to side by side quantitation control carriers, when tested at room temperature (25.0-30.3°C).

Odorox Mobile Disinfection Unit Hydroxyl Generator, demonstrated a 93.9% (1.211 log₁₀) overall reduction on stainless steel and greater than a 99.9% (>3.5 log₁₀) overall reduction on cotton fabric for *Staphylococcus aureus* (ATCC 6538) following a 4 hour exposure period, greater than a 99.8% (2.841 log₁₀) overall reduction on stainless steel and greater than a 99.9% (>3.5 log₁₀) overall reduction on cotton fabric for *Staphylococcus aureus* (ATCC 6538) following an 8 hour exposure period, and greater than a 99.999% (>5.1 log₁₀) overall reduction on stainless steel and greater than a 99.9% (>3.5 log₁₀) overall reduction on cotton fabric for *Staphylococcus aureus* (ATCC 6538) following a 12 hour exposure period as compared to the time zero quantitation control carriers, when tested at room temperature (25.0-30.3°C).

Odorox Mobile Disinfection Unit Hydroxyl Generator, demonstrated greater than a 99.99% (>4.9 log₁₀) relative reduction on stainless steel and greater than a 99.8% (>2.9 log₁₀) relative reduction on cotton fabric for *Pseudomonas aeruginosa* (ATCC 15442) following a 4 hour exposure period, greater than a 99.99% (>4.5 log₁₀) relative reduction on stainless steel and greater than a 99.8% (>2.8 log₁₀) relative reduction on cotton fabric for *Pseudomonas aeruginosa* (ATCC 15442) following an 8 hour exposure period, and greater than a 99.99% (>4.3 log₁₀) relative reduction on stainless steel and greater than a 99.8% (>2.7 log₁₀) relative reduction on cotton fabric for *Pseudomonas aeruginosa* (ATCC 15442) following a 12 hour exposure period, as compared to side by side quantitation control carriers, when tested at room temperature (25.0-30.3°C).

Odorox Mobile Disinfection Unit Hydroxyl Generator, demonstrated greater than a 99.999% (>5.1 log₁₀) overall reduction on stainless steel and greater than a 99.9% (>3.5 log₁₀) overall reduction on cotton fabric for *Pseudomonas aeruginosa* (ATCC 15442) following a 4 hour exposure period, greater than a 99.999% (>5.1 log₁₀) overall reduction on stainless steel and greater than a 99.9% (>3.5 log₁₀) overall reduction on cotton fabric for *Pseudomonas aeruginosa* (ATCC 15442) following an 8 hour exposure period, and greater than a 99.999% (>5.1 log₁₀) overall reduction on stainless steel and greater than a 99.9% (>3.5 log₁₀) overall reduction on cotton fabric for *Pseudomonas aeruginosa* (ATCC 15442) following a 12 hour exposure period as compared to the time zero quantitation control carriers, when tested at room temperature (25.0-30.3°C).

ANALYSIS (continued)

Odorox Mobile Disinfection Unit Hydroxyl Generator, demonstrated greater than a 99.9% ($>3.4 \log_{10}$) relative reduction on stainless steel and greater than a 99.4% ($>2.2 \log_{10}$) relative reduction on cotton fabric for *Escherichia coli* (ATCC 11229) following a 4 hour exposure period, greater than a 99.9% ($>3.1 \log_{10}$) relative reduction on stainless steel and greater than a 99.0% ($>2.0 \log_{10}$) relative reduction on cotton fabric for *Escherichia coli* (ATCC 11229) following an 8 hour exposure period, and greater than a 99.8% ($>2.8 \log_{10}$) relative reduction on stainless steel and greater than a 99.2% ($>2.4 \log_{10}$) relative reduction on cotton fabric for *Escherichia coli* (ATCC 11229) following a 12 hour exposure period, as compared to side by side quantitation control carriers, when tested at room temperature (25.0-30.3°C).


Odorox Mobile Disinfection Unit Hydroxyl Generator, demonstrated greater than a 99.99% ($>4.2 \log_{10}$) overall reduction on stainless steel and greater than a 99.9% ($>3.4 \log_{10}$) overall reduction on cotton fabric for *Escherichia coli* (ATCC 11229) following a 4 hour exposure period, greater than a 99.99% ($>4.2 \log_{10}$) overall reduction on stainless steel and greater than a 99.9% ($>3.4 \log_{10}$) overall reduction on cotton fabric for *Escherichia coli* (ATCC 11229) following an 8 hour exposure period, and greater than a 99.99% ($>4.2 \log_{10}$) overall reduction on stainless steel and greater than a 99.9% ($>3.4 \log_{10}$) overall reduction on cotton fabric for *Escherichia coli* (ATCC 11229) following a 12 hour exposure period as compared to the time zero quantitation control carriers, when tested at room temperature (25.0-30.3°C).

This study was performed following ATS Labs' Standard Operating Procedures (SOPs) and internal quality systems.

PROFESSIONAL PERSONNEL INVOLVED:

- | | |
|--------------------------|---|
| David Rottjakob, M.T. | - Director, Microbiology Services |
| Scott R. Steinagel, B.S. | - Manager, Microbiology Laboratory Operations |
| Becky Lien, B.A. | - Research Scientist I |
| Joy Salverda, B.S. | - Research Scientist I |
| Adam W. Pitt, B.S. | - Research Assistant II |
| Matthew Sathe, B.S. | - Research Assistant II |
| Peter Toll, B.S. | - Research Assistant II |
| Katherine C. Sager, B.S. | - Research Assistant I |
| Erin Hawkinson, B.S. | - Research Assistant I |
| Megan McDonald, B.S. | - Research Assistant I |
| John Kathrein | - Laboratory Assistant |

PREPARED BY:

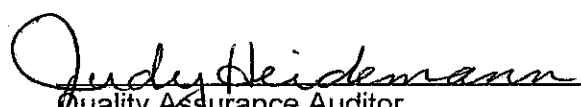


 Scott R. Steinagel, B.S.
 Manager, Microbiology Laboratory Operations

1-21-09

 Date

REVIEWED BY:



 Judy Heidemann
 Quality Assurance Auditor

1-21-09

 Date

The use of the ATS Labs name, logo or any other representation of ATS Labs without the written approval of ATS Labs is prohibited. In addition, ATS Labs may not be referred to in any form of promotional materials, press releases, advertising or similar materials (whether by print, broadcast, communication or electronic means) without the express written permission of ATS Labs.