

ATS實驗室最終報告 -黃金葡萄球菌+大腸桿菌+綠膿桿菌



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

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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

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STUDY REPORT

GENERAL STUDY INFORMATION

Study Title:

Evaluation of Antimicrobial Activity of UV Illumination/Hydroxyl Generator

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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
Staphylococcus aureus	6538	Synthetic Broth	Tryptic Soy Agar +
Escherichia coli	cherichia coli 11229		5% Sheep's blood
Pseudomonas aeruginosa	15442	Nutrient Broth	(BAP)

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:

Letheen 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

		Results				
Type of Control		Staphylococcus aureus (ATCC 6538)	Escherichia coli (ATCC 11229)	Pseudomonas aeruginosa (ATCC 15442)		
Purity (Control	Pure	Pure Pur			
Neutralizing Subculture Medium Sterility Control		No Growth				
Carrier Sterility	Stainless Steel	·	No Growth			
Control	▼		No Growth			

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

Test Organism	Carrier type	CFU/carrier	Log ₁₀
Staphylococcus	Stainless Steel	2.72 x 10 ⁶	6.435
aureus (ATCC 6538)	Cotton Fabric	6.4 x 10 ⁴	4.81
Escherichia coli (ATCC 11229) Col	Stainless Steel	3.00 x 10⁵	5.477
	Cotton Fabric	4.6 x 10 ⁴	4.66
Pseudomonas	Stainless Steel	2.70 x 10 ⁶	6.431
aeruginosa (ATCC 15442)	Cotton Fabric	5.8 x 10 ⁴	4.76

CFU = Colony Forming Unit

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

Test Organism	Carrier type	Time Point	Average CFU/carrier	Average Log ₁₀
		4 hours	3.15 x 10 ⁶	6.498
	Stainless Steel	8 hours	3.78 x 10 ⁶	6.578
Staphylococcus		12 hours	2.63 x 10 ⁶	6.420
aureus (ATCC 6538)		4 hours	7.2 x 10⁴	4.86
	Cotton Fabric	8 hours	2.2 x 10⁴	4.35
		12 hours	5.68 x 10⁴	4.754
		4 hours	5.48 × 10⁴	4.739
	Stainless Steel	8 hours	2.71 × 10 ⁴	4.433
Escherichia		12 hours	1.3 x 10 ⁴	4.10
coli (ATCC 11229) Cotton Fabric		4 hours	3.1 x 10 ³	3.49
	Cotton Fabric	8 hours	2.1 x 10 ³	3.32
		12 hours	2.36 x 10 ³	3.373
		4 hours	1.7 x 10 ⁶	6.22
Pseudomonas Stee	Stainless Steel	8 hours	5.6 x 10⁵	5.75
		12 hours	4.33 x 10 ⁵	5.636
aeruginosa (ATCC 15442)		4 hours	1.6 x 10⁴	4.20
	Cotton Fabric	8 hours	1.3 x 10⁴	4.10
		12 hours	1.0 x 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
		Stainless Steel	4 hours	1.67 x 10 ⁵	5.224
			8 hours	3.93 x 10 ³	3.594
	Staphylococcus		12 hours	< 2 x 10 ¹	< 1.3
	aureus (ATCC 6538)		4 hours	< 2 x 10 ¹	< 1.3
		Cotton Fabric	8 hours	< 2 x 10 ¹	< 1.3
			12 hours	< 2 x 10 ¹	< 1.3
Odorox		Stainless Steel	4 hours	< 2 x 10 ¹	< 1.3
	Escherichia coli (ATCC 11229)		8 hours	< 2 x 10 ¹	< 1.3
Mobile Disinfection			12 hours	< 2 x 10 ¹	< 1.3
Unit Hydroxyl		Cotton Fabric	4 hours	< 2 x 10 ¹	< 1.3
Generator			8 hours	< 2 x 10 ¹	< 1.3
			12 hours	< 2 x 10 ¹	< 1.3
•			4 hours	< 2 x 10 ¹	< 1.3
	Pseudomonas aeruginosa (ATCC 15442)	Stainless Steel	8 hours	< 2 x 10 ¹	< 1.3
			12 hours	< 2 x 10 ¹	< 1.3
		Cotton Fabric	4 hours	< 2 x 10 ¹	< 1.3
			8 hours	< 2 x 10 ¹	< 1.3
			12 hours	< 2 x 10 ¹	< 1.3

CFU = Colony Forming Unit

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

Test Substance	Test Organism	Carrier type	Exposure Time	Percent Reduction	Log₁₀ Reduction
		<u> </u>	4 hours	94.7%	1.274
		Stainless	8 hours	>99.8%	2.984
	Staphylococcus	Steel	12 hours	>99.999%	>5.1
	aureus		4 hours	>99.9%	>3.6
	(ATCC 6538)	Cotton	8 hours	>99.9%	>3.1
		Fabric	12 hours	>99.9%	>3.5
Odorox		Stainless Steel	4 hours	>99.9%	>3.4
Mobile	Escherichia coli (ATCC 11229)		8 hours	>99.9%	>3.1
Disinfection			12 hours	>99.8%	>2.8
Unit		Cotton Fabric	4 hours	>99.4%	>2.2
Generator Pseud			8 hours	>99.0%	>2.0
			12 hours	>99.2%	>2.4
		Stainless Steel	4 hours	>99.99%	>4.9
	Dooudomonoo		8 hours	>99.99%	>4.5
	Pseudomonas		12 hours	>99.99%	>4.3
	aeruginosa (ATCC 15442)	Cotton	4 hours	>99.8%	>2.9
·	(ATCC 15442)	Cotton Fabric	8 hours	>99.8%	>2.8
	<u> </u>	I abite	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	Log₁₀ Reduction
		Otricles	4 hours	93.9%	1.211
	Otanbulananau	Stainless	8 hours	>99.8%	2.841
	Staphylococcus	Steel	12 hours	>99.999%	>5.1
	aureus (ATCC 6538)	Cattan	4 hours	>99.9%	>3.5
•	(ATCC 0556)	Cotton	8 hours	>99.9%	>3.5
Odorox		Fabric	12 hours	>99.9%	>3.5
		Otalalaaa	4 hours	>99.99%	>4.2
Mobile		Stainless Steel	8 hours	>99.99%	>4.2
Disinfection	Escherichia		12 hours	>99.99%	>4.2
Unit	COLI	229) Cotton Fabric	4 hours	>99.9%	>3.4
Hydroxyl	(ATCC 11229)		8 hours	>99.9%	>3.4
Generator			12 hours	>99.9%	>3.4
		Stainless Steel	4 hours	>99.999%	>5.1
6	Dagudamaria		8 hours	>99.999%	>5.1
	Pseudomonas		12 hours	>99.999%	>5.1
	aeruginosa (ATCC 15442)	Cotton	4 hours	>99.9%	>3.5
	(A100 15442)	Cotton	8 hours	>99.9%	>3.5
		Fabric	12 hours	>99.9%	>3.5

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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 99.99% (>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 99.99% (>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 99.99% (>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 99.99% (>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 99.99% (>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).

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ANALYSIS (continued)

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Odorox Mobile Disinfection Unit Hydroxyl Generator, demonstrated greater than a 99.9% (>3.4 log₁₀) relative reduction on stainless steel and greater than a 99.4% (>2.2 log₁₀) relative reduction on cotton fabric for *Escherichia coli* (ATCC 11229) following a 4 hour exposure period, greater than a 99.9% (>3.1 log₁₀) relative reduction on stainless steel and greater than a 99.0% (>2.0 log₁₀) relative reduction on cotton fabric for *Escherichia coli* (ATCC 11229) following an 8 hour exposure period, and greater than a 99.8% (>2.8 log₁₀) relative reduction on stainless steel and greater than a 99.2% (>2.4 log₁₀) 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 log₁₀) overall reduction on stainless steel and greater than a 99.9% (>3.4 log₁₀) overall reduction on cotton fabric for *Escherichia coli* (ATCC 11229) following a 4 hour exposure period, greater than a 99.99% (>4.2 log₁₀) overall reduction on stainless steel and greater than a 99.9% (>3.4 log₁₀) overall reduction on cotton fabric for *Escherichia coli* (ATCC 11229) following an 8 hour exposure period, and greater than a 99.99% (>4.2 log₁₀) overall reduction on stainless steel and greater than a 99.9% (>3.4 log₁₀) 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.

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