ATS LABS

NON-GLP STUDY REPORT

STUDY TITLE

Evaluation of Antimicrobial Effectiveness of Hand-Held Sterilray Far-UV Generating Device on Hard Nonporous Glass and Porous Fabric Surfaces

Test Organisms:

Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592)
Pseudomonas aeruginosa (ATCC 15442)
Acinetobacter baumannii (ATCC 19606)
Clostridium difficile - spore form (ATCC 700792)
Bacillus subtilis - spore form (ATCC 19659)

PRODUCT IDENTITY

Sterilray

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STUDY COMPLETION DATE

March 30, 2010

PERFORMING LABORATORY

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PROJECT NUMBER

A09049

This study was not performed under
EPA Good Laboratory Practice Regulations
(40 CFR Part 160)

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TABLE 3: TESTING EXPOSURE VALUES

Test Substance/Surface: Sterilray, Glass Slides				
Organism Carrier Type	**Carrier #**	**Sterilray on High/Low**	**Neutralization Confirmation Dose (mj/cm^2)/ Time to Reach Dose**	**Test Dose (mj/cm^2)/ Time to Reach Dose**
Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592)	1	Low	51 5 seconds	49.2 5 seconds
	2		44.8 5 seconds	48 5 seconds
Pseudomonas aeruginosa (ATCC 15442)	1		51.4 5 seconds	47.7 4 seconds
	2		53.5 6 seconds	53.2 6 seconds
Acinetobacter baumannii (ATCC 19606)	1		53 5 seconds	47.7 5 seconds
	2		46.6 5 seconds	48.8 5 seconds
Clostridium difficile - spore form (ATCC 700792)	1	High	103.9 7 seconds	103.1 7 seconds
	2		106 7 seconds	101.7 7 seconds
Bacillus subtilis (ATCC 19659)	1		*49.8 *6 seconds	99.6 7 seconds
	2		*49.8 *5 seconds	103.5 7 seconds

*The Neutralization Confirmation carriers were treated on low with a lower dose, this was changed for the test carriers to the high setting and higher dose once the Sponsor realized the *Bacillus subtilis* was a spore culture.

TABLE 3: TESTING EXPOSURE VALUES (continued)

Test Substance/Surface: Sterilray, Fabric Carriers						
Organism Carrier Type	**Carrier #**	**Sterilray on High/Low**	***Neutralization Confirmation Dose (mj/cm^2)/ Time to Reach Dose**		**Test Dose (mj/cm^2)/ Time to Reach Dose**	
			Side 1	**Side 2**	**Side 1**	**Side 2**
Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592)	1	Low	48.4 3 seconds	47 3 seconds	49.9 5 seconds	50.6 5 seconds
	2		48.7 3 seconds	70 4 seconds	51 5 seconds	53.4 5 seconds
Pseudomonas aeruginosa (ATCC 15442)	1		48.8 3 seconds	54.8 4 seconds	41 4 seconds	52 5 seconds
	2		54.3 4 seconds	53 3 seconds	49 5 seconds	51.2 5 seconds
Acinetobacter baumannii (ATCC 19606)	1		54.8 3 seconds	51.3 3 seconds	49.5 4 seconds	53.4 3 seconds
	2		53.1 4 seconds	51.1 3 seconds	54.7 4 seconds	52.6 3 seconds
Clostridium difficile - spore form (ATCC 700792)	1	High	52.5 4 seconds	51.4 3 seconds	51.6 3 seconds	52.6 4 seconds
	2		57.5 4 seconds	50.2 3 seconds	52.2 3 seconds	48 3 seconds
Bacillus subtilis (ATCC 19659)	1		54.5 3 seconds	49.8 3 seconds	52.1 3 seconds	57.8 3 seconds
	2		51.1 3 seconds	53.6 3 seconds	49.1 3 seconds	52.4 3 seconds

*All Neutralization Confirmation carriers were treated on both sides of the fabric with Sterilray on High

The inoculated fabric carriers in the Petri dish were irradiated, turned over in the same dish, and irradiated a second time. There is a possibility that the lower log reduction for *Clostridium difficile* and *Bacillus subtilis* may be the result of leftover organism being transferred from the dish to the first side of the fabric after turning it over.

TABLE 6: CALCULATED VALUES

Test Substance/Surface: Sterilray, Glass Slides						
Organism Carrier Type	Carrier #	# Survivors/ Carrier	Log_{10}	Average Log_{10}	Geometric Mean	Percent Reduction
Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592)	1	4×10^1	1.60	1.45	2.82×10^1	>99.99% (4.83)
	2	2×10^1	1.30			
Pseudomonas aeruginosa (ATCC 15442)	1	6×10^1	1.78	1.54	3.5×10^1	>99.99% (4.86)
	2	2×10^1	1.30			
Acinetobacter baumannii (ATCC 19606)	1	1.5×10^3	3.18	<2.24	$<1.74 \times 10^2$	>99.9% (>3.97)
	2	$<2 \times 10^1$	<1.30			
Clostridium difficile - spore form (ATCC 700792)	1	2×10^2	2.30	3.21	1.62×10^3	99.8% (2.65)
	2	1.3×10^4	4.11			
Bacillus subtilis (ATCC 19659)	1	6×10^1	1.78	2.15	1.41×10^2	99.99% (4.13)
	2	3.2×10^2	2.51			

TABLE 6: CALCULATED VALUES (continued)

Test Substance/Surface: Sterilray, Fabric Carriers						
Organism Carrier Type	Carrier #	# Survivors/ Carrier	Log_{10}	Average Log_{10}	Geometric Mean	Percent Reduction/ Log_{10} Reduction
Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592)	1	4×10^1	1.60	<1.45	$<2.82 \times 10^1$	>99.99% (4.53)
	2	$<2 \times 10^1$	<1.30			
Pseudomonas aeruginosa (ATCC 15442)	1	$<2 \times 10^1$	<1.30	<1.54	$<3.47 \times 10^1$	>99.9% (>3.37)
	2	6×10^1	1.78			
Acinetobacter baumannii (ATCC 19606)	1	$<2 \times 10^1$	<1.30	<1.30	$<2.00 \times 10^1$	>99.99% (>4.75)
	2	$<2 \times 10^1$	<1.30			
Clostridium difficile - spore form (ATCC 700792)	1	3.8×10^3	3.58	3.52	3.31×10^3	91.3% (1.06)
	2	2.8×10^3	3.45			
Bacillus subtilis (ATCC 19659)	1	6.0×10^3	3.78	3.80	6.31×10^3	98.6% (1.85)
	2	6.6×10^3	3.82			

CONTROL RESULTS

The results of controls run for culture purity, carrier sterility, neutralizing subculture medium sterility, neutralization confirmation, antibiotic resistance, and carrier quantitation were all acceptable.

The inoculated fabric carriers in the Petri dish were irradiated, turned over in the same dish, and irradiated a second time. There is a possibility that the lower log reduction for *Clostridium difficile* and *Bacillus subtilis* may be the result of leftover organism being transferred from the dish to the first side of the fabric after turning it over.