

NON-GLP STUDY REPORT

STUDY TITLE

Evaluation of Antimicrobial Effectiveness of a UVC Generating Device on Hard Nonporous Surfaces

Test Organisms:

Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592)
Clostridium difficile - spore form (ATCC 43598)

PRODUCT IDENTITY

ARTZ

AUTHOR

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STUDY COMPLETION DATE

May 4, 2011

PERFORMING LABORATORY

ATS Labs
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SPONSOR

American Ultraviolet Company
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Lebanon, IN 46052

PROJECT NUMBER

A11323

Page 1 of 8

EXACT COPY
INITIALS *JS* DATE 5/4/11

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Evaluation of Antimicrobial Effectiveness of a UVC Generating Device on Hard Nonporous Surfaces

Project Number: A11323

TRF Number: AUC01040711.CUST

TEST SUBSTANCE IDENTITY

Test Substance Name: ARTZ

STUDY DATES

Date Sample Received: April 20, 2011
Study Initiation Date: April 20, 2011
Experimental Start Date: April 22, 2011
Experimental End Date: April 26, 2011
Study Completion Date: May 4, 2011

Test Organism	ATCC #	Culture Medium	Incubation Parameters
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA	33592	Synthetic Broth	35-37°C, aerobic
<i>Clostridium difficile</i> - spore form	43598	CDC Anaerobic Blood Agar	35-37°C, anaerobic

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

Exposure Time: Automated cycle time determined by Sponsor
(14 minutes for Methicillin Resistant *Staphylococcus aureus* –MRSA test run and 41 minutes for *Clostridium difficile* test run)

Exposure Temperature: Room temperature (20.3-20.7°C)

Number of Carriers Tested: 2 per organism per location

Soil Load Description: No organic soil load required

Neutralizer: Lethen Broth + 0.07% Lecithin + 0.5% Tween 80

Agar Plate Medium: Tryptic Soy Agar with 5% Sheep Blood (BAP) [for MRSA]
CCFA-HT Agar [for *Clostridium difficile*]

EXPERIMENTAL DESIGN

Glass carriers (1" x 3") inoculated with a dry film of the test organism were placed into the testing room and exposed to the UV-C generating device for the Sponsor specified exposure time. Duplicate carriers per organism were placed around the testing area as indicated by the Sponsor. Briefly, two carriers per organism were placed near the wall opposite the device approximately 4.5 feet off the floor. Two carriers per organism were also placed on each bedrail of a hospital bed. For the set of carriers located on the bedrail closest to the device, the inoculated side was directed towards the device. For the set of carriers located on the furthest bedrail, the inoculated side was directed away from the device and towards the wall as directed by the Sponsor. Each test carrier was oriented so that the inoculated area of the carrier was perpendicular to the ground, parallel to the device and as vertical as possible. After exposure, the carriers were transferred to vessels containing subculture media and assayed for survivors. Appropriate culture purity, media sterility, carrier sterility, carrier quantitation, HCl resistance (for *Clostridium difficile*) and neutralization confirmation controls were performed.

Per Sponsor's direction, the study was not required to be conducted under US EPA 40 CFR Part 160 or US FDA 21 CFR Part 58.

STUDY RESULTS**TABLE 1: CONTROL RESULTS**

The following results from controls confirmed study validity:

Type of Control	Results	
	Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	<i>Clostridium difficile</i> - spore form (ATCC 43598)
Purity Control	Pure	Pure
Neutralizer Sterility Control	No Growth	
Carrier Sterility Control	No Growth	

TABLE 2: NEUTRALIZATION CONFIRMATION CONTROL RESULTS

Test Substance	Test Organism	Dilution Plated	Neutralization Confirmation (CFU/plate)		±1.0 Log ₁₀ Pass/Fail
			Numbers Control	Results	
ARTZ	Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	10 ⁻⁵	9,15	16,11	-0.07 (Pass)
	<i>Clostridium difficile</i> - spore form (ATCC 43598)		20,17	20,27	-0.10 (Pass)

CFU = Colony Forming Unit

TABLE 3: CARRIER QUANTITATION CONTROL RESULTS

Test Organism	Carrier #	Result	Average Log ₁₀	Geometric Mean
		CFU/Carrier (Log ₁₀)		
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	3.2 x 10 ⁶ (6.51)	6.56	3.63 x 10 ⁶
	2	4.0 x 10 ⁶ (6.60)		
<i>Clostridium difficile</i> - spore form (ATCC 43598)	1	3.2 x 10 ⁶ (6.51)	6.62	4.17 x 10 ⁶
	2	5.40 x 10 ⁶ (6.73)		

CFU = Colony Forming Unit

TABLE 4: EVALUATION OF TEST CARRIER DATA

Test Substance: ARTZ						
Carrier Location: Furthest bedrail (inoculum facing wall)						
Test Organism	Carrier #	Number of Survivors (CFU)				
		Dilution				
		Filtered 10 ⁰	10 ⁰	10 ⁻¹	10 ⁻²	10 ⁻³
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	0	0,0	0,0	0,0	0,0
	2	0	0,0	0,0	0,0	0,0
<i>Clostridium difficile</i> - spore form (ATCC 43598)	1	T	52,46	6,6	2,2	0,0
	2	T	T,T	T,T	29,36	2,2
Carrier Location: Nearest bedrail (inoculum facing unit)						
Test Organism	Carrier #	Number of Survivors (CFU)				
		Dilution				
		Filtered 10 ⁰	10 ⁰	10 ⁻¹	10 ⁻²	10 ⁻³
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	0	0,0	0,0	0,0	0,0
	2	0	0,0	0,0	0,0	0,0
<i>Clostridium difficile</i> - spore form (ATCC 43598)	1	0	0,0	0,0	0,0	0,0
	2	0	0,0	0,0	0,0	0,0
Carrier Location: Near Wall (~4.5 feet off ground)						
Test Organism	Carrier #	Number of Survivors (CFU)				
		Dilution				
		Filtered 10 ⁰	10 ⁰	10 ⁻¹	10 ⁻²	10 ⁻³
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	0	0,0	0,0	0,0	0,0
	2	0	0,0	0,0	0,0	0,0
<i>Clostridium difficile</i> - spore form (ATCC 43598)	1	0	0,0	0,0	0,0	0,0
	2	0	0,0	0,0	0,0	0,0

CFU = Colony Forming Unit

T = Too Numerous Too Count

A value of <1 was used in place of zero for calculation purposes only.

TABLE 5: CALCULATED VALUES

Test Substance: ARTZ					
Carrier Location: Furthest bedrail (inoculum facing wall)					
Test Organism	Carrier #	# Survivors/ Carrier (Log₁₀)	Average Log₁₀	Geometric Mean	Percent Reduction (Log₁₀ Reduction)
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	<1	<0.00	<1.00 x 10 ⁰	>99.9999% (>6.56)
	2	<1			
<i>Clostridium difficile</i> - spore form (ATCC 43598)	1	2.0 x 10 ⁴ (4.30)	5.21	1.62 x 10 ⁵	96.1% (1.41)
	2	1.3 x 10 ⁶ (6.11)			
Carrier Location: Nearest bedrail (inoculum facing unit)					
Test Organism	Carrier #	# Survivors/ Carrier (Log₁₀)	Average Log₁₀	Geometric Mean	Percent Reduction (Log₁₀ Reduction)
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	<1	<0.00	<1.00 x 10 ⁰	>99.9999% (>6.56)
	2	<1			
<i>Clostridium difficile</i> - spore form (ATCC 43598)	1	<1	<0.00	<1.00 x 10 ⁰	>99.9999% (>6.62)
	2	<1			
Carrier Location: Near Wall (~4.5 feet off ground)					
Test Organism	Carrier #	# Survivors/ Carrier (Log₁₀)	Average Log₁₀	Geometric Mean	Percent Reduction (Log₁₀ Reduction)
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	<1	<0.00	<1.00 x 10 ⁰	>99.9999% (>6.56)
	2	<1			
<i>Clostridium difficile</i> - spore form (ATCC 43598)	1	<1	<0.00	<1.00 x 10 ⁰	>99.9999% (>6.62)
	2	<1			

TABLE 6: VERIFICATION OF ANTIBIOTIC RESISTANCE

Organism (ATCC)	Zone of Inhibition (mm)	CLSI* Resistant Range (mm)
Methicillin Resistant <i>Staphylococcus aureus</i> – MRSA (ATCC 33592)	6	≤ 10
Quality Control Organism (ATCC)	Zone of Inhibition (mm)	CLSI* Acceptable Range (mm)
<i>Staphylococcus aureus</i> (ATCC 25923)	20	18 - 24

*CLSI = Clinical and Laboratory Standards Institute

TABLE 7: HCL RESISTANCE VERIFICATION

Test Organism	Exposure Time	Growth (+)/No Growth (-)	Pass/Fail
<i>Clostridium difficile</i> - spore form (ATCC 43598)	2 minutes	+,+	Pass
	5 minutes	+,+	
	10 minutes	+,+	
	20 minutes	+,+	

CONTROL RESULTS

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

ANALYSIS

The UV-C light generating device, ARTZ, demonstrated a >99.9999% (>6.56 log₁₀) reduction of Methicillin Resistant *Staphylococcus aureus* - MRSA on the test carriers at each carrier location following the Sponsor determined 14 minute cycle time when tested at room temperature (20.3°C).

The UV-C light generating device, ARTZ, demonstrated a >99.9999% (>6.62 log₁₀) reduction of *Clostridium difficile* – spore form on the bedrail test carriers facing the device and the test carriers near the wall following the Sponsor determined 41 minute cycle time when tested at room temperature (20.7°C).

The UV-C light generating device, ARTZ, demonstrated a 96.1% (1.41 log₁₀) reduction of *Clostridium difficile* – spore form on the bedrail test carriers facing the wall following the Sponsor determined 41 minute cycle time when tested at room temperature (20.7°C).

PROFESSIONAL PERSONNEL INVOLVED:

- | | |
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