

Study Report



Study Title

Antibacterial Activity and Efficacy Evaluation of UVC Cleaning System's UV Device

Test Method

Custom Device Study Based on: ASTM E1153
Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces

Study Identification Number

NG5622-II

Study Sponsor

UVC Cleaning Systems 7876 S Van Dyke Rd Marlette, MI 48453

Test Facility

Antimicrobial Test Laboratories 1304 W. Industrial Blvd Round Rock, TX 78681 (512) 310-8378





History of the Laboratory

Antimicrobial Test Laboratories was launched in 2006 to provide testing services to the antimicrobial industry. The company has grown considerably since then but its focus remains the same: Test antimicrobial agents, test them well, and test them fast! Antimicrobial Test Laboratories operates a 15,000+ square foot facility near Austin, Texas, where hundreds of studies are conducted annually by a staff of friendly, knowledgeable, and experienced microbiologists and virologists.

Laboratory Qualification Statement

Antimicrobial Test Laboratories was founded by microbiologist Dr. Benjamin Tanner. The laboratory ensures consistent, reproducible results by utilizing a well-trained and educated scientific staff who work from a comprehensive system of Standard Operating Procedures, official standard methods from ASTM, AOAC, and other organizations, and custom study protocols. The laboratory provides testing services to dozens of Fortune 500 companies and has been inspected for GLP compliance by the US government.

Scientist Qualifications

This study was designed, conducted, and reported by: Katelyn Hammond, B.S.

Katelyn graduated from the University of Texas with a Bachelors of Science in Microbiology.

Katelyn is well-versed with regard to a variety of microbiological test methods and procedures. As a Microbiologist at Antimicrobial Test Laboratories, she has taken part in hundreds of studies and mastered several test methods. Katelyn works with clients throughout the course of their projects to ensure that their technical needs are met. She is highly regarded in the laboratory for her keen troubleshooting skills and positive attitude.



If you have any questions about your study, please don't hesitate to contact Katelyn at:

Katelyn@AntimicrobialTestLabs.com or (512) 310-8378



<u>Test Device Information</u>



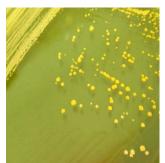
Test Device: M20

Setup and operated by Study Sponsor, 17-19NOV2014.



<u>Test Microorganism Information</u>

The test microorganism(s) selected for this test:



Staphylococcus aureus 6538

This bacterium is a Gram-positive, spherical-shaped, facultative anaerobe. *Staphylococcus* species are known to demonstrate resistance to antibiotics such as methicillin. *S. aureus* pathogenicity can range from commensal skin colonization to more severe diseases such as pneumonia and toxic shock syndrome (TSS). *S. aureus* is commonly used in several test methods as a model for gram positive bacteria. It can be difficult to disinfect but does demonstrate susceptibility to low level disinfectants.



Listeria monocytogenes

This bacteria is a Gram-positive, rod shaped, facultative anaerobe that is motile due to the presence of flagella. These bacteria are common cause of the foodbourne illness listeriosis, which can be fatal. Listeriosis can cause meningitis and sepsis and is particularly dangerous to pregnant women and unborn infants. *Listeria monocytogenes* is pervasive and can be found in soil, water, and certain livestock animals. They can resist both heat and freezing and can survive for several years.



Clostridium difficile 43598

This bacteria is a Gram-positive, rod shaped, endospore generating obligate anaerobe. *Clostridium* species are part of the normal human gut flora that produce spores which are highly resistant to chemical and environmental conditions. *C. diff* is commonly associated with hospital acquired infections and is know to cause antibiotic assisted colitis. Because of it's high resistance to antimicrobials, *C. difficile* is a benchmark bacteria for sporicidal and sterilant activity of chemicals.





Summary of the Procedure

- Overnight cultures were centrifuged at 1,000 RPM (as applicable) for 10 minutes, resuspended in sterile R/O water, and supplemented with 5% FBS.
- Stainless steel carriers (1"x3") were inoculated with 0.01 ml of the culture.
- Inoculum was spread over approximately 10 cm² of each carrier.
- Carriers were left to dry at room temperature for 10 minutes in Petri dishes with lids ajar.
- Visibly dry carriers/test microorganism were harvested in 20 ml D/E to determine the initial numbers control.
- Test carriers were treated at a specified distance and time period then harvested in 20 ml D/F
- Standard dilution and pour plating techniques were used for all enumerations.
- Calculations are based off of the averaged initial and final control numbers compared to CFU/carrier recovered from treated test carriers.

Study Timeline

Culture Inoculated	Carriers Inoculated	Carriers Treated	Carriers Harvested	Carriers Evaluated	Report Delivered
16NOV2014	17NOV2014	17NOV2014	17NOV2014	18NOV2014	
17NOV2014 18NOV2014	18NOV2014 19NOV2014	18NOV2014 19NOV2014	18NOV2014 19NOV2014	19NOV2014 20NOV2014	03DEC2014





Criteria for Scientific Defensibility of a Custom Device Study

For Antimicrobial Test Laboratories to consider a Device Study study to be scientifically defensible, the following criteria must be met:

- 1. The average number of viable bacteria recovered from the time zero samples must be approximately 1×10^5 cells/carrier or greater.
- 2. Positive/Growth controls must demonstrate growth of the appropriate test microorganism.
- 3. Negative/Purity controls must demonstrate no growth of test microorganism.

Passing Criteria

Because of the nature of the study, passing criteria may be determined by the Study Sponsor.

Testing Parameters used in this Study

Carrier (Size): Stainless Steel (1" x 3")

Replicates: See Data

Culture Dilution Media: Sterile Reverse Osmosis (R/O) Water

Culture Supplement: 5% FBS

Inoculum Target: 1.0 x 10⁷ CFU/Carrier

Inoculum Volume:

O.01 ml
Inoculum Surface Area:

Carrier Dry Time:

10 Minutes

Carrier Dry Temperature: Ambient (23±2°C)

Contact Time(s):

Contact Distance(s):

See Data

See Data

Contact Temperature: Ambient (23±2°C)

<u>Listeria</u> and <u>Staph</u> <u>Endospores</u>

Neutralizer (Vol.): D/E Broth (20 ml) D/E Broth (20 ml)
Enumeration Media, Method: TSA, pour plate CDA, pour plate

Enum. Media Supplement: N/A 0.1% Sodium Taurocholate

Enum. Plate Incubation Temp.: $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$ $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$ Enum. Plate Incubation Time: 24-48 hours $\geq 48 \text{ hours}$ Enum. Plate Incubation Conditions: Aerobic Anaerobic

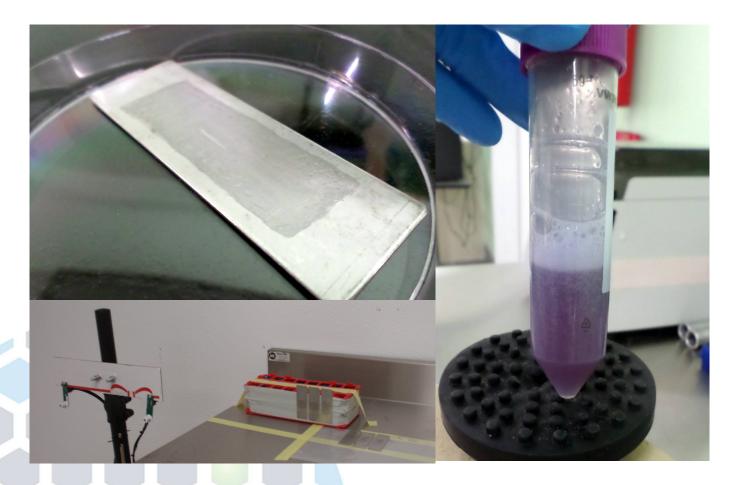
Page 7 of 15



Study Notes

Test Room Dimensions: 11' 3" x 18' 8" (8' ceiling)

Study Photographs



Top: Inoculated carrier drying at room temperature

Bottom: Test carriers at 5 meters and 5 meters, perpendicular prior to treatment. Right: Test carrier harvested and vortex mixed in 20 ml of D/E neutralizing broth.



Control Results

Neutralization Method: D/E (20 ml) Vortex Media Sterility: Sterile Growth Confirmation: Colony Morphology Antibiotic Resist. N/A

Calculations

Percent Reduction =
$$(\frac{B-A}{B}) \times 100$$

Where:

B = Average number of viable test microorganisms on the control carriers

A = Number of viable test microorganisms on the test carriers after the contact time

$$log_{10} Reduction = log(\frac{B}{A})$$

Where:

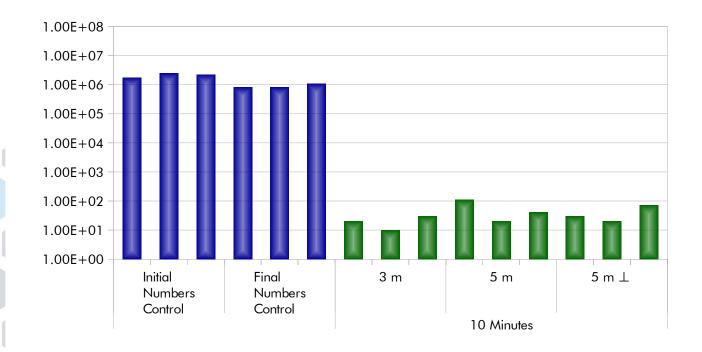
B = Average number of viable test microorganisms on the control carriers.

A = Number of viable test microorganisms on the test carriers after the contact time



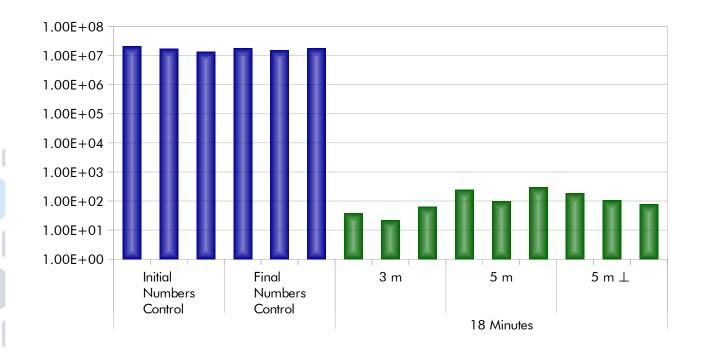


Test Microorganism	Device	Contact Time	Contact Distance	CFU/Carrier	Geometric Mean CFU/ Carrier	% Reduction vs Numbers Control	Log ₁₀ Reduction vs Numbers Control	
			nitial ers Control	2.42E+06				
		TAOTIO	ers Cornion	2.19E+06	1.36E+06	N	N/A	
		_	-· ,	8.20E+05	1.305+00	17,	A	
			Final ers Control	8.10E+05				
S. aureus		TAOTTIBE	ers Cormon	1.08E+06				
ATCC 6538				2.00E+01				
	M20		3 Meters	1.00E+01	1.82E+01	99.9987%	4.88	
(D 1)				3.00E+01				
(Run 1)				1.10E+02				
		10 Minutes	5 Meters	2.00E+01	4.45E+01	99.9967%	4.49	
				4.00E+01				
			5.44.	3.00E+01				
			5 Meters Perpendicular	2.00E+01	3.48E+01	99.9975%	4.59	
			rerpendicular	7.00E+01				



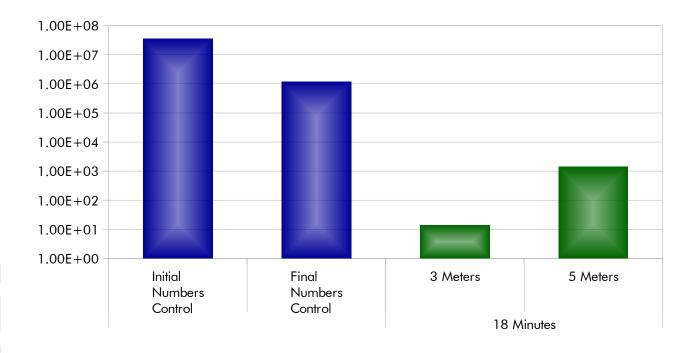


Test Microorganism	Device	Contact Time	Contact Distance	CFU/Carrier	Geometric Mean CFU/ Carrier	% Reduction vs Numbers Control	Log ₁₀ Reduction vs Numbers Control	
			. 101 . 1	2.07E+07				
			nitial ers Control	1.69E+07				
		1 (01115)	cra Cormon	1.32E+07	1.68E+07	N	1/A	
		_	,	1.76E+07	1.001+07	IN	5.65	
			Final ers Control	1.54E+07				
S. aureus		14011150		1.77E+07				
ATCC 6538				3.80E+01			5.45	
	M20		3 Meters	2.20E+01	3.75E+01	99.9998%	5.65	
(D O)				6.30E+01				
(Run 2)				2.46E+02				
		18 Minutes	5 Meters	9.80E+01	1.92E+02	99.9989%	4.94	
				2.95E+02				
			<i>5</i> 14 1	1.82E+02				
			5 Meters Perpendicular	1.05E+02	1.14E+02	99.9993%		
		rer	i ei perialcolai —	7.80E+01				



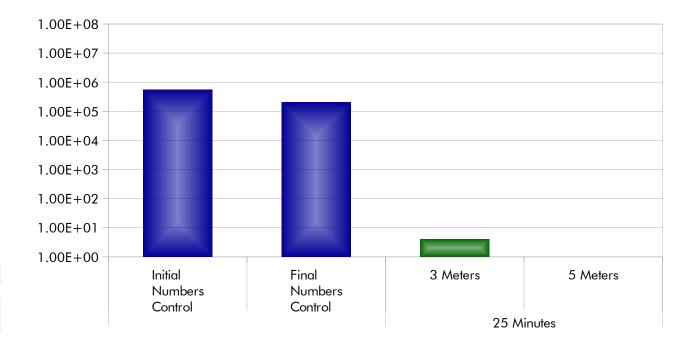


Test Microorganism	Device	Contact Time	Contact Distance	CFU/Carrier	Geometric Mean CFU/ Carrier	% Reduction vs Numbers Control	Log ₁₀ Reduction vs Numbers Control	
		Numbers Control		3.53E+07	6.43E+06	+06 N/A		
L. monocytogenes ATCC 15313	M20	Nonibe	ers Common	1.17E+06	0.431+00	IVA		
(Run 1)	MZO	18 Minutes	5 Meters	1.40E+01	1.40E+01	99.9998%	5.66	
		10 Minutes	5 Meters, Perpendicular	1.39E+03	1.39E+03	99.978%	3.66	





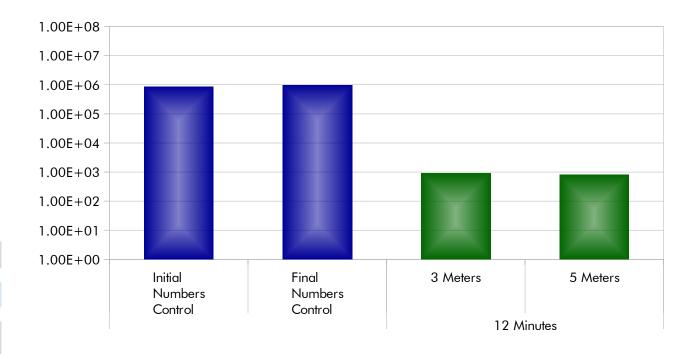
Test Microorganism	Device	Contact Time	Contact Distance	CFU/Carrier	Geometric Mean CFU/ Carrier	% Reduction vs Numbers Control	Log ₁₀ Reduction vs Numbers Control
L. monocytogenes		5.60E+05 Numbers Control 3.41E+05	N	N/A			
ATCC 15313				2.08E+05			
(Run 2)	MZO	05 Min. 4	5 Meters	4.00E+00	4.00E+00	99.9988%	4.93
,		25 Minutes	5 Meters, Perpendicular	<1.00E+00	<1.00E+00	>99.9997%	>5.53



Note: The limit of detection for this study is 1.00E+00 CFU/Carrier. Values below this limit are shown as 0 in the chart above.

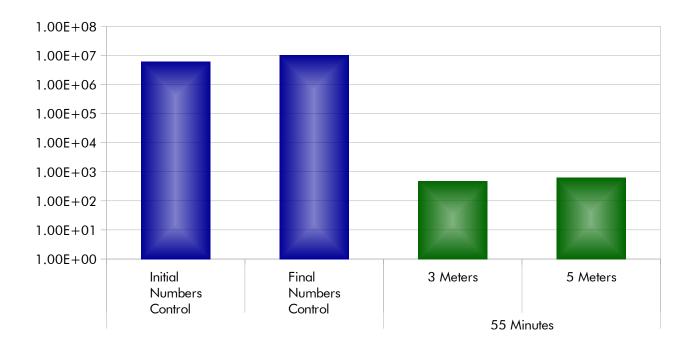


Test Microorganism	Device	Contact Time	Contact Distance	CFU/Carrier	Geometric Mean CFU/ Carrier	% Reduction vs Numbers Control	Log ₁₀ Reduction vs Numbers Control		
C. difficile		Numbers Cor	ntrol	8.58E+05	9.41E+04	N/A			
ATCC 43598				9.63E+05					
Endospores (Run 1)	M20	12 Minutes	3 Meters	9.15E+02	9.15E+02	99.03%	2.01		
	///20	12 Minutes	5 Meters	7.90E+02	7.90E+02	99.16%	2.08		





Test Microorganism	Device	Contact Time	Contact Distance	CFU/Carrier	Geometric Mean CFU/ Carrier	% Reduction vs Numbers Control	Log ₁₀ Reduction vs Numbers Control
C. difficile ATCC 43598		Numbers Cor	ntrol	6.05E+06 9.90E+06	7.74E+06	N/A	
Endospores (Run 2)	M20	55 Minutes	3 Meters	4.68E+02	4.68E+02	99.994%	4.22
	M20 :	33 Minutes	5 Meters	6.25E+02	6.25E+02	99.992%	4.09



The results of this study apply to the tested substances(s) only. Extrapolation of findings to related materials is the responsibility of the Sponsor.

Copyright © Antimicrobial Test Laboratories, 2014 Reproduction and ordinary use of this study report by the entity listed as "Sponsor" is permitted. Other copying and reproduction of all or part of this document by other entities is expressly prohibited, unless prior permission is granted in writing by Antimicrobial Test Laboratories.

Page 15 of 15