

ANTIMICROBIAL TEST LABORATORIES



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-I

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

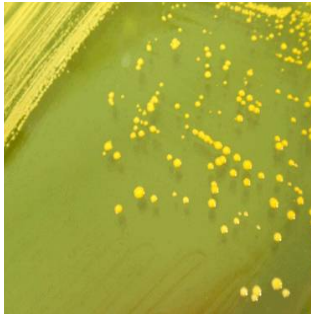
Test Device Information



Test Device: W15
Setup and operated by Study Sponsor, 17-19NOV2014.

Test Microorganism Information

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 foodborne 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 known to cause antibiotic assisted colitis. Because of its 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, re-suspended 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/E.
- 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



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.

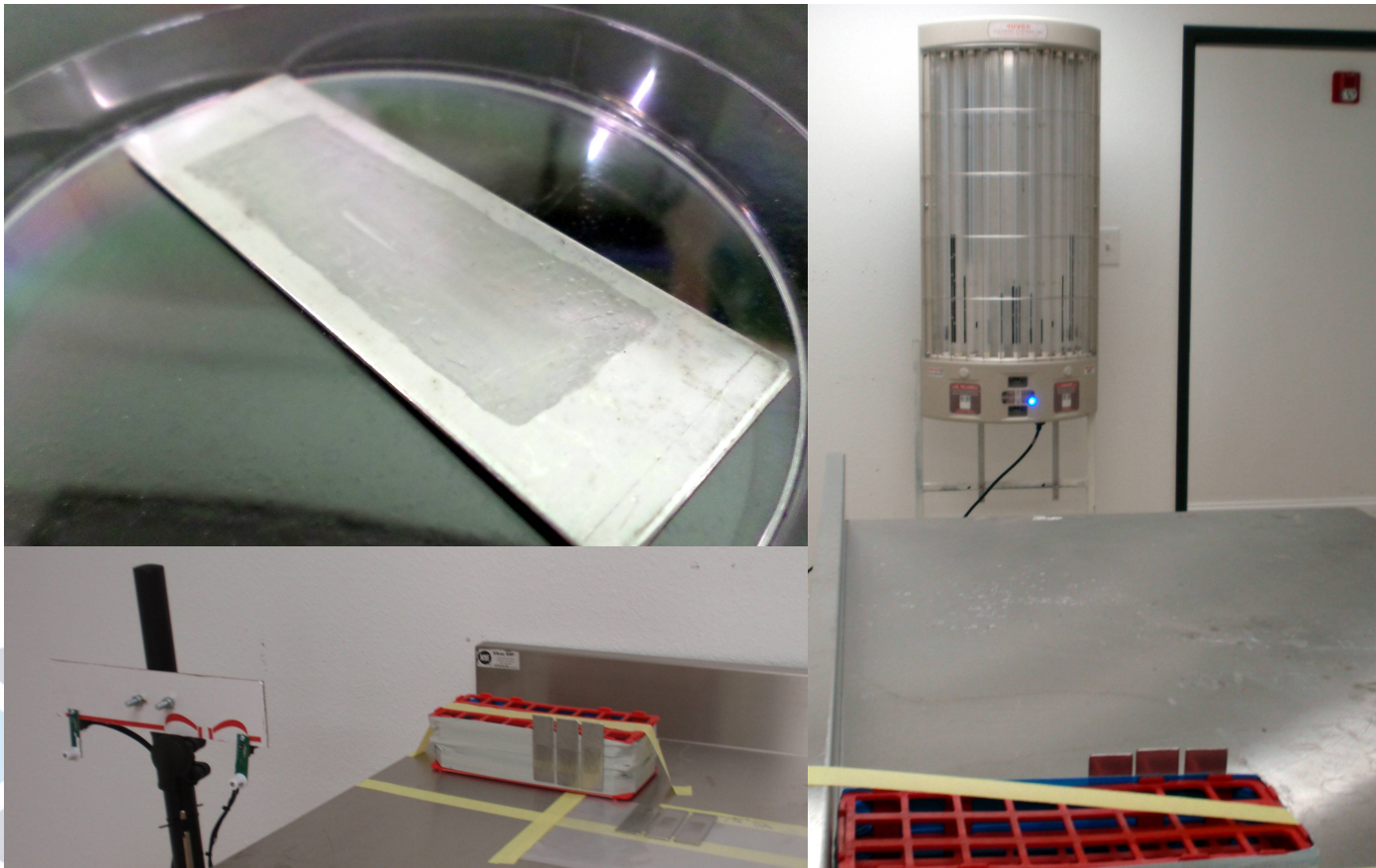
Testing Parameters used in this Study

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:	1.0×10^7 CFU/Carrier	
Inoculum Volume:	0.01 ml	
Inoculum Surface Area:	10 cm ²	
Carrier Dry Time:	10 Minutes	
Carrier Dry Temperature:	Ambient (23±2°C)	
Contact Time(s):	See Data	
Contact Distance(s):	See Data	
Contact Temperature:	Ambient (23±2°C)	
	<i>Listeria and Staph</i>	Endospores
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°C ± 1°C	36°C ± 1°C
Enum. Plate Incubation Time:	24-48 hours	≥48 hours
Enum. Plate Incubation Conditions:	Aerobic	Anaerobic

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 carriers at 3 meters facing UV device.

Control Results

Neutralization Method: D/E (20 ml) Vortex
Growth Confirmation: Colony Morphology

Media Sterility: Sterile
Antibiotic Resist. N/A

Calculations

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

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

$$\text{Log}_{10} \text{Reduction} = \text{Log} \left(\frac{B}{A} \right)$$

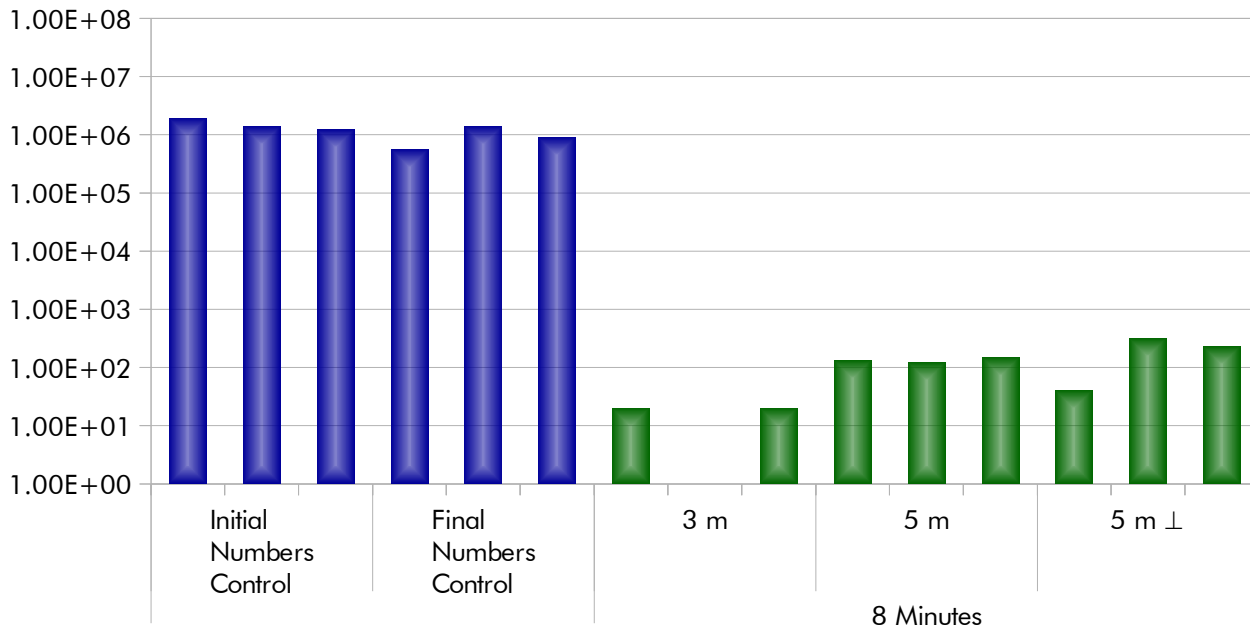
Where:

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

Results

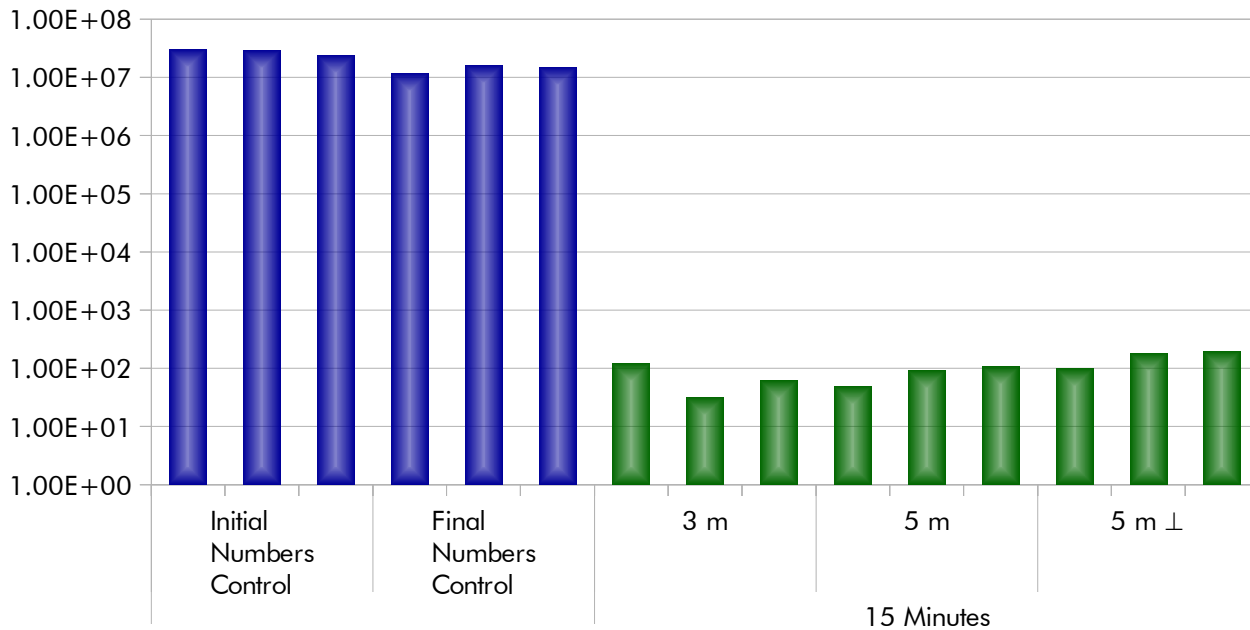
Test Microorganism	Device	Contact Time	Contact Distance	CFU/Carrier	Geometric Mean CFU/Carrier	% Reduction vs Numbers Control	Log ₁₀ Reduction vs Numbers Control
<i>S. aureus</i> ATCC 6538 (Run 1)	W15	Initial Numbers Control		1.90E+06	1.14E+06	N/A	N/A
				1.36E+06			
				1.23E+06			
				5.60E+05			
				1.35E+06			
				9.00E+05			
		8 Minutes	3 Meters	2.00E+01	<1.59E+01	>99.9986%	>4.86
				<1.00E+01			
				2.00E+01			
			5 Meters	1.30E+02	1.33E+02	99.9883%	3.93
				1.20E+02			
				1.50E+02			
			5 Meters Perpendicular	4.00E+01	1.42E+02	99.9875%	3.90
				3.10E+02			
				2.30E+02			



Note: The limit of detection for this study is 1.00E+01 CFU/Carrier. Values below this limit are shown as 0 in the chart above.

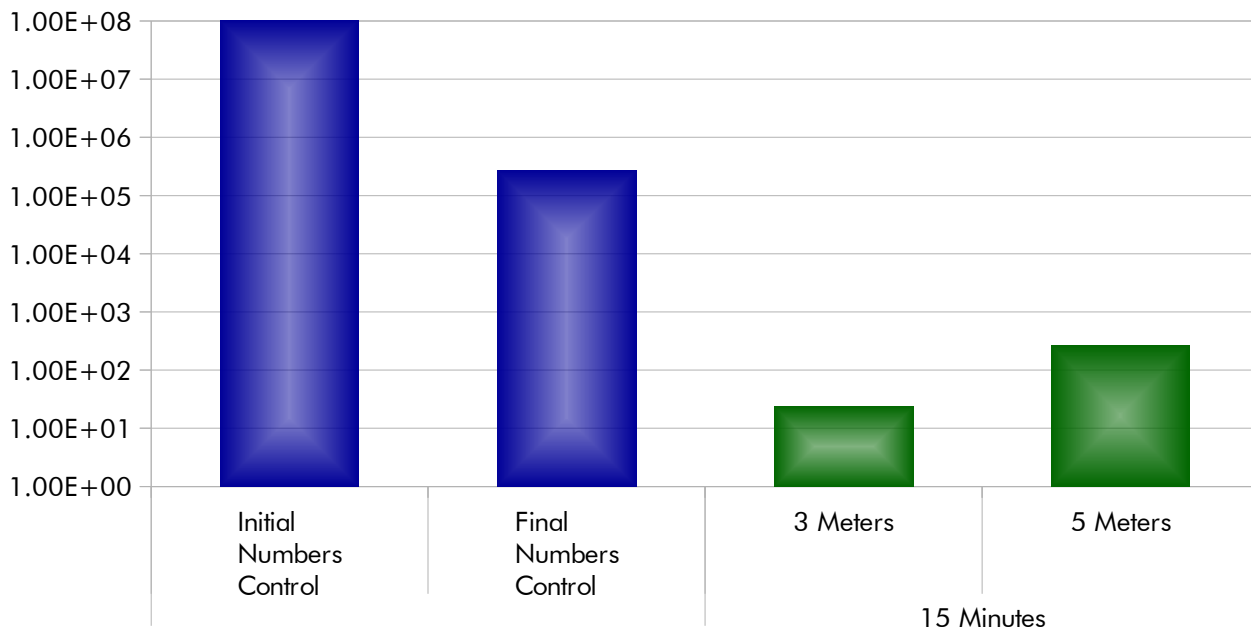
Results

Test Microorganism	Device	Contact Time	Contact Distance	CFU/Carrier	Geometric Mean CFU/Carrier	% Reduction vs Numbers Control	Log ₁₀ Reduction vs Numbers Control	
<i>S. aureus</i> ATCC 6538 (Run 2)	W15	Initial Numbers Control		2.98E+07	1.96E+07	N/A	N/A	
				2.85E+07				
				2.35E+07				
				1.18E+07				
				1.60E+07				
				1.49E+07				
		Final Numbers Control		3 Meters	1.20E+02	6.13E+01	99.9997%	5.50
					3.10E+01			
					6.20E+01			
				5 Meters	4.90E+01	7.79E+01	99.9996%	5.40
					9.20E+01			
					1.05E+02			
				5 Meters Perpendicular	9.90E+01	1.51E+02	99.9992%	5.11
					1.79E+02			
					1.95E+02			



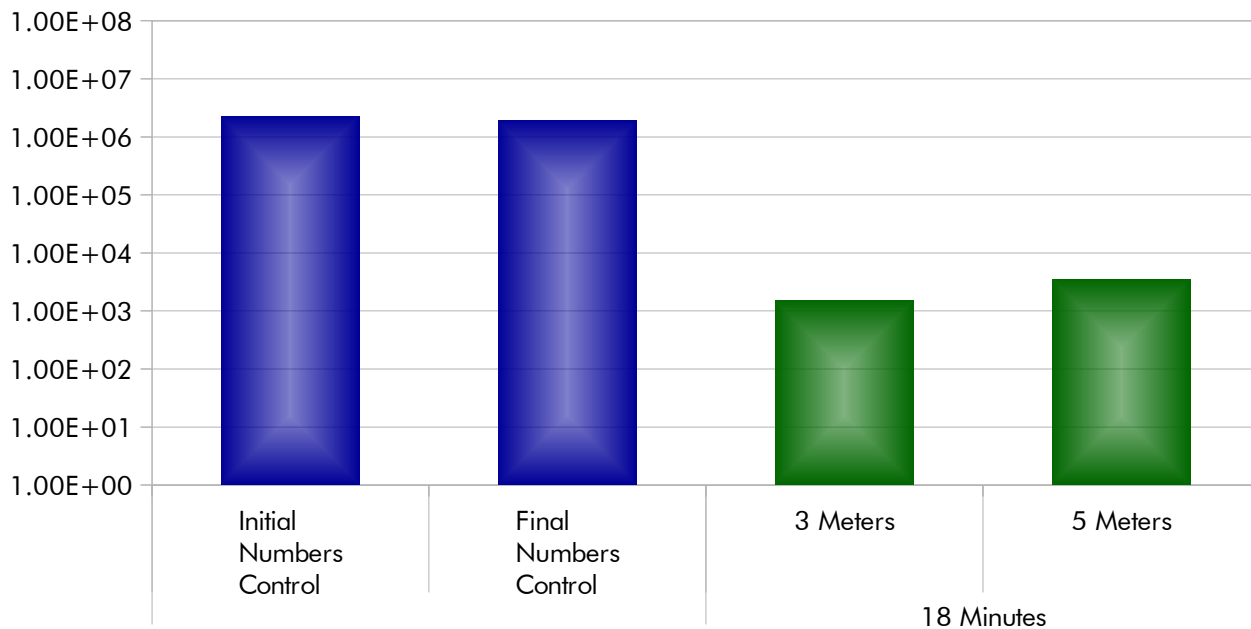
Results

Test Microorganism	Device	Contact Time	Contact Distance	CFU/Carrier	Geometric Mean CFU/Carrier	% Reduction vs Numbers Control	Log ₁₀ Reduction vs Numbers Control
<i>L. monocytogenes</i> ATCC 15313 (Run 1)	W15	Numbers Control		9.90E+07	5.17E+06	N/A	
				2.70E+05			
		15 Minutes	5 Meters	2.40E+01	2.40E+01	99.9995%	5.33
			5 Meters, Perpendicular	2.60E+02	2.60E+02	99.995%	4.30



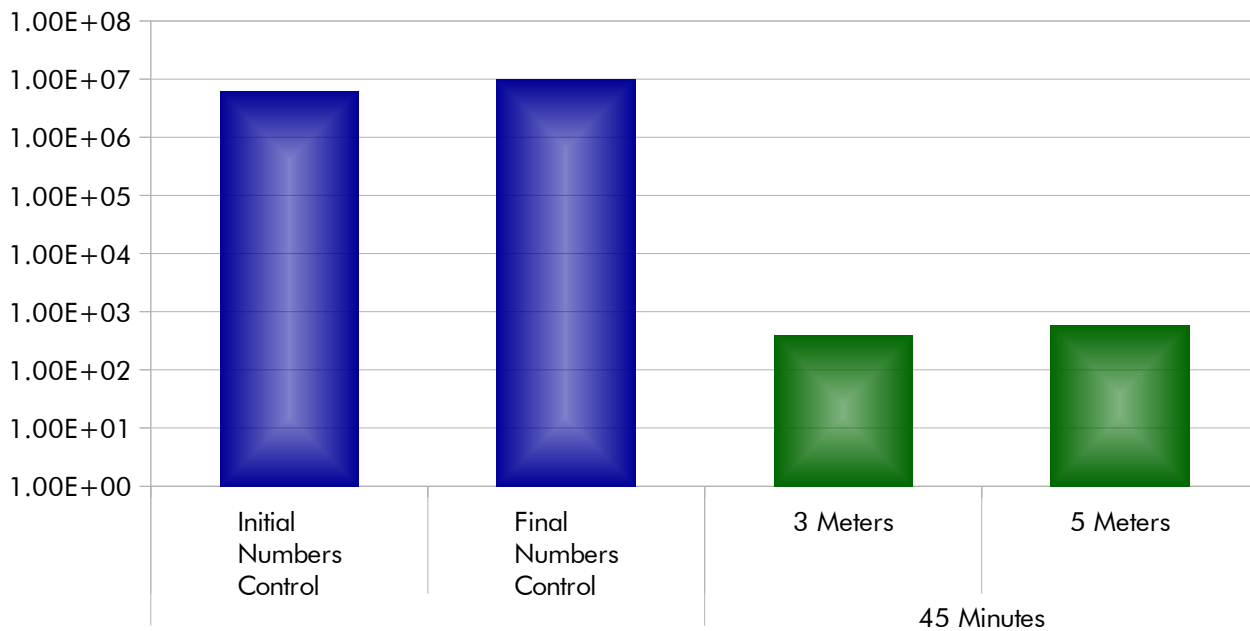
Results

Test Microorganism	Device	Contact Time	Contact Distance	CFU/Carrier	Geometric Mean CFU/Carrier	% Reduction vs Numbers Control	Log ₁₀ Reduction vs Numbers Control
<i>C. difficile</i> ATCC 43598 Endospores (Run 1)	Numbers Control			2.19E+06	2.05E+06	N/A	
				1.91E+06			
	W15	18 Minutes	3 Meters	1.48E+03	1.48E+03	99.928%	3.14
			5 Meters	3.47E+03	3.47E+03	99.83%	2.77



Results

Test Microorganism	Device	Contact Time	Contact Distance	CFU/Carrier	Geometric Mean CFU/Carrier	% Reduction vs Numbers Control	Log ₁₀ Reduction vs Numbers Control
<i>C. difficile</i> ATCC 43598 Endospores (Run 2)	Numbers Control			1.01E+07	8.76E+06	N/A	
	Numbers Control			7.60E+06			
	W15	45 Minutes	3 Meters	3.85E+02	3.85E+02	99.996%	4.36
			5 Meters	5.77E+02	5.77E+02	99.993%	4.18



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

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