ANTIMICROBIAL TEST LABORATORIES

Study Report

www.AntimicrobialTestLabs.com - Info@AntimicrobialTestLabs.com - (512) 310-8378

Study Title

Antibacterial Activity and Efficacy of Spectra254 Device

Test Method

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

Study Identification Number

NG5138

Study Sponsor

George Jay Lichtblau

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

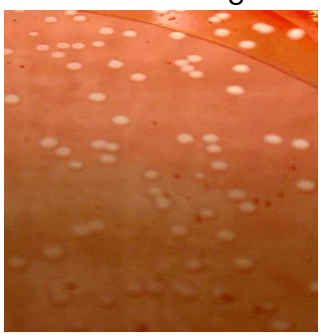
Test Device Information

The test device was received on 01 MAY 2014 and the following pictures were taken:

Test Device arrived in shipping crate. New UV bulbs were sent to replace damaged bulbs. UVC dosage labels, and device remote were also included with device.

Test Microorganism Information

The test microorganism(s) selected for this test:



***Clostridium difficile* 43598 (Endospores)**

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.

***Staphylococcus aureus* 33592 (MRSA)**

This bacteria is a Gram-positive, cocci shaped, aerobe which is resistant to the penicillin-derivative antibiotic methicillin. MRSA can cause troublesome infections, and their rapid reproduction and resistance to antibiotics makes them more difficult to treat. MRSA bacteria are resistant to drying and can therefore survive on surfaces and fabrics for an extended period of time and therefore makes this bacteria an excellent representative for antimicrobial efficacy testing on surfaces.

Summary of the Procedure

- Test microorganisms are diluted to the target concentration to create the test inoculum.
- Test inoculum is spread over approximately 1" x 1" of a glass slide.
- Inoculated slides (test carriers) are dried at 36±1°C until visibly dry.
- Test Carriers are treated with UV device according to Study Sponsor's instruction.
- After carrier treatment, microbial concentrations are determined, and reductions of microorganisms are calculated relative to the Initial Numbers Control Value.
- Additionally, three untreated test carriers are enumerated within 2 hours of drying to determine the Initial Numbers Control Value.

Study Timeline

MRSA	19MAY2014	20MAY2014	20MAY2014	20MAY2014	22MAY2014	23MAY2014
Spores	17MAR2014					

MRSA	01JUN2014	02JUN2014	02JUN2014	02JUN2014	04JUN2014	11JUN2014
Spores	03FEB2014					

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 x 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.

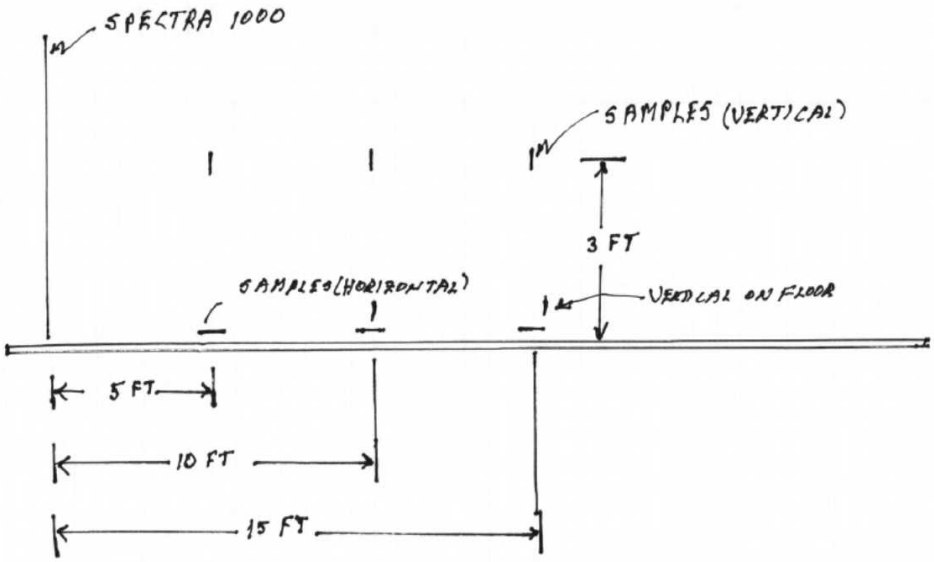
Testing Parameters used in this Study

Test Carrier Type	Glass Slides
Test Carrier Size	1" x 3"
Contact Time	5 Minutes*
Contact Temperature	Ambient
Contact Distance(s)	5, 10, and 15 Feet
Carrier Height(s)	Floor (0 Feet) and 3 Feet
Carrier Orientation(s)	Facing Device, Facing Ceiling

	Bacteria:	Endospores:
Culture Growth Media	TSB	N/A
Culture Growth Time	18-24 hours	N/A
Culture Dilution Media	PBS	Sterile RO Water
Culture Supplement	None	5% FBS
Inoculum Target Concentration	10^6 CFU/Carrier	
Inoculum Volume	0.010 ml	
Neutralizer (Volume)	Dey/Engley Broth (20 ml)	
Enumeration Media	TSA	CDA
Plate Incubation Temperature	36 ± 1°C	36 ± 1°C
Plate Incubation Conditions	Aerobic	Anaerobic
Plate Incubation Time	24-48 hours	>48 hours

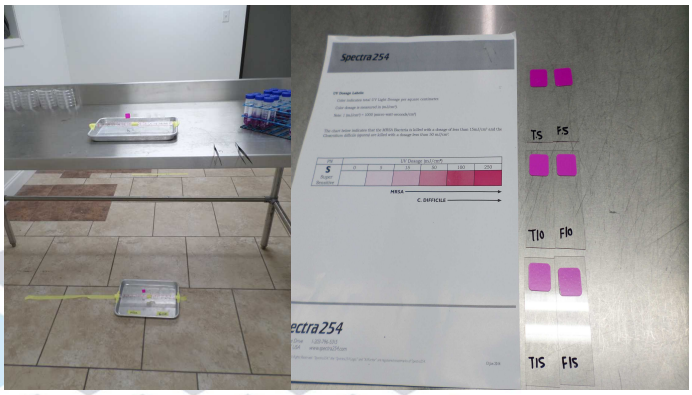
*Total device run time approximately 6 minutes and 6 seconds.

Study Setup



Left: Device setup showing contact distances tested in this study.

Study Photographs



Left: Test carriers are held in place on tray for treatment. Photo shows carriers facing device at floor height and 3 feet. Carriers 5 feet from test device.

Right: UVC Dosage labels. 'T' represents a height of 3 feet. 'F' represents floor height. Number represents distance from device.

Study Notes

Distance between device and test carriers measured from front edge of device. To start each cycle, the 5 minute button on the device remote was pressed. The device was terminated manually at 6 minutes for the first round of testing. For the second round of testing (carriers facing ceiling), the device was run until it automatically shut off after pressing the 5 minute button. Treatment time included a one minute "warm up" and a five minute "treatment" period.

Control Results

Neutralization Method: N/A
Media Sterility: Sterile
Growth Confirmation: Morphology on Appropriate Growth Media

Calculations

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

Where:
B = Number of viable test microorganisms on the control carriers immediately after inoculation
A = Number of viable test microorganisms on the test carriers after the contact time

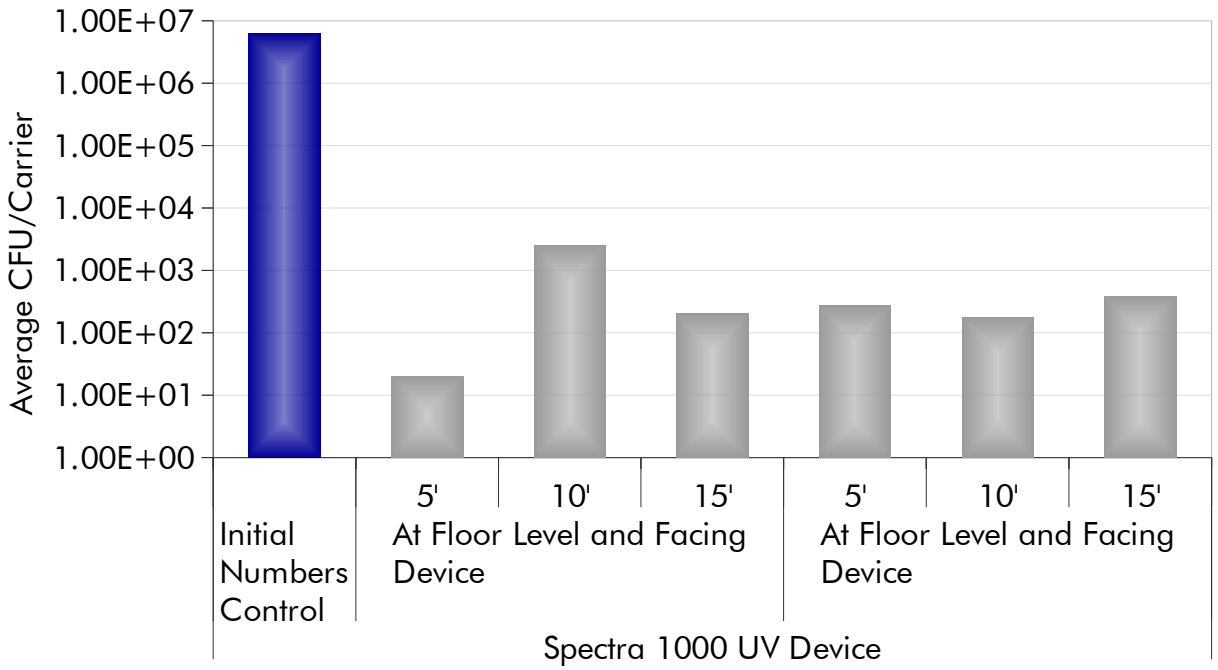
$$\text{Log}_{10}\text{Reduction} = \text{Log}\left(\frac{B}{A}\right)$$

Where:
B = Number of viable test microorganisms on the control carriers immediately after inoculation
A = Number of viable test microorganisms on the test carriers after the contact time

Results

Microorganism	Carrier Orientation	Carrier Distance	Replicate CFU/Carrier	Average CFU/Carrier	Percent Reduction vs. Control	Log_{10} Reduction vs. Control
S. aureus (MRSA) 33592	At Floor Level and Facing Device	5	1.00E+01	2.00E+01	99.9997%	5.48
			4.00E+01			
			1.00E+01			
		10	6.70E+03	2.52E+03	99.9587%	3.38
			3.10E+02			
			5.40E+02			
		15	1.30E+02	2.00E+02	99.9967%	4.48
			3.10E+02			
			1.60E+02			
	Raised 3 Feet And Facing Device	5	3.30E+02	2.77E+02	99.9955%	4.34
			2.80E+02			
			2.20E+02			
		10	2.40E+02	1.77E+02	99.9971%	4.54
			1.60E+02			
			1.30E+02			
		15	7.00E+01	3.87E+02	99.9937%	4.20
			9.30E+02			
			1.60E+02			

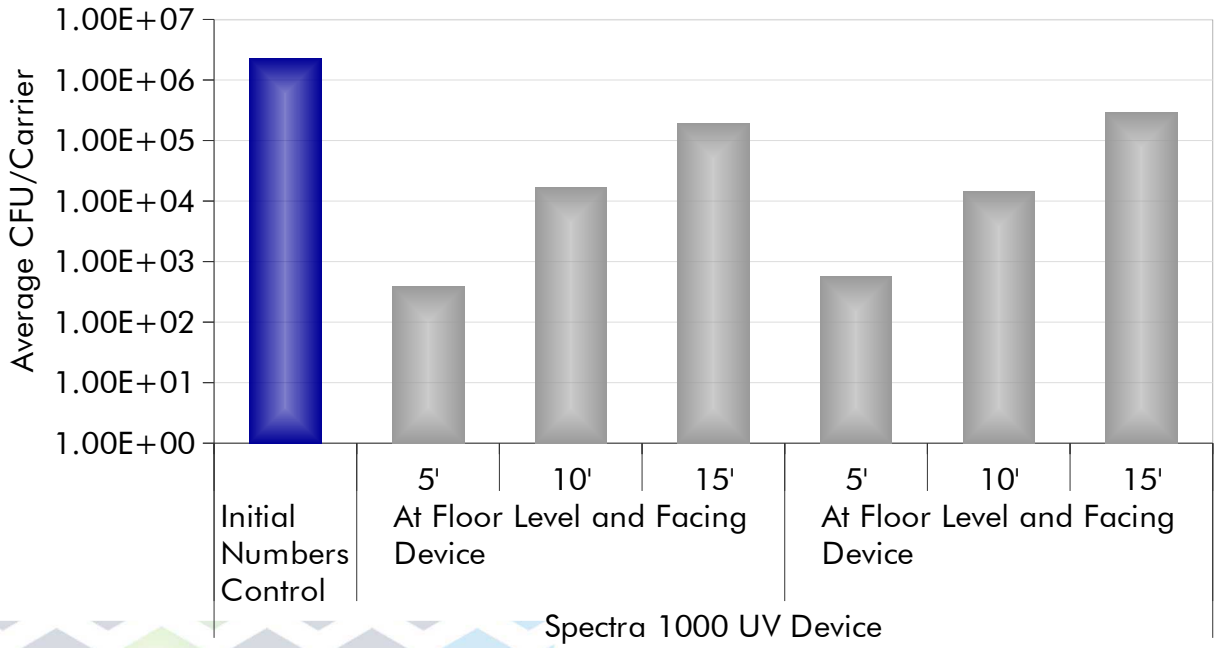
Note: Calculations based off an initial numbers control value of 6.10E+06 CFU/carrier.



Results

Microorganism	Carrier Orientation	Carrier Distance	Replicate CFU/Carrier	Average CFU/Carrier	Percent Reduction vs. Control	Log_{10} Reduction vs. Control
C. difficile (Endospores) 43598	At Floor Level and Facing Device	5	7.20E+02	3.83E+02	99.9831%	3.77
			2.40E+02			
			1.90E+02			
		10	3.50E+04	1.66E+04	99.2676%	2.14
			2.80E+03			
			1.20E+04			
		15	2.43E+05	1.92E+05	91.5441%	1.07
			1.89E+05			
			1.43E+05			
	Raised 3 Feet And Facing Device	5	1.20E+02	5.63E+02	99.9751%	3.60
			1.28E+03			
			2.90E+02			
		10	1.30E+04	1.44E+04	99.3647%	2.20
			1.50E+04			
			1.52E+04			
		15	3.04E+05	2.92E+05	87.1029%	0.89
			3.13E+05			
			2.60E+05			

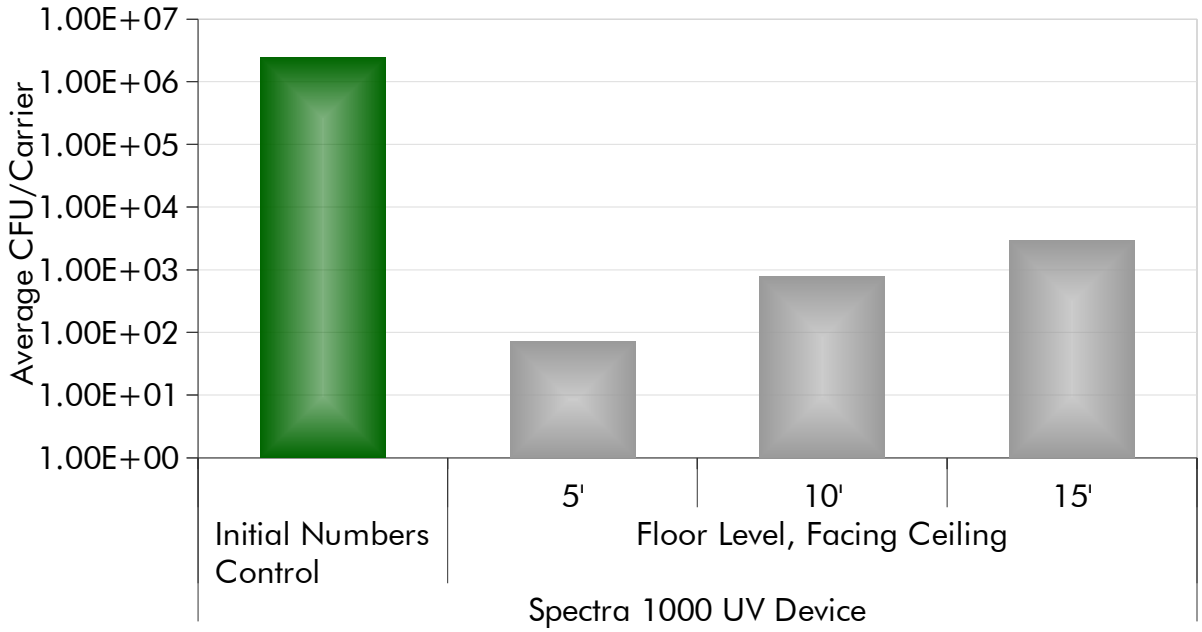
Note: Calculations based off an initial numbers control value of 2.27E+06 CFU/carrier.



Results

Microorganism	Carrier Orientation	Carrier Distance	Replicate CFU/Carrier	Average CFU/Carrier	Percent Reduction vs. Control	Log_{10} Reduction vs. Control
S. aureus (MRSA) 33592	Floor Level Facing Ceiling	5	<1.00E+01	<7.00E+01	>99.997%	>4.54
			1.00E+01			
			1.90E+02			
		10	1.22E+03	7.70E+02	99.982%	3.74
			8.00E+01			
			1.01E+03			
		15	6.90E+03	2.90E+03	99.932%	3.17
			4.40E+02			
			1.37E+03			

Note: Calculations based off an initial numbers control value of 2.41E+06 CFU/carrier.

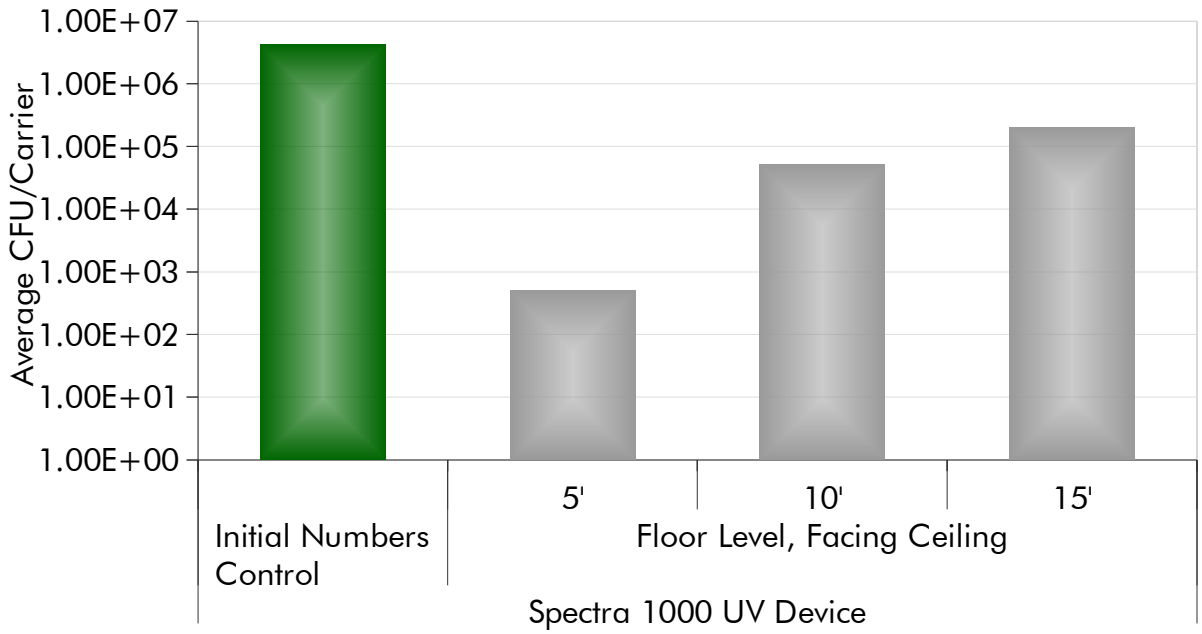


Note: The limit of detection for this study is 1.00E+01 CFU/Carrier.

Results

Microorganism	Carrier Orientation	Carrier Distance	Replicate CFU/Carrier	Average CFU/Carrier	Percent Reduction vs. Control	Log_{10} Reduction vs. Control
C. difficile (Endospores) 43598	Floor Level Facing Ceiling	5	1.00E+03	5.00E+02	99.988%	3.93
			4.00E+02			
			1.00E+02			
		10	6.70E+04	5.07E+04	98.814%	1.93
			3.10E+04			
			5.40E+04			
		15	1.30E+05	2.00E+05	95.320%	1.33
			3.10E+05			
			1.60E+05			

Note: Calculations based off an initial numbers control value of 4.27E+06 CFU/carrier.



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