# ANTIMICR BIAL TEST LABORATORIES

## Study Report



## 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 NG6152

## Study Sponsor

George Jay Lichtblau

## Test Facility

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

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## 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: Elizabeth Richard, B.S.

Elizabeth graduated from Indiana University of Pennsylvania with Bachelor of Science in Biology.

Elizabeth is an organized and detail oriented scientist with a positive work ethic. Formerly a chemist, she brings a unique perspective to the work she does as an associate microbiologist. Elizabeth's analytical and creative approach to microbiology makes her a valuable asset to the company and clients alike.

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

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

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## **Test Device Information**

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





Test Device arrived in shipping crate. UV bulbs were damaged and inoperable. New bulbs were sent and used for testing. UVC Dosage labels, Device Remote, and Caution signs were also included. Dosage labels were not used for this Study.

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## Test Microorganism Information

The test microorganism(s) selected for this test:



#### 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.

## Study Setup



Treatment = 5 minutes (+1 minute warm-up)

\*Note: Photo depicts the setup requested by the Study Sponsor







## Summary of the Procedure

- Test microorganisms are prepared in liquid culture medium for bacteria or on agar for fungi.
- The suspension of test microorganism is standardized by dilution in a buffered saline solution.
- A standardized spore suspension is diluted in a buffered saline solution.
- Control and test carriers are inoculated and are incubated at 36°C until visibly dry.
- Test Carriers are treated for the Study Sponsor specified time and contact distance.
- Microbial concentrations are determined at "time zero" by enumeration of control carriers immediately after inoculation.
- An additional control is implemented to verify microorganism viability at the close of the study.
- After carrier treatment, microbial concentrations are determined, and reductions of microorganisms are calculated relative to control materials are calculated.

## 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  $1 \times 10^5$  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

Carriers (Size):	Glass Carriers (1" x 3")	Locations: 3 (5 Feet,	10 Feet, 15 Feet)							
Replicates:	3 Test Carriers/Location, Controls in triplicate									
Growth Media:	Tryptic Soy Broth	Inoculum concentration:	5.90 x 10 <sup>6</sup> CFU/Carrier							
Culture Growth Time:	24 Hours	Inoculum Volume:	0.020 ml							
Culture Dilution Medi	a: Reverse Osmosis Water	Contact Distance(s):	5 Feet, 10 Feet, 15 Feet							
Culture Supplement:	5% Fetal Bovine Serum	Contact Time:	5 Minutes*							
Neutralizer (Vol.):	D/E Broth (2 <mark>0 ml</mark> )	Contact Light:	Office lighting							
Enumeration Media:	Tryptic Soy A <mark>gar</mark>	Contact Temperature:	Ambient							

\*The 5 minute button on remote pressed to allow device to run for  $\sim$ 6 minutes (1 minute warm up + 5 minute cycle) and shut off automatically.

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## Study Photos:



<u>\*Note:</u> Photo depicts the setup from five feet. Not in view directly behind is the ten feet setup and to the left is the fifteen feet setup. Both of the latter are similar to the former.





## **Control Results**

Neutralization Method: N/A Media Sterility: Sterile Growth Confirmation: Colony Morphology on Appropriate Growth Media, Viability Controls

## **Calculations**

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

$$Log_{10}Reduction = Log(\frac{B}{A})$$

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



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## Results of the Study:

Microorganism	Device	Treatment Time	Contact Distance	Replicate	CFU/Carrier	Average CFU/Carrier	Percent Reduction vs. Numbers Control	Log Reduction vs. Numbers Control
Listeria monocytogenes ATCC 15313	Spectra 1000A	Numbers Control		1	6.70E+06	5.90E+06	N/A	
				2	6.50E+06			
				3	4.50E+06			
		5 Minutes*	5 Feet	1	1.32E+02	1.57E+02	99.997%	4.57
				2	2.55E+02			
				3	1.15E+02			
			10 Feet	1	2.36E+02	4.35E+02	99.993%	4.13
				2	3.36E+02			
				3	1.04E+03			
			15 Feet	1	5.90E+02	6.76E+02	99.989%	3.94
				2	1.38E+03			
				3	3.80E+02			

\*The 5 minute button on remote pressed to allow device to run for  $\sim$ 6 minutes (1 minute warm up + 5 minute cycle) and shut off automatically.



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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