MICROCHEM LABORATORY

STUDY REPORT

Study Title

Antibacterial Activity and Efficacy of 3B Medical, Inc. Device: Lumin Wand

Test Method

Custom Device Study Based on: Modified ASTM E1153

Study Identification Number

NG15884

Study Sponsor

Alex Lucio
3B Medical, Inc.
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Test Facility

Microchem Laboratory
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Round Rock, TX 78681
(512) 310-8378
Report Author: Patricia Castro, B.S.

Purpose of the Study

The purpose of this study was to determine the antimicrobial properties of the submitted test device: Lumin Wand.

Brief History of the Performing Laboratory

Microchem Laboratory is located in the greater Austin, Texas area. It is owned and operated by microbiologist Dr. Benjamin Tanner. The core of the company was founded by Dr. Tanner as Antimicrobial Test Laboratories in 2006. Antimicrobial Test Laboratories was later combined with a niche cosmetic testing lab and Microchem Laboratory, founded in 1988 by Dr. Norman Miner. The combined labs have operated under one roof as Microchem Laboratory since 2016. Microchem Laboratory is ISO 17025 accredited and offers testing in compliance with current Good Laboratory Practice (GLP) regulations as stipulated by EPA and FDA. Clients are always welcome to tour the lab, observe studies, and audit the lab's quality systems.

Study Timeline

Devices Received	Cultures Initiated	Carriers Inoculated	Carriers Treated	Enumeration Plates Evaluated	Report Delivered
02 JUL 2020	29 JUL 2020	30 JUL 2020	30 JUL 2020	03 AUG 2020	06 AUG 2020

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Test Device Information

Name of Test Device: Lumin Wand
Manufacturer: 3B Medical, Inc.
Mode of Active: UV Light (Germicidal)

A description of how to operate the device was provided by the Study Sponsor prior to test initiation.

Figure 1. Lumin Wand

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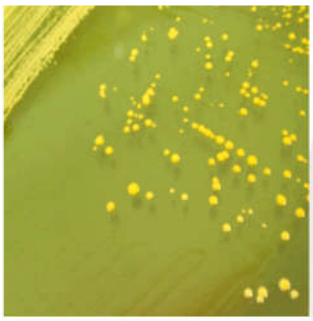
Test Microorganism Information

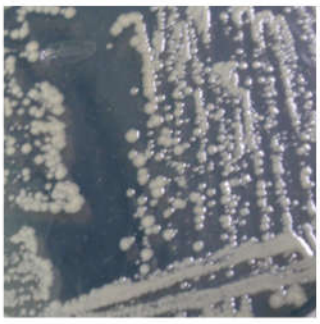
The test microorganism(s) selected for this test:

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.



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.

Salmonella enterica
This bacteria is Gram-negative, rod-shaped, facultative anaerobe. Like the closely related *Escherichia* genus, *Salmonella* are common to all parts of the world and share habitats in the digestive systems of cold and warm-blooded animals. *S. enterica* is one of the most common bacteria associated with zoonotic and foodbourne illness. Because of it's regular occurrence and pathogenicity, *S. enterica* is a common bacteria for measuring disinfectant efficacy.



Escherichia coli
This bacteria is a Gram-negative, rod shaped, facultative anaerobe commonly found in the gastrointestinal tract of mammals. Although most serotypes of this microorganism are harmless there are pathogenic groups of *E. coli* such as enterohemorrhagic (EHEC), verocytotoxin producing (VTEC) and Shiga-like toxin producing (STEC) that can cause a multitude of illnesses. *E. coli* is relatively susceptible to disinfection when dried on a surface, yet it can be a challenging microorganism to mitigate in solution.

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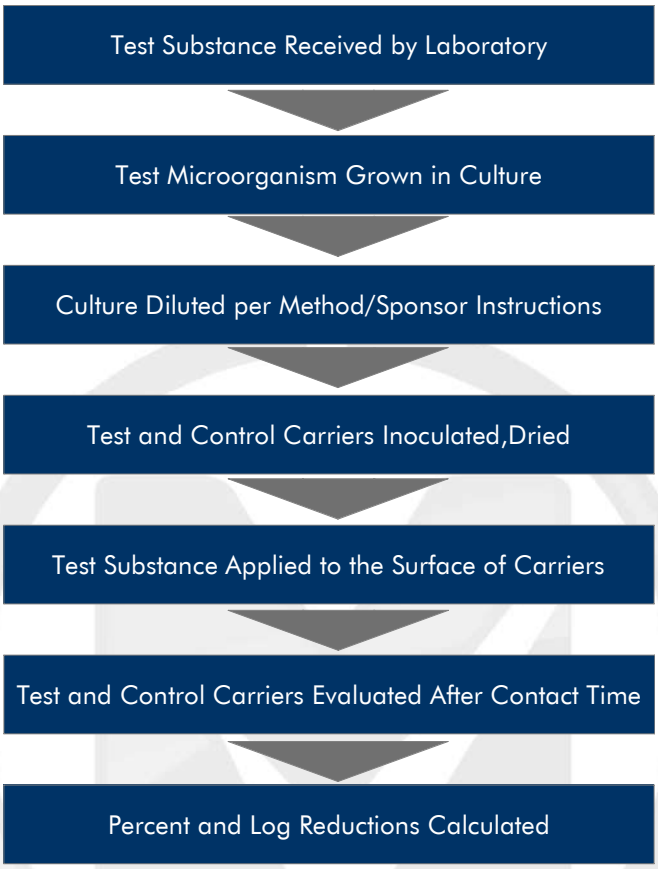
Diagram of the Procedure



Summary of the Procedure

- The test microorganism is prepared, usually by growth in liquid culture medium or on an appropriate agar plate.
- The test culture may be supplemented with an artificial soil load, such as horse or fetal bovine serum, for one-step cleaner/sanitizer claims.
- Sterilized carriers are inoculated with a volume of the test culture. Inoculated slides are dried. Only completely dried carriers are used in the test.
- Test carriers are treated with the test device and incubated for the predetermined contact time.
- Control carriers are harvested at appropriate intervals to accurately represent any reduction during the contact time.
- At the conclusion of the contact time, test and control carriers are chemically neutralized.
- Dilutions of the neutralized test substance are evaluated using appropriate growth media to determine the surviving microorganisms at the respective contact time.
- The effect of the test substance is compared to the effect of the control substance in order to determine microbial reductions.

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Criteria for Scientific Defensibility of a Custom Device Study

For Microchem Laboratory to consider a Device Study study to be scientifically defensible, the following criteria must be met:

1. The initial and final concentration of microorganisms must be significantly high enough to observe the passing criteria/log reduction.
2. The media used for testing must be sterile.
3. The target microorganism must be pure colony morphology.

Passing Criteria

Due to the modified nature of the study, passing criteria may be determined by the Study Sponsor prior to test initiation. If no passing criteria is established, a conclusion about the data is not provided by Microchem Laboratory, but the Study Sponsor may determine significance based on statistical interpretation or other means.

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Testing Parameters

L. monocytogenes ATCC 15313, *S. enterica* ATCC 10708, and *E. coli* ATCC 11775

Culture Growth Media:	Tryptic Soy Broth	**Culture Growth Time:**	18-24 hours
Culture Dilution Media	See Study Notes	**Culture Supplement**	See Study Notes
Carrier Type	1″ x 3″ Glass Slides	**Inoculum Volume**	0.030 ml
Carrier Dry Time	10-20 minutes	**Carrier Dry Temp.**	Ambient
Contact Time	5 seconds at 0.5 inches	**Contact Temperature**	Ambient
Harvest Media (Volume)	Phosphate Buffered Saline with 0.1% Triton X-100 (20.0 ml)	**Enumeration Media**	Tryptic Soy Agar
Incubation Temperature	36 ± 1°C	**Incubation Time**	24-48 hours

S. aureus ATCC 6538

Culture Growth Media:	Tryptic Soy Broth	**Culture Growth Time:**	18-24 hours
Culture Dilution Media	N/A	**Culture Supplement**	N/A
Carrier Type	1″ x 3″ Glass Slides	**Inoculum Volume**	0.020 ml
Carrier Dry Time	10-20 minutes	**Carrier Dry Temp.**	Ambient
Contact Time	5 seconds at 0.5 inches	**Contact Temperature**	Ambient
Harvest Media (Volume)	Phosphate Buffered Saline with 0.1% Triton X-100 (20.0 ml)	**Enumeration Media**	Nutrient Agar
Incubation Temperature	36± 1°C	**Incubation Time**	24-48 hours

Study Notes

The overnight culture of *E. coli* was concentrated by centrifuging and resuspending in 1.0 ml of tryptic soy broth. All other cultures were not manipulated.

Control Results

Neutralization Method: N/A Media Sterility: Sterile
Growth Confirmation: Confirmed, morphology on required plating media

Calculations

CFU/ml = (Average plate count) x 1:10 serial dilution factor

CFU/carrier = (Average plate count) x 1:10 serial dilution factor x media dilution factor

CFU/carrier = CFU/ml x total harvest media volume

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

$$\text{Log}_{10}\ \text{Reduction} = \text{Log}(B/A)$$

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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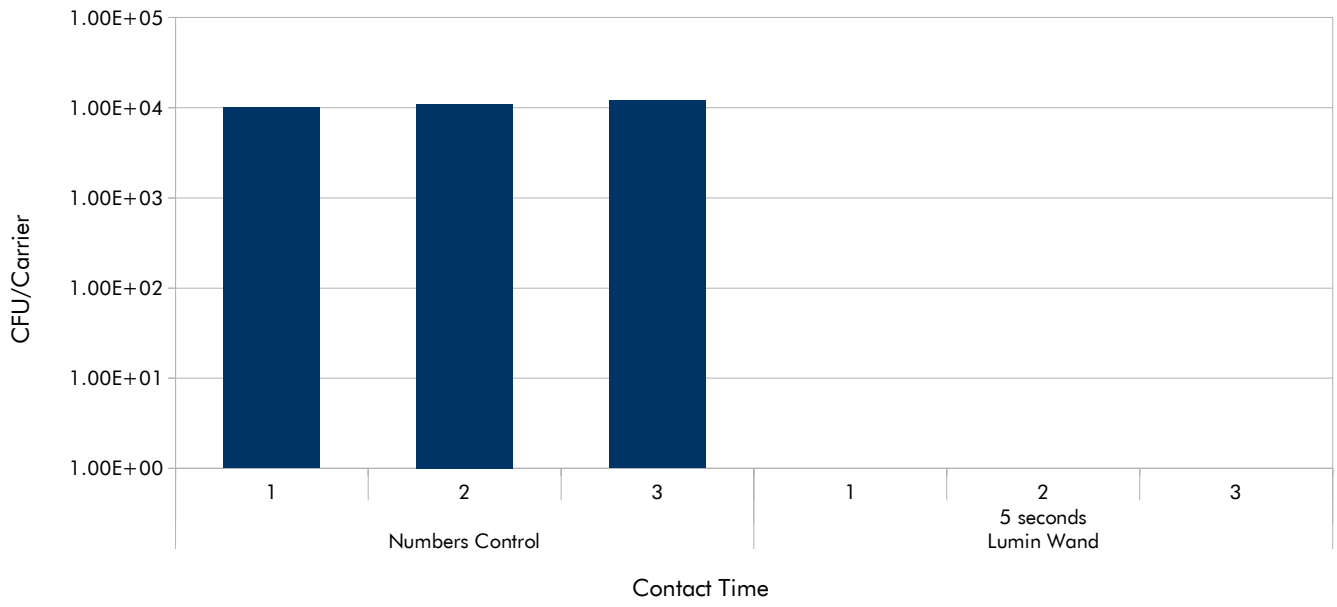
Results of the Study – *L. monocytogenes* ATCC 15313

Test Microorganism	Test Device	Contact Time	Replicate	CFU/Carrier	Average CFU/Carrier	Average Percent Reduction Compared to Controls	Average Log_{10} Reduction Compared to Controls
L. monocytogenes ATCC 15313	Numbers Control		1	1.00E+04	1.10E+04	N/A	N/A
			2	1.10E+04			
			3	1.20E+04			
	Lumin Wand	5 seconds	1	<1.00E+01	<1.00E+01	>99.91%	>3.04
			2	<1.00E+01			
			3	<1.00E+01			

Note: The limit of detection for this assay was 1.00E+01 CFU/Carrier.
Values observed below the limit of detection are reported as <1.00E+01 CFU/Carrier in the table and as zero in the graph.

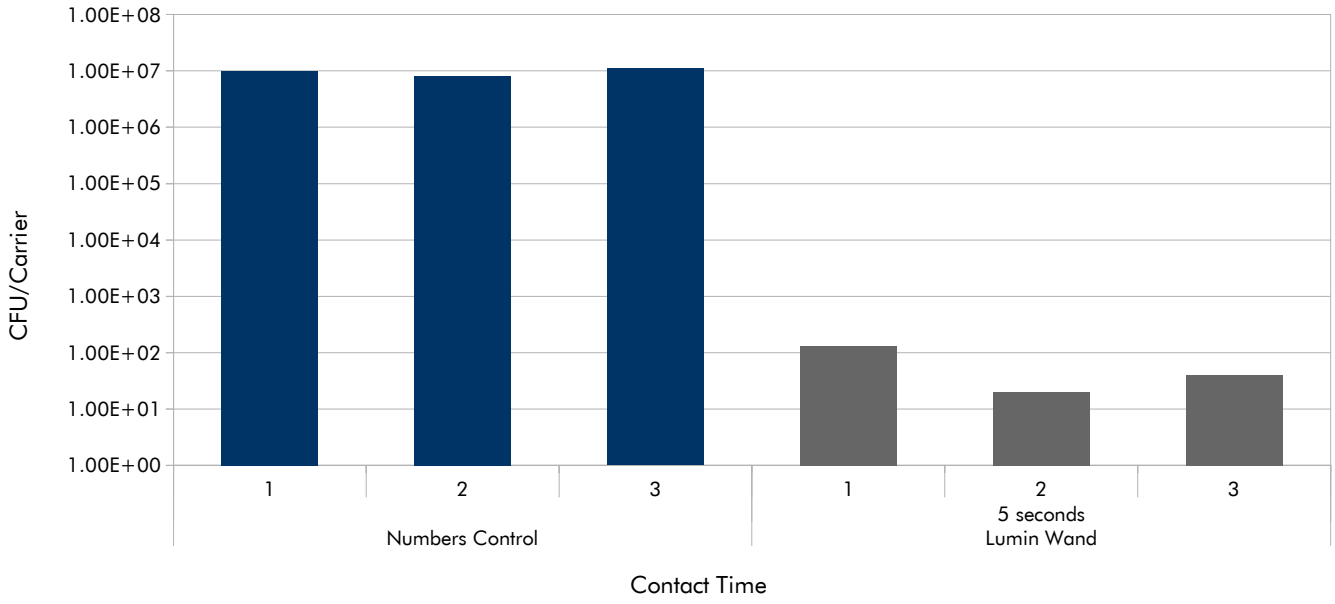


RESULTS

Results of the Study – *S. aureus* ATCC 6538

Test Microorganism	Test Device	Contact Time	Replicate	CFU/Carrier	Average CFU/Carrier	Average Percent Reduction Compared to Controls	Average Log_{10} Reduction Compared to Controls
S. aureus ATCC 6538	Numbers Control		1	9.90E+06	9.63E+06	N/A	N/A
			2	8.10E+06			
			3	1.09E+07			
	Lumin Wand	5 seconds	1	1.30E+02	6.33E+01	99.9993%	5.18
			2	2.00E+01			
			3	4.00E+01			

Note: The limit of detection for this assay was 1.00E+01 CFU/Carrier.
Values observed below the limit of detection are reported as <1.00E+01 CFU/Carrier in the table and as zero in the graph.



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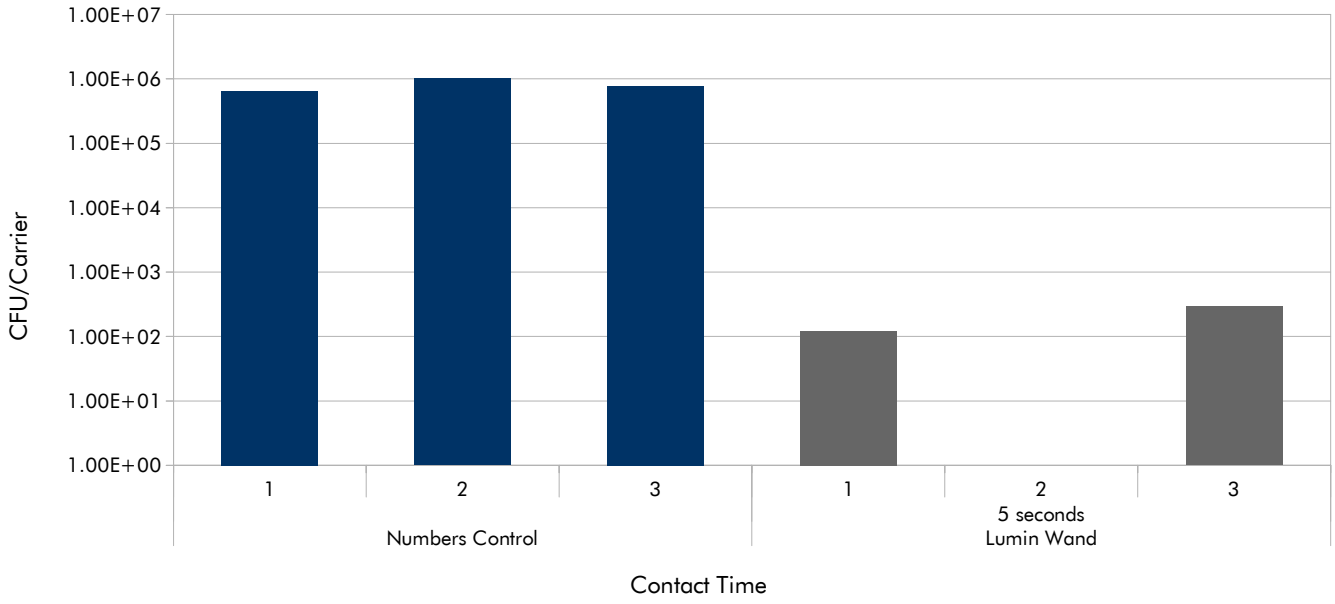
Results of the Study – *S. enterica* ATCC 10708

Test Microorganism	Test Device	Contact Time	Replicate	CFU/Carrier	Average CFU/Carrier	Average Percent Reduction Compared to Controls	Average Log_{10} Reduction Compared to Controls
S. enterica ATCC 10708	Numbers Control		1	6.50E+05	8.10E+05	N/A	N/A
			2	1.01E+06			
			3	7.70E+05			
	Lumin Wand	5 seconds	1	1.20E+02	<1.40E+02	>99.98%	>3.76
			2	<1.00E+01			
			3	2.90E+02			

Note: The limit of detection for this assay was 1.00E+01 CFU/Carrier.
Values observed below the limit of detection are reported as <1.00E+01 CFU/Carrier in the table and as zero in the graph.



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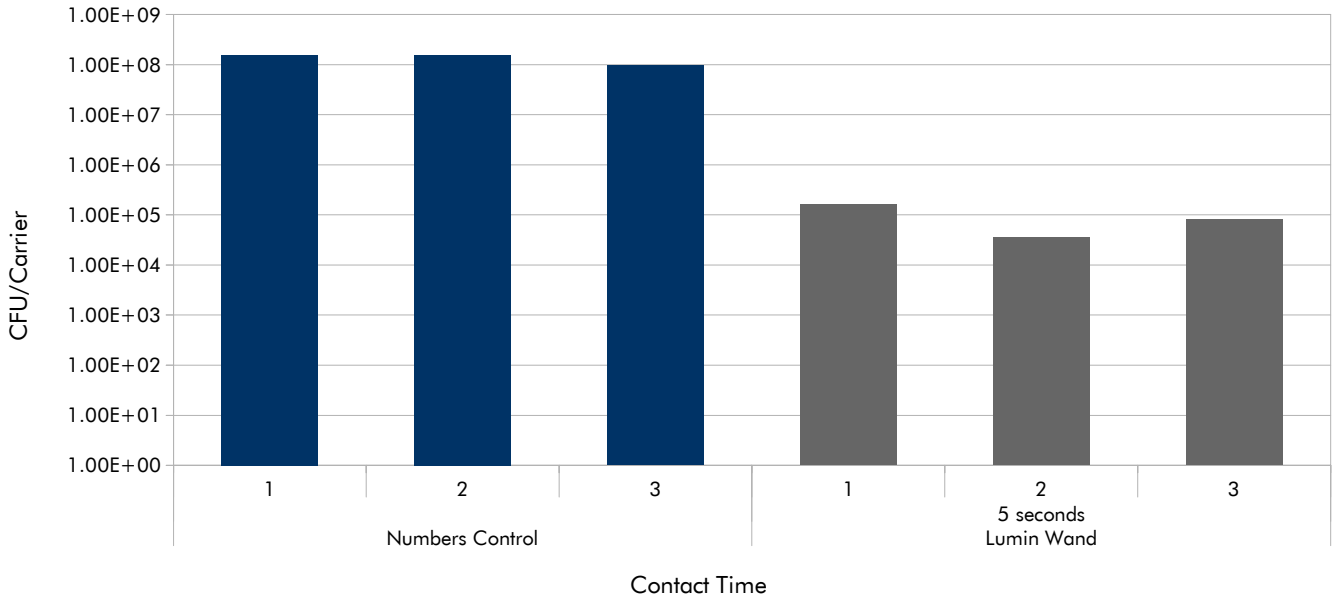
Results of the Study – *E. coli* ATCC 11775

Test Microorganism	Test Device	Contact Time	Replicate	CFU/Carrier	Average CFU/Carrier	Average Percent Reduction Compared to Controls	Average Log_{10} Reduction Compared to Controls
E. coli ATCC 11775	Numbers Control		1	1.54E+08	1.36E+08	N/A	N/A
			2	1.57E+08			
			3	9.60E+07			
	Lumin Wand	5 seconds	1	1.61E+05	9.20E+04	99.93%	3.17
			2	3.50E+04			
			3	8.00E+04			

Note: The limit of detection for this assay was 1.00E+01 CFU/Carrier.
Values observed below the limit of detection are reported as <1.00E+01 CFU/Carrier in the table and as zero in the graph.



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