MICROCHEM LABORATORY

STUDY REPORT

Study Title

Antibacterial Activity and Efficacy of the Test Device Provided by Green Technology Environmental

Test Method

Custom Device Study Based on: Modified ASTM E1153

Study Identification Number

NG16644-R1

Study Sponsor

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Green Technology Environmental
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Test Facility

Microchem Laboratory
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Report Author: Brady Ryan, B.S.

Purpose of the Study

The purpose of this study was to determine the antimicrobial efficacy of Green Technology Environmental's test device.

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
30 JUL 2020	11 NOV 2020	12 NOV 2020	12 NOV 2020	16 NOV 2020	16 NOV 2020

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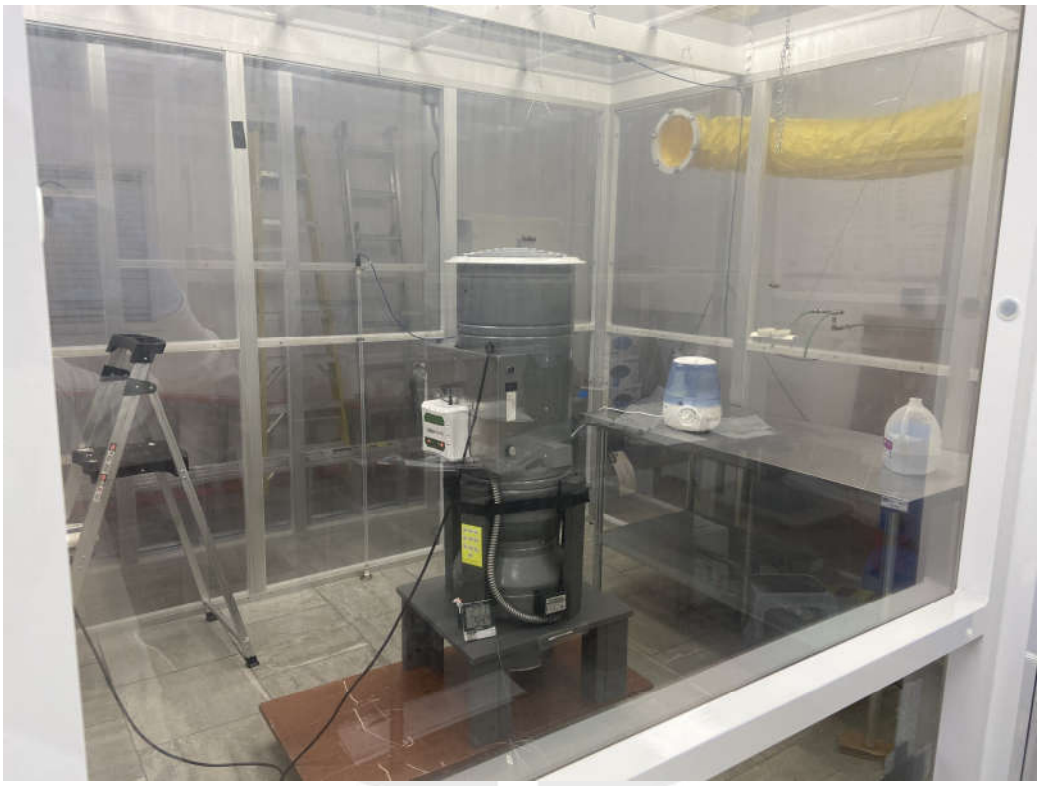
Test Device Information

Name of Test Device: PureAire HVAC
Manufacturer: Green Technology Environmental
Mode of Active: UV Light (Germicidal)

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



Note: Image above depicts the test device on day of testing for NG16034. Setup was identical to this study. Image is taken from Corner 2, looking across to Corner 4.

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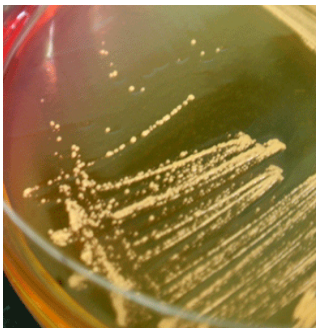
Test Microorganism Information

The test microorganism(s) selected for this test:



Staphylococcus aureus (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.

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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.

Testing Parameters

Culture Growth Media:	Tryptic Soy Broth	**Culture Growth Time:**	18-24 hours
Carrier Type	1" x 3" Glass Slides	**Inoculum Volume**	0.020 ml
Carrier Dry Time	20 to 40 minutes	**Carrier Dry Temp. and Humidity**	Ambient
Contact Time	6 hours	**Contact Temp. and Humidity**	Ambient / ≥60%
Harvest Media (Volume)	Phosphate Buffered Saline w/ 0.1% Tween-80 (20 ml)	**Enumeration Media**	Nutrient Agar
Incubation Temperature	36°C	**Incubation Time**	24-48 Hours

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Study Notes

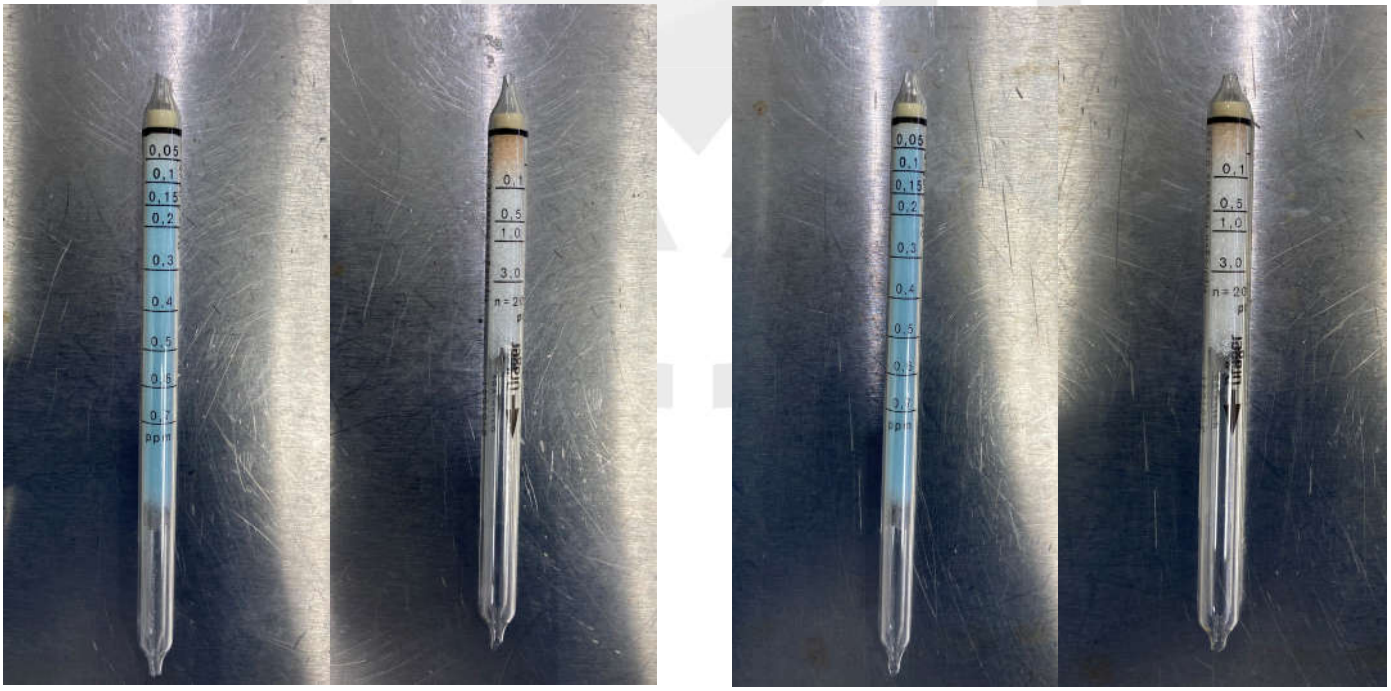
A humidifier was used to increase the humidity to the Study Sponsor specified ≥60%. The ambient temperature was 25°C ±1°C for the duration of the test.

The original study was repeated due to the carrier concentrations being too high. The test culture for this repeat was diluted in phosphate buffered saline to a target concentration of ~10^5 CFU/Carrier.

The chamber was pre-saturated with the test device for ≥4 hours prior to introduction of the inoculated carriers. Carriers were placed ~34" from the floor per study sponsor instructions.

Draeger tubes were used to determine the H_2O_2 and O_3 concentrations prior to testing and at the end of the contact time. Readings were taken via gloved ports between corners 2 and 3 at the appropriate test height.

Study Photographs



Note: (Left) Images depict the O_3 (blue) and H_2O_2 (white) readings prior to testing.
(Right) Images depict the O_3 (blue) and H_2O_2 (white) readings immediately prior to carrier harvesting at the end of the contact time.

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Control Results

Neutralization Method: N/A
Growth Confirmation: Pure and Viable
Media Sterility: Confirmed Sterile

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

Test Microorganism	Contact Time	Corner	CFU/Carrier	Average CFU/Carrier	Percent Reduction Compared to Control	Log_{10} Reduction Compared to Control
S. aureus ATCC 33592 (MRSA)	Time Zero	N/A	6.30E+04	6.90E+04	N/A	
			7.50E+04			
	Time Final		7.00E+03			
			1.40E+04			
	6 hours	1.1	2.00E+01	1.50E+01	99.98%	3.66
		1.2	1.00E+01			
		2.1	5.00E+01	3.00E+01	99.96%	3.36
		2.2	1.00E+01			
		3.1	4.00E+01	7.50E+01	99.89%	2.96
		3.2	1.10E+02			
		4.1	5.00E+01	3.50E+01	99.95%	3.29
		4.2	2.00E+01			

Pre and Post Test H_2O_2 readings were 0.1 ppm and <0.1 ppm, respectively. Pre and Post Test O_3 readings were 0.15 ppm and 0.05 ppm, repectively.

Test Device	Contact Time	Drager O_3 Reading (ppm)	Drager H_2O_2 Reading (ppm)
PureAire HVAC	Pre-Test	>0.05	<0.1
	~6 hours	~0.05	<0.1

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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