

STUDY REPORT

Study Title

Antibacterial Activity and Efficacy of Sarin Energy's Test Device Item 10996

Test Method

Custom Device Study Based on: ASTM E1153

Study Identification Number

NG15610

Study Sponsor

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Test Facility

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Purpose of the Study

The purpose of this study was to determine the antimicrobial efficacy of Sarin Energy's test device Item 10996 – Large UVC 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

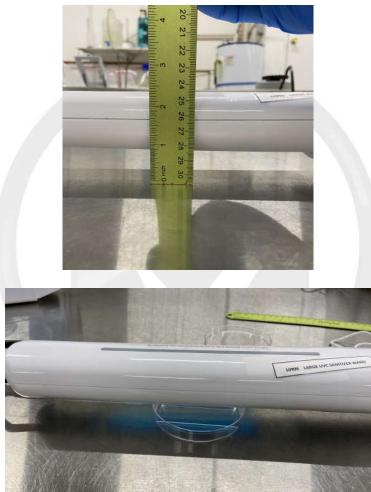
Devices Received	Cultures Initiated	Carriers Inoculated	Carriers Treated	Enumeration Plates Evaluated	Report Delivered
19MAY2020	07JUN2020	08JUN2020	08JUN2020	09JUN2020 10JUN2020	18 JUN 2020



Test Device Information

Name of Test Devices:Item 10996 – Large UVC WandManufacturer:Sarin EnergyMode of Active:UV Light (Germicidal)

Instructions for use were included with the device.



Note: (Top) Picture shows study setup with Item 10996. (Bottom) Picture shows carriers were placed directly underneath UVC lamp during the study for the entirety of the contact time.



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.





Summary of the Procedure

- Test microorganism is prepared in appropriate liquid broth.
- Test microorganism is harvested and the resulting suspension is diluted to achieve ≥1x10⁶ CFU/carrier.
- Test and control carriers are inoculated and allowed to dry in optimal conditions for test microorganism.
- Test carriers are placed in test device for the Sponsor-determined contact time.
- Test carriers are harvested into liquid media and plated in optimal incubation conditions and time for the test microorganism.
- After incubation, microbial concentrations are determined and reductions relative to pretreatment controls are calculated.





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:	24 hours ± 4 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	15 minutes ± 5 minutes	Carrier Dry Temp.	Ambient
Contact Times and Distances (Item 10996)	20 seconds at 1 inch	Contact Temperature	Ambient
Harvest Media (Volume)	Phosphate Buffered Saline with 0.1% Tween-80 (20.0 ml)	Enumeration Media	Tryptic Soy Agar
Incubation Temperature	36°C	Incubation Time	24-48 Hours



Study Notes

Device was allowed to warm up for \sim 20 seconds prior to each carrier treatment. Warm-up procedure performed before each replicate.





Control Results

Neutralization Method: N/A Growth Confirmation: Confirmed Target Morphology

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

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

 Log_{10} Reduction = Log(B/A)

Where:

 $\mathsf{B}=\mathsf{Number}$ of viable test microorganisms on the control carriers immediately after inoculation

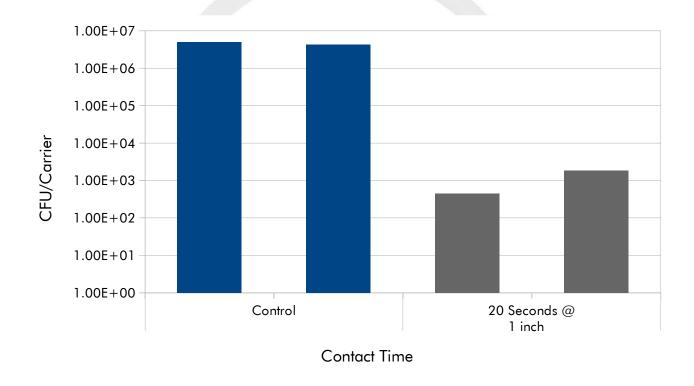
A = Number of viable test microorganisms on the test carriers after the contact time



Results of the Study (Item 10996 – Large Wand) – S. aureus ATCC 6538

Tes t Microorganism	Contact Time	Carrier Distance	Replicate	CFU/Carrier	Average CFU/Carrier	Percent Reduction Compared to Control at Time Zero	Log ₁₀ Reduction Compared to Control at Time Zero
<i>S. aureus</i> ATCC 6538	Time Zero	N/A	1	5.00E+06	4.65E+06	N/A	
			2	4.30E+06			
	20 Seconds	1 inch	1	4.50E+02	1.15E+03	99.98%	3.61
			2	1.84E+03			

Note: The lower limit of detection for this study was 1.00E+01 CFU/Carrier. Values observed less than the limit are reported as "<1.00E+01" in the results table and 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.

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