

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



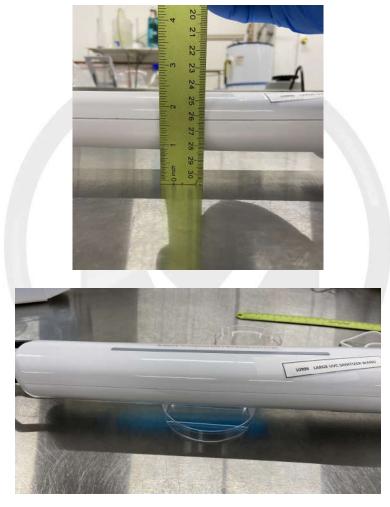
Test Device Information

Name of Test Devices: Item 10996 – Large UVC Wand

Manufacturer: Sarin Energy

Mode 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:



MS2 Bacteriophage (MS2), ATCC 15597-B1

This virus is a non-enveloped positive-stranded RNA virus of the bacteriophage family Leviviridae. Bacterial cells are the hosts for bacteriophages, and *E. coli* 15597 serves this purpose for MS2 bacteriophage. Its small size, icosohedral structure, and environmental resistance has made MS2 ideal for use as a surrogate virus (particularly in place of picornaviruses such as poliovirus and human norovirus) in water quality and disinfectant studies.

Permissive Host Cell System for MS2: Escherichia coli, 15597



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.

<u>Testing Parameters</u>

Culture Growth Media:	Freezer Stock	Host Culture Growth Time:	6-24 hours
Culture Dilution Media	Phosphate Buffered Solution	Culture Supplement	N/A
Carrier Type	1" x 3" Glass Slides	Inoculum Volume	0.020 ml
Carrier Dry Time	15 ± 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 (20.0ml)	Enumeration Media	50% Tryptic Soy Agar
Incubation Temp.	36°C ± 1°C	Incubation Time	12-18 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 Media Sterility: Confirmed Sterile

Growth Confirmation: Confirmed Target Morphology

Calculations

 $CFU/mI = (Average plate count) \times 1:10 serial dilution factor$

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

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

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

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

Where:

B = Number of viable test microorganisms on the control carriers immediately after inoculation

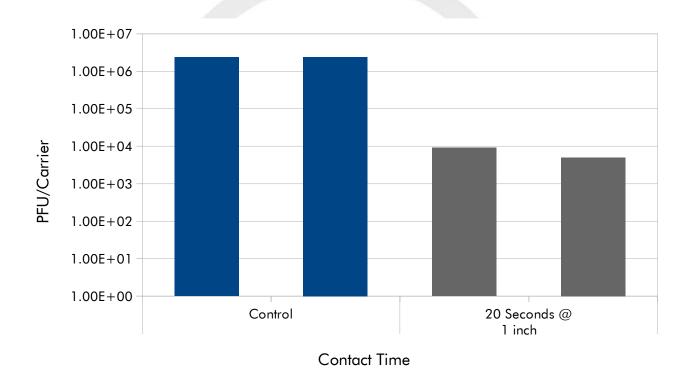
A = Number of viable test microorganisms on the test carriers after the contact time



Results of the Study (Item 10996 – Large Wand) – MS2 Bacteriophage

Test Microorganism	Contact Time	Carrier Distance	Replicate	PFU/Carrier	Average PFU/Carrier	Percent Reduction Compared to Control at Time Zero	Log ₁₀ Reduction Compared to Control at Time Zero
MS2	Time Zero	N/A	1	2.35E+06	2.38E+06	N/A	
Bacteriophage			2	2.40E+06			
ATCC 15597-	20 Seconds	1 inch	1	9.00E+03	7.00E+03	99.71%	2.53
B1			2	5.00E+03			

Note: The lower limit of detection for this study was 1.00E+01 PFU/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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