

STUDY REPORT

<u>Study Title</u> Antimicrobial Activity and Efficacy of Nemesis UVC's Device

> Test Method Custom Device Study Based on: ASTM E1153

Study Identification Number

NG17836

Study Sponsor

Brett Johnson Nemesis UVC, LLC 3301 Wood Drive Garland, TX 75041 brett@nemesisuvc.com 972-670-3422

Test Facility

Microchem Laboratory 1304 W. Industrial Blvd Round Rock, TX 78681 (512) 310-8378 Report Author: Brady Ryan, B.S.



Purpose of the Study

The purpose of this study was to determine the antimicrobial efficacy of Nemesis UVC's submitted 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
04 MAY 2021	03 MAY 2021	04 MAY 2021	04 MAY 2021	06 MAY 2021	14 MAY 2021

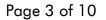


Test Device Information

Name of Test Device:Hydra DC Surface UVCManufacturer:Nemesis UVCMode of Active:UV (Germicidal)

The Study Sponsor was on-site the day of testing to instruct on operation of the test device.

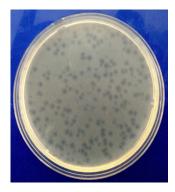






Test Microorganism Information

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

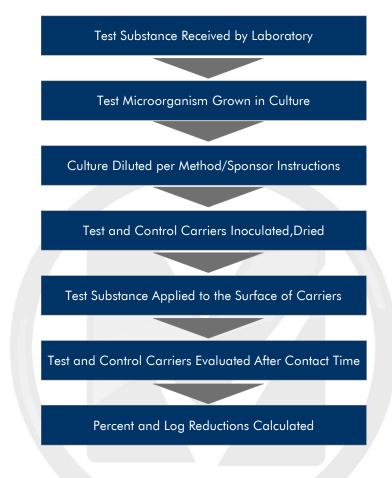


Staphylococcus aureus (MRSA)

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.



Diagram of the Test Procedure



Summary of the Procedure

- Test microorganism is prepared in appropriate liquid broth.
- Test microorganism is harvested and the resulting suspension is diluted to achieve $\geq 1 \times 10^6$ CFU/mL.
- 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:	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	20 minutes	Contact Distance	2 meters
Harvest Media (Volume)	PBS with 0.1% Tween- 80 (20.0 ml)	Enumeration Media	NTA (SA33592)
			50% TSA (MS2)
Incubation Temperature	36°C ± 1°C	Incubation Time	24 to 48 hours (SA33592)
			12 to 24 hours (MS2)



Study Notes

For all microorganisms tested, replicates were aligned sequentially left to right.





Control Results

Neutralization Method: N/A Growth Confirmation: Pure and Viable Media Sterility: No Growth

Calculations

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

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

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

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

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

Where:

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

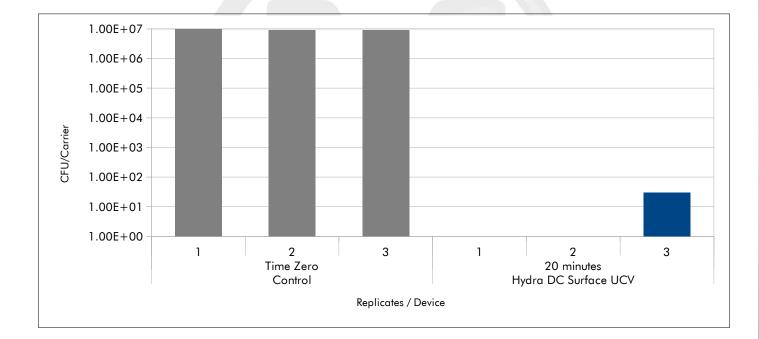
A = Number of viable test microorganisms on the test carriers after the contact time

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Results of the Study – S. aureus ATCC 33592 (MRSA)

Test Microorganism	Device	Contact Time	Contact 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 33592 (MRSA)	Control	Time Zero	N/A	1	9.80E+06	9.33E+06	N/A	
				2	9.00E+06			
				3	9.20E+06			
	Hydra DC Surface UCV	20 minutes	2 meters	1	<1.00E+01	<1.67E+01	>99.9998%	>5.75
				2	<1.00E+01			
				3	3.00E+01			
Note: The lower limit of detection for this study was 1.00E+01 CFU/mL. Values observed less than the limit are reported as "<1.00E+01" in the results table and zero in the graph.								

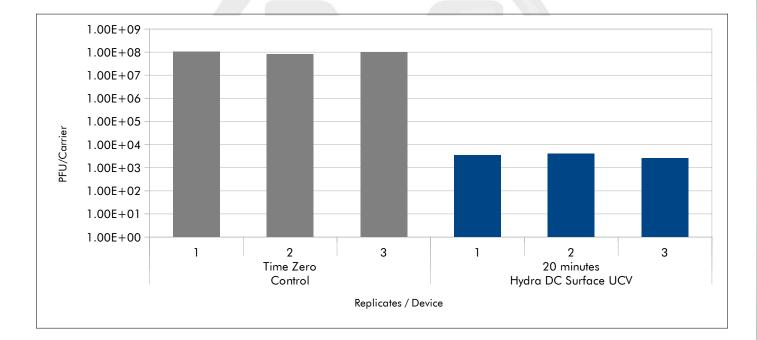


RESULTS



Results of the Study – MS2 Bacteriophage ATCC 15597-B1

Test Microorganism	Device	Contact Time	Contact Distance	Replicate	PFU/Carrier	Average CFU/Carrier	Percent Reduction Compared to Control at Time Zero	Log ₁₀ Reduction Compared to Control at Time Zero
MS2 Bacteriophage ATCC 15597-B1	Control	Time Zero	N/A	1	1.03E+08	9.47E+07	N/A	
				2	8.08E+07			
				3	1.00E+08			
	Hydra DC Surface UCV	20 minutes	2 meters	1	3.46E+03	3.34E+03	99.9965%	4.45
				2	4.04E+03			
				3	2.51E+03			
Note: The lower limit of detection for this study was 1.00E+01 PFU/mL. 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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