MICROCHEM LABORATORY

STUDY REPORT

Study Title

Antibacterial Activity and Efficacy of the Test Device from PleXus Health Science

Test Method

Custom Device Study Based on: ASTM E1153

Study Identification Number

NG16129-A1

Study Sponsor

Dario Gristina
PleXus Health Science
(212) 664-7600
dariog@cplgroupusa.com

Test Facility

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

Purpose of the Study

The purpose of this study was to determine the antimicrobial properties of the 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 AUG 2020	06 OCT 2020	06 OCT 2020	06 OCT 2020	07 OCT 2020	12 OCT 2020

Amended report delivered 06NOV2020.

1304 W. INDUSTRIAL BLVD ROUND ROCK, TX 78681 | © 2016 | CONTACT@MICROCHEMLAB.COM | 512.310.8378

Test Device Information

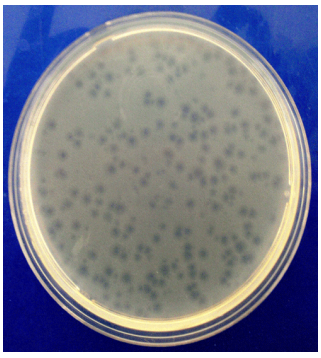
Name of Test Device: UVGI Unit (UV650)
Manufacturer: CPL Group
Mode of Active: UV Light (Germicidal)

Instructions for operation of the device were provided by the Study Sponsor prior to test initiation.

Note: The above image depicts the device used on the day of testing.

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

- 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, usually between 0.010ml and 0.030ml. Inoculated slides are dried for 20-40 minutes under ambient conditions within a biological safety cabinet or within an incubator set to 36°C±1°C. Only completely dried carriers are used in the test.
- Test carriers are placed onto the test device per study sponsor instruction and the test device is turned on and allowed to run 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 harvested into Phosphate Buffered Saline (PBS) which may be supplemented with 0.1% surfactant, such as TritionX-100 or Tween 80.
- Dilutions of the harvested carriers are evaluated using appropriate growth media to determine the concentration of surviving microorganisms at the respective contact time.
- The effect of the test device on the test carriers is compared to the effect of the untreated control carriers in order to determine microbial reductions.

1304 W. INDUSTRIAL BLVD. ROUND ROCK, TX 78681 | © 2016 | CONTACT@MICROCHEMLAB.COM | 512.310.8378

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

MS2 Bacteriophage ATCC 15597-B1

Test Microorganism Initiation Date	05 AUG 2020	**Test Culture Dilution Media**	Phosphate Buffered Saline
Host Microorganism Growth Time	6-24 hours	**Host Microorganism Growth Media**	Tryptic Soy Broth
Carrier Type	1" x 3" glass slide	**Inoculum Volume**	0.020 ml
Carrier Dry Time	20-40 minutes	**Harvest Media (Volume)**	Phosphate Buffered Saline + 0.1% Tween80 (20.0 ml)
Contact Time(s)	5, 10, and 15 minutes	**Enumeration Media**	50% Tryptic Soy Agar
Incubation Temperature	36°C	**Incubation Time**	12-24 Hours

PARAMETERS

1304 W. INDUSTRIAL BLVD. ROUND ROCK, TX 78681 | © 2016 | CONTACT@MICROCHEMLAB.COM | 512.310.8378

Study Notes

The device was operated according to the instructions provided by the study sponsor.

Test carriers were treated at 5, 10, and 15 feet from the test device. Carriers were oriented such that there was no obstruction between the light from the test device and the inoculated surface of the test carrier.

A 2 minute warm up period was incorporated into the total run times and was not included as part of the overall contact time. For example, on the 5 minute contact time, the device was set to run for 7 minutes to account for the warm up period.

Report amended 06NOV2020 to update Sponsor Company name from CPL Group to PleXus Health Science, per sponsor request.

Control Results

Growth Confirmation: Pure Growth Observed Media Sterility: Sterility Confirmed

Calculations

MS2 Bacteriophage ATCC 15597-B1

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

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

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

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

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

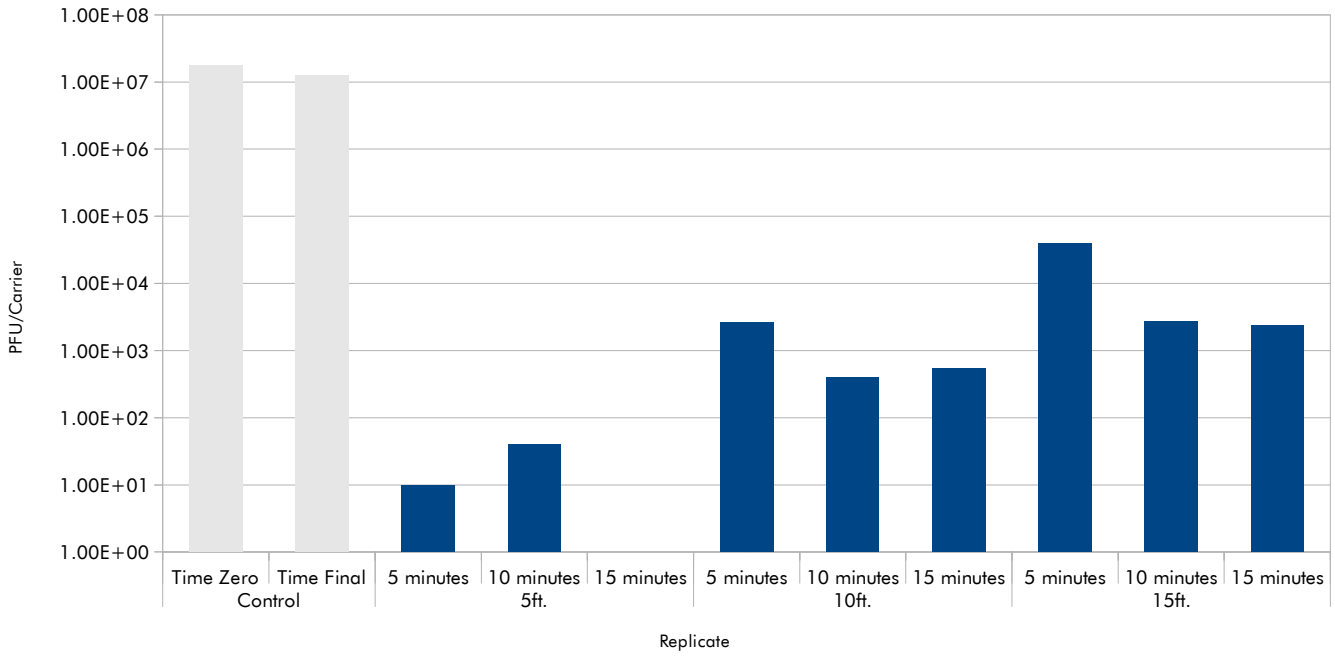
Where:
B = Average number of viable test microorganisms on the control carriers immediately after inoculation and after the final contact time
A = Number of viable test microorganisms on the test carriers after the contact time

1304 W. INDUSTRIAL BLVD. ROUND ROCK, TX 78681 | © 2016 | CONTACT@MICROCHEMLAB.COM | 512.310.8378

Results of the Study:

Test Microorganism	Carrier Distance	Contact Time	PFU/Carrier	Average PFU/Carrier	Percent Reduction Compared to Control	Log_{10} Reduction Compared to Control
MS2 Bacteriophage ATCC 15597-B1	Control	Time Zero	1.74E+07	1.50E+07	N/A	
		Time Final	1.26E+07			
	5ft.	5 minutes	1.00E+01	1.00E+01	99.99993%	6.18
		10 minutes	4.00E+01	4.00E+01	99.9997%	5.57
		15 minutes	<1.00E+01	<1.00E+01	>99.99993%	>6.18
	10ft.	5 minutes	2.58E+03	2.58E+03	99.98%	3.76
		10 minutes	3.90E+02	3.90E+02	99.997%	4.59
		15 minutes	5.50E+02	5.50E+02	99.996%	4.44
	15ft.	5 minutes	4.00E+04	4.00E+04	99.73%	2.57
		10 minutes	2.73E+03	2.73E+03	99.98%	3.74
		15 minutes	2.40E+03	2.40E+03	99.98%	3.80

The limit of detection for this assay is 1.00E+01 PFU/carrier and values below the limit of detection are noted as "<1.00E+01" in the data 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.

1304 W. INDUSTRIAL BLVD. ROUND ROCK, TX 78681 | © 2016 | CONTACT@MICROCHEMLAB.COM | 512.310.8378