MICROCHEM LABORATORY

STUDY REPORT

Study Title

Antimicrobial Activity and Efficacy of the Cres Guard Mobile Decontamination

Test Method

Custom Device Study Based on: ASTM E1153

Study Identification Number

NG18029 – A1

Study Sponsor

Cres Cor Health and Safety
5925 Heisley Rd.
Mentor, OH 44060-1833
yramadoss@crescor.com

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 activity and efficacy of Cres Guard Mobile Decontamination.

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
MS2 Bacteriophage (185°F / 65% RH)					
17JUN2021	N/A – Freezer Stock	22JUN2021	22JUN2021	23JUN2021	18AUG2021

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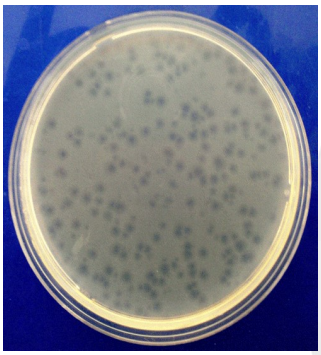
Test Device Information

Name of Test Device: Cres Guard Mobile Decontamination
Manufacturer: Cres Cor Health and Safety
Mode of Active: Moist Heat

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 $\geq 1x10^6$ 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 pre-treatment controls are calculated.

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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

Host Culture Growth Media:	Tryptic Soy Broth	**Culture Growth Time:**	6 – 18 hours
Culture Dilution Media	Phosphate Buffered Saline	**Culture Supplement**	N/A
Carrier Type	See Notes	**Inoculum Volume**	0.030 ml
Carrier Dry Time	20 – 40 minutes	**Carrier Dry Temp. and Humidity**	Ambient
Contact Time	15 minutes	**Contact Temperature/Humidity**	185°F/65% RH
Harvest Media (Volume)	Phosphate Buffered Saline with 0.1% Tween-80 (20 ml)	**Enumeration Media**	50% Tryptic Soy Broth
Incubation Temperature	36°C	**Incubation Time**	12 – 24 hours

PARAMETERS

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Study Notes

The study sponsor provided carriers for this study were: Turnout Jacket, Gloves, Helmet and Ballistic Vest. For each set of parameters and microorganisms evaluated, all carriers were treated simultaneously within the test device. See Study Photos section for image of carriers within the device.

The jacket, gloves and vest control and test carriers were all harvested by cutting out the inoculated section of the carrier into 20 mL of harvest media. The jacket and vest were inoculated on the chest portion of the carriers, while the gloves were inoculated on both sides of the fingertips. As each inoculation site was removed for harvesting, the locations were slightly different between each run. The helmet control and test carriers were harvested via sterile swabbing of the inoculation site.

No time final controls were able to be taken for the helmet due to test method constraints. In the results section, the reductions for the helmet are calculated based on the time zero controls. Time zero and time final controls were taken for all other test carriers.

After loading the inoculated carriers into the test device, the contact time was not started until the temperature and humidity values reached their target values. Carriers were loaded as quickly as possible to reduce the amount of time the device needed to reach the prescribed parameters.

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Study Photos:

Note: Image above depicts the carrier orientation for all treatment runs of the test device.

Control Results

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

Calculations

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 = PFU/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

Results of the Study (185°F/65% RH/15 minutes)

Test Microorganism	Test Article	Contact Time	Replicate	PFU/Carrier	Average PFU/Carrier	Percent Reduction Compared to Control at Time Zero	Log_{10} Reduction Compared to Control at Time Zero
MS2 Bacteriophage ATCC 15597-B1	Jacket	Time Zero Control	1	4.20E+07	4.32E+07	N/A	
			2	4.40E+07			
			3	4.36E+07			
		Time Final Control	1	5.00E+07	4.73E+07	No Reduction	
			2	4.56E+07			
			3	4.64E+07			
		15 minutes	1	<1.00E+01	<1.00E+01	>99.99998%	>6.64
			2	<1.00E+01			
			3	<1.00E+01			
	Helmet	Time Zero Control	1	3.40E+06	1.45E+06	N/A	
			2	1.50E+05			
			3	8.00E+05			
		Time Final Control	N/A				
		15 minutes	1	<1.00E+01	<1.00E+01	>99.9993%	>5.16
			2	<1.00E+01			
			3	<1.00E+01			
	Vest	Time Zero Control	1	2.52E+07	2.54E+07	N/A	
			2	2.23E+07			
			3	2.87E+07			
		Time Final Control	1	3.42E+07	3.29E+07	No Reduction	
			2	3.92E+07			
			3	2.54E+07			
		15 minutes	1	<1.00E+01	<1.00E+01	>99.99996	>6.40
			2	<1.00E+01			
			3	<1.00E+01			
	Gloves	Time Zero Control	1	6.70E+06	9.67E+06	N/A	
			2	8.20E+06			
			3	1.41E+07			
		Time Final Control	1	1.31E+07	1.21E+07	No Reduction	
			2	1.21E+07			
			3	1.10E+07			
		15 minutes	1	<1.00E+01	<1.00E+01	>99.999897%	>5.99
			2	<1.00E+01			
			3	1.00E+01			

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.

RESULTS

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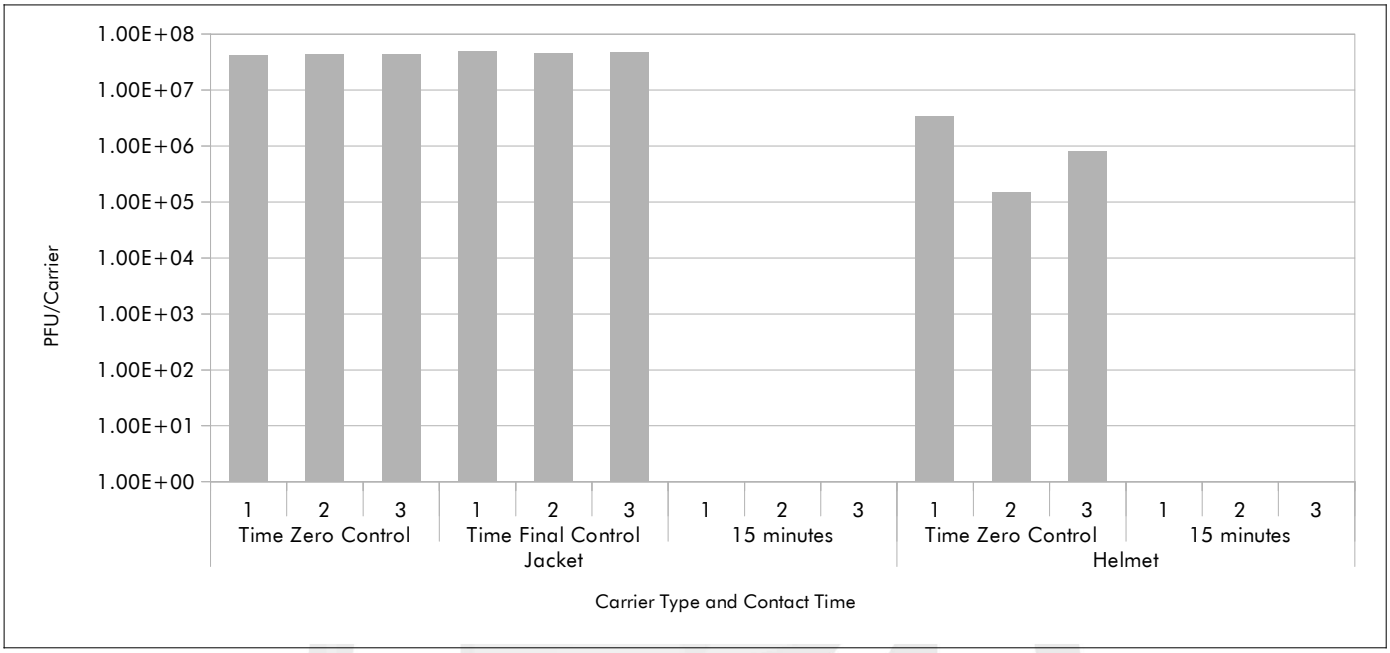
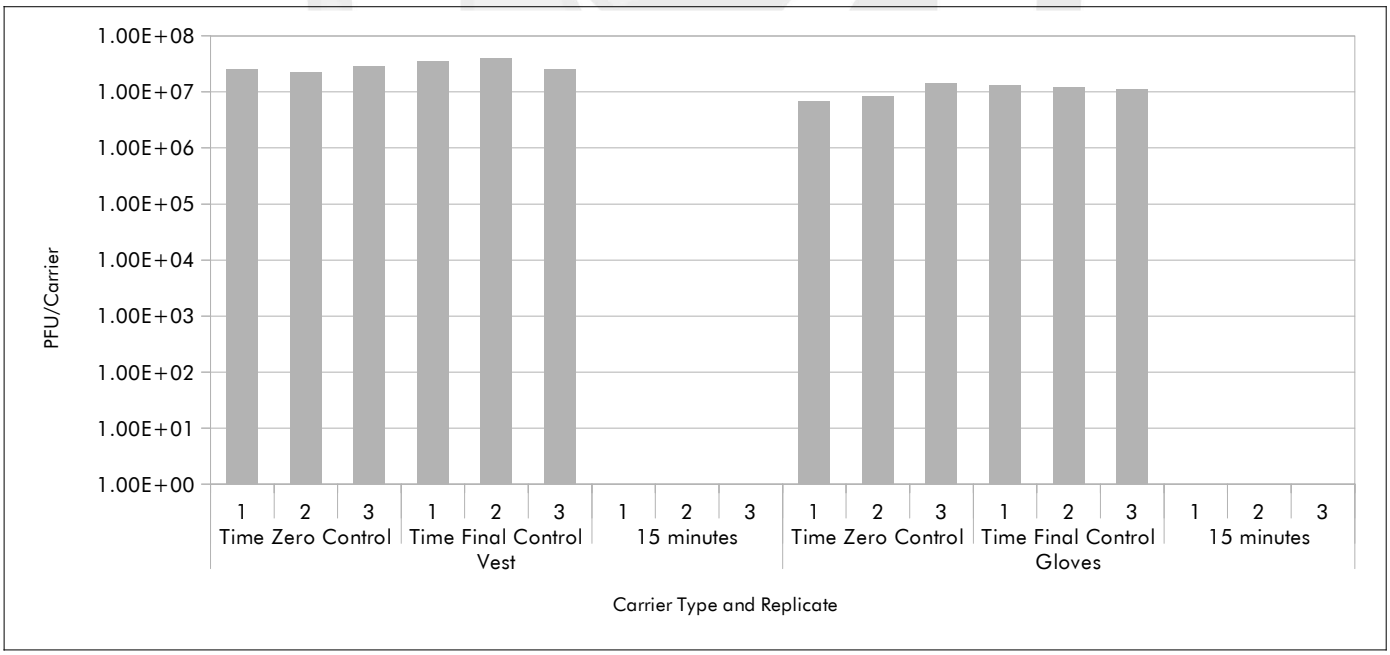
Results of the Study (cont.)





RESULTS

Report Amendments

Per Study Sponsor request, this report was amended to on 16AUG2021 to make the following changes:

- Remove individual Study Sponsor's name from the title page.
- Split the original report into 2 separate reports by microorganism.
- Include images of the carriers.
- Change the Mode of Active to "Moist Heat"
- Change name of the Study Sponsor company to "Cres Cor Health and Safety".
- Change the name of the device to "Cres Guard Mobile Decontamination".

Per Study Sponsor request, this report was amended on 20AUG2021 to make the following changes:

- Amendments were moved from the "Study Notes" section to a separate "Report Amendments" section.

The results of this study apply to the tested substances(s) only. Extrapolation of findings to related materials is the responsibility of the Sponsor.