MICROCHEM LABORATORY

STUDY REPORT

Study Title

Antibacterial Activity and Efficacy of Cres Cor's Device

Test Method

Custom Device Study Based on: ASTM E1153

Study Identification Number

NG20708 and NG20913

Study Sponsor

Cres Cor Health and Safety | www.crescor-hs.com

Test Facility

Microchem Laboratory
1700 Chisholm Trail Rd.
Round Rock, TX 78681
(512) 310-8378
Testing performed by: Christopher Sun

ASTM E1153: General Information

ASTM International, formerly the American Society for Testing and Materials (ASTM), is an internationally recognized organization that develops and publishes product and testing standards. ASTM E1153 is a quantitative test method designed to evaluate the antimicrobial efficacy of sanitizers on pre-cleaned inanimate, nonporous, non-food contact surfaces. The method is typically used with a maximum contact time of 5 minutes, during which the sanitizer reduces the concentration of viable test microorganisms. ASTM E1153 utilizes non-antimicrobial agents as controls to establish baselines for microbial reductions. The ASTM E1153 method is a benchmark method for non-food contact surface sanitizers and is recognized by several regulatory agencies as an approved method for claim substantiation. See study modifications for changes made to the study method to accommodate a device.

Laboratory Qualifications Specific to ASTM E1153

Microchem Laboratory began conducting the ASTM E1153 test method in 2007. Since then, the laboratory has performed hundreds of ASTM E1153 tests on a broad array of test substances, against a myriad of bacterial and fungal species. The laboratory is also experienced with regard to modifying the test method as needed in order to accommodate customer needs. Every ASTM E1153 test at Microchem Laboratory is performed in a manner appropriate for the test substances submitted by the Study Sponsor, while maintaining the integrity of the method.

Study Timeline

NG20708

Culture Initiated	Surfaces Inoculated	Surface Treatment Initiated	Surfaces Harvested	Enumeration Plates Evaluated	Report Delivered
09FEB2023	10FEB2023	10FEB2023	10FEB2023	13FEB2023	16JUN2023
20FEB2023	21FEB2023	21FEB2023	21FEB2023	23FEB2023	16JUN2023

NG20913

Culture Initiated	Surfaces Inoculated	Surface Treatment Initiated	Surfaces Harvested	Enumeration Plates Evaluated	Report Delivered
21MAR2023	22MAR2023	22MAR2023	22MAR2023	24MAR2023	16JUN2023

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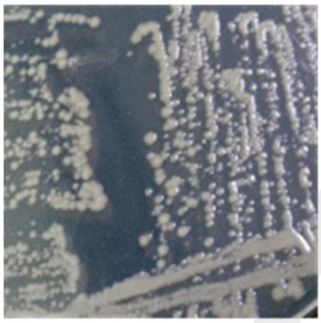
Test Substance Information

The CresGuard Mobile Decontamination Unit Model# CGUV57A and Carriers were received on 27JAN2023.

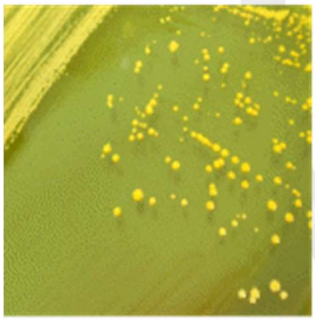
Test Microorganism Information

The test microorganism(s)selected for this test:



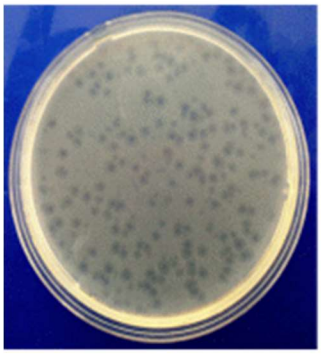
Escherichia coli

This bacteria is a Gram-negative, rod shaped, facultative anaerobe commonly found in the gastrointestinal tract of mammals. Although most serotypes of this microorganism are harmless there are pathogenic groups of *E. coli* such as enterohemorrhagic (EHEC), verocytotoxin producing (VTEC) and Shiga-like toxin producing (STEC) that can cause a multitude of illnesses. *E. coli* is relatively susceptible to disinfection when dried on a surface, yet it can be a challenging microorganism to mitigate in solution.



***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.



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

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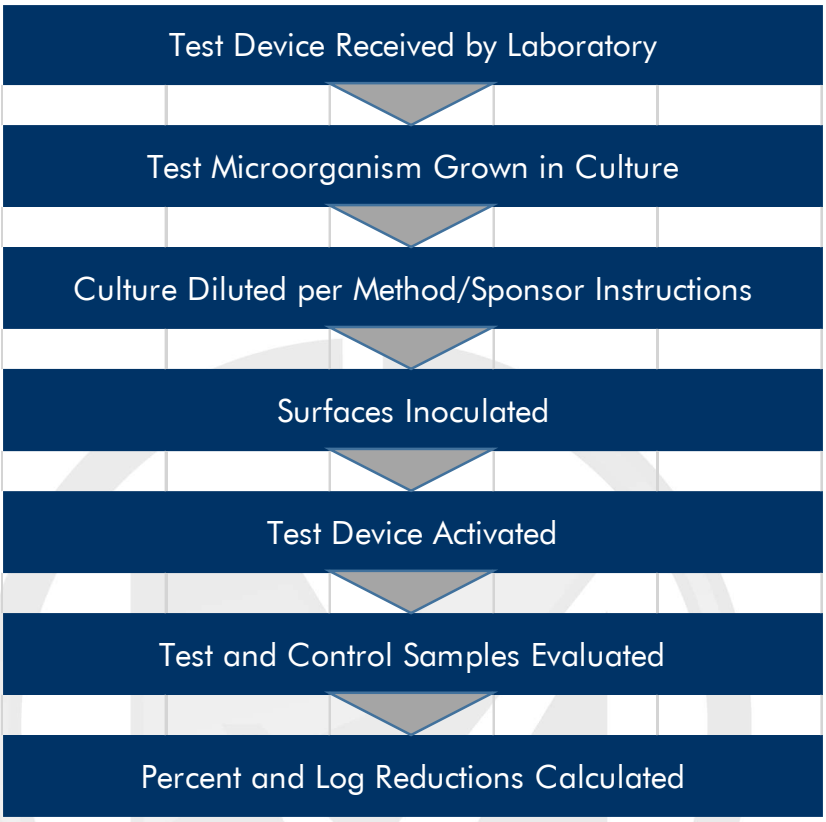
Diagram of the Procedure



Summary of the Procedure

- The test microorganisms were prepared in liquid culture medium and allowed to incubate overnight.
    - Following incubation, microorganisms were pooled to form the test inoculum.
- Sterilized carriers were inoculated with 0.02 ml of the pooled test inoculum at each of three test sites and allowed to dry. Only completely dried carriers were used in the test.
- Test carriers were loaded into test device, and device was set to sponsor-defined parameters and allowed to run for test cycle duration.
- Following test device run, test carriers were harvested via swab.
- Test samples and Control samples were enumerated and incubated.

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Criteria for Scientific Defensibility of a Custom Device Study

For Microchem Laboratory to consider a Device Study to be scientifically defensible, the following criteria must be met:

1. Positive/Growth controls must demonstrate growth of the appropriate test microorganism.
2. Negative/Purity controls must demonstrate no growth of test microorganisms.

Passing Criteria

Due to the modified nature of the study, passing criteria may be determined by the Study Sponsor.

Testing Parameters (NG20708)

Test Substance Mode of Use:	Heat, UV light	Carriers:	Radio
Carrier Sterilization Method:	UV light	Replicates:	Single Replicate (3 sites evaluated per carrier type)
Culture Growth Media:	Tryptic Soy Broth	Culture Growth Time:	24±4 hours
Contact Time(s):	15 Minute UVC, and 30 Minutes of UVC and Heat (120°F)	Inoculum Volume:	0.020 ml
Neutralizer (Vol.):	Phosphate Buffered Saline (20 ml)	Enumeration Media:	Tryptic Soy Agar (Bacterial) 50% TSA (MS2)
Enumeration Plate Incubation Temperature:	36°C ± 1°C	Enumeration Plate Incubation Time:	24-48 Hours (Bacterial) 24±4 Hours (MS2)

PARAMETERS

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Testing Parameters (NG20913)

Test Substance Mode of Use:	Heat, UV light	Carriers:	1"x3" Glass Carriers
Carrier Sterilization Method:	UV light and Ethyl Alcohol	Replicates:	Single Replicate (3 sites evaluated per carrier type)
Culture Growth Media:	Tryptic Soy Broth	Culture Growth Time:	24±4 hours
Contact Time(s):	15 Minute UVC, and 30 Minutes of UVC and Heat (120°F)	Inoculum Volume:	0.020 ml
Neutralizer (Vol.):	Phosphate Buffered Saline (10 ml)	Enumeration Media:	Tryptic Soy Agar (Bacterial) 50% TSA (MS2)
Enumeration Plate Incubation Temperature:	36°C ± 1°C	Enumeration Plate Incubation Time:	24-48 Hours (Bacterial) 24±4 Hours (MS2)

OBSERVATIONS

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Study Notes (NG20708)

The carriers were UV sterilized for approximately 15 minutes per side prior to each test run.

The carriers were placed in the test device in a staggered arrangement with each carrier occupying its own rack. The inoculation locations were facing up for each carrier.

The inoculation locations can be seen in Figure 1 of "Study Photographs (NG20708)" section.

Amendments

Amendment 1: Per study sponsor request, all data for helmet, radio strap, tablet, tablet case, and knife were omitted from the report.

Amendment 2: Per study sponsor request, the temperature was added to all results tables that included results of UVC and Heat and UV was corrected to UVC throughout the results.

Study Photographs (NG20708)

Figure 1: Inoculation Locations are represented by the yellow tape. The numbers represent the Test Site Number and are referenced in the "Results of the Study" section.

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Study Photographs (NG20708)

Figure 2: Location of carriers in the Test Device

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Study Notes (NG20913)

The settings evaluated were 15 minutes of UVC, and 30 Minutes of UVC and Heat (120°F).

The glass slides were placed on a rack located in the center of the device with the inoculated locations facing up. Please see Figure 3 in the "Study Photographs (NG20913)" section.

Study Photographs (NG20913)

Figure 4: Location of carriers in the Test Device

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Control Results

Neutralization Method:	N/A [1]	Media Sterility:	Sterile
Growth Confirmation:	Pure Growth		

[1] *Note: Neutralization not evaluated for this study.*

Calculations

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

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

$$\text{Log}_{10}\text{Reduction} = \text{Log}\left(\frac{B}{A}\right)$$

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

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Results (NG20708)

Table 1: Results of 30-minute cycle UVC and Heat Against MS2.

Test Microorganism	Test Setting	Test Carrier	Sample ID/Location	PFU/Carrier	Percent Reduction Compared to Time Zeroes	Log Reduction Compared to Time Zeroes
MS2 Bacteriophage	UVC and Heat (120°F) (30 minutes)	Radio	Time Zero, Site 1	1.23E+06	N/A	
			Time Zero, Site 2	9.20E+05		
			Time Zero, Site 3	9.90E+05		
			Test, Site 1	1.13E+04	99.08%	2.04
			Test, Site 2	4.80E+03	99.48%	2.28
			Test, Site 3	2.90E+02	99.97%	3.53
Limit of detection for this assay was 1.00E+01 PFU/Carrier. All enumerations below this limit of detection were written as <1.00E+01.						

Table 2: Results of 15-minute cycle UVC Against MS2.

Test Microorganism	Test Setting	Test Carrier	Sample ID/Location	PFU/Carrier	Percent Reduction Compared to Time Zeroes	Log Reduction Compared to Time Zeroes
MS2 Bacteriophage	UVC (15 minutes)	Radio	Time Zero, Site 1	1.23E+06	N/A	
			Time Zero, Site 2	9.20E+05		
			Time Zero, Site 3	9.90E+05		
			Test, Site 1	4.40E+03	99.64%	2.45
			Test, Site 2	3.60E+03	99.61%	2.41
			Test, Site 3	9.80E+02	99.90%	3.00
Limit of detection for this assay was 1.00E+01 PFU/Carrier. All enumerations below this limit of detection were written as <1.00E+01.						

Table 3: Results of 30-minute cycle UVC and Heat Against *S. aureus* ATCC 6538.

Test Microorganism	Test Setting	Test Carrier	Sample ID/Location	CFU/Carrier	Percent Reduction Compared to Time Zeroes	Log Reduction Compared to Time Zeroes
Staphylococcus aureus ATCC 6538	UVC and Heat (120°F) (30 minutes)	Radio	Time Zero, Site 1	2.06E+06	N/A	
			Time Zero, Site 2	2.44E+06		
			Time Zero, Site 3	6.30E+06		
			Test, Site 1	4.00E+01	99.998%	4.71
			Test, Site 2	8.00E+02	99.97%	3.48
			Test, Site 3	5.00E+01	99.9992%	5.10
Limit of detection for this assay was 1.00E+01 CFU/Carrier. All enumerations below this limit of detection were written as <1.00E+01.						

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Results, Continued (NG20708)

Table 4: Results of 15-minute cycle UVC Against *S. aureus* ATCC 6538.

Test Microorganism	Test Setting	Test Carrier	Sample ID/Location	CFU/Carrier	Percent Reduction Compared to Time Zeroes	Log Reduction Compared to Time Zeroes
Staphylococcus aureus ATCC 6538	UVC (15 minutes)	Radio	Time Zero, Site 1	2.06E+06	N/A	
			Time Zero, Site 2	2.44E+06		
			Time Zero, Site 3	6.30E+06		
			Test, Site 1	6.30E+02	99.97%	3.51
			Test, Site 2	5.30E+02	99.98%	3.66
			Test, Site 3	9.80E+02	99.984%	3.81
Limit of detection for this assay was 1.00E+01 CFU/Carrier. All enumerations below this limit of detection were written as <1.00E+01.						

Table 5: Results of 30-minute cycle UVC and Heat Against *E. coli* ATCC 8739.

Test Microorganism	Test Setting	Test Carrier	Sample ID/Location	CFU/Carrier	Percent Reduction Compared to Time Zeroes	Log Reduction Compared to Time Zeroes
Escherichia coli ATCC 8739	UVC and Heat (120°F) (30 minutes)	Radio	Time Zero, Site 1	5.40E+05	N/A	
			Time Zero, Site 2	5.10E+05		
			Time Zero, Site 3	1.07E+06		
			Test, Site 1	1.60E+02	99.970%	3.53
			Test, Site 2	2.00E+02	99.96%	3.41
			Test, Site 3	<1.00E+01	>99.9991%	>5.03
Limit of detection for this assay was 1.00E+01 CFU/Carrier. All enumerations below this limit of detection were written as <1.00E+01.						

Table 6: Results of 15-minute cycle UVC Against *E. coli* ATCC 8739.

Test Microorganism	Test Setting	Test Carrier	Sample ID/Location	CFU/Carrier	Percent Reduction Compared to Time Zeroes	Log Reduction Compared to Time Zeroes
Escherichia coli ATCC 8739	UVC (15 minutes)	Radio	Time Zero, Site 1	5.40E+05	N/A	
			Time Zero, Site 2	5.10E+05		
			Time Zero, Site 3	1.07E+06		
			Test, Site 1	3.10E+02	99.94%	3.24
			Test, Site 2	1.30E+02	99.97%	3.59
			Test, Site 3	1.50E+02	99.99%	3.85
Limit of detection for this assay was 1.00E+01 CFU/Carrier. All enumerations below this limit of detection were written as <1.00E+01.						

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Results, Continued (NG20913)

Table 7: Results of 30-minute cycle UVC and Heat Against MS2.

Test Microorganism	Test Setting	Test Carrier	Sample ID/Location	PFU/Carrier	Percent Reduction Compared to Time Zeroes	Log Reduction Compared to Time Zeroes
MS2 Bacteriophage	UVC and Heat (120°F) (30 Minutes)	Glass Slides	Time Zero, Site 1	1.15E+06	N/A	
			Time Zero, Site 2	1.27E+06		
			Time Zero, Site 3	1.41E+06		
			Test, Site 1	5.00E+00	99.9996%	5.36
			Test, Site 2	>5.00E+00	>99.9996%	>5.40
			Test, Site 3	2.00E+01	99.9986%	4.85
Limit of detection for this assay was 5.00E+00 CFU/Carrier. All enumerations below this limit of detection were written as <5.00E+00.						

Table 8: Results of 15-minute cycle UVC Against MS2.

Test Microorganism	Test Setting	Test Carrier	Sample ID/Location	PFU/Carrier	Percent Reduction Compared to Time Zeroes	Log Reduction Compared to Time Zeroes
MS2 Bacteriophage	UVC (15 Minutes)	Glass Slides	Time Zero, Site 1	1.15E+06	N/A	
			Time Zero, Site 2	1.27E+06		
			Time Zero, Site 3	1.41E+06		
			Test, Site 1	5.50E+01	99.995%	4.32
			Test, Site 2	3.00E+01	99.998%	4.63
			Test, Site 3	6.00E+01	99.996%	4.37
Limit of detection for this assay was 5.00E+00 PFU/Carrier. All enumerations below this limit of detection were written as <5.00E+00.						

Table 9: Results of 30-minute cycle UVC and Heat Against *S. aureus* ATCC 6538.

Test Microorganism	Test Setting	Test Carrier	Sample ID/Location	CFU/Carrier	Percent Reduction Compared to Time Zeroes	Log Reduction Compared to Time Zeroes
Staphylococcus aureus ATCC 6538	UVC and Heat (120°F) (30 Minutes)	Glass Slides	Time Zero, Site 1	8.60E+06	N/A	
			Time Zero, Site 2	9.25E+06		
			Time Zero, Site 3	8.05E+06		
			Test, Site 1	<5.00E+00	>99.99994%	>6.24
			Test, Site 2	<5.00E+00	>99.99995%	>6.27
			Test, Site 3	<5.00E+00	>99.99994%	>6.21
Limit of detection for this assay was 5.00E+00 CFU/Carrier. All enumerations below this limit of detection were written as <5.00E+00.						

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Results, Continued (NG20913)

Table 10: Results of 15-minute cycle UVC Against *S. aureus* ATCC 6538.

Test Microorganism	Test Setting	Test Carrier	Sample ID/Location	CFU/Carrier	Percent Reduction Compared to Time Zeroes	Log Reduction Compared to Time Zeroes
Staphylococcus aureus ATCC 6538	UVC (15 Minutes)	Glass Slides	Time Zero, Site 1	8.60E+06	N/A	
			Time Zero, Site 2	9.25E+06		
			Time Zero, Site 3	8.05E+06		
			Test, Site 1	2.50E+02	99.9971%	4.54
			Test, Site 2	3.50E+02	99.996%	4.42
			Test, Site 3	1.50E+02	99.9981%	4.73
Limit of detection for this assay was 5.00E+00 CFU/Carrier. All enumerations below this limit of detection were written as <5.00E+00.						

Table 11: Results of 30-minute cycle UVC and Heat Against *E. coli* ATCC 8739.

Test Microorganism	Test Setting	Test Carrier	Sample ID/Location	CFU/Carrier	Percent Reduction Compared to Time Zeroes	Log Reduction Compared to Time Zeroes
Escherichia coli ATCC 8739	UVC and Heat (120°F) (30 Minutes)	Glass Slides	Time Zero, Site 1	3.80E+06	N/A	
			Time Zero, Site 2	5.65E+06		
			Time Zero, Site 3	2.40E+06		
			Test, Site 1	<5.00E+00	>99.99987%	>5.88
			Test, Site 2	<5.00E+00	>99.99991%	>6.05
			Test, Site 3	<5.00E+00	>99.9998%	>5.68
Limit of detection for this assay was 5.00E+00 CFU/Carrier. All enumerations below this limit of detection were written as <5.00E+00.						

Table 12: Results of 15-minute cycle UVC Against *E. coli* ATCC 8739.

Test Microorganism	Test Setting	Test Carrier	Sample ID/Location	CFU/Carrier	Percent Reduction Compared to Time Zeroes	Log Reduction Compared to Time Zeroes
Escherichia coli ATCC 8739	UVC (15 Minutes)	Glass Slides	Time Zero, Site 1	3.80E+06	N/A	
			Time Zero, Site 2	5.65E+06		
			Time Zero, Site 3	2.40E+06		
			Test, Site 1	5.00E+01	99.9987%	4.88
			Test, Site 2	5.00E+02	99.991%	4.05
			Test, Site 3	5.00E+02	99.98%	3.68
Limit of detection for this assay was 5.00E+00 CFU/Carrier. All enumerations below this limit of detection were written as <5.00E+00.						

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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