MICROCHEM LABORATORY

STUDY REPORT

Study Title

Antibacterial Activity and Sanitizing Efficacy of ClorDiSys's Lantern UV Device

Test Method

ASTM International Method E1153 Modified for Devices
Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces

Study Identification Number

NG7440

Study Sponsor

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Test Facility

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Testing performed by: B. Richard, B.S.

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

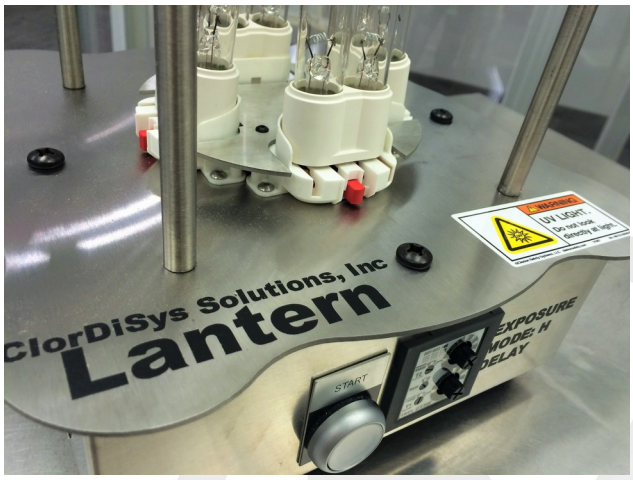
Microchem Laboratory began conducting the ASTM E1153 test method in 2007. Since then, the laboratory has performed hundreds of ASTM E1153 tests on a broad array of test substances, against a myriad of bacterial and fungal species. The laboratory is also experienced with regard to modifying the test method 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.

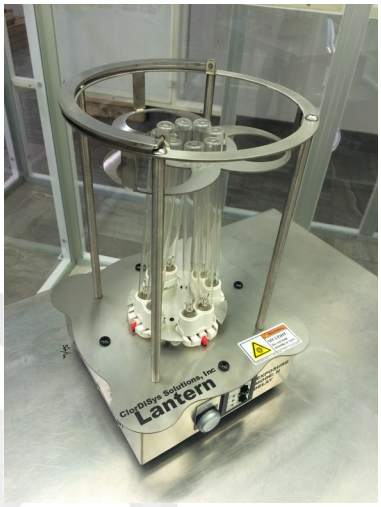
Study Timeline

N/A Spore Stock	15 JUL 2016	15 JUL 2016	18 JUL 2016	27 JUL 2016

Test Device Information

The test device was received on 13 JUL 2016 and the following pictures were taken:



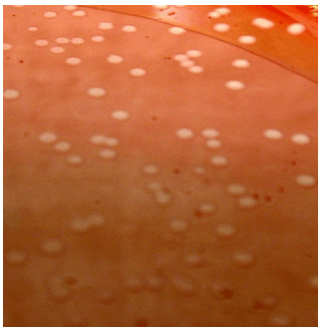


Note: the photos above depicts the test device evaluated in this study

Test device received: ClorDiSys Solutions' Lantern UV system

Test Microorganism Information

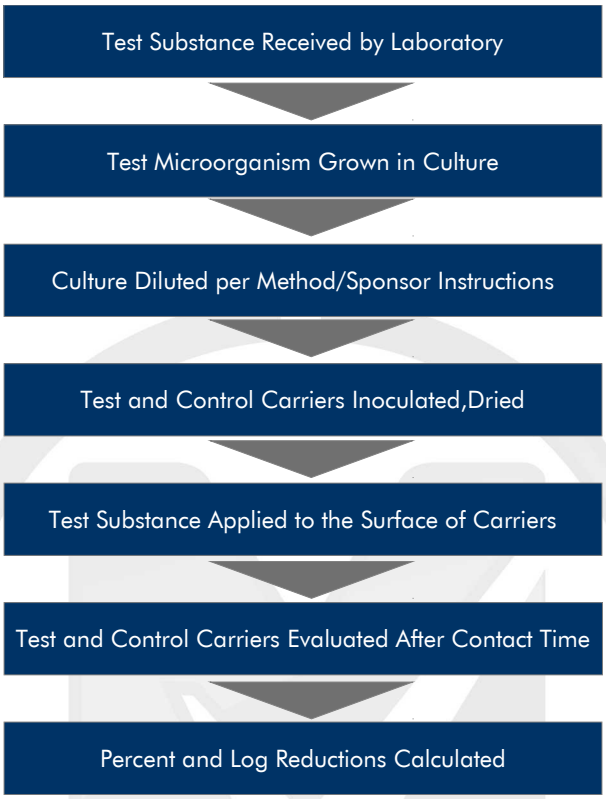
The test microorganism(s) selected for this test:



***Clostridium difficile* 43598**

This bacteria is a Gram-positive, rod shaped, endospore generating obligate anaerobe. *Clostridium* species are part of the normal human gut flora that produce spores which are highly resistant to chemical and environmental conditions. *C. diff* is commonly associated with hospital acquired infections and is know to cause antibiotic assisted colitis. Because of it's high resistance to antimicrobials, *C. difficile* is a benchmark bacteria for sporicidal and sterilant activity of chemicals.

Diagram of the Procedure



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. Inoculated slides are dried. Only completely dried carriers are used in the test.
- Test carriers are treated with the test device and incubated 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 chemically neutralized.
- Dilutions of the neutralized test substance are evaluated using appropriate growth media to determine the surviving microorganisms at the respective contact time.
- The effect of the test substance is compared to the effect of the control substance in order to determine microbial reductions.

Criteria for Scientific Defensibility of an ASTM E1153 Study

For Microchem Laboratory to consider an ASTM E1153 study to be scientifically defensible, the following criteria must be met:

1. Ordinary consistency between replicates must be observed for the control carriers.
2. Positive/Growth controls must demonstrate growth of appropriate test microorganism.
3. Negative/Purity controls must demonstrate no growth of test microorganism.

Passing Criteria

Due to the modified nature of testing, the study sponsor may determine success criteria.

Testing Parameters used in this Study

C. difficile 43598 (Endospores)			
Carrier size and type	1" x 3" glass slides	Replicates	3
Culture growth media	N/A Spore Stock	Incubation time	24-72 hours
Culture dilution media	Trip-part Soil	Culture supplement	Trip-part Soil
Target concentration	~1 x 10^6 CFU/Carrier	Inoculum volume	0.010ml
Contact time	5, 15, and 30 minutes	Contact temperature	Ambient
Carrier distances	4 feet	Neutralizer (Vol.)	Dey Engley Broth (20 ml)

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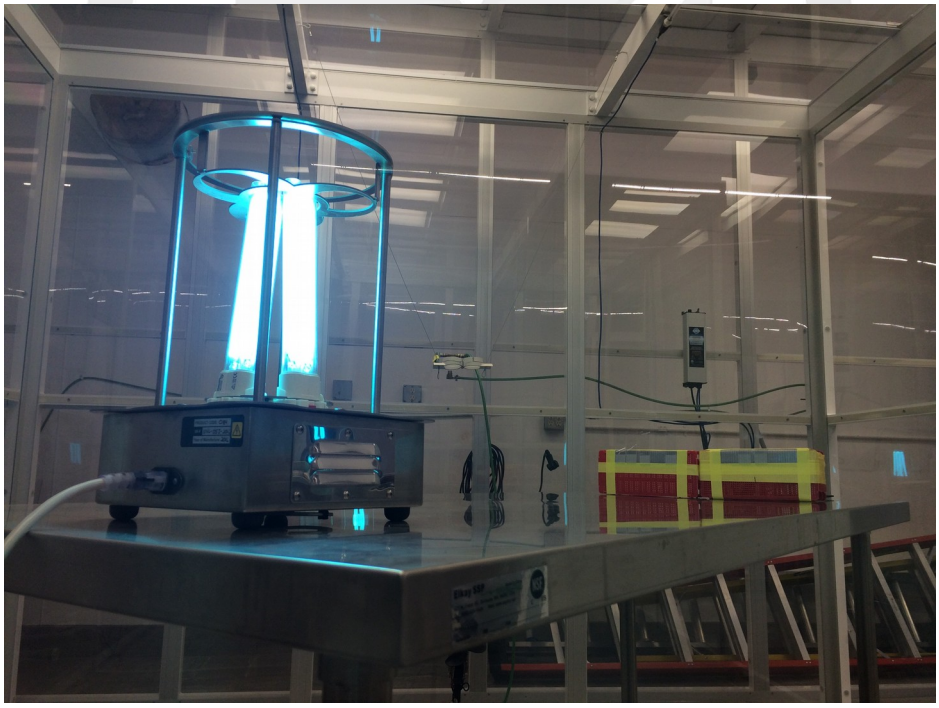
Study Notes

The device was plugged into the outlet inside the chamber. The timer for the device was set for longer than the designated contact time. The device was manually shut off by the scientist at the contact time.

Carriers were dried at ambient (room) temperature (~23°C) for approximately 20 minutes until visibly dry. Carriers were aseptically placed onto the carrier holder immediately after drying. The device operated on a light switch that was outside of the test chamber.

The carriers were treated for 5 minutes three of the nine carriers were harvested. Carriers were then treated for an additional 10 minutes to total 15 minutes and an additional three carriers were harvested. The device was run for a final 15 minutes to total 30 minutes and the last three carriers were harvested.

Study Photographs



The photograph above depicts the device operating in the chamber. The carriers being treated are attached to the carrier holders at t 4 foot distance.

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Control Results

Neutralization Method: Not applicable
Growth Confirmation: Confirmed
Media Sterility: Confirmed

Calculations

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

Where:
B = Number of viable test microorganisms on the control carriers
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
A = Number of viable test microorganisms on the test carriers after the contact time

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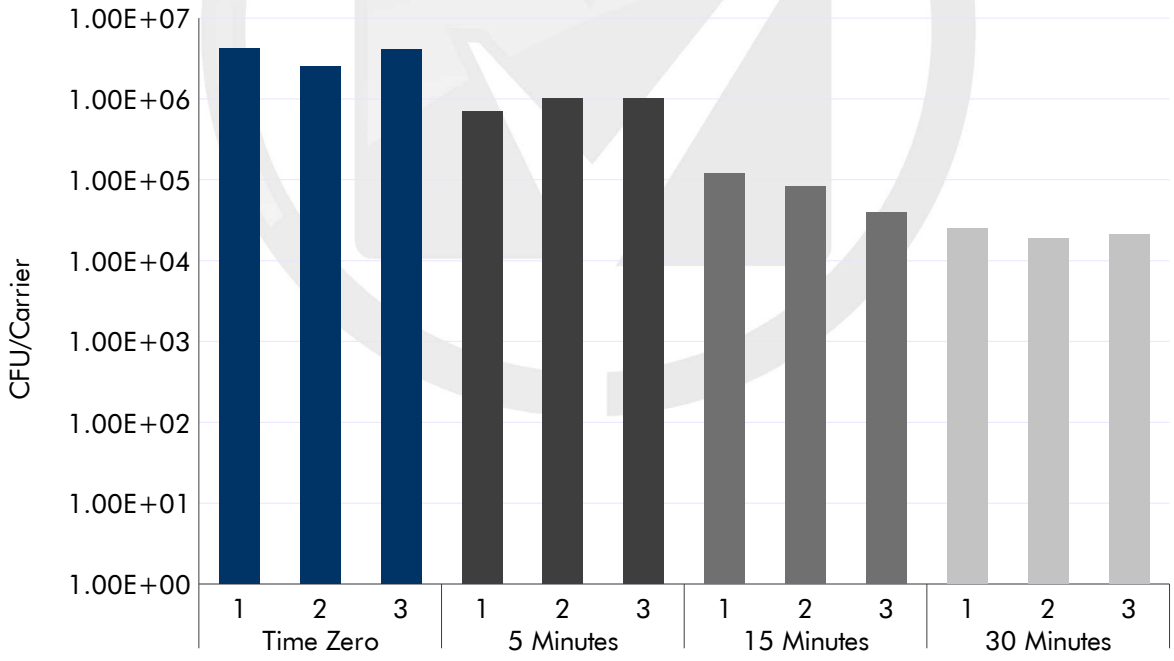
Results of the Study (*C. difficile* 43598)

Microorganism	Test Device	Contact Time	Replicate	Replicate CFU/Carrier	Average CFU/Carrier	Percent Reduction vs. Time Zero Control	Log_{10} Reduction vs. Time Zero Control
C. difficile ATCC 43598 Endospores	ClorDiSys' UV Lantern	Time Zero	1	4.20E+06	3.60E+06	N/A	
			2	2.50E+06			
			3	4.10E+06			
		5 Minutes	1	7.00E+05	9.00E+05	75.0%	0.60
			2	1.00E+06			
			3	1.00E+06			
		15 Minutes	1	1.20E+05	8.07E+04	97.8%	1.65
			2	8.30E+04			
			3	3.90E+04			
		30 Minutes	1	2.50E+04	2.17E+04	99.4%	2.22
			2	1.90E+04			
			3	2.10E+04			



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