MICROCHEM LABORATORY

STUDY REPORT

Study Title

Efficacy of Integrated UVC Solutions LLC's Spectra 1000

Test Method

Modified ASTM E1153 Method

Study Identification Number

NG21121

Study Sponsor

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Test Facility

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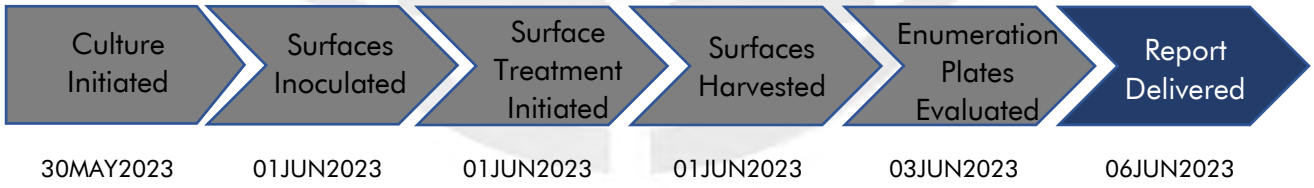
ASTM E1153: General Information

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



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Test Substance Information

The test device and belt carriers were received on 04MAY2023.

Test Cycle Information

- Carriers placed 5 feet from the device and UV activated for 10 minutes.
- Carriers placed 10 feet from the device and UV activated for 15 minutes.

Test Microorganism Information

The test microorganism(s)selected for this test:

***Candida auris* AR Bank #0381**

This fungi grows as a yeast and is ascomycetous. *C. auris* is an emerging pathogen and the epidemiology for transmission is still under investigation. Infections have most often occured in hospitalized patients and healthcare facilities. This yeast has developed resistance to commonly used antifungal drugs and specialized laboratory methods are needed to accurately identify *C. auris* infections. Because of this, *C. auris* infections are increasingly difficult to identify and treat.

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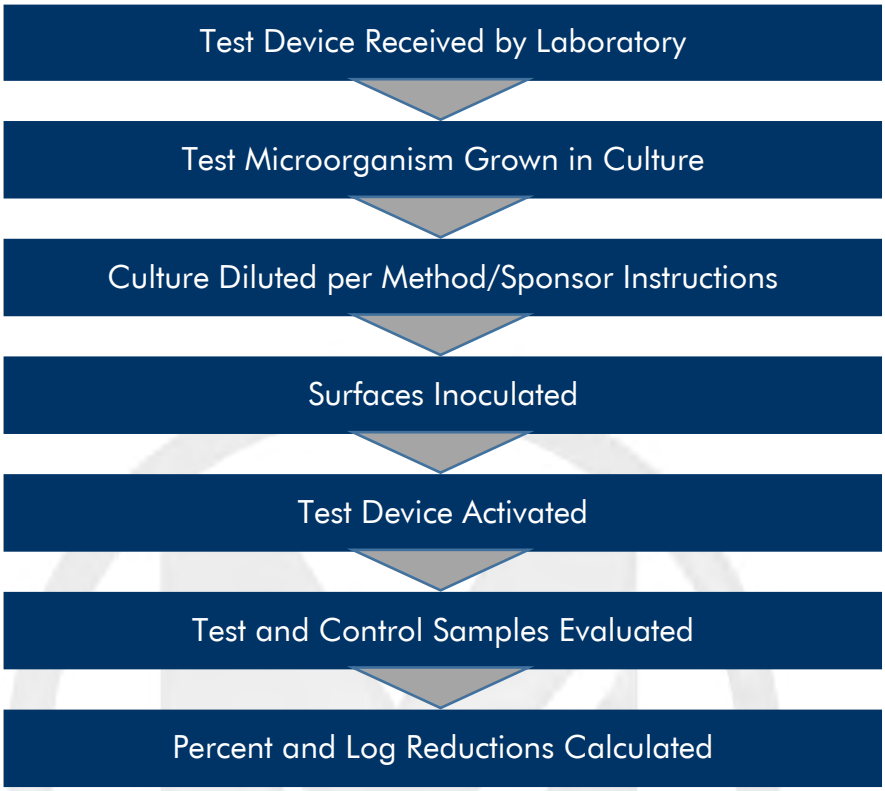
Diagram of the Procedure



Summary of the Procedure

- The test microorganism is prepared, usually by growth in liquid culture medium or on an appropriate agar plate.
- Sterilized carriers are inoculated with a volume of the test culture. Inoculated carriers are dried. Only completely dried carriers are used in the test.
- Test carriers are treated with the test device for the predetermined contact time.
- Control carriers are harvested prior to beginning the contact times.
- At the conclusion of the contact times, test carriers are harvested.
- Dilutions of the control and test samples are evaluated using appropriate growth media to determine the surviving microorganisms at the respective contact times.

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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. The average number of viable bacteria recovered from the time zero samples must be approximately 1 x 10^5 cells/carrier or greater. (See Study Notes)
2. Positive/Growth controls must demonstrate growth of the appropriate test microorganism. (See Study Notes)
3. Negative/Purity controls must demonstrate no growth of test microorganism.

Passing Criteria

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

Testing Parameters

Carriers (Size):	1″ x 3″ Glass Slides	Replicates:	Triple

Culture Growth Media:	Potato Dextrose Agar
Culture Growth Time:	48±4 hours
Culture Dilution Media:	Phosphate Buffered Saline
Inoculum Volume:	0.020 ml
Time Zero Concentration:	≥1.0 x 10^5 CFU/Carrier
Contact Temperature:	Ambient
Contact Times:	10 and 15 Minutes
Contact Distance:	5 and 10 Feet
Neutralizer (Vol.):	Phosphate Buffered Saline (20 ml)
Enumeration Media:	Potato Dextrose Agar
Enumeration Plate Incubation Time:	24-48 hours
Enumeration Plate Incubation Temperature:	30□ ± 2□

PARAMETERS

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Study Notes

The test carriers were positioned where the middle of the glass slides would be at approximately 3 feet above the floor. The inoculated locations were oriented to face the Spectra 1000 throughout the test cycles. Please see Figure 1. and 2. in the "Study Photo" section.

The device was activated for approximately 10 minutes with the carriers positioned approximately 5 feet away. The device was then activated for approximately 15 minutes with the carriers positioned approximately 10 feet away.

The settings used were Location/Building: NEWBUILDING1, Location/Room Number: custo, Location/Room Type: Treatment/Exam Room, and Room/Isolation: N/A. The appropriate contact time was then chosen.

Study Photo

Figure 1. Carrier orientation at 10 feet.

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Study Photo

Figure 2. Carrier orientation at 10 feet while Test Device was activated.

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Control Results

Neutralization Method:	N/A	Media Sterility:	Sterile
Growth Confirmation:	Pure and Viable		

Calculations

CFU/ml= ((Count 1+Count 2))/2 x 10^DF

CFU/carrier = CFU/ml * Total Sample Volume

CFU is colony forming units
DF is the dilution factor plated

Percent Reduction = [(B – A) / B] x 100

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

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

Table 1. Results of *Candida auris* CDC AR BANK 381

Test Microorganism	Device	Contact Time	Replicate	CFU/Carrier	Average CFU/Carrier	Average Percent Reduction Compared to Controls	Average Log10 Reduction Compared to Controls
Candida auris CDC AR BANK 381	N/A	Time Zero	Control 1	1.24E+06	1.89E+06	N/A	
			Control 2	2.01E+06			
			Control 3	2.41E+06			
	Spectra 1000	5 Ft 10 Minutes	Replicate 1	<1.00E+01	<4.50E+02	>99.98%	>3.62
			Replicate 2	1.00E+01			
			Replicate 3	1.33E+03			
		10 ft 15 Minutes	Replicate 1	3.90E+03	1.93E+03	99.898%	2.99
			Replicate 2	9.00E+02			
			Replicate 3	1.00E+03			
The limit of detection for this assay was 1.00E+01 CFU/carrier. For all values below this amount, the value is recorded as <1.00E+01.							

RESULTS

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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