Study Report: GLP2940

GLP Device Study Based on the ASTM E1153 Surface Time Kill Against C. difficile

UVC Disinfecting Cabinet, Model UVC-18-75-1

PUREWORKS

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2-6-2022

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BRIEF OVERVIEW OF PRODUCT

The UVC Disinfecting Cabinet, Model UVC-18-75-1 is manufactured by UVC Hygenix Inc dba PureWorks.

The UVC LED Disinfecting Cabinet is designed to decontaminate contents from harmful viruses and bacteria while providing a safe environment for the workplace. By optimally positioning UVC LED modules inside the cabinet to eliminate blind spots, contents are disinfected within one minute. Additional safety features include a digital timer and an interlock cabinet door to ensure the UVC modules cannot be powered on until the cabinet door is securely closed. Controls include On-Off Power, timer control, safety door interlock, and in use LED indicator. This technology is covered by one or more patent applications, including U.S. Pat. App. S/N 62/706,059.

An image of the cabinet is shown in Figure 1 below.

Figure 1 UVC Disinfecting Cabinet, Model UVC-18-75-1

1 INTRODUCTION

UVC Hygenix Inc DBA PureWorks, the manufacturer of UVC Hygenix Inc subcontracted Blackbriar Regulatory Services, LLC (BRS) to conduct studies supporting the label claim about the device's efficacy against the specified microorganisms.

BRS, in collaboration with a qualified laboratory (Michrochem Laboratory, Texas, USA) prepared a Study Protocol using experimental design and specified test method.

Testing was performed in accordance with Good Laboratory Practice Standards (GLPS) stipulated by US EPA 40 CFR Por1 160 as well as the US EPA Product Performance Test Guidelines outlined in OCSPP 810.2200.

Blackbriar Regulatory Services, LLC (BRS) was acquired by Accorto Regulatory Solutions, LLC, while the studies were still ongoing. Upon completion of the testing, the report was issued by Accorto Regulatory Solutions, LLC (Accorto).

2 PURPOSE

The purpose of this study was to document the antimicrobial resistance and susceptibility of the test device against the test system (microorganism) under the test parameters specified in this protocol. The device's efficacy was evaluated using a test method based on ASTM E1153 Surface Time Kill Test. The test protocol was prepared with the intention to verify specific antimicrobial claims supported by relevant test systems (microorganisms) outlined in the US EPA 40 CFR 160 and in EPA Product Performance Test Guidelines, OCSPP 810.2200, Disinfectants for Use on Environmental Surfaces - Guidance for Efficacy Testing.

3 SCOPE AND APPLICATION

The test device was subjected to a microorganism that had been dried onto the surface of a carrier (representing a hard, nonporous surface) and held for the specified contact time. At the conclusion of the contact time, the recovered microorganism was assayed. Plate recovery and cell culture controls were performed concurrently with the test.

3.1 Test Device

The details for the test Device, UVC Disinfecting Cabinet, are summarized in Table 1 below.

Table 1 Test Device Description

Item	Description
Test Device	UV-C LED Disinfecting Cabinet (or UVC Disinfecting Cabinet)
Model	UVC-18-75-1
Received date	11/09/2021
Form	UV-C Device
Storage Conditions	Ambient room temperature

3.2 Experimental Design Information

The primary information for the experimental design is summarized in Table 2 below.

Details can be found in the Study Report for GLP2940, titled " GLP Device Study Based on the ASTM E1153 Surface Time Kill Against C. difficile

Table 2 Experimental Conditions and Details

Item	Description
Study Title	GLP Device Study Based on the ASTM E1153 Surface Time Kill Against C. *difficile*
Study ID	GLP2940
Protocol ID	P3640
Test Microorganism	*Clostridioides difficile* ATCC 43598 (Endospores)
Organic Soil Load	none
lnoculum Volume	0.020 ml
Carrier Type	Sterile Glass Slides (1 x 3 inch)
Number of Test Carriers	Two
Contact Time	1 minute

Table 2 Experimental Conditions and Details

Item	Description
Exposure Temperature	Ambient room temperature (19.6° C) and relative humidity (RH)(36.1%)
Neutralization Method	NA
Experimental Start Date/Time	12/20/2021/ 11:45
Experimental End Date/Time	12/22/2021/14:50
Study Completion Date	01/28/2022

3.2.1 Test Procedure

Clostridioides difficile ATCC 43598, originally received from the American Type Culture Collection (ATCC), Manassas, VA, was used in this study. The Microchem Laboratory lot number used in testing was CD21SEP2021A.

The test device was set up and operated per the device manual. The interior of the device was not wiped down prior to testing. The device rack was placed on the top level during testing. The test device was placed on a flat surface and powered on when the device switch was flipped to the ON position, as indicated by the green light on the front of the device. Photos of the setup were taken. A device warm-up cycle was not performed prior to testing.

An appropriate number of sterile 1" x 3" glass slides, free from scratches, chips, or cracks, were soaked in 70-95% reagent alcohol to remove oil and film. The carriers were then thoroughly rinsed in tap water, followed by two rinses in deionized water and dried using a lint-free cloth. The dry carriers were placed on a drying rack, covered in aluminum foil and autoclave sterilized on a fast/dry cycle for ≥20 minutes at approximately 121° C. The carriers were placed into a 36±1°C incubator to dry after sterilization. Inside a biosafety cabinet, sterile carriers were aseptically transferred using sterile forceps to individual Petri dishes.

The test culture was propagated internally by Microchem Laboratory personnel per EPA SOP MP- 28. The prepared spore stock was stored at -70° C ± 10° C. On the day of testing, a cryovial of spore stock was removed from cryostorage and thawed. As no soil load was requested, 0.160 mL of phosphate buffered saline (PBS) was added to the 0.34mL of the thawed spore suspension.

A total of six carriers were inoculated with 0.020 mL of the test culture in a biological safety cabinet. The inoculum was spread on approximately 1 in2 of each carrier, ensuring the inoculum did not touch the edge. Each carrier was covered immediately after inoculation. The carriers were then placed in an environmental chamber to dry for 48 minutes and 20 seconds at 36.0 − 36.1° C in a relative humidity of 41 − 42%.

Using sterile forceps, two dried, inoculated carriers were aseptically placed directly onto the test device rack, and the device door was shut and secured. Timer on device was set to 2 minutes, and the blue button pressed to begin treatment at an ambient exposure temperature of 19.6° C in a relative humidity of 36.1%. The red indicator light was on for the duration of 2 minutes. At the conclusion of the contact time, once the device had been turned off, each carrier was removed from the device and immediately harvested into conicals containing 20 mL of sterile PBS, supplemented with 0.1% Tween-80 (PBS-T). After harvesting, the carriers were then vortex mixed for 1 minute.

The following controls were used during the experiment:

- Harvesting of Control Carriers
- Enumeration of Test and Control Carriers
- Carrier Sterility Control
- Media Sterility Control
- Test Microorganism Purity Control

Harvested carriers were serially diluted 1:10 in sterile PBS and plated using spread plating techniques. The dilutions targeted a countable range of 25 − 250 CFU/plate. Plates with counts >250 were recorded as "Too Numerous To Count" (TNTC). Only counts from a single dilution were used for calculations however all dilutions plated were recorded, including counts of "0" and "TNTC".

All test materials were incubated for 48 hours and 17 minutes at 35.9° C − 36.0° C.

Data obtained from the final reading are documented in the Results section of this report.

3.3 Acceptance Criteria

The experimental success (controls) criteria follow::

- The test microorganism must demonstrate a concentration of at least 2.5×10^4 CFU/Carrier.
- All media sterility controls demonstrate no growth.
- The carrier sterility control demonstrates no growth.
- The test microorganism purity control plate demonstrates the presence of the target microorganism and the absence of contaminant microorganisms.

4 STUDY RESULTS

Study results are summarized in Table 3 below.

Table 3 Study Results Summary

Test Microorganism	Carrier Designation	Replicate	CFU/Carrier	Average CFU/Carrier	Percent Reduction Compared to Control	Log10 Reduction Compared to Control
C. *difficile* ATCC 43598	Control	1	4.07E+06	4.35E+06	N/A	
		2	4.63E+06			
	Test	1	3.64E+05	3.85E+05	91.16%	1.05
		2	4.05E+05			

Detailed data for each test can be found in Study Report GLP2940.

5 STUDY CONCLUSIONS

The purpose of the study was to determine the sporicidal efficacy of UV-C LED Disinfecting Cabinet (model: UVC-18-75-1), against *Clostridioides difficile* ATCC 43598 (endospores), with no organic soil load, at a contact time of 2 minutes at ambient room temperature (19.6° C) and relative humidity (36.1%).

The evaluated test device, UV-C LED Disinfecting Cabinet (model: UVC-18-75-1), demonstrated an average 1.05 $\log_{10}$ reduction as compared to the corresponding time zero controls.

No microbial contamination of any media or test culture was observed during the course of the study.

This study was carried out in compliance with the approved protocol. All experimental controls met the established acceptance criteria unless otherwise noted in the Protocol Changes Section the report GLP2940.

There were no circumstances that may have affected the quality or the integrity of the data.

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6 REFERENCES

- Study Protocol P3640, Titled" GLP Device Study Based on the ASTM E1153 Surface Time Kill Against C.difficile", by Microchem Laboratory
- Study Report GLP2940 Titled" GLP Device Study Based on the ASTM E1153 Surface Time Kill Against C.difficile", by Microchem Laboratory, completed 01/28/2022