

ACUVA TECHNOLOGIES INC.

TEST REPORT

SCOPE OF WORK

ASTM E1153, Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces
Evaluation of ACUVA Handheld Disinfection Device against SARS-CoV-2

REPORT NUMBER

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TEST REPORT FOR ACUVA TECHNOLOGIES INC.

Report No.: 104493277CRT-002

Date Issued: December 23, 2020

MANUFACTURERAcuva Technologies Inc.
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Canada**Project Summary****Scope of Work:****ASTM E1153, Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces. The procedures in the referenced document are adapted for use with a UV-based product.**

This study will consist of one (1) test trial that will evaluate three (3) replicate test samples at four (4) disinfection time periods (5, 10, 15 and 20 seconds) at a fixed distance of 5 cm. The lab to perform the test at 10 seconds first and deliver preliminary results. Based on these results, Acuva will instruct what would be the exposure time for the next 3 tests.

The study will consist of the following samples:

- Twelve (12) stainless steel test samples (contaminated, disinfected)
- Three (3) dose confirmation controls (contaminated, not disinfected; validates challenge)
- Three (3) positive controls (contaminated, not disinfected)
- One (1) negative control (not contaminated, not disinfected)

AUTHORIZATION

Quote No.: Qu-01112662-2

PO No.: PO-10338

PRODUCT DESCRIPTION

Product type: ACUVA Handheld Disinfection Device

SAMPLE INFORMATION

Dates of Testing: November 29 – December 11, 2020

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TEST REPORT FOR ACUVA TECHNOLOGIES INC.

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SECTION 1

CONCLUSION

This test report completes the testing covered by proposal number Qu-01112662-2.

If there are any questions regarding the results contained in this report, or any of the other services offered by Intertek, please do not hesitate to contact the undersigned.

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12-23-2020

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SECTION 2

TEST DATA SHEETS

*Testing Performed by CUBRC, Inc. Buffalo, NY; Project No. 08252.01. Technical Report attached.



Evaluation of the Acuva™ Solarix UV-LED Portable Disinfection Device

**TECHNICAL REPORT
18 December 2020**

Prepared by:
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**Purchase Order No. USA20-0000246181
and USA20-0000246340
CUBRC Project No. 08252.01**

Prepared for:
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Evaluation of the Acuva™ Solarix UV-LED Portable Disinfection Device

TECHNICAL REPORT
18 December 2020

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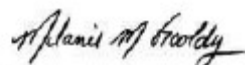
Acuva Solarix™ UV-LED Portable Disinfection Device

C08252.01-FR-02-R00

APPROVALS

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Acuva Solarix™ UV-LED Portable Disinfection Device

C08252.01-FR-02-R00

TABLE OF CONTENTS

APPROVALS	III
LIST OF TABLES	IV
LIST OF FIGURES.....	IV
1. EXECUTIVE SUMMARY.....	1
2. TECHNICAL APPROACH.....	1
2.1 TEST MATRIX	1
2.2 SAMPLES AND CONTROLS	1
3. TEST PROCEDURES	2
3.1 TEST PREPARATION	2
3.2 TEST PROCEDURE	2
3.3 CALCULATIONS OF DISINFECTION EFFICACY	3
4. RESULTS AND DISCUSSION	4

LIST OF TABLES

TABLE 1 – CONTROL SAMPLE RESULTS	4
TABLE 2 – TEST RESULTS (7-SECOND EXPOSURE AT 5 CM)	5
TABLE 3 – TEST RESULTS (5-SECOND EXPOSURE AT 5 CM)	5
TABLE 4 – TEST RESULTS (2-SECOND EXPOSURE AT 5 CM)	5

LIST OF FIGURES

FIGURE 1: SAMPLE TYPES AND QUANTITIES FOR A TEST TRIAL	1
FIGURE 2: ACUVA™ SOLARIX DEVICE WITH COUPON	2
FIGURE 3: INOCULATED TEST SAMPLES BEFORE AND AFTER DRYING	3
FIGURE 4: TEST SAMPLE DISINFECTION WITH THE ACUVA™ SOLARIX DEVICE	3
FIGURE 5: EXAMPLE PLAQUE ASSAY TEST RESULTS	4

1. EXECUTIVE SUMMARY

CUBRC performed a series of laboratory experiments to evaluate the performance of the Acuva™ Solarix UV-LED Portable Disinfection Device against SARS-CoV-2 on stainless steel surfaces. Three test conditions were evaluated consisting of 7-second, 5-second, and 2-second UV-C exposures at a 5-cm standoff distance. The results demonstrate that the Acuva™ Solarix UV-LED Portable Disinfection Device achieved viral inactivation (i.e., viral particles rendered non-infectious) of 2.80-log reduction corresponding to 99.81% inactivation at the 7-second exposure time, 2.35-log reduction corresponding to 99.53% inactivation at the 5-second exposure time, and 1.90-log reduction corresponding to 98.72% inactivation at the 2-second exposure time.

Testing was performed within CUBRC's CDC-permitted Biosafety Level 3 facility. All work was performed in accordance with external regulatory requirements and following approved internal safety and technical protocols. The experiments covered in this technical report were performed over the period beginning 29 November 2020 and ending 11 December 2020.

2. TECHNICAL APPROACH

CUBRC used a modified test protocol using ASTM E1153, *Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces*, as guidance to prepare an internal Standard Operating Procedure (SOP) that adapted the procedures in the referenced document for use with SARS-CoV-2 and UV-based disinfection products. The SOP, titled *Standard Operating Procedure for the Evaluation of UV-C and Ozone Sanitizers Recommended for Inanimate Non-Food Contact Surfaces* (Document ID No. SOP-ASTM-E1153) was used to conduct the testing.

2.1 Test Matrix

Three test trials were performed to evaluate the device at a 7-second, 5-second, and 2-second exposure time. Testing was performed using stainless steel test samples.

2.2 Samples and Controls

To ensure that the test procedures produce dependable and defensible results, CUBRC included the following samples in the test trial: 1) Test Samples – these are the samples that receive the full test process to include inoculation, drying, disinfection, extraction and analysis; 2) Positive Control Samples – these samples serve to define the baseline challenge (contamination level), from which efficacy can be calculated, and receive inoculation, drying, extraction and analysis (i.e., no disinfection); and 3) Negative Control Samples – these serve to ensure that the test method doesn't introduce errant contamination and receive disinfection, extraction and analysis (i.e., no inoculation). Figure 1 presents the quantities of each sample type in the test trial.

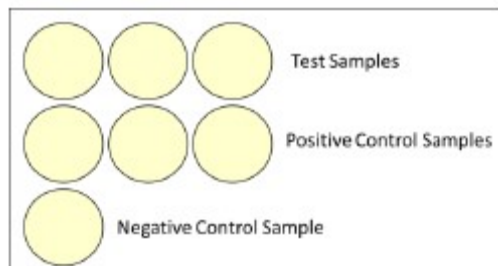


Figure 1: Sample Types and Quantities for a Test Trial

3. TEST PROCEDURES

3.1 Test Preparation

One day before the test trial, one 12-well plate was prepared for each test sample by seeding each well with Vero E6 (ATCC CRL-1586) cells and incubating overnight to produce host cell monolayers in each well at approximately 90% confluency. On each plate, three wells were dedicated to controls and the remaining nine wells were used for triplicate analyses of each of undiluted test sample, 10-fold diluted test sample and 100-fold diluted test sample. Seven 12-well plates were prepared for the trial to accommodate the three test samples, the three positive controls and one negative control.

3.2 Test Procedure

On the day of the test, the Acuva™ Solarix UV-LED Portable Disinfection Device was placed within the biosafety cabinet (BSC) in preparation for the disinfection treatment as shown in Figure 2. The device was positioned into the holder, as shown to achieve an accurate and consistent distance of 5 cm.

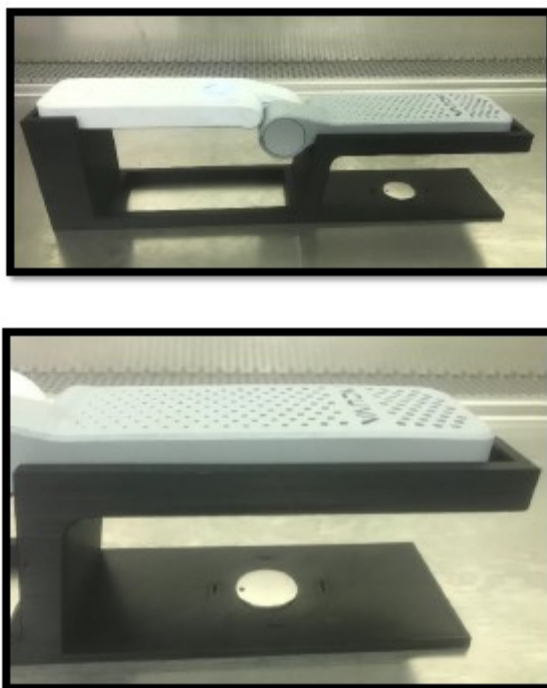


Figure 2: Acuva™ Solarix Device with Coupon

Small circular stainless steel coupons were laid out in the BSC, inoculated with 100 μ L of viral preparation and allowed to dry for 45 minutes (Figure 3). The viral preparation had a titer of approximately 1×10^5 plaque forming units (PFU) per milliliter, independently confirmed through the analysis of control samples where 100 μ L of the viral preparation was placed directly into pre-filled extraction tubes. Viral plaques form when a virus infects a cell within the cell monolayer. This resulted in approximately 1×10^4 PFU being placed onto each test sample.

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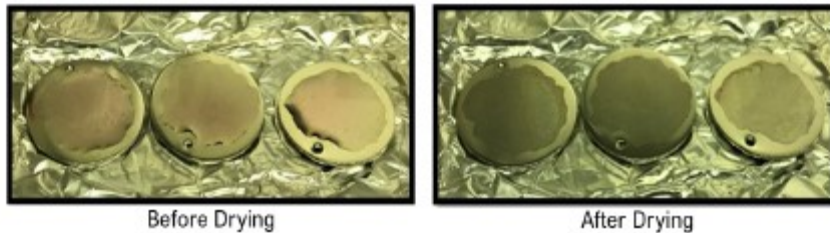


Figure 3: Inoculated Test Samples Before and After Drying

Following the drying period, test samples were placed in the BSC. At this time, the positive control samples were removed from the BSC to protect them from exposure to the UV-C disinfection.

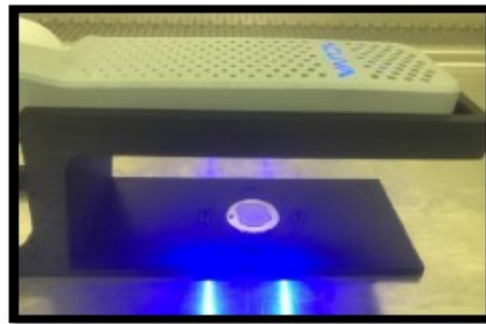


Figure 4: Test Sample Disinfection with the Acuva™ Solarix Device

One at a time, the samples were placed under the Acuva™ Solarix Device and disinfected by activating the device for 7, 5, or 2 seconds. Following disinfection, each test coupon and negative control coupon was placed into separate tubes containing prepared media consisting of Eagle's Minimal Essential Media (EMEM) with Fetal Bovine Serum (FBS). The tubes were vortexed, coupons were rinsed four times, and appropriate dilutions were performed for analysis. The positive control coupons were also placed into pre-prepared tubes for processing and analysis. Triplicate aliquots of each dilution from all samples (test samples and positive controls) were transferred onto the 12-well plates containing the confluent monolayers of host cells as described in Section 3.1. The plates were incubated at 37 °C for one hour with CO₂ and gently rocked every 15 minutes to promote virus adsorption. After the initial 1-hour incubation, the dilution aliquots were removed from each well and an overlay of microcrystalline cellulose was added to each well. The plates were incubated at 37 °C for 96 hours.

After completion of the 96-hour incubation period, the microcrystalline cellulose overlays were removed, and formalin was added to each well. The plates were incubated for one hour to allow for cell fixation and virus inactivation. The formalin was removed, and each well was washed with water, stained with crystal violet, and incubated for 10 minutes. After incubation, the crystal violet was removed, each well was washed with water, and the plates were allowed to dry. Once the plates were dry, the plaques (indicating the presence of live virus) were counted in each well.

3.3 Calculations of Disinfection Efficacy

The PFUs counted were used to perform calculations of disinfection efficacy of the Acuva™ Solarix Device as shown in the equations below.

Acuva Solarix™ UV-LED Portable Disinfection Device

C08252.01-FR-02-R00

$$\text{Log Reduction} = \log_{10}(V_c/V_s)$$

$$\text{Percent Reduction} = (1 - 10^{-LR}) \times 100\%$$

where:

V_s = number of viable organisms remaining on the test sample

V_c = average number of viable organisms on the positive control samples

LR = Log Reduction

Calculations were made for each individual test sample using the average value of the positive control samples as the value of V_c . When no plaque formation is observed on the test samples, V_s is set to < 1 PFU.

4. RESULTS AND DISCUSSION

The test results for the Acuva™ Solarix Device are presented in the tables below. Table 2 presents the results of the control samples including the inoculation controls, positive controls and negative control.

Table 1 – Control Sample Results

Sample No.	Inoculation (PFU)	Positive Control (PFU)	Negative Control (PFU)
1	1.36×10^4	4.64×10^3	0
2	-	4.17×10^3	-
3	-	6.55×10^3	-
Mean:		5.12×10^3	

The results of the control samples demonstrate that the average number of viable SARS-CoV-2 particles placed onto each sample is 1.36×10^4 PFU (see inoculation column). The drying process results in some degree of viral inactivation and this is an expected phenomenon. After drying, the average amount of viable virus remaining on the test samples was 5.12×10^3 PFU. The negative control sample showed no observable plaque formation.

Figure 5 presents typical results for the three types of samples including a negative control, positive control and a disinfected test sample. The positive control shows plaque formation indicating the presence of live virus and the negative control shows no plaque formation indicating the absence of viable virus. The test sample shown is from the 2-second UVC exposure.

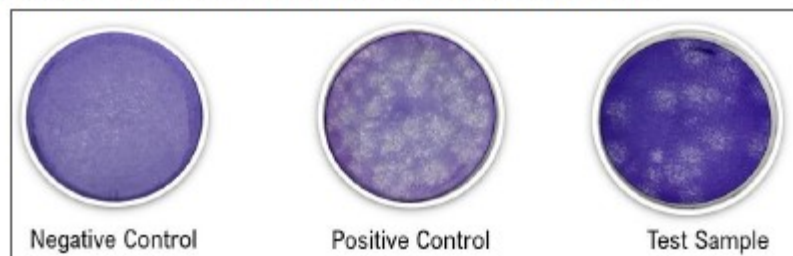


Figure 5: Example Plaque Assay Test Results

Tables 2-4 show the disinfection efficacy results for the three test conditions.

Table 2 – Test Results (7-second Exposure at 5 cm)

Test Replicate	Plaque Count (PFU/sample)	Log Reduction	Percent Reduction
Sample 1	3	3.16	99.93%
Sample 2	8	2.73	99.81%
Sample 3	13	2.52	99.70%
	Mean:	2.80	99.81%

Table 3 – Test Results (5-second Exposure at 5 cm)

Test Replicate	Plaque Count (PFU/sample)	Log Reduction	Percent Reduction
Sample 1	20	2.33	99.53%
Sample 2	26	2.22	99.40%
Sample 3	14	2.49	99.67%
	Mean:	2.35	99.53%

Table 4 – Test Results (2-second Exposure at 5 cm)

Test Replicate	Plaque Count (PFU/sample)	Log Reduction	Percent Reduction
Sample 1	68	1.80	98.42%
Sample 2	42	2.01	99.02%
Sample 3	55	1.89	98.72%
	Mean:	1.90	98.72%

The results demonstrate that the Acuva™ Solarix UV-LED Portable Disinfection Device achieved viral inactivation (i.e., viral particles rendered non-infectious) of 2.80-log reduction corresponding to 99.81% inactivation at the 7-second exposure time, 2.35-log reduction corresponding to 99.53% inactivation at the 5-second exposure time, and 1.90-log reduction corresponding to 98.72% inactivation at the 2-second exposure time.