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
104493277CRT-001

ISSUE DATE
December 18, 2020

PAGES
12

DOCUMENT CONTROL NUMBER
RT-L-US-Test-3470 (9/1/2017)

3933 US Route 11
Cortland, New York 13045

Telephone: 1-607-753-6711
Facsimile: 1-607-756-9891
www.intertek.com

TEST REPORT FOR ACUVA TECHNOLOGIES INC.

Report No.: 104493277CRT-001
Date Issued: December 18, 2020

MANUFACTURER

Acuva Technologies Inc.
Unit # 1 3771 North Fraser Way
Burnaby, BC V5J 5J2
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-01118845-1 Qu-01112662-2
PO No.:	PO-10364 PO-10338

PRODUCT DESCRIPTION

Product type: ACUVA Handheld Disinfection Device

SAMPLE INFORMATION

Dates of Testing: November 16 -25, 2020

3933 US Route 11
Cortland, New York 13045

Telephone: 1-607-753-6711
Facsimile: 1-607-756-9891
www.intertek.com

SECTION 1

CONCLUSION

This test report completes the testing covered by proposal number Qu-01118845-1.

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.

Please note: This Test Report does not represent authorization for the use of any Intertek certification marks. The observations and test results in this report are relevant only to the sample tested. Intertek makes no representations or warranties, express or implied, regarding units that were not tested including, but not limited to, units that may be part of the same lot.

Project Owner:	Kristine Perrotti	**Project Reviewer:**	Jason Allen
Title:	Engineer, Team Lead	**Title:**	Technical Advisor
Signature:		**Signature**	
Date	12-18-2020	**Date:**	12-18-2020

SECTION 2

TEST DATA SHEETS

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

CUBRC
Advantage through technology

Evaluation of the Acuva™Solarix Device

TECHNICAL REPORT
4 December 2020

Prepared by:
CUBRC, Inc.
4455 Genesee Street, Suite 106
Buffalo, New York 14225

Purchase Order No. USA20-0000246181
and USA20-0000245910
CUBRC Project No. 08252.01

Prepared for:
Intertek Testing Services NA
3933 US Route 11
Cortland NY 13045

Evaluation of the Acuva™ Solarix Device

TECHNICAL REPORT
4 December 2020

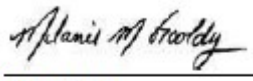
Authors:

Melanie Gooldy, M.S.
Christelle Roux, Ph.D.
Nicole Spaulding

CUBRC, Inc.
4455 Genesee Street, Suite 106
Buffalo, New York 14225

APPROVALS

Preparation

Melanie Gooldy		12/4/2020
Program Manager	Signature	Date

Technical Review

Christelle Roux, PhD		12/4/2020
Research Scientist	Signature	Date

Approval

Katie Edwards, PhD		12/4/2020
Director Biological & Medical Sciences	Signature	Date

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

1. EXECUTIVE SUMMARY

CUBRC performed a series of laboratory experiments to evaluate the performance of the Acuva™ Solarix Device against SARS-CoV-2 on stainless steel surfaces. One test condition was evaluated consisting of a 10-second UV-C exposure. The results demonstrate that the Acuva™ Solarix Device achieved viral inactivation (i.e., viral particles rendered non-infectious) exceeding 3.57-log reduction and > 99.97% at the 10-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 16 November 2020 and ending 25 November 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

One test trial was performed to evaluate the Acuva™ Solarix Device at a 10-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 defendable 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.

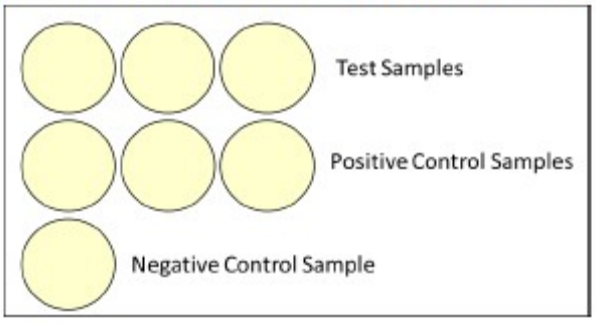


Figure 1: Sample Types and Quantities for a Test Trial

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 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.

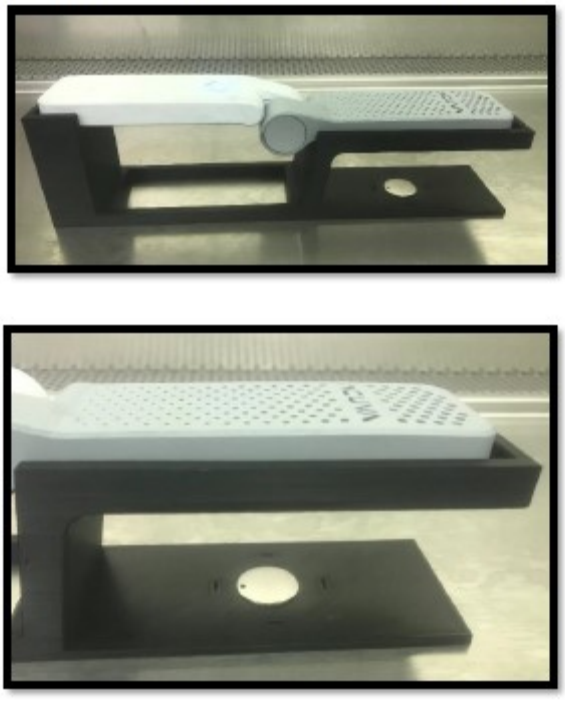


Figure 2: Acuva™ Solarix Device with Coupon

Small circular stainless steel coupons were laid out in the BSC, inoculated with 100 µL 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 µL of the viral preparation was placed directly into prefilled 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.

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.

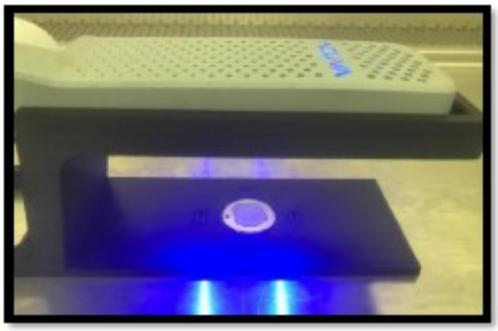


Figure 4: Test Sample Disinfection with the Acuva™ Solarix Device

One at a time, the samples were placed under the Acuva™ Solarix Device and disinfected by activating the device for 10 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 CO_2 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.

$$Log\ Reduction = \log_{10}(Vc/Vs)$$

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

where:

Vs = number of viable organisms remaining on the test sample
Vc = 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 *Vc*. When no plaque formation is observed on the test samples, *Vs* 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 2 – Control Sample Results

Sample No.	Inoculation (PFU)	Positive Control (PFU)	Negative Control (PFU)
1	1.31×10^4	3.81×10^3	0
2	-	4.05×10^3	-
3	-	3.93×10^3	-
Mean:	-	$\mathbf{3.93 \times 10^3}$	-

The results of the control samples demonstrate that the average number of viable SARS-CoV-2 particles placed onto each sample is > 1.0×10^4 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 3.93×10^3 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 representative test sample shown is from the 10-second UVC exposure test and shows no plaque formation indicating the absence of viable virus.

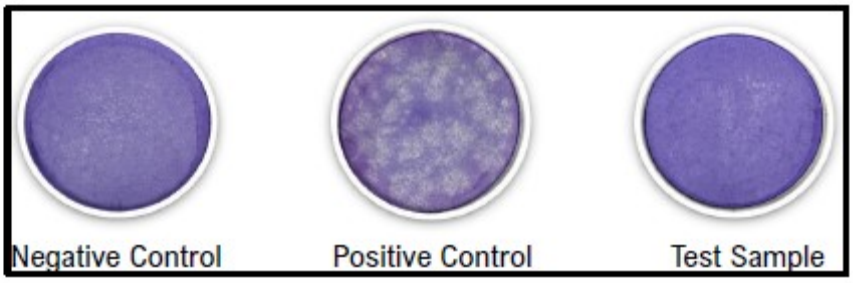


Table 3 shows the disinfection efficacy results for the trial at the 10-second exposure time for each of the three sample replicates. Note that where no plaque growth is observed, reported values are presented as *less than* one PFU and a value of one PFU is used in the calculations.

Table 3 – Test Results (10-second exposure at 5 cm)

Test Replicate	Plaque Count (PFU/sample)	Log Reduction	Percent Reduction
Sample 1	1.19	3.52	99.97%
Sample 2	< 1	> 3.59	> 99.97%
Sample 3	< 1	> 3.59	> 99.97%
	Mean:	**> 3.57**	**> 99.97%**

The results demonstrate that the Acuva™ Solarix Device achieved viral inactivation (i.e., viral particles rendered non-infectious) exceeding 3.57-log reduction and > 99.97% at the 10-second exposure time and at a distance of five centimeters.