CleanSlate UV

Product Efficacy Report SARS-CoV-2

cleanslate UV

Experience life, safely.

CleanSlate UV Mobile Device Sanitizer

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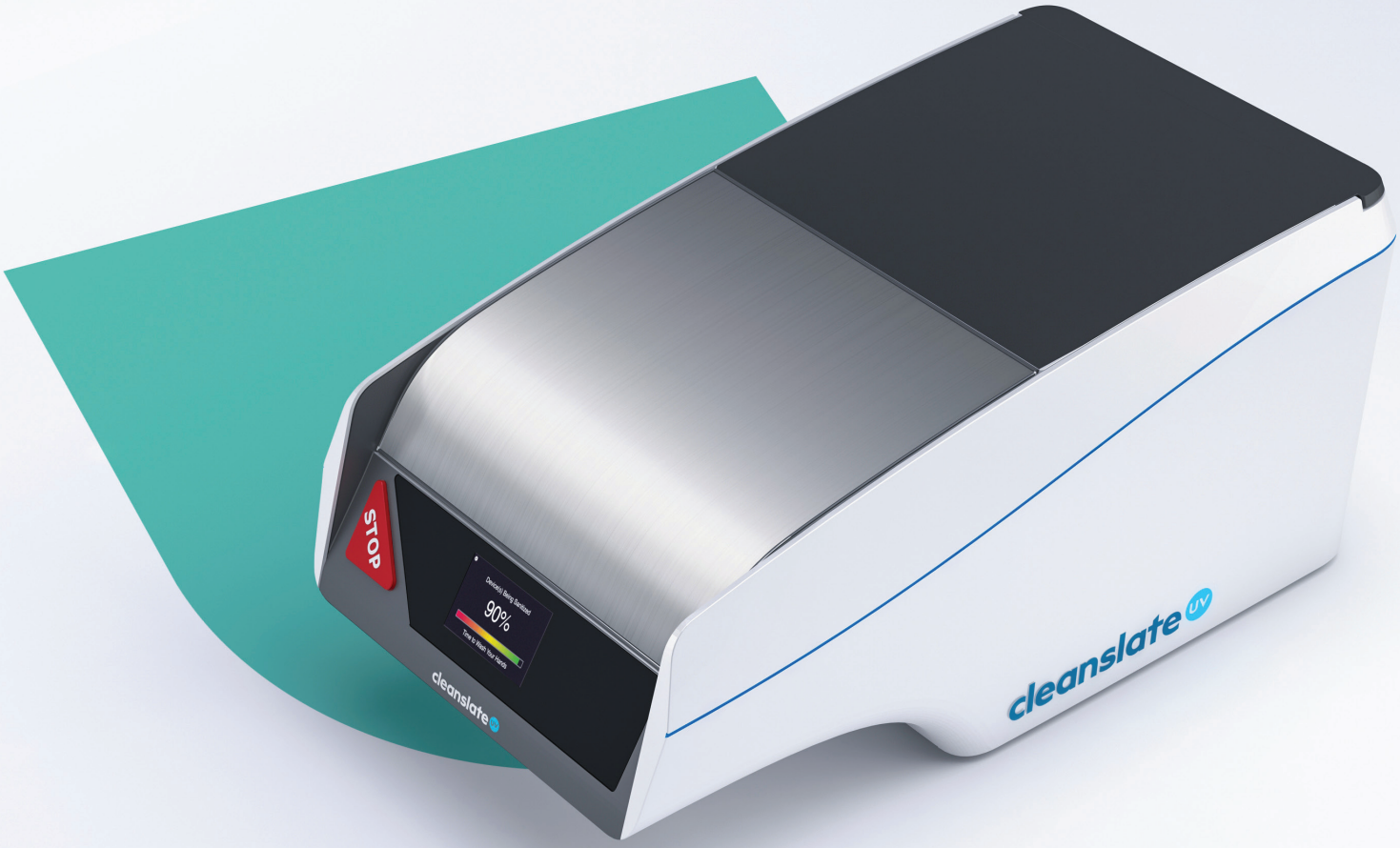

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Simple. Proven. Effective.

CleanSlate UV is the fastest and simplest way to sanitize mobile devices such as cell phones, tablets, smart watches, Spectralink phones, Vocera devices, Ascom Myco devices, and more. It takes just **20 seconds** to sanitize a device.

CleanSlate UV has demonstrated efficacy against viral and bacterial pathogens that spread by contact and can cause serious infections (Table 1). All efficacy claims have been validated using ASTM standards developed to assess microbial activity of disinfectants on inanimate, nonporous surfaces, conforming to U.S. EPA guidelines for efficacy data required for disinfectant claims. The tests were conducted at independent, leading laboratories in Canada and the US. All testing included bioburden (5% FBS) where feasible, as per standards. As such, CleanSlate UV has been tested as a **one-step sanitizer**. Pre-cleaning of lightly soiled devices is not required to achieve the kill rates herein. However, visibly or heavily soiled devices (i.e. blood spatter, food grease, etc.) should be wiped down prior to UV sanitization.

Our company's core product values are *simple, effective, and proven*. We strive not just to design great products but to prove that they perform to our customer's expectations.

CleanSlate UV and COVID-19

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), is the strain of coronavirus that causes coronavirus disease 2019 (COVID-19). One of the primary routes of transmission of COVID-19 is through physical contact with respiratory droplets deposited on a surface and subsequently transferred to respiratory mucosa.

The CleanSlate UV is capable of inactivating 99.995% (>4 log) of SARS-CoV-2 on surfaces in just 20 seconds, without the use of any chemicals.

The testing supporting this claim was conducted by a 3rd party independent laboratory (MRIGlobal) and followed the ASTM standard 1053, which conforms to U.S. EPA guidelines for efficacy data required for disinfectant claims.

Continued

Table 1. CleanSlate UV Testing Summary (20 Second Cycle).

Challenge Microorganism	% Reduction vs. Control	Log Reduction vs. Control
Clostridium difficile spores	99.97%	3.51
MS2 bacteriophage (model for norovirus)	99.9791%	3.68
SARS-CoV-2	>99.995%	>4
Salmonella enterica	>99.999%	>5.02
Escherichia coli	>99.9991%	>5.03
Enterococcus faecalis (VRE)	>99.9992%	>5.10
Methicillin-Resistant Staphylococcus aureus (MRSA)	>99.99981%	>5.71

Additional Certifications and Regulatory Compliance

CleanSlate UV is regulated by the EPA and Industry Canada. It has been certified by TUV SUD according to UL/IEC 61010-1 standards and has a CE marking. The product meets IEC 62471 standards on UV safety (exempt group) as well as FCC Part 15 Subpart B, ICES-003 and IEC 61326 standards for EMI/EMC.

Questions or Comments? Get in Touch.

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MRIGlobal

The science you expect.
The people you know.

Verification of the Effectiveness of the CleanSlate UV-C Device in Decontamination of SARS-CoV-2

Final Report

FOR

Limestone Labs Limited d/b/a CleanSlate UV

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MRIGlobal Project No. 311706.01.001

November 2, 2020

Preface

This report was prepared at MRIGlobal for the work performed under MRIGlobal Task No. 311706.01.001, "Verification of the Effectiveness of the CleanSlate UV-C Device in Decontamination of SARS-CoV-2."

The experimental phase of this task was initiated by MRIGlobal on October 15, 2020 and ended on October 20, 2020.

The test was managed and performed by Kristy Solocinski, Ph.D. She was assisted by Sam Humphrey.

The study was not performed in compliance with the FDA Good Laboratory Practice Regulations (21 *CFR* 58). All operations pertaining to this study, unless specifically defined in this protocol, were performed according to the Standard Operating Procedures of MRIGlobal, and any deviations were documented.

All study records are stored at MRIGlobal.

Sincerely,

MRIGLOBAL

Kristy Solocinski, Ph.D.
Staff Scientist
Life Sciences Division

Approved:

Claire R. Croutch, Ph.D.
Portfolio Director,
Medical Research

November 2, 2020

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Executive Summary

Objective:

The objective of this project was to determine if the CleanSlate UV device has the ability to control the replication of SARS-CoV-2 *in vitro*.

Study Design:

ASTM 1053 was used as a reference protocol for this testing. Glass slides, approximately 1x3 inches, were inoculated with 200ul of SARS-CoV-2 and allowed to dry. Once dry the glass slides were exposed to 15 and 20 second decontamination cycles. Virus was resuspended and added to an empty 96 deep well plate and diluted 1:10 from row A to row H. These dilutions were then transferred to Vero cells. After everything was added to cells, they were incubated for 5 days and then read for cytopathic effect (CPE).

Results and Conclusions:

Based on this experiment, we conclude that both the 15 and 20 second decontamination cycles were very effective at reducing SARS-CoV-2 viability on glass slides.

Section 1.
Objective

The objective of this project was to determine if the CleanSlate UV device has the ability to control the replication of SARS-CoV-2 *in vitro*. Two cycles of 15 or 20 seconds were tested on glass slides.

Section 2.
Sponsor, Testing Laboratory, and Personnel Responsibilities

2.1 Sponsor's Representative

Carolina Koutras, Ph.D.
Limestone Labs Limited d/b/a CleanSlate UV

2.2 Testing Laboratories

MRIGlobal
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2.3 Personnel Responsibilities

2.3.1 Study Director—MRIGlobal

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2.3.2 Analyst – MRIGlobal

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Section 3.
Test Conditions

3.1 Test Device

3.1.1 CleanSlate UV Sanitizer

Model: CSUV-UG6CX

3.1.2 Cell Media

DMEM/F12 (Serum-free media)
Vendor: Gibco
Lot No.: 2186786
Expiration date: 5/21

Growth Media – 5% FBS (fetal bovine serum)
Lot No.: 20200901KS
Expiration date: 3/21

3.1.3 Challenge Virus

Severe Acute Respiratory Syndrome-related Coronavirus-2 (SARS-CoV-2) (COVID-19 Virus)
Strain: USA-WA1/2020
Vendor: BEI Resources
Passage number in assay: 8

3.1.4 Host

Vero E6 Cells
Vendor: ATCC
Cat: CRL 1586
Passage number in Assay: 16

Section 4.
Test System

MRIGlobal utilized the USA-WA1/2020 strain of the virus, acquired from BEI Resources (NR-52281). This was propagated in Vero E6 cells (ATCC CRL-1586); these cells were also used for the neutralization assay. Vero E6 cells were cultured in growth media consisting of Dulbeco's Modified Eagle Medium/F12 (DMEM/F12) supplemented with 5% FBS (Fetal Bovine Serum), and PSN (penicillin, streptomycin, and neomycin).

Section 5.
Study Design

The Vero E6 cells were plated on 96-well plates the day before the assay and were allowed to grow to ~ 60%-70% confluence. On the day of the assay, coupons were inoculated with 200 µL of virus stock (2.6E6 TCID50/ml) and were left in a biosafety cabinet to dry. This took approximately 65 minutes. Glass slides were placed on an opaque black surface with the inoculated surface facing up and individually exposed to 15 and 20 second decontamination cycles. Each cycle was independently timed using the timer on a cell phone to confirm the cycle duration. The device was run using the opaque black surface to block UV rays from the lamps located below the decontamination stage from reaching the coupons.These are given in Table 1.

Table 1. Measured cycle times for the CleanSlate UV device

Sample	Measured Time (s)	Average Time (s)
GS15-1	14.48	14.535
GS15-2	14.94	
GS15-3	14.17	
GS15-4	14.55	
GS20-1	19.44	19.2775
GS20-2	18.87	
GS20-3	19.85	
GS20-4	18.95	

After all of the exposures were complete, 2 mL of DMEM/F12 media was added to glass coupons and lightly scraped with a cell scraper to aid in viral resuspension. Samples were added to an empty 96 deep well plate and diluted 1:10 down the plate in DMEM/F12. These dilutions were transferred to a plate of Vero cells with media removed. After at least 15 minutes, DMEM/F12 supplemented with FBS was added to cells to feed them for the next 5 days. This incubation period of at least 15 minutes is to allow the virus to adsorb to cells without interference from FBS. The assay was executed in four technical and five plated replicates for each condition.

After 5 days, cells were examined for the presence of cytopathic effect (CPE) associated with viral presence and replication. Examination is done using a microscope (10x objective to view the entire well at once) and observing the morphology of the cells. Healthy Vero cells are semitransparent with a fusiform appearance (pinched or narrowing ends and more round in the middle) in a monolayer of cells with little to no space between cells. Dead cells displaying CPE are often detached from the plate, round, less transparent, and much smaller than living cells. Furthermore, the healthy Vero cells cover much of the surface of the well but wells containing cells with CPE have areas of the well where no cells are adherent, described as empty space. Any well displaying CPE is marked as positive whether the whole well is affected or only a small patch as both are indicative of the presence of viable virus.

Section 6.
Statistical Analysis of Data

The number of positive and negative wells were entered into a modified Excel spreadsheet that was published as part of Lindenbach BD. Measuring HCV infectivity produced in cell culture and in vivo. Methods Mol Biol. 2009;510:329-336. doi:10.1007/978-1-59745-394-3_24. The TCID50/ml is calculated using the below equations, all using Microsoft Excel.

$$\text{Proportionate Distance (PD)} = \frac{\%\text{CPE at dilution above 50\%} - 50\%}{\%\text{ CPE at next dilution above 50} - \%\text{ CPE at next dilution below 50}}$$

$$\text{TCID50} = 10^{\text{log of dilution above 50\% CPE}} - \text{PD}$$

$$\text{TCID50/ml} = \frac{1}{\text{volume used per well}} x \frac{1}{\text{TCID50}}$$

The log10 of the three technical replicates was averaged for control and treatment samples. This number for the treatment is subtracted from the number for the control and is reported as “log reduction.” This log reduction is converted into a percent log reduction via the following equation.

$$\%\text{ Log Reduction} = 1 - 10^{-\log \text{reduction}}$$

Section 7.
Results

Plates were read 5 days after the initiation of the assay. The glass slides were successfully sterilized, removing greater than 4 logs of virus in both the 15 and 20 second tests compared to controls. Table 2 summarizes these findings.

Table 2. Wells displaying CPE after treatment with CleanSlate device

Sample Name	Sample Type	Test Description	Replicate No.	$TCID_{50}$/mL	Log10 $TCID_{50}$/mL	Average $TCID_{50}$/mL	Average Log10 $TCID_{50}$/mL	Log Reduction	Percent Log Reduction
GS15-1	Glass	15s Test	1	≤32	1.51	1.23E+03	2.05	4.19	99.99%
GS15-2			2	4.81E+03	3.68				
GS15-3			3	≤32	1.51				
GS15-4			4	≤32	1.51				
GS20-1	Glass	20s Test	1	≤32	1.51	1.32E+02	1.92	4.32	99.995%
GS20-2			2	3.16E+02	2.50				
GS20-3			3	1.47E+02	2.17				
GS20-4			4	≤32	1.51				
GSC-1	Glass	Control	1	2.37E+06	6.38	1.95E+06	6.24	N/A	N/A
GSC-2			2	2.37E+06	6.38				
GSC-3			3	2.37E+06	6.38				
GSC-4			4	6.81E+05	5.83				

Section 8.
Conclusions

Based on this experiment, we conclude that the CleanSlate UV device is highly effective at decreasing SARS-CoV-2 viability on glass surfaces. In a 15 or 20 second test, there was greater than 99.99% reduction of viable SARS-CoV-2.