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Effectiveness of the Wellisair Model WADU-02 Disinfection Purifier Against SARS-CoV-2 Contaminated Surfaces

Final Report – CO1, A

FOR

Wellis Co., Ltd.

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MRIGlobal Project No. 311732.01.001

May 26, 2021

Preface

This report was prepared at MRIGlobal for the work performed under MRIGlobal Task No. 311732.01.001, "Effectiveness of the Wellisair Model WADU-02 Disinfection Purifier against SARS-CoV-2 Contaminated Surfaces."

The experimental phase of this task was initiated by MRIGlobal on April 20, 2021 and ended on April 23, 2021.

The test was performed by and They were assisted by The project was managed by

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

Staff Scientist
Life Sciences Division

Approved:

Portfolio Director

May 26, 2021

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Executive Summary

Objective:

The objective of this project was to determine if the Wellisair Model WADU-02 Disinfection Purifier device has the ability to decrease viral infectivity of SARS-CoV-2 *in vitro* after exposure. The device was tested on SARS-CoV-2 virus inoculated on stainless steel coupons.

Study Design:

Stainless steel coupons were inoculated with 200 µL virus stock (2.37E5 $TCID_{50}$/ml of Washington 1 USA SARS-CoV-2 isolate). Virus was evenly spread over the coupons and allowed to dry. Test coupons were transferred to the testing room and placed into an aerosol test system inside a Class III Biosafety and exposed to Wellisair Model WADU-02. After the exposure time, any remaining virus was resuspended with a cell scraper and 2 ml Dulbecco's Modified Eagle Medium with supplement F-12 (DMEM/F12). Samples were diluted 1:10 down a 96 deep well plate in DMEM/F12. These dilutions were transferred to a plate of cells with media removed. After approximately 45 minutes, DMEM/F12 supplemented with 5% fetal bovine serum (FBS) was added to cells to feed them for the next three days. The inoculated plates were then read for cytopathic effects (CPE).

Results and Conclusions:

Based on these experiments, viral infectivity was reduced by 1.08 log (91.75%) after exposure to Wellisair Model WADU-02 for two hours when compared to control samples.

Section 1.
Objective

The objective of this project was to determine if the Wellisair Model WADU-02 Disinfection Purifier device has the ability to decrease viral infectivity of SARS-CoV-2 *in vitro* after exposure. The device was tested on SARS-CoV-2 virus inoculated on stainless steel coupons.

Section 2.
Sponsor, Testing Laboratory, and Personnel Responsibilities

2.1 Sponsor's Representative

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Sales Engineer
1502 Geumgang Penterium IT Tower,
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2.2 Testing Laboratories

MRIGlobal
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Fax: (816) 753-8823

2.3 Personnel Responsibilities

2.3.1 Study Directors—MRIGlobal

Phone:
Email:

Phone:
Email:

2.3.2 Analyst – MRIGlobal

Phone:
Email:

Section 3.
Test Conditions

3.1 Test Product

3.1.1 Test Unit

Wellisair Model WADU-02 Disinfection Purifier

3.1.2 Test Cartridge

Hydrogen Peroxide (Cartridge 1)

3.2 Test Components

3.2.1 Cell Media

DMEM/F12 (Serum-free media)
Vendor: Gibco
Lot No.: 2186794
Expiration date: 8/21

Growth Media – 5% FBS (fetal bovine serum)
Lot No.: 202010414JW
Expiration date: 8/21

3.2.2 Challenge Virus

Severe Acute Respiratory Syndrome-related Coronavirus-2 (SARS-CoV-2)
Strain: USA-WA1/2020
Vendor: BEI Resources
Lot: 202010216KS
Passage: 10

3.2.3 Host

Vendor:
Cat:
Passage No.:

Section 4.
Test System

MRIGlobal utilized the USA-WA1/2020 strain of the virus, acquired from BEI Resources (NR-52281). This was propagated in these cells were also used for the neutralization assay. cells were cultured in growth media consisting of Dulbecco'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. Stainless steel coupons (approximately 1" × 3") were inoculated with 200 µL SARS-CoV-2 Washington 1 isolate virus stock (2.37E5 $TCID_{50}$/ml). Coupons were allowed to dry in the biosafety cabinet for approximately 40 minutes. Test coupons were transferred to the testing room and placed into an aerosol test system fabricated out of Plexiglas (Figure 1). The test system was housed in the Class III Biosafety Cabinet for all conducted tests. The aerosol containment system has internal dimensions of 2.5ft high × 3.5ft wide × 1.5ft deep, with a displacement volume of approximately 370 liters or 13.1 cubic feet. The coupons were suspended 2 inches away from the device for the duration of the tests.

Coupons were exposed Wellisair Model WADU-02 for two hours. After the exposure time was complete, coupons were removed from the test room and placed in the biosafety cabinet. 2 ml of DMEM/f12 was added to each coupon and any remaining viral film was resuspended with a cell scraper. Samples were diluted 1:10 down a 96 deep well plate in DMEM/F12. These dilutions were transferred to a plate of cells with media removed. After approximately one hour, DMEM/F12 supplemented with 5% FBS was added to cells to feed them for the next three days. This incubation period allowed the virus to adsorb to cells without interference from FBS.

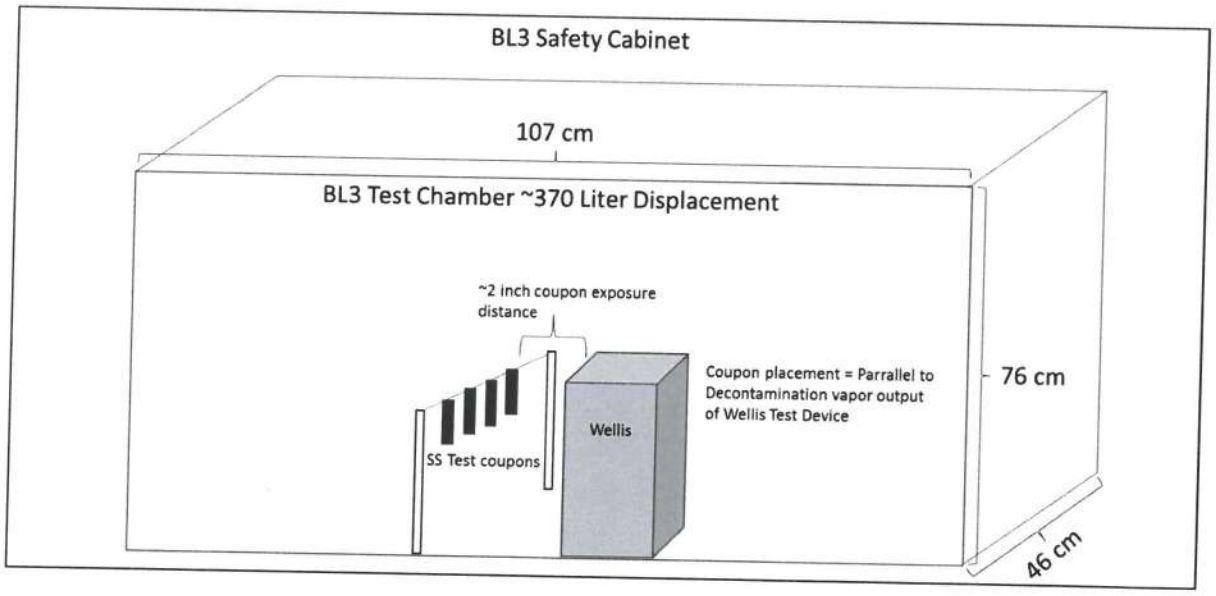

Figure 1. Testing Setup

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 $TCID_{50}$/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.

$$\%\text{ Log Reduction} = \left(1 - 10^{-\text{log reduction}}\right) x\ 100$$

Section 7.
Results

Plates were read 3 days after the initiation of the assay. Wellisair Model WADU-02 exposure resulted in a log reduction of 1.08 compared to controls. Thus, in two hours 91.75% of SARS-CoV-2 infectivity was reduced *in vitro*.

Table 1. Results of viral exposure to Wellisair Model WADU-02

Sample Name	Test Article	Description	TCID50/ml	Log 10 TCID50/ml	avg TCID50/ml	avg log10 TCID50/ml	Log Reduction	% Reduction
T1	Wellisair WADU-02	Test	6.81E+03	3.83	8.78E+03	3.92	1.08	91.75%
T2			6.81E+03	3.83				
T3			1.47E+04	4.17				
T4			6.81E+03	3.83				
C1		Control	4.22E+04	4.63	1.24E+05	5.00		
C2			1.47E+05	5.17				
C3			6.81E+04	4.83				
C4			2.37E+05	5.38				

Section 8.
Conclusions

Based on these experiments, we conclude that viral infectivity was reduced by 1.08 log (91.75%) after exposure to Wellisair Model WADU-02 for two hours when compared to control samples.