FINAL REPORT

TEST FOR virucidal EFFECTIVENESS FOR PRODUCTS TO BE USED IN NON POROUS AND INANIMATE SURFACES

PRODUCT USED	Decco Plasma (SIWA Air Purifier)
MICROORGANISM PROJECT	Human Coronavirus Strain 229E, ATCC VR-740
PERSON IN	SQ-20/000086
CHARGE	Esteban Corales Toledo
COMPLETION DATE	December 1, 2020
NAME OF THE MANUFACTURER	PLASMA INNOVA
PLACE OF DEVELOPMENT OF THE TEST	Sargento Aldea, 2650, Puerto Montt, Región de Los Lagos, Chile

GENERAL INFORMATION

Title of the Study:	Virucidal efficacy test for products to be used on non-porous and inanimate surfaces according to ASTM E1053 (adapted)
Study Identification Code:	SQ-20/000086

PROTOCOL

Microorganism Used:	Human Coronavirus Strain 229E, ATCC VR-740 Vero
Host Cell:	Cell ATCC® CCL-81
Evaluated Product:	Decco Plasma (SIWA Air Purifier)

PARAMETERS ASSESSED AND STUDY DATA

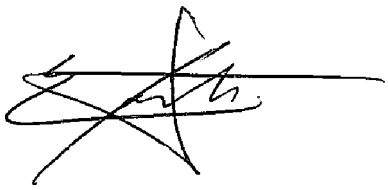
Dilution:	Undiluted
Control Organic Soil Load:	Not Applicable for this Study
Number of Samples:	1
Number of Replicas:	1
Serial and Lot Number:	No series // Lot does not apply.
Lot Manufacturing Date:	Without information
Time of Contact:	1 hour
Neutralization Method:	Dilution in Minimum Essential Medium + 2% Fetal Bovine Serum + 1% Non-essential amino acids
Culture Medium:	Dilution in Minimum Essential Medium + 2% Fetal Bovine Serum + 1% Non-essential amino acids
Study Applicant:	DECCO CHILE SpA
Study Start Date:	November 16, 2020
Study End Date:	November 30, 2020
Date of Issue:	December 2, 2020
Environmental Exposure Conditions:	22°C + 2°C and 60% RH + 5%

Test substance identification Decco Plasma (SIWA Air Purifier)

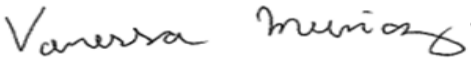
QUALITY MANAGEMENT SYSTEM

The laboratory has a Quality Management System based on the standard 17025 Of 2017 "General requirements for the competence of testing and calibration laboratories".

The participants in this study are:



Esteban Corales Toledo
Head of Molecular and Cellular Biology Laboratory



Vanessa Muñoz
Laboratory Technical Specialist

The confidentiality agreements for this study are:

The study data is the property of the client.

EXPERIMENTAL PROCEDURE

The stock viral inoculum was thawed and was not supplemented with organic load.

Sterile petri dishes (90x15 mm) were inoculated with a volume of the suspended virus. Enough petri dishes were prepared considering the amount of assay controls and product.

The inoculum was dried in a biosafety cabinet under controlled environmental conditions.

The product was prepared according to the manufacturer's recommendations.

Controls were evaluated under the same protocols as the products.

The viral suspension was quantified to determine the level of infectivity using appropriate cell culture methods (TC Dso)-

The trial was monitored for certain periods of time (minimum 7 days).

After the incubation period, monitoring was performed to assess the presence or absence of the virus. The Spearman-Kärber method was used

Log10 and %Reduction were calculated from the exposure of the virus to the product and the tites obtained with the controls analyzed, and reported in this study

STATISTICAL CALCULATIONS AND ANALYSIS

TCID (Tissue Culture Infectivity Dose) represents the endpoint dilution where 50% of the cell culture exhibits a cytopathic effect produced by the infection of the viral agent under study. The TCU was determined using the Spearman-Kãrber method and calculated as detailed below:

—*Log*(Final Point) = [— log (First *Dilution*] — [Σ%Infected Cells 100/ — 0,5]*Log*(dilution)]

The results of these calculations are expressed in TCID /0, 1 milliliter

LOG (REDUCTION) CALCULATION

The Log (reduction) of the viral titer was calculated as follows:

logt9 Reduction = *Control of Recovery* logtt *rC/Dt* — *Inactivated Virus* logtt rC/D_{50}

CALCULATION OF THE REDUCTION PERCENTAGE

The percentage of viral titer reduction was calculated as detailed below:

$$\%\text{Reduction} = 1 - \frac{C}{B} * 100$$

Where B is TCID of the virus control

Where C is TCID› of the virus exposed to the product used.

The presence of any substance that produces cytotoxicity was considered when calculating the Log and the %Reduction in the viral titer.

RESULTS

Table 1: Viral Title Results and Recovery Control

		Recovery Time 0	Time 1 hour
Control	0 0 0 0	0 0 0 0	0 0 0 0
Dilution 10-1	+ + + +	+ + + +	+ + + +
Dilution 10-2	++++	++++	++++
Dilution 10-3	+ + + +	++++	+ + + +
Dilution 10-4	++++	++++	+ + + +
Dilution 10-5	+ + + +	++++	+++-
Dilution 10-6	++++	++++	++--
TCID50 per 0.1ml	6,50	6,50	5,75
TCID50 per Carrier	6,80	6,80	6,05

Table 2: Test Results

	Test results Time 1 hour
Control	0 0 0 0
Dilution 10-1	0 0 0 0
Dilution 10-2	0 0 0 0
Dilution 10-3	0 0 0 0
Dilution 10-4	0 0 0 0
Dilution 10-5	0 0 0 0
Dilution 10-6	0 0 0 0
TCID50 per 0,1	0,50
TCID50 per Carrier Log	0,80
Log Reduction	6,05
% Reduction	**99,99%**

+: Recovered virus/ Presence of cytopathic effect
0: Virus non recovered and/or non presence of cytotoxic
effect. T: Observed Citotoxicity
*Note: For all analyses performed, cytotoxicity and neutralization controls were incorporated.

CONCLUSIONS

The purpose of this study was to determine the virucidal efficacy of the Decco Plasma equipment (SIWA Air Purifier) against Human Coronavirus Strain 229E, ATCC VR-740 at an exposure time of 1-hour, controlled temperature and humidity conditions and a viral titer sufficient to recover at least 10^{4}''infective units/carrier.

A reduction of 99,99% was obtained at the exposure time of 1 hour.

For the assay to be considered valid for the determination of virucidal efficacy, it must demonstrate a reduction of at least 99,9% over an untreated parallel control.

The test product will be disposed of after 30 days from the issuance of this report, unless required by the study applicant.

The results of this study apply only to the analyzed products, times and dilutions established by the manufacturer. Extrapolation of results to similar products is the sole responsibility of the product manufacturer.

REFERENCES

Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of lnanimate, Nonporous Environmental Surfaces. In Annual Book of ASTM Standards. USA; Current edition.

Media and Reagents Preparation and Quality Evaluation -MB-10-05.

ANNEX

THERE ARE NO ASSOCIATED ANNEXES