



Via A. Gabelli 63 - 35121 Padua
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VIRUCIDAL EFFICACY REPORT

Quantitative suspension test for the evaluation of the virucidal activity of the virus *SARS-CoV-2*

PRODUCT:

SANITY SYSTEM

A device

for environmental (air and surfaces) sanitation with Ozone technology

CLIENT

Sanity System Italia Sri. Address: Via delle Industrie, 13/C- 35010 Limena (PD)

VAT no. and tax code 04954700284

SCIENTIFIC MANAGER

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1. PURPOSE

The purpose of the following report is to clearly define the execution methods and the results of the study carried out for the verification of the virucidal activity on equipment surfaces which use ozone.

2. TERMS AND DEFINITION

Virucidal or antiviral activity: the ability of a product to produce a reduction in the number of infecting viral particles through experimental procedures under exact and defined test conditions.

Plaque Forming Units (PFU): number of infecting viral particles per mL.

ID₅₀: infectious dose of 50% of viral suspension or of the dilution of the viral suspension which causes 50% of viral cytopathic effect (CPE) in cell cultures.

Viral cytopathic effect (CPE): morphological alteration of the cells and / or of their destruction following the multiplication of the virus.

Viral inactivation: reduction of the infectivity of a virus with regards to the product in question.

3. INTRODUCTION

The test method to verify the viral inhibition activity (virucidal activity) of the SARS-CoV-2 virus of the “Sanity System” device (test product) was carried out at the Molecular Medicine Department (University of Padua). All experiments were conducted in the Biosafety Level 3 Laboratory (BSL3).

Virucidal activity was tested using the SARS-CoV-2 strain. All experiments were conducted in the Biosafety Level 3 Laboratory (BSL3).

4. SAMPLE CHARACTERIZATION

Product: "Sanity System" device

Product description: Sanity System, model SANYMED is a professional sanitizing device for the elimination of bacteria, mould, viruses, and the general microbial load as well as pollutants and odours

Storage conditions: room temperature

Equipment instructions: see attachment

5. EXPERIMENT CONDITIONS

Test temperature: carried out at $+20^{\circ}\text{C} \pm 1^{\circ}\text{C}$.

Contact time: according to the manufacturer's instructions

Analysis time: test start date: 16-08-2020 ÷ Test end date 30-09-2020

6. MATERIALS AND REAGENTS

Test microorganisms:

SARS-CoV2

7. EQUIPMENT

- Inverted microscope for the observation of cell cultures
- Stopwatch
- Vortex stirrer
- Centrifuge
- CO₂ incubator (5% v/v) capable of maintaining the temperature at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$.
- "BioHazard" class II vertical laminar flow hood
- Freezers

8. RESULTS AND VIRUCIDAL ACTIVITIES

Summary Results obtained from Repeated Testing Using Programme 2

<i>Program</i>	<i>Initial viral titre*</i>	<i>Viral titre after treatment</i>	<i>%Reduction</i>
P2	<i>7.0</i>	<i>0.01</i>	<i>99.9%</i>
	<i>7.0</i>	<i>0.01</i>	<i>99.9%</i>
	<i>7.0</i>	<i>0.05</i>	<i>99.7</i>
	<i>7.0</i>	<i>0.05</i>	<i>99.7</i>

9. CONCLUSION

The results obtained show that the Sanity System device (ozone-based technology) offers an **effective virucide against SARS-CoV-2 with a reduction of the viral load higher than 99% with the P2 program.**

10. REFERENCES

- EUROPEAN STANDARD EN 17272: 2020 Chemical disinfectants and antiseptics - Method for environmental disinfection using automatic processes
- EUROPEAN STANDARD EN 14476: 2019 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area
- ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
- ISO 15189:2012 Medical laboratories- Requirements for quality and competence