# Testing Report

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## TESTING PROTOCOL FOR AIR DECONTAMINATION: AIRBORNE VIRUS

## OBJECTIVES

To define the testing and evaluation program to measure the efficacy of the FailSafe Air Safety System's Mobile Containment Systems to mitigate the spread of airborne contamination and to provide air and surface decontamination.

## PURPOSE

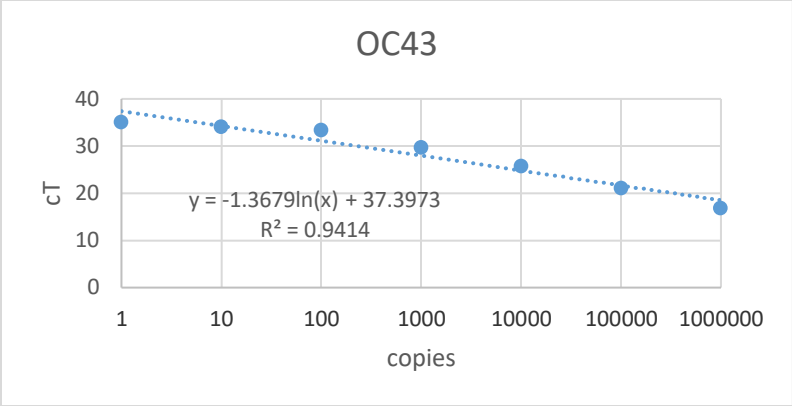
The purpose of this document is to summarize the test approach and functional test protocols to demonstrate the efficacy of FASS Mobile Containment Systems (FASS SALLI, FASS 1000 and FASS 2000) to filter and eradicate a coronavirus from Nebulized air samples reflective of breathing, coughing or sneezing related ejection of contaminated droplets into surroundings in a simulated patient care environment.

The specific aim of this T&E program is to demonstrate the technical capability of FailSafe's FASS Mobile Containment Systems. The test performance standards applied define the ability of the FailSafe system to capture and decontaminate air on a single pass when the system is subjected to a high viral inoculum.

## VIRUS ASSAY RESULTS

The OC43 viral testing was performed on April 11th, 2021, with results available on April 14th, 2021.

The RT-PCR standard curve for quantification for the sample run is displayed at the right. The X axis is viral count and the Y axis is cycle time (CT). All standards and samples were run in triplicate and the cycle time associated with the detection of 100 viral units was 35.5. CT values above this value were reported out as <100 viral copies.




## RESULTS: TESTING (INTAKE) IN FRONT OF THE FASS SALLI UNIT

1. Viral count of Solution prior to Nebulizer: 2 x 10^7 viral units/mL
2. Viral count of Nebulizer opening after complete discharge of viral solution: 3 x 10^6 viral units/mL
3. Viral count on the inside of metal cowl after complete discharge of viral solution: <100 viral units/mL
4. Viral count on floor of BioSafety cabinet, taken anterior to the edge of the cowl: <100 viral units/mL
5. Viral count on Screen inside the cowl: <100 viral units/mL

## COMMENTS AND INTERPRETATION: ANTERIOR INTAKE

Some residual contamination of the Neck of the Nebulizer was expected, as the surface remained wet with condensate. The concentration is reported as viral units/mL but the volume remaining on the wet surfaces is estimated at 0.01mL. Thus, the amount of virus remaining in the Nebulizer was approximately 3 x 10^4, representing 0.15% of the starting count. **We conclude that 99.85% of the virus added to the Nebulizer entered the FASS SALLI unit.** There were no significant viral units detected on the Floor of the biosafety cabinet, the most likely interpretation was complete intake of the virus into the FASS SALLI device.

## RESULTS: TESTING OF THE EXHAUST AIR FROM THE FASS SALLI UNIT

1. Viral count of the rear screen surface of the FASS unit: < 100 viral units/mL
2. Viral count of the Filter when washed thru with 250 ul of media: <100 viral units/ml
3. Viral count of the Fluid trap, which contained 5.0 ml of media: <100 viral units/mL

## COMMENTS AND INTERPRETATION: EXHAUST AIR VS VIRAL EXPOSURE

**Capture of Virus on a filter to Sample the exhaust of the FASS unit:** During the operation of the test, 34 liters (of the total 83 liters) of air was drawn thru a sampling filter and capture fluid with a volume of 5.0ml. Since the filter at the exhaust end was drawing in air at 2 liters/minute (a total of 34 liters in 17 minutes), it would be expected to capture virus in those 34 liters at a maximum concentration of 9 x 10^4 per Liter, assuming the air coming out of the FASS unit had the same amount of virus per liter as the air going in. No virus was detected, either from the filter or in the capture fluid. Both samples read <100 viral units. It should be acknowledged that based on the level of detection of the RT-PCR assay, there could be up to 100 organisms total in 34 liters of air and that would not be detected by the assay.

## CONCLUSIONS AND RECOMMENDATIONS

At the level of viral shedding from an infected person and infection of a person in that environment, there FASS unit rendered the air entering it functionally sterile. Although there could be up to 100 viral units escaping from the machine over 17 minutes of operation, we conclude from the data that the FASS SALLI removed the entire infectious inoculum. At this level of efficiency, there should be no need to use an exhaust to the outside in a normal hospital room or home environment.

Accordingly, this device can be used in re-circulation mode as supportive to the treatment of betacoronavirus infections. We believe OC43 to be an accurate mimetic for testing the nebulization and airborne transmission properties of SARS-CoV-2.

The size of the room does matter for the rate and timing of clearing the air, and it should be noted that the fan speed setting of 3.5 is very quiet and does not cause a draft. In high contamination areas, the fan speed should probably be set higher, just to ensure that all virus droplets in air are quickly drawn into the machine, thereby ensuring that viral capture and eradication is rapid and efficient.

## REFERENCES

1. Schentag J, Akers C, Campagna P, Chirayath PM**.** SARS: Clearing the Air. Workshop Summary: Learning from SARS: Preparing for the Next Disease Outbreak. 2005;National Academy of Sciences(http://www.nap.edu/catalog/10915.html):193-205.
2. Jones TC, Biele G, Muhlemann B, Veith T, Schneider J, Beheim-Schwarzbach J, et al. Estimating infectiousness throughout SARS-CoV-2 infection course. Science. 2021.