INACTIVATION OF THE NOVEL CORONAVIRUS SARS-CoV-2 ON PPE USING SUPERCRITICAL CO_2

Application Note Med01-03

The NovaClean™ process, a supercritical carbon dioxide ($scCO_2$)-based decontamination modality, rapidly and completely inactivates SARS-CoV-2, the novel coronavirus that causes COVID-19, on N95 respirator surfaces.

COVID-19 AND PERSONAL PROTECTIVE EQUIPMENT (PPE) SHORTAGES

Although current guidelines state that disposable personal protective equipment (PPE), such as N95 respirators, surgical masks, and gowns, are intended for single use only, supply shortages caused by the COVID-19 pandemic have made the re-use of PPE in hospitals and other healthcare facilities necessary. These PPE shortages prompted NovaSterilis to evaluate the viability of the $scCO_2$-based NovaClean process for reprocessing and decontaminating N95 respirators. Inactivation of SARS-CoV-2, the novel coronavirus that causes COVID-19, has been at the forefront of the NovaSterilis decontamination testing efforts because of its central gating role in the re-use of PPE.

SARS-CoV-2 INACTIVATION WITH SUPERCRITICAL CO_2

The NovaClean process is a low temperature (35°C), minimally to non-reactive, deep penetrating, bioburden reduction and decontamination solution. NovaSterilis has previously shown that treatment with $scCO_2$ and the peracetic acid-based NovaKill™ additive can achieve repeated and total inactivation of various microbial agents, including bacterial biofilms, highly-resistant bacterial endospores, fungi, and viruses[1,2,3]. Here, the NovaClean process was applied to swatches of 3M 1860 N95 respirator material inoculated with two different strains of human coronavirus.

Figure 1: NovaSterilis equipment and inoculation setup

Human coronavirus strain HCoV-NL63 was tested as proof of concept in the Nova2200 instrument (Fig. 1A). Respirator material was inoculated on either the outside surface (simulating surface contamination), or inside surface (simulating aerosol penetration), as shown in Figs. 1C and 1D, respectively. Novel coronavirus strain SARS-CoV-2 was inoculated on the outside surface of the respirator material and tested using the NovaGenesis instrument (Fig. 1B) within a biosafety level 3 (BSL3) laboratory.

The inoculated swatches were left to dry and subjected to the same 90-min NovaClean cycle; both instruments operated within the same process parameters, including pressure, temperature, mixing velocity, and NovaKill concentration. The surviving viral load was recovered and enumerated using Vero (E6) cell lines. Cytopathic effects (CPE) were visually observed over the 7-day assay using serial dilutions in cell culture conditions and microscopic visualization of CPE. The median tissue culture infectious dose ($TCID_{50}$) was determined using the Reed-Muench calculator and recalculated to show logs of recovered viral load as reported here. Untreated controls were included to measure the magnitude of viral inactivation**. As shown in Figure 2, the NovaClean process caused complete inactivation of all coronavirus.** HCoV-NL63 viral loads of 3.8 log_{10} and 3.4 log_{10}, were recovered from the inside and outside of control respirator samples, respectively (as shown in Fig. 2A), whereas NovaClean treated samples showed no signs of infective virus whatsoever. Similarly, as shown in Fig. 2B, SARS-CoV-2 controls showed a viral load of 5.5 log_{10}, whereas no infective virus was collected from NovaClean-treated samples.

CONCLUSIONS

These studies demonstrate that the NovaClean process successfully reduces relevant viral loads of human coronavirus strains, including SARS-CoV-2, which is the causative agent of COVID-19. Previous studies have shown the ability of the NovaClean process to achieve sterility assurance levels (SAL) of 10^{-6}, demonstrating that the technology is extremely effective against a wide variety of pathogens beyond SARS-CoV-2.[3] The total processing time required to achieve complete inactivation of up to 5 log_{10} of viral load is 120 min, only 90 min of which is active decontamination time. The compact footprint of the Nova2200, coupled with a short processing time and a cycle capacity of up to fifty (50) N95 respirators per cycle, make this point-of-use platform particularly well-suited for placement inside hospitals, clinics, and nursing home settings, where healthcare employee safety is at greatest risk.

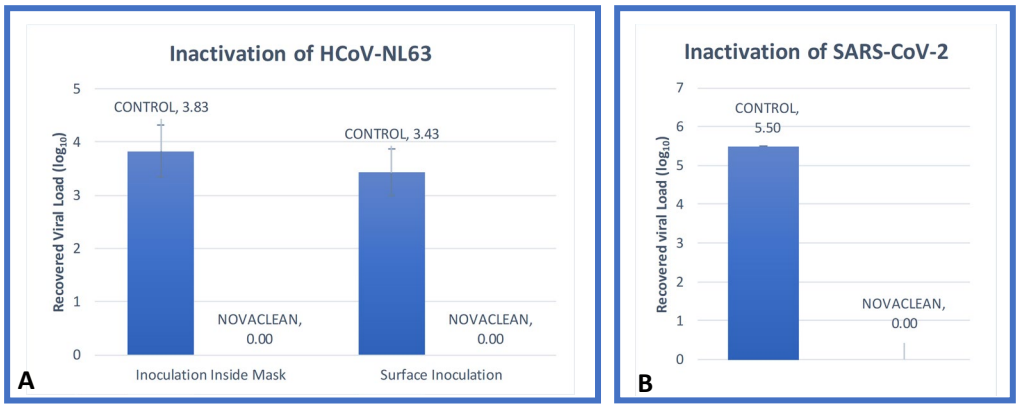

Figure 2: Inactivation of human coronavirus using the NovaClean process

ACKNOWLEDGMENTS

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REFERENCES

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