Frequently Asked Questions about Duke Health's Use of Hydrogen Peroxide Vapor for Decontamination of N95 Respirators

What is the proof that vaporized hydrogen peroxide specifically kills SARS-CoV-2(Covid-19) on N95 respirators?

While this method has been known for years to kill many similar and tougher organisms, Fischer et al, 2020 (National Institute of Allergy and Infectious Diseases) recently showed that vaporized hydrogen peroxide rapidly kills SARS-CoV-2 on N95 respirators.(1)

How are we sure that the respirator still meets all standards for a N95 respirator?

Filtration: The U.S. Food and Drug Administration (FDA) supported a study of the same cleaning method in 2016. The study showed that the respirators meet all National Institute for Occupational Safety and Health (NIOSH) standards even after 50 cleaning cycles but that the elastic straps began to breakdown after 30 cleaning cycles.(2) They stopped testing after 50 cycles.

Fit Testing: While the FDA research showed that the respirators maintained their shape and fit testing function after 50 cycles using a mannequin; Duke went one step further. Duke took nearly 400 different N95 respirators and different employees and proved that they still performed the same as a brand-new N95 respirator using the same OSHA-approved (29 CFR 1910.134) quantitative fit testing method that we use for fit testing for Duke Employees. We have now put respirators through over 15 cycles and the respirators still meet Duke/OSHA fit testing standards. We have not had a single fit testing failure yet.

Is it safe for me to use a respirator that someone previously used?

Yes. The vaporized hydrogen peroxide will kill any bacteria or virus that might have been on the respirator from a previous user, including SARS-CoV-2.

How do I know that this virus and the other possible pathogens are killed on the respirator that I am about to use?

We use several methods to assure the integrity of the cleaning process. During each and every cycle, we monitor and record the level of hydrogen peroxide in the processing room and the time of the run to assure that the appropriate level has been reached. We place biological and chemical indicators in the room at various locations to assure that the vapor was distributed throughout the room to every N95 before releasing the

batch. These indicators contain organisms (spores) that are much more difficult to kill than SARS-CoV-2 and other viruses and bacteria. The biological indicators are then cultured in growth medium and all must demonstrate that there is no growth of the indicator organism, which confirms the exposure to hydrogen peroxide vapor was effective.

I know the FDA approved the use of vaporized hydrogen peroxide to decontaminate N95 respirators but I hear that was under an emergency use authorizations (EUA). Does that mean that they really did their homework in approving these applications?

Unlike many other EUA applications, the FDA is the one who actually commissioned the original research back in 2016 after the H1N1 (swine flu) epidemic. However, nobody subsequently applied for approval to use this method to decontaminate N95 respirators until now. Duke, Battelle, and Fischer et al. and others have now confirmed the FDA's original findings that hydrogen peroxide vapor is indeed effective in decontaminating N95 respirators.

Are there any chemicals left on the respirator after the process?

No. The hydrogen peroxide vapor converts to water and oxygen on exposure to air so there is no residual or smell at the completion of the decontamination process.

The OSHA Permissible Exposure Limit (PEL) for Hydrogen Peroxide is 1 part per million (PPM). The research conducted on behalf of the FDA in 2016 utilized a sensor that can detect 0.1 PPM and showed that there is no detectible hydrogen peroxide after five hours of aeration of the respirator. Duke's process includes testing for hydrogen peroxide using the same sensor technology the FDA study used and we continue to use an active monitoring analytical method to quantitatively demonstrate that the level of hydrogen peroxide in the respirators is below the limit of detection (0.1ppm) of the instrument before they even leave the decontamination room. The respirators are then aerated for a minimum of 12 hours before being released for redistribution, thus giving even more confidence that there is no detectable hydrogen peroxide.

Two external organizations have weighed in on the criteria necessary to ensure the decontamination process is safe and effective. A national nursing organization noted that based on their review of the science that there is no method for decontamination that meets their three criteria for a method to be safe and effective. A manufacturer of N95 respirators, said there should be four criteria. What is the difference and does Duke meet all of these criteria?

There is essentially no difference in the criteria. They are just listed differently. Duke and the FDA believe that all criteria have been met as outlined below.

National Nursing Organization:

1) Must effectively inactivate the pathogen
2) Must not degrade the filtration, structural integrity, and face seal
3) Must not introduce additional hazard to the worker

Manufacturer:

1) be effective against the target organism, such as the virus that causes COVID-19
2) not damage the respirator's filtration
3) not affect the respirator's fit; and
4) be safe for the person wearing the respirator (e.g. no off-gassing of chemicals into the breathing zone).

The nursing organization expressed concern that hydrogen peroxide in high concentration can be harmful. In their communication they did not reference the research supported by the FDA in 2016 that showed there was no detectible hydrogen peroxide after five hours, let alone the 12 hours that we set as our minimum.

In March 2020, the N95 manufacturer raised concerns that the fit testing research had not been done on humans. This has now been conducted by both Duke and the National Institute of Allergy and Infectious Diseases. (1)

Thus all of the criteria have been meet.

I see that the FDA approved other companies to decontaminate N95 respirators using hydrogen peroxide vapor but they differ in how many times this can be done. Why?

Battelle was the first to receive FDA approval using nearly identical methodology as the original FDA research and the Duke Health process. They were approved for 20 cycles. The process only uses hydrogen peroxide. Although the other companies use hydrogen peroxide, their method differs significantly from the method used by Duke and studied by the FDA in 2016. They decontaminate by diffusing hydrogen peroxide vapor into a chamber and then electromagnetically exciting the hydrogen peroxide molecules into a low-temperature plasma state. At high doses, this method was shown to reduce filtration efficiency and thus they were limited in the number of cycles that can be used on a particular respirator.

How many times does Duke intend to decontaminate the N95 respirators?

While Duke has shown the N95 respirators perform well for over 15 cycles, our original intent is perform up to 10 cycles and then reevaluate based on further data. The FDA research showed that the N95 respirators functioned well in all aspects for up to 30 cycles before the elastic bands began to breakdown. Battelle was approved for up to 20 cycles.

How long has vaporized hydrogen peroxide been used for decontamination?

This technology has been used in many hospitals and pharmaceutical processes for well over 10 years. In addition, Duke has used this method to decontaminate many objects in our National Institutes of Health (NIH) -funded Regional Biocontainment Laboratory for over a decade.

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1. Fischer RJ, Morris DH, van Doremalen N, Sarchette S, Matson MJ, Trenton Bushmaker T, Yinda CK, Seifert SN, Gamble A, Williamson BN, Judson SD, de Wit E, Lloyd-Smith JO, and Munster VJ, Assessment of N95 respirator decontamination and re-use for SARS-CoV-2. Online April 11, 2020, doi:10.1101/2020.04.11.20062018

2. Final Report for the Bioquell Hydrogen Peroxide Vapor (HPV) Decontamination for Reuse of N95 Respirators. Prepared by Battelle Columbus, Ohio. Prepared under Contract No. HHSF223201400098C. Study Number 3245. Prepared for the FDA. July 2016.