

1 **Decontamination and Reuse of N95 Respirators with Hydrogen Peroxide Vapor**
2 **to Address Worldwide Personal Protective Equipment Shortages During the**
3 **SARS-CoV-2 (COVID-19) Pandemic**

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16 **Abstract**

17 The SARS-CoV-2 (COVID-19) pandemic has placed a tremendous amount of strain on resources
18 in the healthcare setting. One of the most pressing issues is the rapid depletion of personal
19 protective equipment (PPE) used in the care of patients. This is a significant concern for
20 healthcare workers' health and safety. Many entities have depleted or soon will exhaust their
21 stockpile of PPE despite adopting PPE sparing practices as the number of COVID-19 cases in the
22 U.S. increases at an almost exponential rate and manufacturers struggle to keep up with the
23 worldwide demand. This potential shortage is particularly concerning for commonly used N95
24 respirators and Powered-Air Purifying Respirators (PAPRs). Recently, the U.S. Occupational
25 Safety and Health Administration (OSHA)¹ even temporarily suspended the requirement to
26 perform annual fit testing of respirators to allow entities to conserve respirators and preserve
27 them for patient care. These measures are unprecedented and highlight the urgent need for
28 entities to develop solutions to proactively address what could be potentially a grave
29 occupational health issue.

30 At Duke University and Health System, we have evaluated and will begin utilizing Hydrogen
31 Peroxide Vapor to decontaminate and reuse N95 respirators. In this communication, we briefly
32 discuss the decontamination validation process and post-decontamination performance
33 validation conducted at Duke. This validation, which is supported by previous laboratory
34 testing, funded by the FDA, demonstrated that N95 respirators still met performance
35 requirements even after decontamination with Hydrogen Peroxide Vapor in the laboratory
36 setting for over 50 times². While previous studies have shown the applicability of the Hydrogen
37 Peroxide Vapor process, we have also confirmed that the respirator still functions as designed,
38 using our standardized human N95 fit testing methodology. We will now use this internally
39 validated and Duke Institutional Biosafety Review Committee (IBRC) approved laboratory
40 decontamination process in the clinical setting to dramatically extend the life of our N95
41 respirators. We hope that sharing our processes through this brief communication can help
42 other entities with access to Hydrogen Peroxide Vapor to evaluate the potential applicability of
43 this technology at their facility or partner with those who may already have this capability
44 including other private sector life science organizations.

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47 **Process/Method**

48 We, like others, have implemented many CDC-approved N95 reuse practices including
49 employees reusing their own N95s for the duration of their shifts. However, this alone may not
50 be adequate to meet our anticipated need, with various centers reporting multiple fold higher

51 use of PPE as their case load increases. In the interest of our workforce safety, the goal was
52 thus to extend the life of our existing supply.

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54 Duke University houses one of the NIAID Regional Biocontainment Laboratories (RBL) as part of
55 a nationwide network of high containment laboratories and has extensive experience with the
56 use of Hydrogen Peroxide Vapor decontamination. In addition, Duke University Health System
57 had past experience with Hydrogen Peroxide Vapor in the clinical setting as part of previous
58 high-consequence pathogen preparedness exercises. The Duke RBL, a BSL3 facility, contains a
59 room specifically designed to use Hydrogen Peroxide Vapor to decontaminate laboratory
60 equipment and has been operational for over a decade. This room currently utilizes a Bioquell
61 Clarus™ C system with a 35% hydrogen peroxide solution and distribution system to disperse
62 Hydrogen Peroxide Vapor into the room in a uniform fashion. In addition, we are evaluating
63 the new Bioquell Z-2 and Bioquell ProteQ systems that will provide increased capacity and
64 flexibility to our reprocessing needs.

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66 The FDA-funded project, referenced previously, validated the decontamination of N95
67 respirators with Hydrogen Peroxide Vapor for over 50 cycles, with the reuse limiting factor
68 being the elastic straps that started to show degradation.² To address this, we plan to
69 decontaminate and reuse N95s up to 30 cycles, with a Quality Assurance (QA) step to ensure
70 both qualitative and quantitative degradation has not occurred. A cohort of respirators will be
71 decontaminated with every cycle and will be used in standardized quantitative fit testing to
72 ensure the integrity of the respirators is maintained over many decontamination cycles.

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75 **Procedures**

76 Approximately 100 3M™ 1860 N95s, previously used in quantitative employee fit testing, were
77 collected and hung from stainless steel wire racks in our Hydrogen Peroxide Vapor processing
78 room in the RBL. The Hydrogen Peroxide Vapor run consisted of the following five stages:
79 Conditioning, Pre-gassing, Gassing, Gassing Dwell and Aeration. The existing RBL Hydrogen
80 Peroxide Vapor standard operating procedure (SOP) was employed and requires that the
81 processing room attain 480+ ppm level of Hydrogen Peroxide Vapor with a “Gassing” time of 25
82 minutes and a “Gassing Dwell” time of 20 minutes. At the end of a cycle, during the aeration
83 stage, fresh air is introduced into the room to increase the rate of catalytic conversion of
84 hydrogen peroxide vapor into oxygen and water. This procedure leaves no residue other than
85 water. When sufficient time had passed, we used a PortaSens II™ sensor to ensure hydrogen
86 peroxide levels were below the OSHA Permissible Exposure Limit³ (PEL) of 1.0 ppm prior to
87 entering the room. In addition, we validated the efficacy of the decontamination process by
88 using eight individual 6-log biological indicators (*Geobacillus stearothermophilus* spores). See
89 Figure 1 for representation of the decontamination setup and placement of biological indicators.

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91 Based on our previous experience with Hydrogen Peroxide Vapor and porous materials, we
92 anticipated the possibility of off-gassing of H₂O₂ from the respirators at the end of the run. For
93 this reason, in our initial tests, we performed a quantitative and qualitative assessment for
94 H₂O₂. For the quantitative assessment, the PortaSens II™ was used to detect H₂O₂ levels over a

95 4 hour time frame taking readings at regular intervals by placing the probe close to the
96 respirators. At approximately 4 hours, the levels decreased below the PortaSens II™ level of
97 detection (0 ppm). In the qualitative test, three individuals did a qualitative smell test to
98 determine if there were any noticeable odors. None were detected. After complete aeration,
99 the respirators went through a quality assurance (QA) process to ensure that there was no
100 physical or performance degradation. The decontaminated respirators then underwent our
101 normal quantitative fit testing process to ensure their continued performance and were tested
102 on two individuals with differing facial structures with no loss of fit or seal, thereby ensuring
103 that N95s decontaminated using this method can be placed back into circulation.

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106 **Conclusion**

107 Using Hydrogen Peroxide Vapor is a proven method of decontamination. Previous studies have
108 shown that N95 respirators retain their filtering capability even after 50 cycles in a laboratory
109 environment. We have taken this one step further to show it can be done in the real world
110 environment using commercially available equipment and performing fit testing on humans
111 rather than “human forms.” We believe that N95 sparing and reuse practices are important but
112 not sufficient given the current situation and thus will begin reuse after decontamination on a
113 large scale. While this alone will not solve the problem, it will allow us to process and reuse a
114 significant number of N95 respirators or other critical items. As healthcare facilities operate in
115 uncharted territories while dealing with a plethora of unanticipated day-to-day issues, solving
116 issues that directly impact the health and safety of our healthcare workers is of utmost

117 importance. Healthcare workers must be equipped with the appropriate personal protective
118 equipment (PPE) that they need to do their jobs with confidence. In times of global shortages,
119 we have to improvise and adapt existing technologies for new uses. We believe that
120 decontamination of N95 respirators with Hydrogen Peroxide Vapor is one such solution that
121 affords us better ability to protect our healthcare workers as we continue to tackle this
122 monumental issue. We will continue to validate this process with other PPE and reusable
123 Hydrogen Peroxide Vapor-compatible medical equipment. We recommend validating this
124 procedure with the respirator used at your facility. This manuscript has been accepted to
125 *Applied Biosafety*, publication forthcoming.

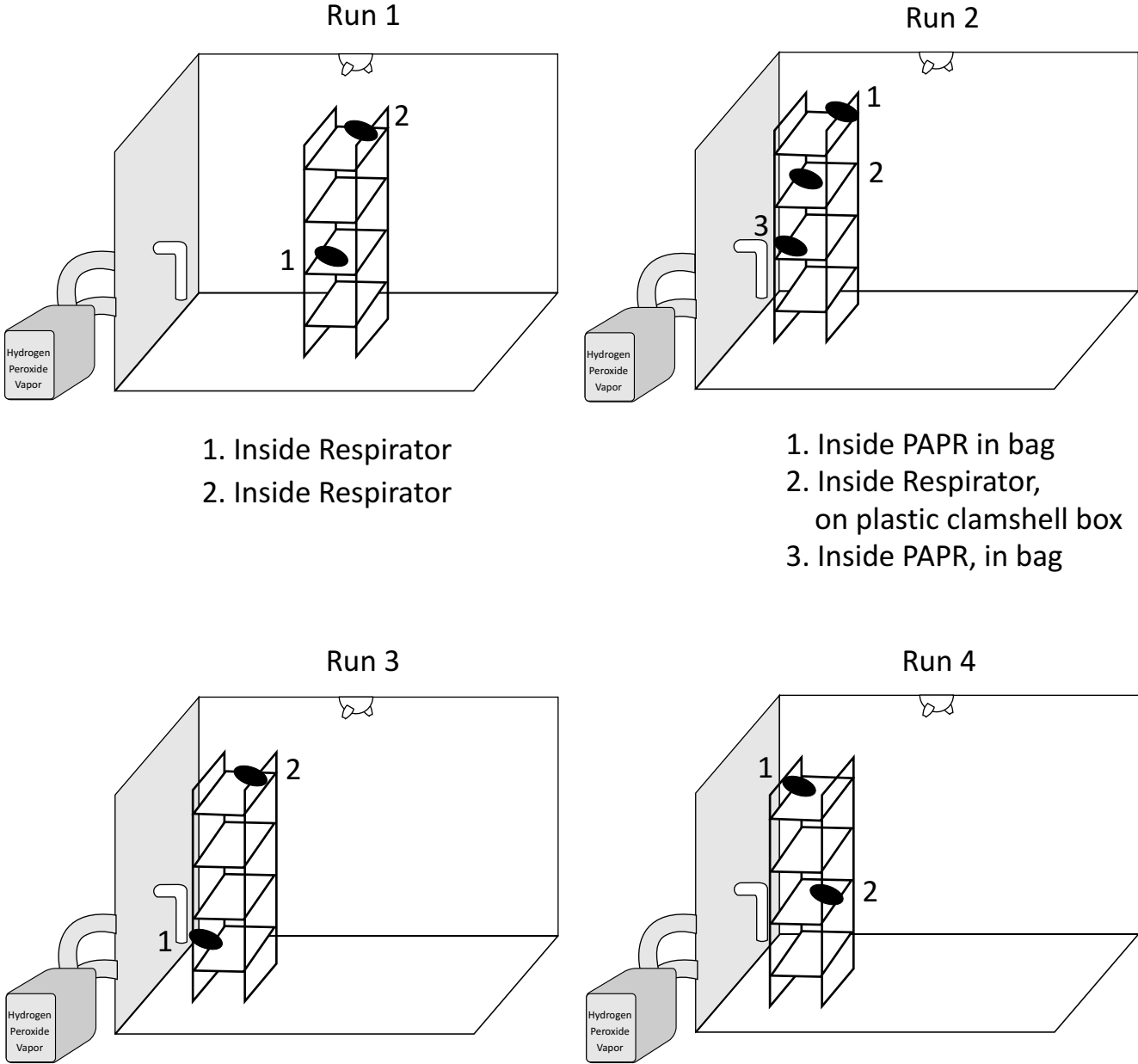
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140 141 **Acknowledgement**

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143 Laboratory, which received partial support for construction from the National Institutes of
144 Health, National Institute of Allergy and Infectious Diseases (UC6-AI058607) and the Duke
145 School of Medicine.

Figure 1: Placement of Biological Indicators (BIs) during Hydrogen Peroxide Vapor Decontamination






1. Inside Respirator
2. Inside Respirator

1. Inside P APR in bag
2. Inside Respirator, on plastic clamshell box
3. Inside P APR, in bag

1. Inside P APR, no bag
2. Under Respirator

1. Under Respirator
2. Under Respirator

-  Biological Indicator
-  Exhaust to Hydrogen Peroxide Vapor Unit
-  Rotating Dispersion Nozzle