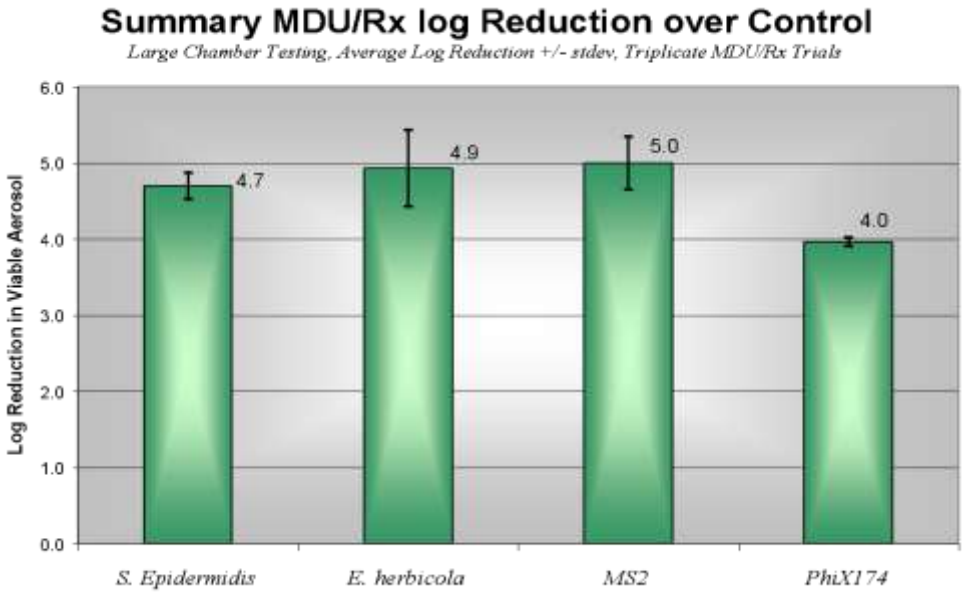
Can HGI Prove Odorox® Technology Kills the Wuhan Coronavirus?

Testing a new, virulent virus like the Wuhan coronavirus that is spreading across China is not possible for several reasons. First, only major national labs like the Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) get samples so soon after the emergence of the virus. Second, commercial labs are not equipped to test such a virulent virus as it would require biosafety containment facilities and protocols beyond their capability. Commercial testing labs usually deal with viruses, bacteria and mold with virulence levels of Bio Safety Level (BSL) 1 or 2. A virus like the Wuhan coronavirus would be categorized for testing as a BSL 4 or 5, requiring full Hazmat protection, given its high rate of infection and unknown mortality rate. The Middle East Respiratory syndrome (MERS) coronavirus in 2012 had a high rate and the Wuhan coronavirus could be as lethal according to sources at the World Health Association and the Wall Street Journal (January 30, 31 2020).

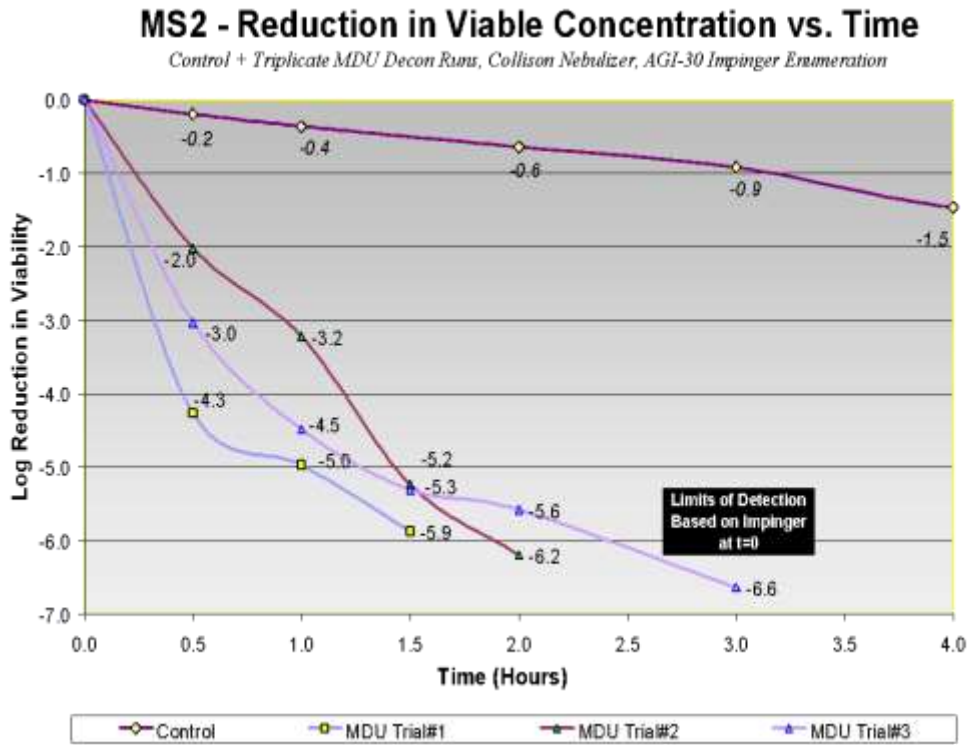
A proven alternative approach – and one adopted by the Food and Drug Administration (FDA) – is to test recognized surrogate viruses in studies where they are aerosolized to mimic the most important transmission mode. HGI conducted such studies at the Aerosol Research & Engineering Laboratories (ARE Labs) for the two virus types shown below. These kill rates were measured to obtain FDA approval for the Odorox® MDU/Rx ™ (FDA 510k #133800, 2014). ARE Labs, a company specializing in the study of aerosolized microorganisms, conducted an FDA approved comprehensive evaluation of the kill rates of two representative bacteria, two representative viruses and a mold as part of the approval process for the use of the MDU/RX™ in occupied spaces in medical facilities. All five kill rates were between 4 and 5 log reductions (99.99% and 99.999%) within two hours, an exceptionally high, fast kill rate.



The FDA selected the MS2 and Phi-X174 viruses for this study because they had different viral sheaths and were representative of the two main type of virus as explained below.

> "Two representative BSL1 viruses were chosen to evaluate the MDU/RX™'s performance against both RNA and DNA based viruses.
>
> *MS2 bacteriophage*
> (ATCC 15597-B1) is positive-sense, single-stranded RNA virus that infects the bacterium Escherichia coli and other members of the Enterobacteriaceae family. MS2 is routinely used as a simulant for pathogenic RNA viruses.
>
> *Phi-X174* (ATCC 13706-B1) *bacteriophage* is a circular single stranded DNA based virus that infects the bacterium *Escherichia coli*. Phi-X174 was selected as a simulant for DNA based pathogenic viruses."

The kill rate profiles for these viruses are shown below. It is notable that the baselines remain very stable during the trial and the rates of viral decline are similar and rapid, and achieve the FDA minimum level of efficacy of 99% (2 log reduction) within 15 to 30 minutes.



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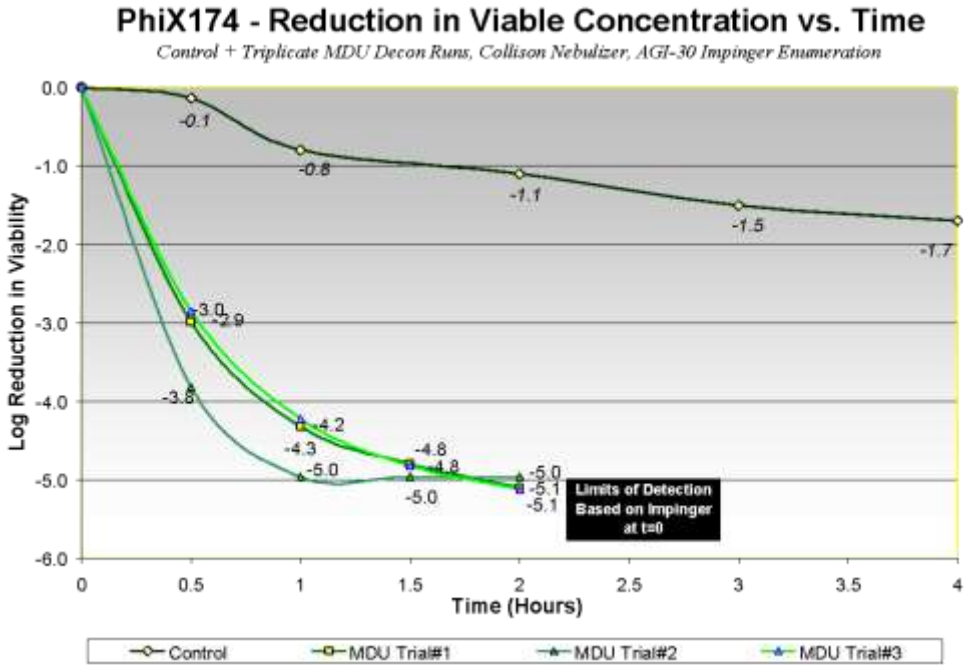

Considering that the FDA threshold for “efficacy” is a 2-3 log kill rate within 8 hours, the MDU/Rx™ kill rate reductions of over 99.99% within one to two hours are exceptional. This reflects the fact that hydroxyls and the secondary organic oxidants they generate kill microorganisms by the physical process of attacking the chemicals in their cell walls. It does not matter if they are protected by protein, lipid or carbohydrate sheaths.

The full ARE Labs study is available upon request and includes all testing protocols and results. The FDA only required testing of the two types of bacteria and viruses that they considered representative of their classes to approve the MDU/Rx™.

Based on extensive microbiological testing done by HGI on surface bound microorganisms and the high, rapid kill rate for the aerosolized, surrogate MS2 virus tested at ARE, HGI believes its proprietary technology should effectively kill the Wuhan coronavirus. The MS2 virus tested at ARE Labs is an excellent surrogate for the coronavirus as they are both positive-sense, single-stranded RNA viruses. Note that the FDA considers the MS2 to be "a simulant for pathogenic RNA viruses".

HGI has developed a range of products that incorporate the same technology found in the FDA approved MDU/Rx™. HGI can deliver turnkey solutions to treat spaces as small as a few hundred square feet to very large spaces of over a million square feet.

Dr. Connie Araps
PhD Organic Chemistry, Princeton University
Chairman, HGI Scientific Advisory Board

Contact: caraps@hgiind.com