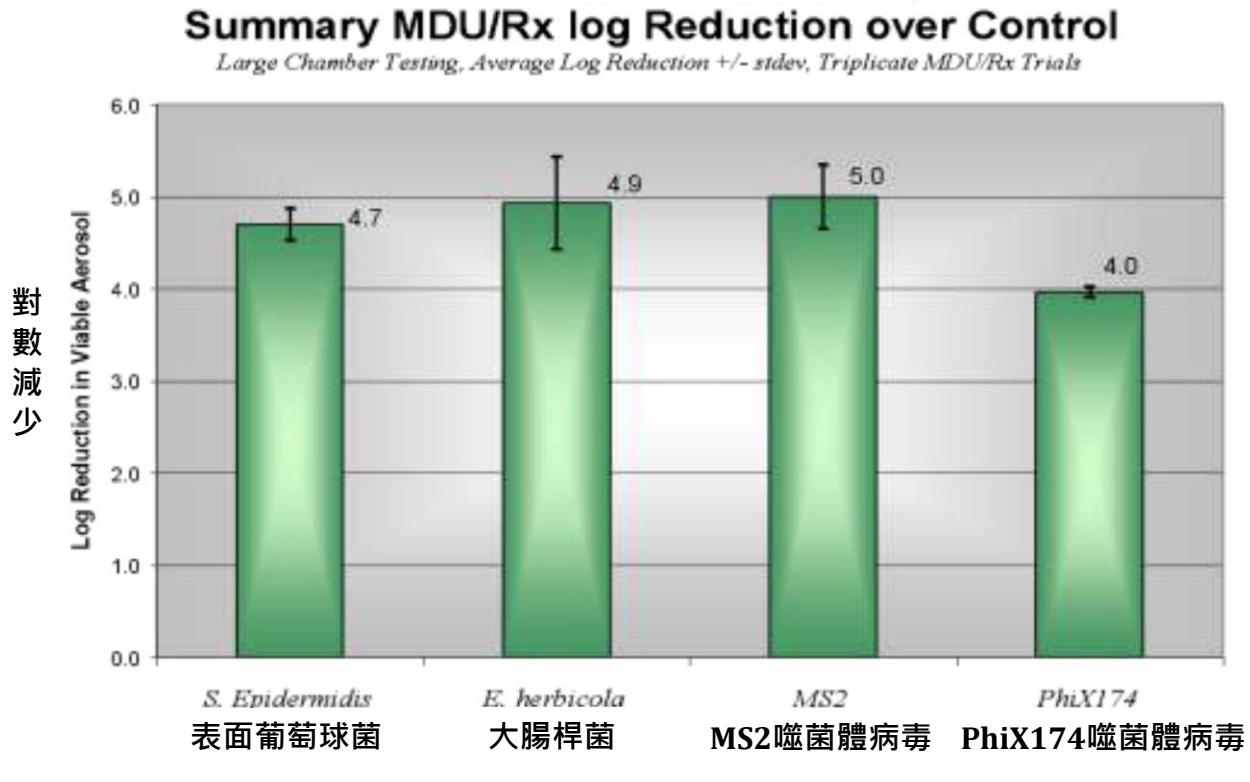
HGI是否可以證明Odorox®技術殺死新型冠狀病毒？

由於諸多原因，想要檢測像當前正在肆虐的新型冠狀病毒是很困難的。首先，只有極少數的國家級實驗室才能夠在疫情發生後，以較快的速度拿到病毒樣本，例如美國國家疾控中心(CDC)和美國國家衛生研究院(NIH)這樣的機構。其次，商業實驗室通常沒有足夠的生物安全設備來測試這種烈性病毒。商業實驗室一般情況下只能處理生物安全等級(BSL：Biosafety Level)1 級或者 2 級的病毒，而新型冠狀病毒的等級為 BSL 4 級或者BSL 5 級，具有高度傳染性和目前尚不明確的致死率，需要進行最高等級的防護。根據世界衛生組織提供的資訊和華爾街日報 2020 年1 月30 日的報導，2012 年的中東MERS 冠狀病毒導致高死亡率，新型冠狀病毒很可能也同樣是致命的。

因為新型冠狀病毒測試的高危險性，美國食品和藥物管理局(FDA)採用了一個替代方案：選擇與新型冠狀病毒類似的氣溶膠傳播型病毒來測試。遵循 FDA 提出的方案，HGI 工業公司在美國氣溶膠研究與工程實驗室(ARE實驗室)，對兩種類似的病毒使用 ODOROX® MUD/Rx™機型進行了有針對性的測試，試驗結果和資料被作為 MUD/Rx™機型申請 FDA 認證的資料通過了美國食品和藥物管理局(FDA)的審核，MUD/Rx™機型同時獲得了 FDA 認證(號碼：FDA 510K #133800, 2014)。ARE 實驗室專注於微生物空氣傳播領域，其按照 FDA 認證的要求和方法，使用三台 MUD/Rx™機型，在醫療機構內，對兩種有代表性的細菌、兩種有代表性的病毒和黴菌進行了殺滅評估試驗。試驗結果顯示，所有細菌和病毒的殺滅率為兩個小時內對數減少在 4 組到5 組的範圍內，即殺滅率為99.99% - 99.999%。如下圖所示：

MDU/Rx設備殺菌測試匯總圖

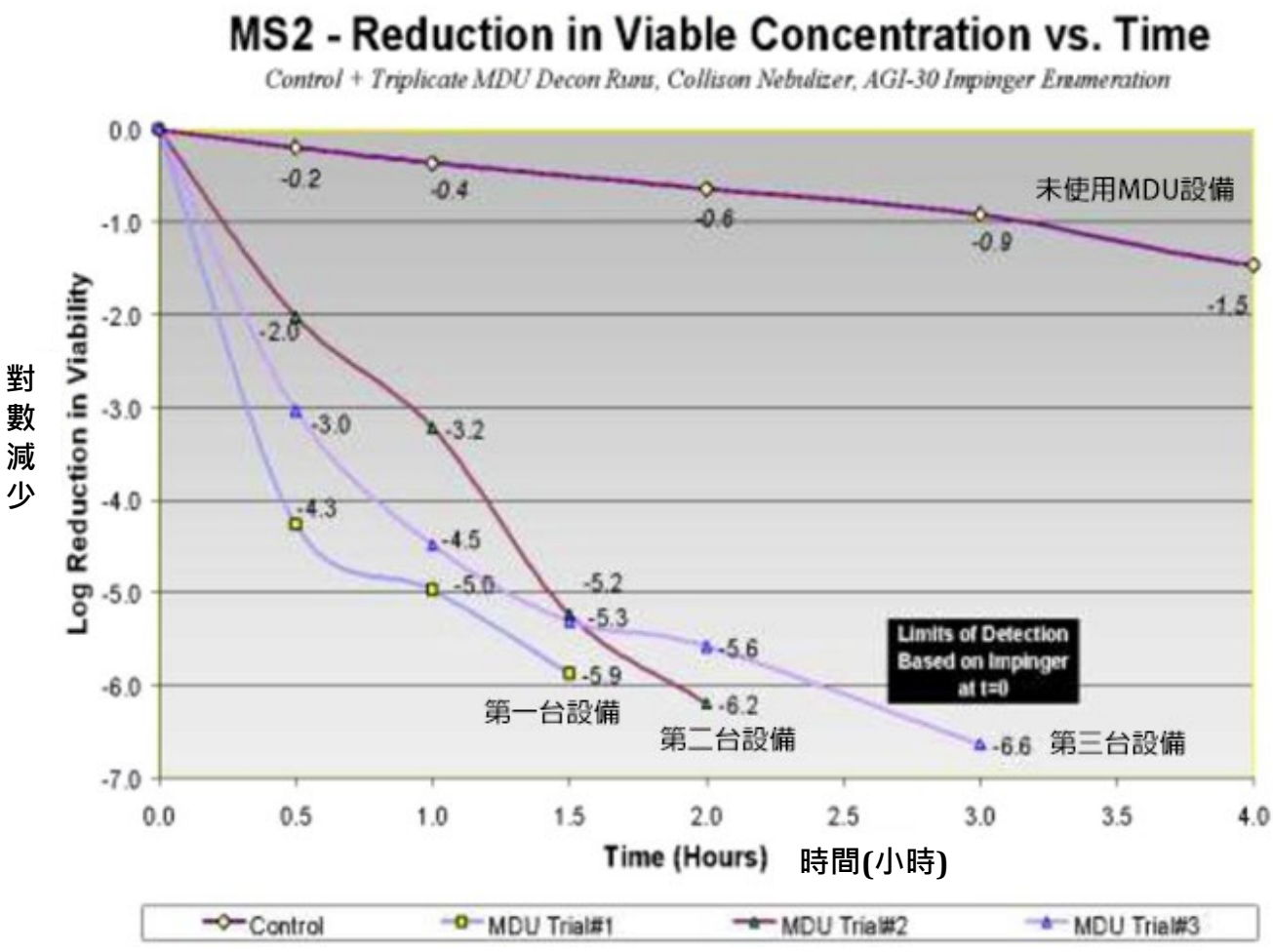


FDA 選擇MS2 和 Phi-X174 兩種病毒作測試樣本，是因為這兩種病毒具有不同的病毒鞘， 可以成為病毒兩大主要類別（RNA/DNA）的典型代表。FDA 測試文檔的相關內容節選如下：

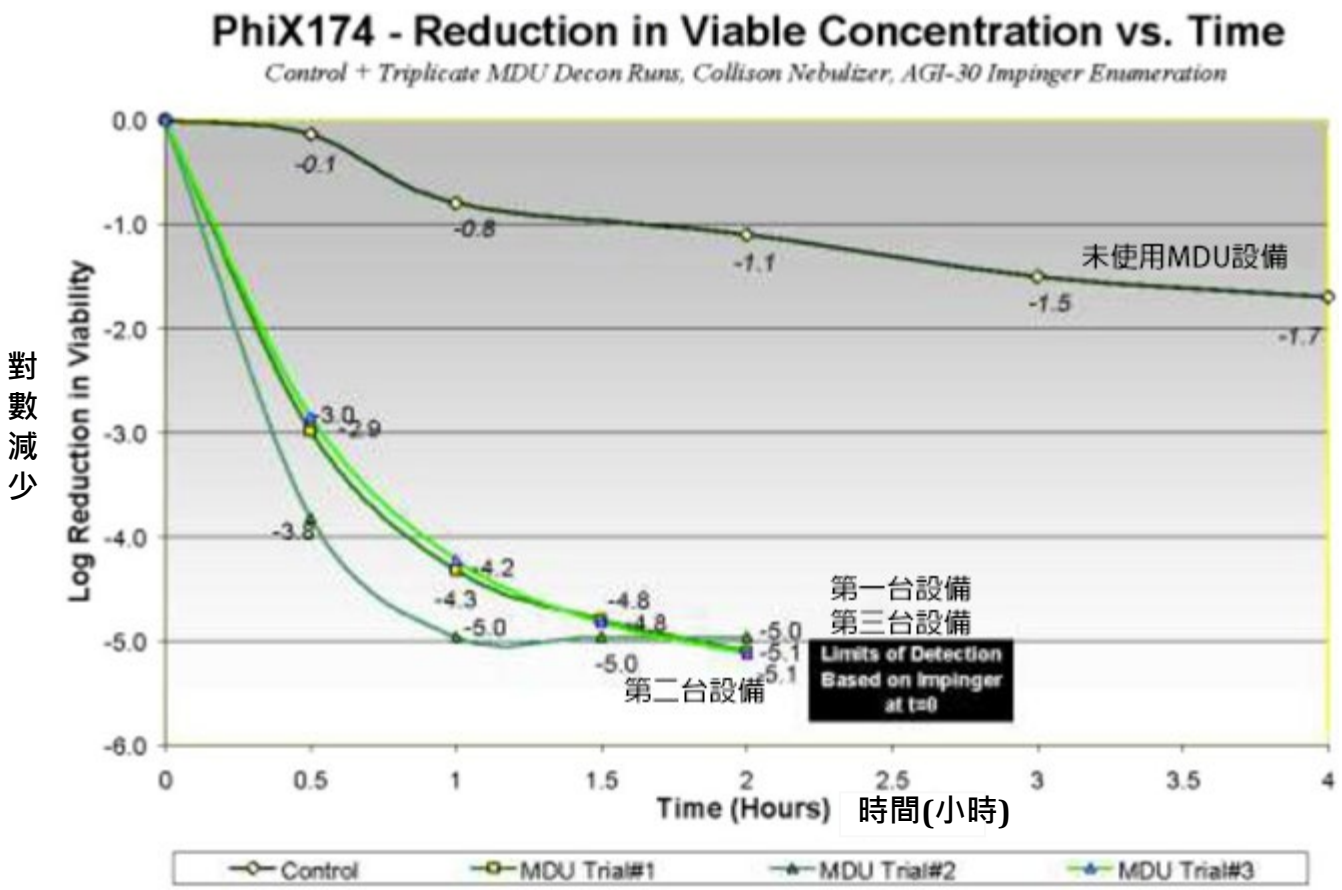
> “這兩種有代表性的病毒被選擇用來評估 MDU/Rx™機型對 RNA 病毒和 DNA 病毒的殺滅性能。
>
> *MS2 噬菌體病毒*(ATCC 15597-B1)是正鏈、單鏈 RNA 病毒，可感染大腸桿菌和其他腸桿菌科細菌，被廣泛用於類比 RNA 病毒。
>
> *PhiX174 噬菌體病毒*(ATCC 13706-B1)為環狀、單鏈 DNA 病毒，被廣泛用於類比 DNA 病毒。”

下面是針對這兩種病毒的試驗結果，值得注意的是，在試驗過程中，基線非常穩定，病毒下降率相似且快速，並在15 至 30 分鐘內達到 FDA 最低療效水準 99% (減少 2 對數)。

MS2病毒殺菌測試對比圖



PhiX174病毒殺菌測試對比圖



從上兩圖的試驗結果可以看出，三台 MDU/Rx™設備的作用非常穩定且具有相似的高殺滅率，僅僅用時 15 分鐘到30 分鐘就達到了 FDA 的要求：8 小時內對數減少 2 組-3 組（99%的殺滅率）。這些試驗證明了 MDU/Rx™設備產生的羥基和次級淨化因數能夠快速、有效地殺滅各種微生物，不管他們的生物結構是擁有蛋白質保護鞘、脂類保護鞘、還是碳水化合物保護鞘。

HGI 工業公司長期以來，還進行了許多其他針對物體表面和空氣中的微生物的殺滅測試。基於這些科學試驗的結果和來自權威機構認可的事實，**HGI公司充滿信心地認為，ODOROX®羥基空氣消毒技術能夠有效地作用於新型冠狀病毒。**MS2病毒試驗就非常有代表性，因為它和冠狀病毒一樣是正鏈、單鏈的 RNA 病毒。

HGI 工業公司擁有完整的產品系列，能夠淨化從小到幾十平方米、大到幾千平方米的空間。

康尼・阿拉普斯 醫生
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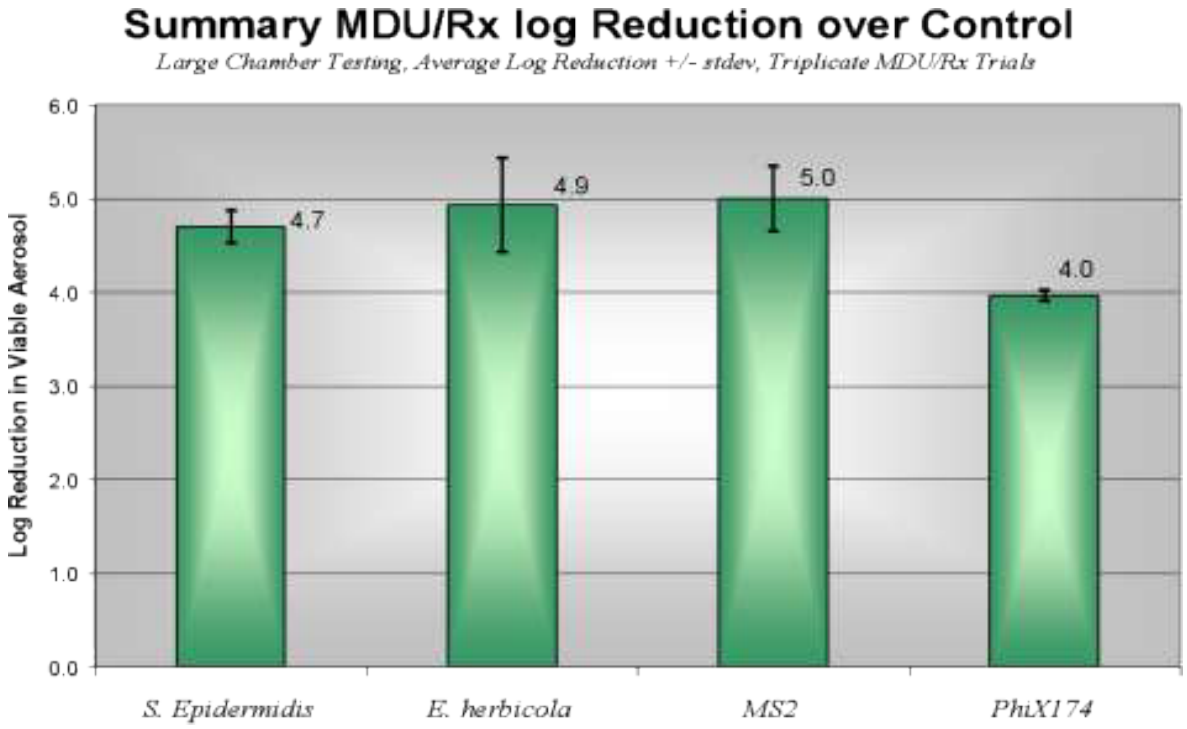
HGI 科學委員會主席

Can HGI Prove Odorox® Technology Kills the New Coronavirus?

Testing a new, virulent virus like the New Coronavirus 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 New 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 New Coronavirus could be as lethal according to sources at the World Health Association and the Wall Street Journal (January 30, 31 2020).

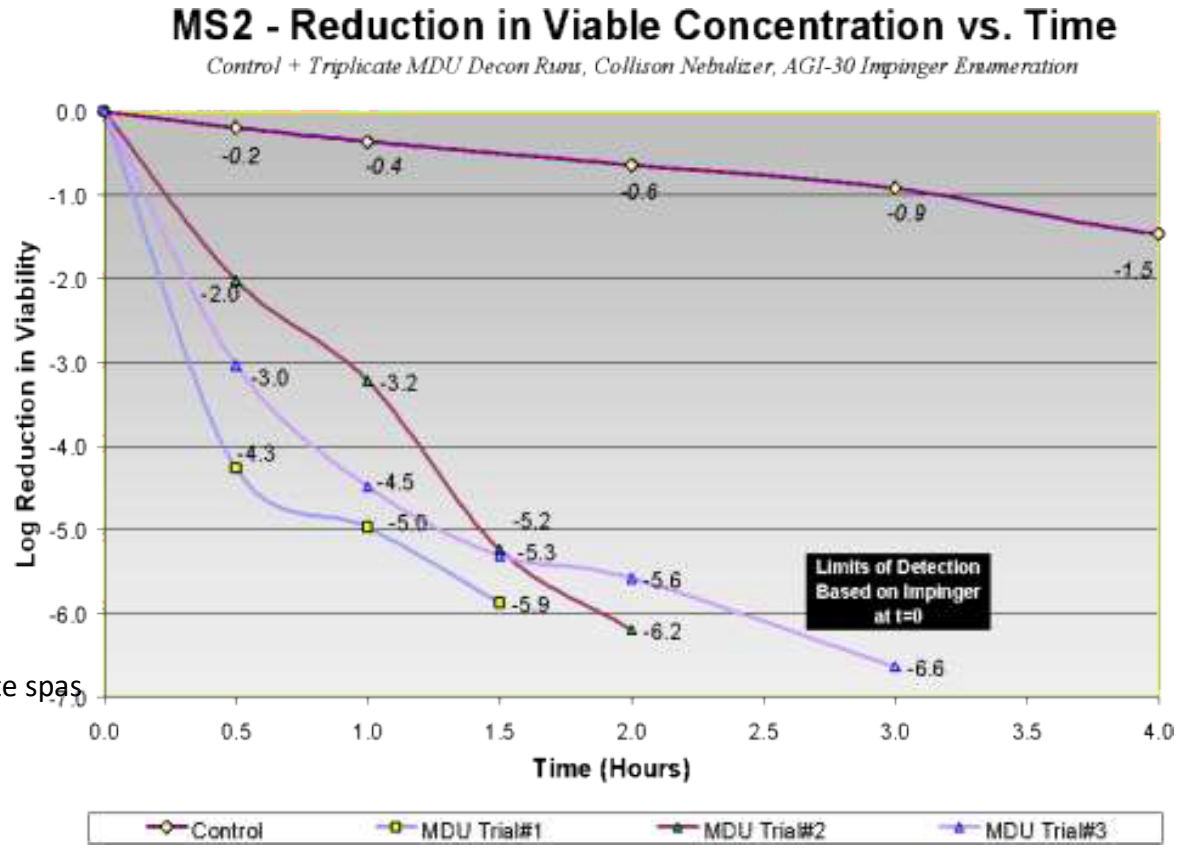
A proven alternative approach – and one adopted by the Food and Drug Administration (FDA) – is to test recognized surrogate viruses in studies where they are aerosolized to mimic the most important transmission mode. HGI conducted such studies at the Aerosol Research & Engineering Laboratories (ARE Labs) 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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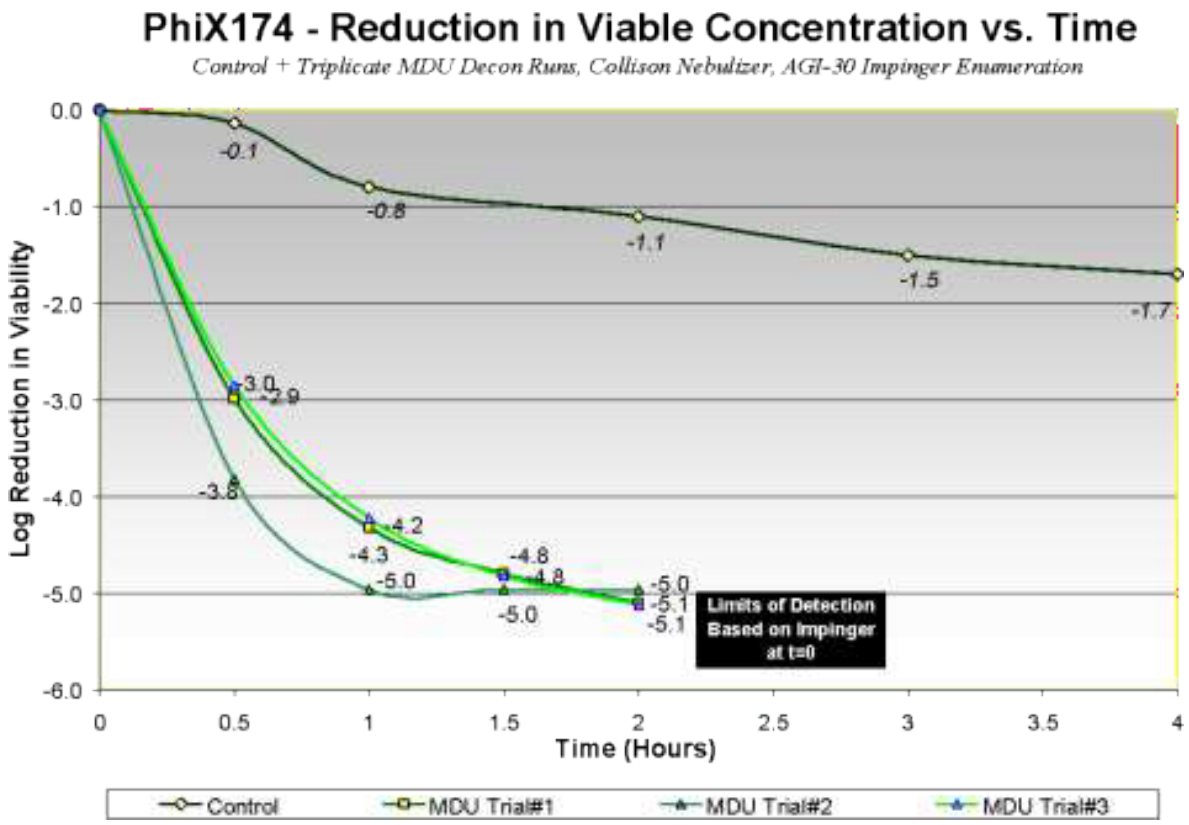

Considering that the FDA threshold for "efficacy" is a 2-3 log kill rate within 8 hours, the MDU/Rx™ kill rate reductions of over 99.99% within one to two hours are exceptional. This reflects the fact that hydroxyls and the secondary organic oxidants they generate kill microorganisms. It does not matter 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 New 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.

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