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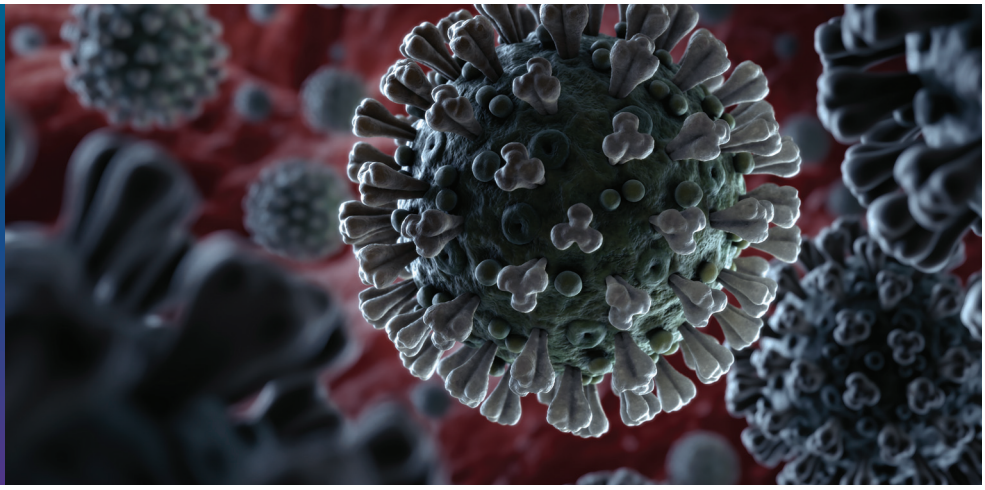
TOXI-GUARD® Protection Against Virus Penetration into Drug Vials



Transmission of Viruses

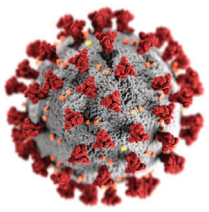
Transmission of influenza and other viruses between humans may occur by three routes:

1. Direct or indirect contact between an infected and a susceptible person, usually resulting in contamination of a susceptible person's hands followed by hand to respiratory mucosa contact
2. Large droplet spray of respiratory fluid
3. Aerosols generated by release of smaller, virus-containing droplets, as may occur during breathing and coughing [1]

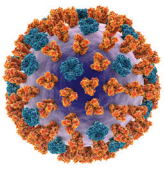
Thus, viruses are carried in the air in aerosol droplets or other particles.
Standard tests were developed to evaluate the ability of the charcoal filter or membrane to filter or capture viruses aerosolized in an air stream.

Virus Sizes

Viruses are much smaller than bacteria. Therefore, there is a risk of their escape through filters that are designed for bacterial protection. Example of virus diameters:
Coronavirus -125 nm [2]
Influenza virus - 80-120 nm [3]
Adenovirus - 70-100 nm [4]
Polio virus - 30 nm [5]
Bacteriophage Phi X174 - 31 nm [6]
MS-2 coliphage - 27 nm [7]



Coronavirus
125 nm



Influenza virus
80-120 nm

Adenovirus
70-100 nm

Bacteriophage Phi X174
31 nm

TOXI-GUARD® air cleaning technology is composed of a hydrophobic filtration membrane (Versapor®; 0.2 µm pores) and an activated carbon filter (Flexzorb™)

Protective Effect of the Membrane [8]

The viral filtration efficiency (VFE) of the Versapor® membrane family was tested by Nelson Labs US. An aerosol of a challenge virus, bacteriophage phi 164, was used. The droplet size of the aerosol was strictly controlled and had a mean particle size of 2.9 µm. The flow rate of the aerosol through the membrane test sample was 28.3 liters per minute.

It was found that the membrane prevents viruses from passing through at an efficiency greater than 99.9%. Practically, no virus passed the membrane in this study.

Protective Effect of the Activated Carbon Cloth [9]

The **carbon layer** was shown to **have a unique ability to deactivate a virus without chemical intervention. A deactivation rate of up to 93% was achieved by Flexzorb™.** These protective effects of the activated carbon layer are added to the efficient viral filtration ability of the 0.2 µm membrane.

TOXI-GUARD® Prevents Viral Contamination of Sterile Drugs [10]

Aim

To evaluate, by qPCR assay, the protective effect of Chemfort™ Closed System Transfer Device (CSTD), which contains the Toxi-Guard® filter, against virus penetration, when used in a human coronavirus OC43 (HCoV-OC43) aerosolized environment.

Method

The test was conducted inside a sealed glove box placed inside a biological safety laminar flow cabinet. The glove box environment was aerosolized using a nebulizer with either sterile growth medium as a negative control or human coronavirus (HCoV-OC43) stock solution of known titer.

Chemfort™ sets consisting of a Vial Adaptor (VA), a Syringe Adaptor (SA) and a Bag Adaptor (BASP) were tested. The Vial Adaptors were either standard (with Toxi-Guard®) or positive controls (without Toxi-Guard®).

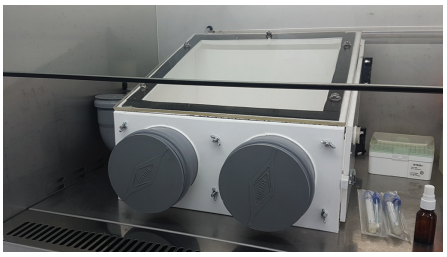
In each test the following activities were conducted:

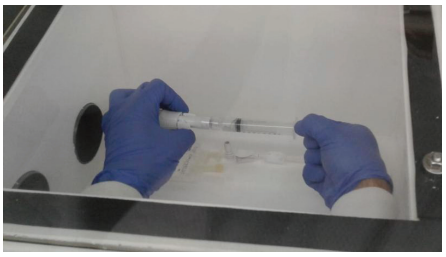
1. Withdraw 10 ml of saline out of a 50 ml IV bag, using a 10 ml syringe + SA
2. Transfer the saline to a vial attached to a VA
3. Shake the vial
4. Withdraw 10 ml of saline from the vial using the syringe + SA and transfer back to the IV bag
5. Take a saline sample from the IV bag for qPCR testing

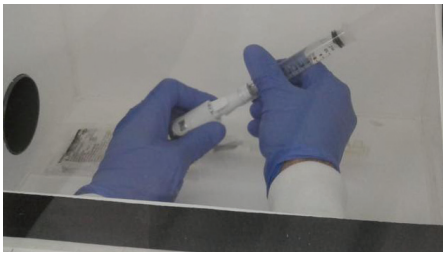
Test groups (triplicates) - using VAs with the complete Toxi-Guard®:

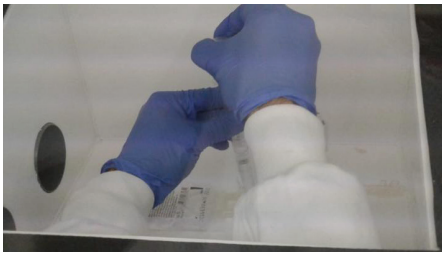
A. Used as is inside the virus-loaded aerosol environment.
B. First challenged by spraying with extra virus-loaded suspension directly on the outer surfaces of the filter area, and then used according to the procedure described previously.

As a positive control, 6 sets that included VAs without Toxi-Guard® that were sprayed with virus-loaded suspension were used according to the qPCR results (Table 1).









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Results

When liquid samples were transferred using the standard VAs (containing the Toxi-Guard® system), there was no evidence of viral RNA traces, even when the Vial Adaptors were directly sprayed with extra HCoV-OC43 stock solution (Table 1: sampling groups 1 and 2). Contrarily, some of the liquid samples that were transferred by the same procedure using the VAs in which Toxi-Guard® was removed and were also challenged by spraying of extra HCoV-OC43 stock solution were found to be positive for viral RNA.

In summary, the results of this study indicate that the Chemfort™ CSTD, and more specifically its Toxi-Guard® filter, play a key role in preventing outer environment viral contamination of liquids transferred by the device.

Table 1.

Sampling group	Sample description	Biological Repeat	PFU/ml		
			Rep. 1	Rep. 2	Rep. 3
1	Standard Vial Adaptor	1	NA	NA	NA
		2	NA	NA	NA
		3	NA	NA	NA
2	Standard Vial Adaptor, sprayed with viruses	1	NA	NA	NA
		2	NA	NA	NA
		3	NA	NA	NA
3	Positive Control: Vial Adaptor without Toxi-Guard®, and sprayed with viruses	1	NA	**1.0**	NA
		2	**7.5**	**8.6**	**8.0**
		3	NA	NA	**1.6**
		4	NA	NA	**1.7**
		5	NA	NA	NA
		6	**0.9**	**6.4**	**3.2**

Conclusion

Both protective layers of the TOXI-GUARD® air cleaning system are active against airborne viruses, and prevent the risk of virus penetration into the vial.

References

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Coronavirus photo by CDC on Unsplash