

# Virucidal Efficacy Testing for Biocides Claiming to Kill COVID-19 in the US

## Regulations of Biocide (virucide) in the US

In the United States, virucidal disinfectants used on environmental surfaces are regulated by the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The EPA regulates disinfectants and sanitizers as pesticides, often referring to them as "antimicrobial pesticides." Before a disinfectant can be sold in the U.S. it must be registered with the EPA. All virucides must meet disinfectant-grade efficacy guidelines.

Unlike chemical pesticides, [a pesticidal device](#), an instrument or other machine that is used to destroy, repel, trap, or mitigate any pests, including viruses (*i.e.* ozone generators, UV lights, *etc.*), is not routinely reviewed by EPA for the safety or efficacy. Hand sanitizers, antiseptic washes and antibacterial soaps are regulated by the Food and Drug Administration (FDA). EPA-registered surface disinfectants, including surface wipes, are not to be applied on skin or ingested.

## Overview of Virucidal Efficacy

To register a virucidal disinfectant in the US, companies must submit efficacy data to the EPA that is generated in compliance with Good Laboratory Practice Regulations (GLP). Test methods are summarized in [the Series 810 guidelines](#); further guidance is in the [EPA's Pesticide Registration Manual](#).

In contrast to Europe, the testing of virucidal efficacy in the US makes use of a great variety of viruses. Viruses, which play an important role in hospital-acquired viral infections, are chosen as test viruses. (In Europe, model viruses have been chosen for virucidal testing using suspension tests.) The EPA currently only recognizes "hard surface carrier" methods for substantiation of virucidal efficacy claims. These methods consist of a non-porous carrier (typically glass) being inoculated with the selected virus, dried, and then treated with the disinfectant. Virucidal hard surface carrier methods are quantitative, meaning that percent and log reductions are calculated by determining the 50% Tissue Culture Infective Dose (TCID<sub>50</sub>) per carrier before and after treatment with the disinfectant. The disinfectant must demonstrate complete inactivation of the virus down to the limit of detection of the assay, or (if cytotoxicity is observed) a  $\geq 3.00$  log<sub>10</sub> reduction (a 1000-fold reduction, 99.9%).

For testing methods using for virucidal claims, EPA recommends to use [ASTM E1053](#) for water soluble powder/liquids and spray product testing, and [ASTM E2362](#) (or AOAC 961.02) for towelette testing. Twelve virus strains and their host cells are recommended (nonmandatory) in the Appendix X1 of E1053 for the virucidal efficacy test. The protocols for testing with EPA recommended viral surrogates are outlined in EPA [810.2000](#).

## Virucidal Efficacy against COVID-19

The virucidal products claiming efficacy against COVID-19 (coronavirus) are currently managed as emerging viral pathogen virucides. COVID-19 virus is not available to perform testing for regulatory requirements due to the novelty of this virus. For this reason, the US EPA [Emerging Viral Pathogen Pesticide Guideline](#) enacts a 'hierarchy-based' policy that if a product has been found to be effective against at least one harder-to-kill viruses or some similar viruses, it is likely to kill a virus like COVID-19. In the EPA guidance, viruses are divided into three viral subgroups (small non-enveloped, large non-enveloped, and enveloped) based on their relative resistance to inactivation (see Table 1). Small non-enveloped viruses are the hardest-to-kill viruses due to their very resistant protein capsid, while enveloped viruses (e.g. coronavirus, influenza *etc.*) are much easier to kill by compromising the fragile lipid envelopes. Therefore, to apply for EPA approvals on claims against COVID-19

coronavirus, one has to demonstrate the virucidal efficacy of the product as a virucide against at least one strain of the non-enveloped viruses.

**Table 1** The ease of killing different types of viruses (EPA Emerging Viral Pathogen Pesticide Guideline)

Ease of Kill	Type of Virus*	Example
Difficult	Small Non-enveloped (<50 nm)	Poliovirus, Canine parvovirus, Feline calicivirus, Hepatitis A Virus, Murine Norovirus, Rhinovirus
↑	Large non-enveloped (50~100 nm)	Adenovirus, Rotavirus
Easy	Enveloped	Coronavirus, Influenza A virus, Cytomegalovirus, Herpes Simplex Virus, Respiratory Syncytial Virus, Vaccinia Virus

\*Based on EPA Emerging Viral Pathogen Pesticide Guideline

### Broad-Spectrum Virucidal Efficacy

There are no specific virus strains recommended by EPA as a broad-spectrum virucidal efficacy testing model. However, [810 guidelines](#) require testing the pesticidal efficacy against *S. enterica* and/or *P. aeruginosa* (ATCC 15442) and *S. aureus* for broad-spectrum disinfectant products.

Meanwhile in Canada, [Health Canada’s guideline](#) requires one to provide the virucidal efficacy testing of a product against Poliovirus (type 1, ATCC VR-1562 Chat strain) or Human Adenovirus (type 5, ATCCVR-5) or Bovine Parvovirus (ATCC VR-767) or Canine Parvovirus (ATCC VR-2017) to register this product as a broad-spectrum virucide.

### Commercial Laboratories for Virucidal Efficacy Testing

Virucidal efficacy tests can be conducted in virology laboratories in compliance with GLP and EPA regulations. There are many virology laboratories in North America that are qualified to conduct virucidal efficacy tests following EPA’s requirements. Five of them are listed as follows. Vireo cannot vouch for any firm since we do not have existing relationships with them.

**Table 2** Some commercial laboratories for virucidal efficacy testing

Laboratory Name	Locations	Phone	Website
Microchem Laboratory	Round Rock, TX	(512) 580-1342	<a href="http://www.microchemlab.com">http://www.microchemlab.com</a>
Nelson Labs	Fairfield, NJ; Ontario, CA; Itasca, IL Mexico City, Mexico	(801) 290-7500	<a href="https://www.nelsonlabs.com">https://www.nelsonlabs.com</a>
Microbac Laboratories	Pittsburgh, PA +30 locations in the US	(412) 459-1060	<a href="https://www.microbac.com">https://www.microbac.com</a>
BioScience Laboratories	Bozeman, MT	(877) 858-2754	<a href="https://www.biosciencelabs.com">https://www.biosciencelabs.com</a>
Analytical Lab Group	Eagan, MN; Concord, CA; Acton, MA	(877) 287-8378	<a href="https://www.analyticalabgroup.com">https://www.analyticalabgroup.com</a>

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