INDEPENDENT TESTING

Effectiveness of the Nevoa Disinfection System

BACKGROUND

Nevoa® is a healthcare innovation company dedicated to reducing the impact of hospital acquired infections (HAIs) through better disinfection technology. Nevoa saw a need to reduce human error and cross-contamination common to manual disinfection protocols. Nevoa developed a system consisting of a proprietary hypochlorous acid (HOCl) solution called Nevoa Microburst Solution™ and an automated robot called Nimbus™. The patented Nimbus device atomizes (fogs) the disinfectant for whole-room disinfection including 100% of a room's surfaces as well as room air. This system is the only US Environmental Protection Agency (EPA) registered disinfectant approved for fogging HOCl in healthcare environments.

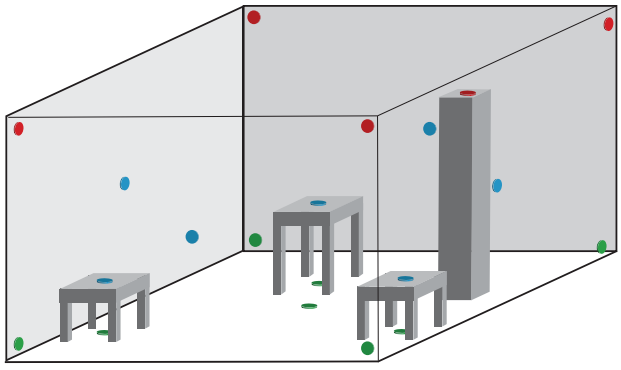
Rigorous testing has been conducted through independent laboratories to provide the necessary validation studies for EPA registration. Additional studies have also been conducted to demonstrate efficacy against several specific pathogens of interest.

METHOD

Nevoa product validation included both laboratory-controlled in-vitro tests as well as in-vivo studies conducted in real-world hospital conditions. All in-vitro testing has been conducted by laboratories that follow EPA/FDA Good Laboratory Practices (GLPs). Microchem Laboratories in Round Rock, TX and ResInnova Laboratories in Silver Spring, MD are accredited facilities maintaining various ISO, ANSI, and IAC certifications. These two independent laboratories are highly regarded and recognized as leaders in the industry. Other in-vivo testing was conducted by the University of Arizona College of Public Health at Banner University Medical Center Tucson.
EPA mandated procedures are employed. For antibacterial testing, the labs used the Germicidal Spray Products Test Method (AOAC 961.02) and modified the procedure for evaluating both the fogging device and liquid disinfectant together. For sporicidal testing, the labs employed the OECD Quantitative Method for Testing Antimicrobial Products against Spores of Clostridium difficile on Inanimate, Hard, Non-porous Surfaces. For virucidal tests (e.g., Influena, Rhinovirus, Norovirus), the ASTM International standard test method E1053 procedures are employed for a specified contact time.

To simulate the presence of bodily fluids often present during in-vivo studies, in-vitro test methods allow for application of artificial soil loads, typically 5% fetal bovine serum. The addition of soil generally increases disinfection difficulty.

The EPA protocol for fogging device testing states that target (test) microorganisms must be placed in 20 different locations within the room (ceilings, walls, floors, under tables, etc.) to ensure the disinfectant is reaching ALL surfaces and is at least 99.99% effective at all locations. **See illustration below.**



Color Legend:
- Specimin near ceiling - 8 ft off ground
- Specimin on table or mid-wall
- Specimin on/near floor & under furniture

EPA registration as a hospital-grade disinfectant required antimicrobial performance testing against three primary microorganisms: S. aureus, S. enterica, and P. aeruginosa. These three microorganisms were tested at each of the 20 room locations in triplicate for a total of 180 total in-vitro samples.

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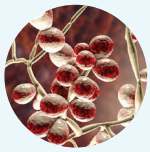
RESULTS



Candida auris

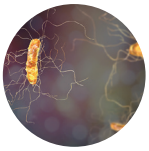
Average results: 5.9 Log_{10} reduction*

Fungus (MDRO) identified in 2009. Tested with soil load, 2 min. contact, CDC Strain B11903.

Methicilin-resistant Staphylococcus aureus-MRSA

Average results: 4.8 Log_{10} reduction *

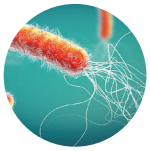
Gram-positive bacteria (MDRO). Tested with and without soil load, 1 min. contact, ATCC #33592.



Clostridium difficile

Up to 6.4 Log_{10} reduction*

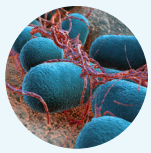
Gram-positive spore forming bacteria (MDRO). Tested with soil load, 10 min. contact, ATCC #43598.



Pseudomona aeruginosa

Average results: 6.5 Log_{10} reduction

Gram-negative bacteria (MDRO). Tested with soil load, 1 min. contact, ATCC #15442.



Escherichia coli

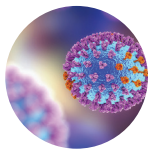
Average results: 4.0 Log_{10} reduction *

Gram-negative bacteria. Tested without soil load, ATCC #15597.

Salmonella enterica

Average results: 6.4 Log_{10} reduction

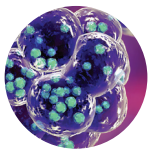
Gram-negative bacteria. Tested with soil load, 1 min. contact, ATCC #10708.



Influenza A

Average results: 4.8 Log_{10} reduction *

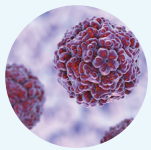
Enveloped virus. Tested with soil load, ATCC #VR-1469.



Staphylococcus aureus

Average results: 6.5 Log_{10} reduction

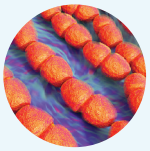
Gram-positive bacteria. Tested with soil load, 1 min. contact, ATCC #6538.



Human Rhinovirus

Average results: 4.8 Log_{10} reduction

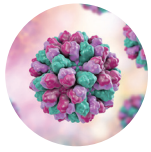
Non-enveloped virus. Tested with soil load, 1 min. contact, ATCC #VR-283, Strain 11757.



Vancomycin-resistant ebericiccys (VRE) enerococcus faecalis

Average results: 5.6 Log_{10} reduction *

Gram-positive bacteria (MDRO). Tested without soil load, ATCC #51575.

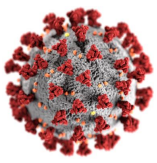


Feline calicivirus (FVC)

Average results: 5.2 Log_{10} reduction

Non-enveloped virus. Tested with soil load, 1 min. contact, ATCC #VR-782, Strain F-9.

EPA Recognized Surrogate For



SARS-CoV-2 & Human Norovirus

Average results: 5.2 Log_{10} reduction

Non-enveloped virus. Tested with soil load, 1 min. contact, ATCC #VR-782, Strain F-9.

CONCLUSION

This product has been tested according to EPA standards for Hospital-Grade Disinfection. Additionally, this product qualifies for emerging viral pathogen claims per the EPA's "Guidance for Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions.

*Additional studies conducted by independent laboratories that follow EPA/FDA Good Laboratory Practices (GLP) demonstrate Nevoa Microburst Solution™ is highly effective in disinfecting various pathogens, including those known to cause HAIs.