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 (HOCI) 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 HOCI in healthcare environments.

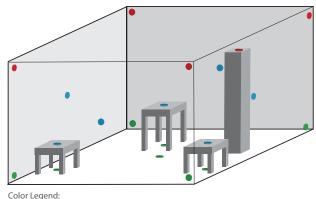
Rigorous testing has been conducted through independent laboratories to provide the necessary validation studies for EPA registration. Additional studies have also been conducted to demonstrate efficacy against several specific pathogens of interest.

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, Nonporous 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.**



Specimin near ceiling - 8 ft off ground

Specimin on table or mid-wall

Specimin on table of find-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.





Candida auris

Average results: 5.9 Log₁₀ reduction

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

Average results: 5.9 Log₁₀ reduction

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

Clostridium difficile

Escherichia coli

Average results: 4.0 Log₁₀ reduction

Gram-negative bacteria. Tested without

soil load, ATCC #15597.

Average results: 5.2 Log₁₀ reduction

Non-enveloped virus, EPA recognized surrogate for Human Norovirus. Tested with soil load, 1 min. contact, ATCC #VR-782, Strain F-9.

Feline calicivirus (FVC) as surrogate for Norovirus

Average results: 4.8 Log₁₀ reduction

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

Human Rhinovirus

Average results: 4.8 Log₁₀ reduction



Average results: 4.8 Log₁₀ reduction

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

Methicilin-resistant Staphylococcus aureus-MRSA

Average results: 6.5 Log₁₀ reduction



Pseudomona aeruginosa

Gram-negative bacteria (MDRO).

Tested with soil load, ATCC #15442.

Average results: 6.4 Log₁₀ reduction



Salmonella enterica

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

Average results: 6.5 Log₁₀ reduction



Staphylococcus aureus

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

Average results: 5.6 Log₁₀ reduction



Vancomycin-resistant ebericiccys (VRE) enerococcus faecalis

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

Enveloped virus. Tested with soil load, 10 min. contact, ATCC #VR-1469.

Influenza A

CONCLUSION

Following EPA guidelines and standardized testing procedures, the automated Nimbus™ device and the Nevoa Microburst Solution™ have been proven by independent laboratories to be highly effective in disinfecting various pathogens, including those known to cause HAIs.