Nelson Labs
A Sotera Health company

Sponsor:
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Bacterial Filtration Efficiency (BFE) at an Increased Challenge Level Final Report

Test Article:	Dynamics Nanowave Air NL2
Purchase Order:	2005000016
Study Number:	1364877-S01
Study Received Date:	19 Nov 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0009 Rev 14
Deviation(s):	None

Summary: This test procedure was performed to evaluate the BFE of test articles at an increased challenge level. A suspension of *Staphylococcus aureus*, ATCC #6538, was delivered to the test article at a challenge level of greater than 10^6 colony forming units (CFU). The challenge was aerosolized using a nebulizer and delivered to the test article at a fixed air pressure and flow rate of 150 liters per minute (LPM). The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) for collection. The challenge was delivered for a one minute interval and sampling through the AGIs was conducted for two minutes to clear the aerosol chamber. Approximately one third of the effluent air was collected for quantification during testing; therefore, the plate count results for the controls and test articles were multiplied by three in order to reflect the entire quantity of air passing through the test article. The mean particle size (MPS) control was performed at a flow rate of 28.3 LPM using a six-stage, viable particle, Andersen sampler for collection.

This test procedure was modified from Nelson Laboratories, LLC (NL), standard BFE test procedure in order to employ a more severe challenge than would be experienced in normal use. This method was adapted from ASTM F2101. NL has not performed a validation using the flow rate performed in this testing; however, adequate controls are included to verify the reliability of this study. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Challenge Flow Rate:	150 LPM
Area Tested:	Entire Test Article
Side Tested:	Tested in Sponsor Labeled Air Flow Direction
Challenge Level:	2.1 x 10^6 CFU
MPS:	~2.9 µm
Test Monitor Results:	Acceptable

James Luskin electronically approved — 23 Nov 2020 19:40 (+00:00)
Study Director James Luskin — Study Completion Date and Time

Results:

Test Article Number	Total CFU Recovered	Filtration Efficiency (%)
1	3.0×10^1	99.9986
2	8.9×10^1	99.9958
3	2.7×10^1	99.9987

Note: Device was run on high power for all 3 replicates.

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = Challenge Level
T = Total CFU recovered downstream of the test article